Monsanto Company and KWS SAAT AG Supplemental Request for Partial Deregulation of Sugar Beet Genetically Engineered to be Tolerant to the Herbicide Glyphosate

Final Environmental Assessment

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Summary

APHIS has received a supplemental request from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 (Petition 03-323-01) pursuant to the regulatory scheme of 7 CFR Part 340. On October 8, 2010, APHIS published a notice[1] in the Federal Register (75 FR 62365-62366, Docket No. APHIS-2010-0047) announcing receipt of a supplemental Petition from the Monsanto Company (Monsanto) and KWS SAAT AG (KWS) requesting “Partial Deregulation” or some similar administrative action under 7 CFR Part 340 for sugar beets (*Beta vulgaris* ssp. *vulgaris*) designated as event H7-1 to authorize its continued cultivation subject to carefully tailored interim measures and conditions. The safeguarding measures set forth in the supplemental request were similar to interim measures that APHIS proposed to United States District Court during the remedies phase of the litigation challenging full deregulation of H7-1 sugar beet. The supplemental Petition is for a Partial Deregulation; it does not request a Full Deregulation of H7-1 sugar beet. Any decision on Full Deregulation of H7-1 sugar beet will not and cannot be made until an EIS is completed in reference to a request for a Full Deregulation of H7-1 sugar beet.

The supplemental petition is related to a petition submitted by Monsanto and KWS on November 19, 2003, seeking a determination of nonregulated status for event H7-1 sugar beets (Petition 03-323-01). On October 19, 2004, APHIS published a notice in the *Federal Register* (69 FR 61466-61467, Docket No. 04-075-1) announcing that the Monsanto/KWS petition and an EA were available for public review. On March 17, 2005, APHIS published a notice in the Federal Register (70 FR 13007-13008, Docket No. 04-075-2) advising the public of its Determination Decision, effective March 4, 2005, that event H7-1 sugar beets posed no plant pest risk and

[1] To review the notice and the supplemental petition, go to http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2010-0047.

should no longer be considered a regulated article under APHIS regulations codified at 7 CFR Part 340. Pursuant to this regulatory Determination Decision, H7-1 sugar beet seed and root crops were fully deregulated and could be grown without any APHIS imposed conditions. On September 21, 2009, the US District Court for the Northern District of California (Court) found that APHIS should have prepared an environmental impact statement (EIS) before making a decision on whether or not to grant nonregulated status to event H7-1 (*Center for Food Safety et al. vs. Thomas Vilsack et al.*). On August 13, 2010, the Court vacated APHIS's decision to fully deregulate event H7-1 sugar beet varieties, making them subject to the Plant Protection Act of 2000 (PPA) and 7 CFR Part 340 once again, and remanded the matter back to the agency to determine regulatory actions, if any, that should be imposed upon event H7-1 sugar beets in the interim until the completion of the EIS and a new Determination Decision could be made by APHIS as to whether it would be appropriate to grant full nonregulated status to event H7-1.The EA analyzes the alternatives available to APHIS for its decision regarding this supplemental request for partial deregulation or for similar administrative action to authorize the cultivation of event H7-1 sugar beets subject to carefully tailored interim measures proposed by APHIS. Based on the scope of the EA, the specific decisions to be made are:

- Should APHIS grant the supplemental Monsanto/KWS Petition request for "partial deregulation" or similar administrative action to authorize the continued cultivation of event H7-1 sugar beets subject to the interim measures proposed by APHIS to the Court?
- Should APHIS continue to regulate the release into the environment and movement of event H7-1 sugar beets (both all root and seed production activities) under 7 CFR Part 340?
- What conditions (interim regulatory measures) should be imposed to prevent any potential plant pest risk from planted event H7-1 sugar beets that are partially deregulated and thus removed from Part 340 regulation, to minimize disruptions to U.S. sugar beet production, and to minimize the likelihood of impacts noted by the Court until APHIS can complete an EIS before making a determination decision on whether or not to grant Full nonregulated status to event H7-1 sugar beets?

- Would the preferred alternative, if selected, have significant impacts on the quality of the human environment requiring preparation of an EIS?

The EA has been prepared to analyze the alternatives available to APHIS for responding to this supplemental request and to provide the public with documentation of APHIS' review and analysis of any potential individual and cumulative environmental impacts associated with the partial deregulation or for similar administrative action to authorize the cultivation of event H7-1 sugar beets subject to carefully tailored interim measures proposed by APHIS.

The EA considers and evaluates four reasonable alternatives. The alternatives analyzed in the EA include:

- Alternative 1 - APHIS Denies Petition Request for Partial Deregulation/ No Further Actions to Authorize Cultivation of Event H7-1 Sugar Beets (No Action). This alternative would deny the request for partial deregulation or any similar administrative action under 7 CFR Part 340 for the cultivation of event H7-1 sugar beets, thereby halting any consideration of authorizing commercial production until the completion of the EIS.
- Alternative 2 - Event H7-1 Sugar Beet Production (Seed/Root) Regulated Under 7 CFR Part 340. This alternative would authorize the commercial production of event H7-1 sugar beets under APHIS permits, in accordance with 7 CFR Part 340, subject to mandatory conditions to prevent any potential plant pest risks from such cultivation. These conditions are intended both to minimize any potential for the escape and dissemination of plant pests and the likelihood of impacts of concern raised by the Court in the lawsuit challenging APHIS' decision to deregulate event H7-1 sugar beets.
- Alternative 3 - Partial Deregulation of Event H7-1 Sugar Beets (Seed/Root). This alternative would grant the petition request for partial deregulation to allow the commercial production of event H7-1 sugar beets. The supplemental request that APHIS received from Monsanto/KWS did not clearly explain what the petitioners mean or envisioned by a "partial deregulation." The petitioner did not identify any specific mechanism(s) that would be used to impose the conditions to prevent any potential plant

pest risks, which parties would be subject to the conditions, or how compliance with the conditions would be ensured. APHIS has interpreted this petition to mean that Monsanto/KWS is requesting that event H7-1 sugar beets would no longer be regulated under 7 CFR Part 340 provided that they are cultivated under the conditions and interim measures that APHIS proposed to the Court. APHIS further interprets the request to mean that Monsanto/KWS would be the responsible party for overseeing implementation and monitoring of conditions for cultivation of event H7-1 sugar beets. Under this alternative, APHIS would grant the petition for partial deregulation; APHIS would no longer regulate event H7-1sugar beets under 7 CFR Part 340; and the cultivation of event H7-1 sugar beets would be allowed under conditions imposed by Monsanto/KWS through technology stewardship agreements, contracts, or other legal instruments.

- Preferred Alternative – Partial Deregulation – Combination of Alternatives 2 and 3. APHIS has determined that it is appropriate to partially deregulate H7-1 sugar beets by combining aspects of Alternative 2 in regards to seed production activities and a modification of Alternative 3 in regards to root production activities. Under this partial deregulation alternative, APHIS would *deny* the supplemental request for partial deregulation with regard to H7-1 sugar beet seed production activities meaning that seed production activities would remain regulated pursuant to 7 CFR Part 340. However, pursuant to and in compliance with 7 CFR 340.6, APHIS would grant the supplemental request with regard to H7-1 root production activities and partially deregulate those activities as long as certain specific mandatory conditions are complied with by anyone desiring to conduct H7-1 sugar beet root production activities. APHIS has evaluated the supplemental petition and has concluded that H7-1 sugar beet root production activities, when conducted under specific mandatory conditions required and enforced by APHIS, are unlikely to pose a plant pest risk (USDA-APHIS 2011). Therefore, APHIS has determined that H7-1 sugar beet root production activities carried out under this interim action, if conducted under these mandatory conditions, should no longer be subject to the procedural and substantive requirements of 7 CFR Part 340. If, however, commercial root production activities are not conducted pursuant to these mandatory conditions, the APHIS Administrator has the regulatory authority and discretion to return such root production activities to regulation under 7 CFR Part 340.

These mandatory conditions under the Preferred Alternative would be imposed and enforced pursuant to written APHIS compliance agreements authorized under the PPA. Similar to a permit, the compliance agreements would be used to authorize the movement and release into the environment of H7-1 root crop and would impose certain mandatory conditions on the movement and environmental release of the H7-1 sugar beet root crop and root production activities. These legally binding and enforceable compliance agreements would specify the mandatory conditions for partial deregulation of the root production activities and would formalize and impose the mandatory conditions under which the root crop and root production activities would be considered partially deregulated; i.e., no longer subject to the procedural and substantive requirements of the Part 340 regulation. APHIS would employ these required compliance agreements to authorize movement and release of H7-1 sugar beets and to impose and enforce the mandatory conditions on the import, movement or environmental release of the root crop and root production activities and the compliance agreements would be a formal, written, and signed agreement between APHIS and a person who wants to import, move, and/or do an environmental release in conjunction with the H7-1 sugar beet root crop production activities [note that movement and the environmental release includes the entire production cycle of H7-1 sugar beet root crop – referred to collectively as all the "root production activities"; and the terms person, import, or move have the meanings as they are so defined in the Plant Protection Act (PPA), as amended]. For the environmental release of H7-1 sugar beets associated with the root crop production activities, required information for the compliance agreement will include: identifying the responsible party, contact information, location of the environmental release(s), and total number of acres to be planted. For the movement and/or importation of H7-1 sugar beets associated with the root crop production activities, required information for the compliance agreement includes: identifying the responsible party, contact information, and point of origin and final destination(s).

Under the Preferred Alternative, the compliance agreements would be enforced under the authority of the PPA and 7 CFR Part 340. If APHIS determines that any of the mandatory conditions of the partial deregulation set forth in the compliance agreements are not complied with, APHIS may revoke, withdraw or otherwise cancel the conditional partial deregulation for the commercial root crop production activities. Further, APHIS may use the full range of PPA authorities to seek, as appropriate and necessary, criminal and/or civil penalties, and to take remedial measures including seizure, quarantine, and /or destruction of any root crop or root production activity in violation of the mandatory conditions of the partial deregulation. APHIS inspections and/or third party inspections/audits will be required to ensure that persons importing, moving, and/or doing an environmental release (planting) in conjunction with the H7-1 sugar beet root crop comply with all conditions and restrictions identified in the compliance agreements.

Actions taken by APHIS under this Preferred Alternative would be interim in nature, meaning that they will be limited in scope and duration, and would neither result in significant impacts to the human environment nor prejudice any future decision to be analyzed in the forthcoming EIS for a determination decision in response to a petition for a full deregulation of H7-1 sugar beets. APHIS is aiming to complete the EIS by May 28, 2012, but unforeseen conditions may affect the specific completion date. This interim, conditional, and partial deregulation of the H7-1 sugar beet root crop and root production activities along with the interim Part 340 permitting of the H7-1 seed crop, which would not be partially deregulated, will remain in effect through December 31, 2012, to allow the harvesting and processing of the 2012 commercial root crop and seed crop unless APHIS issues a Final EIS, Record of Decision, and Determination decision for a Full Deregulation of H7-1 sugar beets before those harvest are completed in 2012. If APHIS makes a determination decision, after completion of the EIS, to fully deregulate

H7-1 sugar beet, the Record of Decision for that EIS for full deregulation will supersede and replace this partial deregulation FONSI, if it occurs prior to termination date of the interim action, which is December 31, 2012.

Moreover, the actions taken by APHIS under this Preferred Alternative are not new or novel. APHIS has a long history of issuing permits under its part 340 regulations and also of entering into compliance agreements similar to the ones that will be required under the Preferred Alternative. Compliance agreements are well established in APHIS as an effective and efficient compliance mechanism to authorize and allow activities governed by the PPA and maintain oversight and compliance with ~~of~~ those authorized activities. Additionally, the Preferred Alternative is similar to other APHIS actions that do not normally require the preparation of an EIS. Similar to the permits issued under 7 CFR Part 340, including the permits that will be issued for this interim action allowing seed crop production activities, the compliance agreements used for the conditional Partial Deregulation of root crop production activities will require responsible parties (for example, the root crop cooperatives and processors) to submit field location and acreage information to APHIS and to be subject to inspections and audits. The compliance agreements are legally binding and enforceable agreements between APHIS and entities involved in H7-1 sugar beets root crop production activities. The APHIS Administrator may, in her discretion, revoke, withdraw, or otherwise cancel the conditional partial deregulation for commercial root crop production activities when it is appropriate to do so because of noncompliance or other violation of the mandatory conditions of the Partial Deregulation. Further, APHIS may use the full range of its PPA authorities to seek, as appropriate and necessary, criminal and/or civil penalties, and to take appropriate remedial measures including seizure, quarantine, and /or destruction of any root crop or root crop production activity that is in noncompliance or other violation of the mandatory conditions of the Partial Deregulation. Moreover, as stated below, APHIS has previously examined the potential impacts of deregulating H7-1 sugar beets in conjunction with its decision in response to an original 2003 Petition for nonregulated status and then an updated 2004 Petition. Based on this vast experience, the impacts that can be expected from implementing the Preferred Alternative are well understood and thoroughly evaluated in this EA.

Alternatives considered but rejected in the EA include: (1) Deregulating root production under conditions imposed by APHIS while prohibiting seed production, (2) deregulating seed production under conditions imposed by APHIS while prohibiting root production, and (3) deregulating seed production under conditions imposed by APHIS while authorizing continued root production under APHIS permits or notification.

APHIS in compliance with all CEQ Regulations provides this environmental assessment as part of the decision-making process to address the supplemental request for partial deregulation of sugar beets genetically engineered (GE) for tolerance to the herbicide glyphosate, or for similar administrative action to authorize continued cultivation of the GE sugar beets subject to conditions proposed by APHIS. The EA was available for public comment for 30 days. Comments received by the end of the 30-day period were analyzed and used to inform APHIS' decision on whether to grant the supplemental request for partial deregulation of the GE sugar beets or to grant some similar administrative action to authorize the continued cultivation of the GE sugar beets.

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A. Purpose and Need

1. Introduction

In 2003, United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) received a petition request to grant nonregulated status to a genetically engineered (GE) variety of sugar beets designated as event H7-1 (here after referred to as H7-1). This sugar beet event and cultivars derived from this event are genetically engineered to be resistant to the herbicide glyphosate. Upon completing an Environmental Assessment (EA) and issuing a Finding of No Significant Impact (FONSI) (70 FR 13007-13008, Docket No. 04-075-2) APHIS advised the public of their determination, effective March 4, 2005, that the Monsanto/KWS SAAT AG sugar beet H7-1 did not pose a plant pest risk and therefore was no longer considered a regulated article under APHIS regulations in 7 CFR Part 340. A complaint was filed in January, 2008, challenging APHIS' decision to grant nonregulated status to H7-1 sugar beets (referred to in the lawsuit as Roundup Ready® sugar beet). On September 21, 2009, the US District Court for the Northern District of California found that APHIS should have prepared an environmental impact statement (EIS) before making a decision on whether or not to grant nonregulated status to H7-1 (*Center for Food Safety et al. vs. Thomas Vilsack et al.*). On August 13, 2010, the Court vacated APHIS's decision to grant nonregulated status to the H7-1 sugar beet varieties, making them subject to the Plant Protection Act of 2000 (PPA) and 7 CFR Part 340 once again, and remanded the matter back to the agency to determine regulatory actions, if any, that should be imposed upon H7-1 sugar beets until the completion of the EIS.

APHIS has received a supplemental request from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 (Petition 03-323-01) pursuant to the regulatory scheme of 7 CFR Part 340. On October 8, 2010, APHIS published a notice[2] in the Federal Register (75 FR

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62365-62366, Docket No. APHIS-2010-0047) announcing receipt of a supplemental Petition from the Monsanto Company (Monsanto) and KWS SAAT AG (KWS) requesting “Partial Deregulation” or some similar administrative action under 7 CFR Part 340 for sugar beets (*Beta vulgaris* ssp. *vulgaris*) designated as event H7-1 to authorize its continued cultivation subject to carefully tailored interim measures and conditions. The safeguarding measures set forth in the supplemental request were similar to interim measures that APHIS proposed to United States District Court during the remedies phase of the litigation challenging full deregulation of H7-1 sugar beet. The supplemental Petition is for a Partial Deregulation; it does not request a Full Deregulation of H7-1 sugar beet. Any decision on Full Deregulation of H7-1 sugar beet will not and cannot be made until an EIS is completed in reference to a request for a Full Deregulation of H7-1 sugar beet.

This EA analyzes the alternatives available to APHIS for responding to this request and has been developed by APHIS in compliance with the requirements of the National Environmental Policy Act of 1969 (NEPA), as amended, the Council of Environmental Quality’s (CEQ) regulations implementing NEPA, and the USDA and APHIS NEPA implementing regulations and procedures. APHIS prepared this EA to facilitate planning, interagency coordination, and to clearly communicate with the public the analysis of potential individual and cumulative impacts that may result from granting partial deregulation or some other regulatory action in response to the petition. APHIS issued a notice to the public informing all interested or affected persons of the availability of the documents submitted to the Agency from Monsanto Company and KWS SAAT AG requesting a “partial deregulation” of H7-1 sugar beets (75 FR 62365-62366, Docket No. APHIS-2010-0047). In that public notice, APHIS informed the public that its receipt of the supplemental request for partial deregulation and the notice to the public regarding that receipt in no way indicates that APHIS agrees with the petitioners’ description, application, or implementation of a partial deregulation. Rather, APHIS informed the public that such matters and related issues are solely determined by APHIS pursuant to its PPA statutory authority and the 7 CFR Part 340 biotechnology regulations. In addition, APHIS’ response to the “partial deregulation” and preparation of this EA by no means is an indication of when APHIS intends to complete the court-ordered EIS and make a determination on whether or not to grant nonregulated status to H7-1 sugar beets. The EIS and subsequent Record of Decision (ROD) are an independent NEPA process that are being prepared for making an informed decision on a petition request to grant full nonregulated status to H7-1 sugar beets. It is anticipated that the process for completing the EIS will be completed by the end of May, 2012.

2. **Purpose of Glyphosate–Tolerant Sugar Beets**

The sugar beet (*Beta vulgaris* ssp. *vulgaris*) cultivars, designated as H7-1 by developers Monsanto Company of St. Louis, MO, and KWS SAAT AG of Einbeck, Germany, is genetically engineered to be resistant to the herbicide glyphosate. H7-1 is marketed to benefit sugar beet growers by providing a tool for managing weeds in sugar beet production and has been in continuous commercial production by growers since 2006. H7-1 sugar beets are genetically engineered to be glyphosate tolerant by inserting a gene (from *Agrobacterium* spp. strain CP4) that encodes the enzyme 5-enolpyruvylshikimate-3-phosphate synthase protein (EPSPS) into the sugar beet genome. H7-1 sugar beets offer sugar beet growers a simpler, more flexible, and less expensive alternative for weed control relative to conventional weed control measures.

3. **Regulatory History of Event H7-1 Sugar Beets**

Monsanto/ KWS submitted a request to APHIS for nonregulated status of H7-1 sugar beet on November 19, 2003. Upon review of the information submitted by the applicant, APHIS published a notice in the *Federal Register* (69 FR 61466-61467, Docket No. 04-075-1) on October 19, 2004 announcing receipt of a petition from Monsanto/KWS SAAT AG requesting a determination of nonregulated status under 7 CFR Part 340 for sugar beet (*Beta vulgaris* ssp. *vulgaris*) designated as H7-1, which has been genetically engineered for tolerance to the herbicide glyphosate. The petition stated that this article should not be regulated by APHIS because it does not present a plant pest risk.

APHIS also announced in that notice the availability of an EA for the proposed determination of nonregulated status. APHIS received 44 comments on the petition and the EA during a 60-day comment period, which ended December 20, 2004. Following review of public comments, and completion of the final EA and subsequent FONSI, on March 17, 2005, APHIS published a notice in the Federal Register (70 FR 13007-13008, Docket No. 04-075-2) advising the public of its Determination Decision, effective March 4, 2005, that event H7-1 sugar beets posed no plant pest risk and should no longer be considered a regulated article under APHIS regulations codified at 7 CFR Part 340. Pursuant to this regulatory Determination Decision, H7-1 sugar beet seed and root crops were fully deregulated and could be grown without any APHIS imposed conditions. Widespread cultivation began in 2006 with H7-1 derived varieties being grown in 10 states. USDA's Economic Research Service estimates that adoption of the GE sugar beet varieties exceeded 95% of U.S. sugar beet production in 2010 (USDA NASS, 2010b). A complaint was filed in January, 2008, challenging APHIS' decision to grant nonregulated status to Roundup Ready® sugar beet (RRSB). On September 21, 2009, the US District Court for the Northern District of California (Court) found that APHIS should have prepared an environmental impact statement (EIS) before making a decision on whether or not to grant nonregulated status to event H7-1 (*Center for Food Safety et al. vs. Thomas Vilsack et al.*). On August 13, 2010, the Court vacated APHIS's decision to fully deregulate event H7-1 sugar beet varieties, making them subject to the Plant Protection Act of 2000 (PPA) and 7 CFR Part 340 once again, and remanded the matter back to the agency to determine regulatory actions, if any, that should be imposed upon event H7-1 sugar beets in the interim until the completion of the EIS and a new Determination Decision could be made by APHIS as to whether it would be appropriate to grant full nonregulated status to event H7-1.

APHIS has authorized over 200 notifications/permits for field release of *Beta* species since 1993. Since 1993, APHIS conducted 5 environmental assessments for confined field releases of beets and reached a FONSI for all EAs. APHIS has authorized over 35 notifications on 98 sites for H7-1 glyphosate tolerant sugar beets in all sugar beet producing states. APHIS authorized well over 100 confined releases for the field planting of all sugar beet varieties from 1998 to 2005, including authorizations for multiple planting locations with up to 270 acres authorized in a single notification/permit.

4. **Production History of the Event H7-1 Sugar Beet**

The U.S. is among the largest producers of sugar beets, and more than half of U.S. refined sugar is produced from sugar beets (USDA NASS, 2010b). The 1.1 million acres of sugar beets grown in the U.S. are primarily localized in the Red River Valley area of Minnesota and North Dakota (57% of U.S. production), with smaller production areas in the Upper and Central Great Plains, and portions of Michigan, Idaho, Washington, and Oregon (USDA NASS, 2010b). In the U.S., beet sugar is processed exclusively in local, farmer-owned processing cooperatives. Producers of sugar beets and their cooperatives, which process sugar beets, rapidly adopted H7-1 derived varieties following APHIS' decision for nonregulated status. Widespread cultivation began in 2006 with H7-1 derived varieties being grown in 10 states. USDA's Economic Research Service estimates that adoption of the GE sugar beet varieties exceeded 95% of U.S. sugar beet production in 2010 (USDA NASS, 2010b).

5. **Legal Challenge to APHIS' Decision for Non Regulated Status for Event H7-1 Sugar Beet**

Almost three years after APHIS granted full nonregulated status to H7-1, on January 23, 2008, the Center for Food Safety, the Sierra Club, Organic Seed Alliance and High Mowing Organic seeds filed a lawsuit against USDA in the U.S. District Court for Northern California, challenging its decision to grant nonregulated status to H7-1 sugar beets (referred to in the lawsuit as Roundup Ready® sugar beet), pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended (42 USC 4321 *et seq*.), the Administrative Procedure Act, and the Plant Protection Act (*Center for Food Safety, et al., v. Thomas J. Vilsack, et al.*). The plaintiffs requested that the Court vacate APHIS' decision to deregulate H7-1 sugar beets and order APHIS to prepare an EIS pursuant to NEPA for any decision to deregulate H7-1 sugar beets. The plaintiffs argued that wind-blown pollen from GE sugar beets will contaminate conventional sugar beets and other closely related crops, such as chard and table beets, and that such gene flow from the GE sugar beets to non-GE sugar beets and other related crops will be economically detrimental to farmers and consumers of conventional and organic varieties.

On September 21, 2009, the US District Court for the Northern District of California ruled that APHIS' EA failed to consider certain environmental and interrelated economic impacts. As a result, the Court ordered APHIS to prepare an EIS for any decision in the future on whether or not to grant nonregulated status to H7-1 sugar beets. In response to the court's decision, APHIS proposes to complete an EIS by May, 2012. Conditions that would affect the actual completion date of the EIS cannot be predicted in advance, and the process of producing an EIS does not commit APHIS to decide to fully deregulate H7-1 sugar beets.

Specific Findings of the Court

1. The Court (Summary Judgment September 21, 2009) found that APHIS' finding of no significant impact was "not supported by a convincing statement of reasons," and that therefore APHIS is required to prepare an EIS.
2. In particular, the Court agreed with an earlier ruling (*Geertson Seed Farms v. Johanns*, 2007 WL 518624, *7 (N.D. Cal. Feb. 13, 2007)) that "potential elimination of a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat nongenetically [sic] engineered food, and an action that potentially eliminates or reduces the availability of a particular plant has a significant effect on the human environment" and therefore requires analysis in an EIS.
3. The Court noted that economic effects of "transmission of the genetically engineered gene into organic and conventional" crops should be considered in APHIS's environmental reviews when determining whether nonregulated status would cause significant environmental impacts.
4. The Court was critical of APHIS' analysis of existing coexistence measures used in Oregon seed production areas, noting that APHIS did not adequately consider that recommended isolation distances were voluntary, might not be followed, and might not be sufficient.

5. Additionally, the Court concluded that APHIS did not provide support for the contention that non-transgenic seed would continue to be available for growers or that growers would discern that varieties derived from H7-1 was transgenic because it was labeled as glyphosate tolerant.

On May 28, 2010, APHIS published a Notice of Intent (NOI) in the *Federal Register* seeking public comment on its intent to prepare an EIS and proposed scope of study. Within this NOI, the public was advised on APHIS plans to prepare an EIS in connection with a court-mandated evaluation of the potential impacts on the human environment associated with the Agency's determination of nonregulated status for a Monsanto/KWS SAAT AG sugar beet line, designated as H7-1. The notice identified the environmental and interrelated economic issues raised by the Court and other potential issues that APHIS may include in the EIS and requested public comment to further delineate the scope of the issues and reasonable alternatives.

On August 13, 2010, the Court issued its order regarding the remedies in the case (i.e. what should happen to H7-1 sugar beets as a result of the September 2009 ruling). The Court vacated APHIS's decision to grant nonregulated status to the H7-1 sugar beet varieties, making them subject to the Plant Protection Act and APHIS biotechnology regulations once again, and remanded to the agency to determine regulatory actions that should be imposed upon H7-1 sugar beets pending completion of an EIS and a final decision about whether or not to grant deregulation. The plaintiffs' request for a permanent injunction against the planting of H7-1 pending completion of the court-ordered EIS was denied. Consistent with Court's Order, H7-1 sugar beets planted *before* August 13, 2010, are *not* treated as regulated articles and are not subject to the Plant Protection Act of 2000 and 7 CFR Part 340 for the duration of those plantings. Thus, H7-1 sugar beet planted for root production before August 13, 2010, may remain in the ground, be harvested, transported, processed and sold as sugar. Based on the Court's Order, H7-1 sugar beets planted for seed production before August 13, 2010, may continue until the seeds or seed stecklings are harvested, transported and stored; and that sugar beet seed producers that used direct seeding (seed plants that will not be transplanted during the steckling stage of seed production) before August 13, 2010 may allow their H7-1 sugar beet seed plants to flower and set seed without any restriction under 7 CFR 340.

6. Interim Production of Sugar Beet under Conditions that do not Evoke Plant Pest Risk (Steckling Production)

At the time a decision was issued by the US District Court for the Northern District of California on August 13, 2010, sugar beet producers had begun planting of stecklings which are used in the next season to produce seed. Seed for the stecklings is planted in fall and allowed to develop into small non-flowering plants (stecklings) that are dug up the same season and stored until planting in late winter of the next year (as early as February). Because an exposure of the plants to cool temperatures or low day length is needed to induce flowering in the following season, no pollen or seed production occurs in the first year phase of the process. After planting the next season (late winter/early spring) these stecklings flower in their new location, and then, after fertilization with the necessary parental types, produce seed with the desired characteristics.

Pursuant to the permit application processes set forth in 7 CFR 340.4, after August 13, 2010, seed producers submitted permit applications to APHIS to continue planting of seed for the production of non-flowering stecklings. APHIS considered the potential environmental impacts of issuing these permits and concluded that the permit requests qualified as an action that is categorically excluded under APHIS NEPA implementing regulations. These plants do not flower, do not produce pollen and are generally removed from the soil at the end of a short season. Upon completing the required NEPA review, APHIS issued four permits on September 3, 2010 to produce only non-flowering stecklings in Arizona and Oregon:

10-228-104r to SESVanderhave for 100 acres

10-230-103r to Syngenta for 63 acres

10-235-106r to Betaseed for 335 acres

10-237-107r to American Crystal Sugar (planted acres are confidential business information (CBI))

This EA evaluates, among other things, the potential environmental impacts of APHIS authorizing the movement and transplanting of these non-flowering stecklings into the flowering stage of seed production.

7. Amended Petition Request for "Partial Deregulation"

APHIS has received a supplemental request from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 for H7-1 sugar beet (Petition 03-323-01) pursuant to the authority of 7 CFR Part 340. On October 8, 2010, APHIS published a notice[3] in the Federal Register (75 FR 62365-62366, Docket No. APHIS-2010-0047) announcing receipt of a supplemental Petition from the Monsanto Company (Monsanto) and KWS SAAT AG (KWS) requesting "Partial Deregulation" or some similar administrative action under 7 CFR Part 340 for sugar beets (*Beta vulgaris* ssp. *vulgaris*) designated as event H7-1 to authorize its continued cultivation subject to carefully tailored interim measures and conditions. The safeguarding measures set forth in the supplemental request were similar to interim measures that APHIS proposed to United States District Court during the remedies phase of the litigation challenging full deregulation of H7-1 sugar beet. The supplemental Petition is for a Partial Deregulation; it does not request a Full Deregulation of H7-1 sugar beet. Any decision on Full Deregulation of H7-1 sugar beet will not and cannot be made until an EIS is completed in reference to a request for a Full Deregulation of H7-1 sugar beet.

8. Need for APHIS Action

As ordered by the Court, H7-1 sugar beets planted after August 13, 2010, are once again subject

[3] To review the notice and the supplemental petition, go to http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2010-0047.

to the Plant Protection Act of 2000 (PPA) and APHIS' biotechnology regulations codified at 7 CFR Part 340. Under the authority of 7 CFR Part 340, APHIS has the responsibility for regulating the planting of genetically engineered organisms under the provisions of the Plant Protection Act of 2000. APHIS has received a supplemental request from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 for H7-1 sugar beet (Petition 03-323-01) pursuant to the authority of 7 CFR Part 340. APHIS must respond to petitioners request for a determination of the regulated status of genetically engineered organisms, including genetically engineered crop plants such as H7-1 sugar beets. If a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk.

APHIS is in the process of developing an EIS in connection with the court-mandated evaluation of the potential impacts on the human environment associated with any future Agency determination on whether or not to grant full nonregulated status for H7-1 sugar beet. On May 28, 2010, APHIS published a Notice of Intent (NOI) in the *Federal Register* seeking public comment on its intent to prepare an EIS and proposed scope of study. This EIS and a subsequent ROD are part of an independent NEPA process that are being prepared for making an informed decision on a petition request to grant full nonregulated status to H7-1 sugar beets. It is anticipated that the process for completing the EIS will take until the end of May 2012. In the meantime, APHIS must respond to the petitioner's request for partial deregulation or similar Administrative action (see *Federal Register* Notice 75 (195), p. 62365-6236, Oct. 8, 2010).

9. Regulatory Authority

"Protecting American agriculture" is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. Consistent with USDA policy, all methods of agricultural production (conventional, organic, or the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income. Thus, USDA seeks to enable coexistence and create an agricultural environment where all types of producers produce all types of crops (Recent statement of Secretary Vilsack). USDA considers biotechnology to be a very important tool for farmers to use in addressing some very important global and domestic farm production issues (Recent statement of Deputy Undersecretary of Agriculture Ann Wright).

In 1986, the Federal Government's Office of Science and Technology Policy (OSTP) published a policy document known as the Coordinated Framework for the Regulation of Biotechnology. This document specifies three Federal agencies that are responsible for regulating biotechnology in the US: USDA APHIS, the US Department of Health and Human Services' Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). APHIS regulates genetically engineered (GE) organisms under the Plant Pest Authority contained in the Plant Protection Act of 2000. FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the *Federal Register* on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). Products are regulated according to their intended use and some products are regulated by more than one agency. USDA, EPA, and FDA enforce agency-specific regulations for products of biotechnology that are based on the specific nature of each GE organism. Together, these agencies ensure that the products of modern biotechnology are safe to grow, safe to eat, and safe for the environment.

10. Scope of Analysis

This EA evaluates the potential impacts on the human environment of actions that APHIS may take under the PPA and 7 CFR Part 340 in response to a supplemental request from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 for H7-1 sugar beet (Petition 03-323-01) pursuant to the authority of 7 CFR 340. Specifically, the petitioner has requested APHIS to grant "partial deregulation" or similar administrative action to authorize the continued cultivation of H7-1 sugar beet subject to the conditions proposed by APHIS in the lawsuit challenging its determination of non-regulated status of H7-1sugar beet. This action, either a partial deregulation (i.e., removal of the crop from regulation pursuant to7 CFR 340) or the continued regulation through issuance of permits pursuant to 7 CFR Part 340, would allow the environmental release of H7-1 sugar beets in the primary sugar beet root or seed production states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming and the interstate movement and importation of H7-1 sugar beets within and into the US. Any action that APHIS may take under this EA would be limited in scope and duration, and would offer temporary protection to the environment pending completion of the court-ordered EIS.

11. Decisions to be Made

Based on the scope of this EA, the specific decisions to be made are:

- Should APHIS grant the supplemental Monsanto/KWS Petition request for "partial deregulation" or similar administrative action to authorize the continued cultivation of event H7-1 sugar beets subject to the interim measures proposed by APHIS to the Court?
- Should APHIS continue to regulate the release into the environment and movement of event H7-1 sugar beets (both all root and seed production activities) under 7 CFR Part 340?
- What conditions (interim regulatory measures) should be imposed to prevent any potential plant pest risk from planted event H7-1 sugar beets that are partially deregulated and thus removed from Part 340 regulation, to minimize disruptions to U.S. sugar beet production, and to minimize the likelihood of impacts noted by the Court until APHIS can complete an EIS before making a determination decision on whether or not to grant Full nonregulated status to event H7-1 sugar beets?

- Would the preferred alternative, if selected, have significant impacts on the quality of the human environment requiring preparation of an EIS?

12. Public Involvement

APHIS-BRS routinely seeks public comment on environmental assessments prepared to analyze potential effects that a regulated GE organism may have on the human environment. APHIS-BRS does this through a notice published in the *Federal Register*. This EA was made available for public comment for a period of 30 days. Comments received by the end of the 30-day period were analyzed and used to inform APHIS' decision on whether to grant the supplemental request to grant "partial deregulation" of H7-1 sugar beets, or whether other regulatory and administrative actions, e.g., permits issued pursuant to 7 CFR Part 340, are appropriate to allow the future planting of regulated RRSB, or whether it is appropriate to develop an Environmental Impact Statement prior to APHIS' decision to grant "partial deregulation" or to allow the planting of regulated RRSB pursuant to permits.

B. Major Issues in EA

The issues (see Affected Environment) analyzed in this EA were developed based upon possible impacts raised by the Court and possible impacts identified in the Notice of Intent to prepare an Environmental Impact Statement which APHIS published in the *Federal Register* on May 28, 2010 seeking public comment. APHIS sought input on issues and alternatives the Agency should consider in preparation of an EIS for granting nonregulated status for H7-1 sugar beets. In its ruling, the Court identified certain specific issues as requiring additional analysis by APHIS (USDC, 2008). While each of these issues will be analyzed in APHIS's court-ordered EIS prior to any decision to grant full nonregulated status to H7-1 sugar beets, these same issues are addressed in this EA to evaluate the possible impacts of APHIS responding to a petition request to grant "partial deregulation" of H7-1 sugar beets under interim APHIS regulatory oversight while APHIS completes the EIS. APHIS proposes that this EIS will be completed before May 28, 2012, but unforeseen conditions may affect actual completion date. APHIS' production of an EIS and an interim EA does not indicate that APHIS will or will not decide to deregulate H7-1. APHIS will not make that decision until the EIS process is complete.

1. Gene Transmission from Event H7-1 Sugar Beets in Production Fields

When grown to produce sugar, sugar beet roots are harvested during the first year and while still in the vegetative (non-flowering) phase. Certain conditions, such as low temperatures after planting and longer day length, can occasionally cause the sugar beet to "bolt" or produce a seed stalk (the flower-producing plant structure) during the first growing season (Bell 1946; Jaggard et al., 1983; Durrant and Jaggard, 1988). The potential for gene transmission from H7-1 sugar beet being grown for root production to other sugar beets under interim APHIS oversight is discussed in the Affected Environment section of this EA.

2. Gene Transmission to Conventional Sugar Beets in Seed Production

Unlike sugar beet root production, seed production requires that the plants flower, become pollinated, and develop seed. APHIS considers whether isolation distances are sufficient to prevent cross-pollination from non-GE crops that are inter-fertile with sugar beets. The potential for gene transmission from sugar beets being produced for seed production to conventional sugar beets under interim APHIS permit conditions or APHIS regulatory oversight is discussed in the Affected Environment section of this EA.

3. Gene Transmission to Red Table Beets and Swiss Chard

Cross-pollination between cultivated sugar beet and sexually compatible *Beta* species can occur when these plants grow close together and have overlapping flowering periods. Analysis is required to determine whether deregulation or other administrative action to allow the planting of H7-1 may significantly affect the environment as a result of any potential cross-pollination. The potential for gene transmission from H7-1 sugar beets being produced for seed or root production under APHIS permit conditions or APHIS regulatory oversight to sexually compatible species is discussed in the Affected Environment section of this EA.

4. Socioeconomic Impacts

The court found that APHIS failed to analyze the socio-economic impacts of deregulating H7-1 sugar beets on farmers and processors seeking to avoid GE sugar beets and derived products in its initial EA for the nonregulated status of H7-1. Further analysis of the potential for socioeconomic impacts under APHIS permit conditions or APHIS regulatory oversight is discussed in the Affected Environment section of this EA.

5. Willingness of Buyers to Accept Sugar Derived from GE Sugar Beets

Concerns have been raised that some buyers of industrial and consumer sugars have expressed reluctance or opposition to receiving sugar derived from GE sugar beet. Currently, H7-1 sugar beet is processed into a large percentage of our domestic sugar supply, with apparent wide acceptance. Nevertheless, analysis of this issue under permit APHIS conditions or APHIS regulatory oversight is discussed in the Affected Environment and Environmental Consequences sections of this EA.

6. Restrictions/labeling Requirements by Some Countries on GE Products

A comment from Imperial Sugar also indicated that some countries will not allow GE products to be imported and that many nations require labeling of food products with GE content. However, less than two percent of the sugar produced in the US is exported (USDA FAS, 2010), and exports of products derived from H7-1 sugar beets are expressly allowed in many foreign countries. Further information about this issue under APHIS permit conditions or APHIS regulatory oversight is discussed in the Affected Environment and Environmental Consequences sections of this EA.

7. Potential for Development of Glyphosate-Resistant Weeds

As the adoption of glyphosate-tolerant crops has grown, the use of glyphosate has increased (NRC, 2010; Young, 2006). Concerns have been expressed that increased use of glyphosate may lead to development of glyphosate-resistant weeds. Further information on the potential for development of glyphosate-resistant weeds under APHIS permit conditions or APHIS regulatory oversight is discussed in the Affected Environment and Environmental Consequences sections of this EA.

8. Cumulative Effects of Increased Use of Glyphosate

Further analysis of cumulative impacts from increased use of glyphosate resulting from the planting of H7-1 under APHIS permit conditions or APHIS regulatory oversight is discussed in the Cumulative Effects section of this EA.

C. Alternatives Considered

On August 13, 2010, the Court vacated APHIS's decision to grant nonregulated status to H7-1 sugar beet varieties, making them again subject to the Plant Protection Act and APHIS biotechnology regulations. The Court also remanded to the agency any regulatory oversight on producers of H7-1 sugar beets until the completion of an EIS. Under all the alternatives under consideration, and consistent with the Court's Order, H7-1 sugar beets planted *before* August 13, 2010, are *not* treated as regulated articles and are not subject to the Plant Protection Act of 2000 and 7 CFR Part 340 for the duration of those plantings. Thus, H7-1 sugar beets planted for root production before August 13, 2010 may remain in the ground, be harvested, transported, processed and sold as sugar. H7-1 sugar beets planted for seed production before August 13, 2010, may continue until harvested, transported and stored. Based on the Court's Order, H7-1 sugar beets planted for seed production before August 13, 2010 may continue until the seeds or seed stecklings are harvested, transported and stored; and that sugar beet seed producers that used direct seeding (seed plants raised directly from seeds in the field rather than from stecklings) before August 13, 2010 may allow their H7-1 sugar beets plants to flower and set seed.

Actions that APHIS may take in response to requests for environmental release or movement of H7-1 sugar beets, including partial deregulation, must provide sufficient protection to the human environment and address the concerns of the Court while APHIS completes its EIS before making a final decision on the petition to grant full nonregulated status to H7-1. The preparation of an EIS and subsequent ROD is an independent NEPA process to assist in making an informed decision on a petition request to grant full nonregulated status to H7-1 sugar beets. Any action that APHIS may take in response to the request for partial deregulation would be an interim action, which is limited in scope and duration, and would neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS. Many of the issues brought forward by the Court requiring preparation of an EIS are centered on the potential impacts of gene transmission (pollen flow) of H7-1 sugar beets. The conditions identified for each of the alternatives were developed to provide sufficient protection to the human environment and ensure that the concerns of the Court are satisfied until the EIS is completed.

In the draft EA published on November 4, 2010, APHIS outlined three alternatives that it was considering in response to the Monsanto/KWS supplemental request for partial deregulation. After receiving comments on the draft EA, for the reasons explained below, APHIS has developed a preferred alternative that combines the administrative aspects of Alternatives 2 and 3. The No Action alternative is a procedural NEPA requirement (40 CFR 1502), is a viable and reasonable alternative that could be selected, and serves as a baseline for comparison with the other alternatives. The No Action alternative, as defined here, is consistent with the Council on Environmental Quality's (CEQ's) definition (CEQ, 1981).

1. Alternative 1 - APHIS Denies Petition Request for Partial Deregulation/ No Further Actions to Authorize Cultivation of Event H7-1 Sugar Beets (No Action)

When the Court vacated APHIS' decision to grant nonregulated status to H7-1 sugar beets, beet seeds and roots not planted before August 13, 2010, became once again subject to regulations under the Plant Protection Act of 2000, including APHIS regulations in 7 CFR 340. As a result, all importation, interstate movements, and environmental releases (i.e. plantings) of H7-1 sugar beets for seed or root production activities after August 13, 2010, are prohibited without prior authorization from APHIS. Under the No Action Alternative, APHIS would deny the petition request for partial deregulation and take no further actions to authorize the movement or environmental release of H7-1 sugar beets. As a result, all importation, interstate movements, and environmental releases of H7-1 sugar beets would be prohibited. Conventional (non-GE) sugar beets could still be planted and made available for commercial use, including processing and sale of sugar. On those agricultural lands that would no longer be allowed to grow H7-1 sugar beets, farmers could plant conventional sugar beets, other agricultural crops, allow the land to become fallow, or used for other purposes. Additionally, since APHIS does not regulate the use of glyphosate, the herbicide would continue to be used to control weeds in agricultural and non-agricultural settings, consistent with the restrictions of the EPA label.

2. Alternative 2 - Event H7-1 Sugar Beet Production (Seed/Root) Regulated Under 7 CFR 340

Under this Alternative, APHIS would authorize the environmental release and movement of H7-1 sugar beets under APHIS permits or notifications in accordance with 7 CFR Part 340. As a result, importation and interstate movements of H7-1 sugar beets would be authorized under notifications that meet performance standards or under APHIS permits in accordance with conditions imposed by APHIS; and the environmental release (planting) of H7-1 sugar beets would be authorized under APHIS permits in accordance with conditions imposed by APHIS. APHIS would impose conditions consistent with conditions that APHIS proposed to the Court.

H7-1 sugar beets could be harvested, processed, stored, transported, processed and sold in commerce, subject to these conditions. Permits issued or notifications acknowledged under this alternative would be an interim action that is limited in scope and duration, and would neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS.

Permit Program. APHIS' permitting and notification process for the environmental release and movement of H7-1 sugar beets would be carried out in accordance with 7 CFR Part 340.

As specified in 7 CFR Part 340.4, applicants must request permits for a field release (planting) in advance of the proposed planting date. Required data for the permit would include the responsible person, description of the regulated article and differences between it and the non-modified parental crop, locations and distribution of the regulated article, size of the permit site(s), any procedures or methods and safeguards employed and methods to dispose of potentially viable residues or reproductive materials. For movement of sugar beet seed, stecklings or beets, quantity of the regulated H7-1 article would be identified for the applications. APHIS will provide States and Tribes copies of its review of permit applications as appropriate based on where the release is planned. Specific permit conditions assigned by APHIS would prevent the escape and dissemination of the regulated article and greatly limit the risk of any potential for inappropriately introducing or disseminating H7-1 sugar beets into the environment.

Importation or interstate movement of H7-1 sugar beet would occur under an APHIS permit or acknowledged notification. H7-1 sugar beets could be imported or moved interstate under notifications acknowledged by APHIS-BRS as long as they meet the requirements found in §340.3 "Notification for the introduction of certain regulated articles." These include §340.3 (c)(1) "Performance standards for introductions under the notification procedure" which require shipment in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment. Permits for importation and interstate movement would meet the requirements identified in 7 CFR 340.4, 340.7 and 340.8, including specific permit conditions assigned by APHIS that would prevent inadvertent release of H7-1 sugar beets into the environment.

APHIS maintains a website, http://www.aphis.usda.gov/biotechnology/status.shtml, which automatically updates information about the status of a permit application on the next weekday morning after such information is inputted in its system. Information about APHIS's receipt of a permit can be obtained by anyone accessing the APHIS website and allows searches for information about the status of a permit. APHIS will also use this website to inform the public in a timely manner on the status of all permit applications for H7-1 sugar beets. In addition, due to the anticipated public interest in these permits, APHIS will post a CBI redacted version of each permit application upon receipt and permit upon issuance to the APHIS e-FOIA Reading Room: http://www.aphis.usda.gov/foia/foia_reading_room.shtml.

Scope. Permits with specific permit conditions could be issued for each of the following sugar beet production systems in the states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming: non-flowering steckling production, seed production from flowering stecklings or directly from seed, and root production. The environmental release of H7-1 sugar beets would be limited to sites that have been in agricultural production for a minimum of 3 years. In addition, importation and interstate movement of seed shipments within and into the US would require a notification acknowledged by APHIS. For each type of sugar beet production system for which APHIS receives a permit application, APHIS could issue a permit to any organization, association, corporation, institution or any other entity that is in the business of growing and/or producing H7-1 sugar beets. This includes, but is not limited to seed companies producing H7-1-derived sugar beet seed or cooperatives or processors that have contractual agreements with producers that grow beets for sugar. Because of the logistical impossibilities of dealing with the huge number of potential individuals involved in growing and transporting H7-1 sugar beets, APHIS does not envision issuing permits to individual farmers or transport drivers.

APHIS has knowledge of four seed companies (American Crystal Sugar Company, Betaseed, Inc., SESVanderhave Sugar Beet Seeds, and Syngenta Seeds, Inc.) that produce H7-1 sugar beet seed, either directly or through a seed production cooperative (West Coast Beet Seed). APHIS could issue permits to any of these four seed companies for steckling and direct seed production upon receipt and review of a completed permit application. All growers and the locations of their glyphosate tolerant sugar beets would be identified in the permits issued to the relevant seed company.

APHIS has knowledge of nine grower-owned processors, including American Crystal Sugar Company, Michigan Sugar, Minn-Dak Farmers Cooperative, Sidney Sugars Incorporated, Snake River Sugar Company, Southern Minnesota Beet Sugar, Spreckels Sugar Company, Western Sugar Cooperative, and Wyoming Sugar Company in the US, with a tenth, Rogers Sugar Company, located in Alberta, Canada. One company, Spreckels Sugar, is in California. None of the processors will be allowed to grow H7-1 derived sugar beets in California and certain counties in Washington State. APHIS could issue permits to any of the nine eligible US processors for root production upon receipt and review of a completed permit application. All growers and the locations of their glyphosate tolerant sugar beets would be identified in the permits issued to the grower-owned processor. The processors have contracts with growers that identify the location, number of acres and conditions for growing the sugar beet root crop. Under an APHIS permit the processors would be required to amend these contracts to require growers to adopt the confinement measures described in the APHIS permit. The H7-1 sugar beets produced in Ontario, Canada, and transported to the Michigan Sugar Company processing facility in the US would need to be imported pursuant to-an APHIS import permit. This APHIS import permit would be issued to the US processor accepting these shipments into the US.

Chronology of Permitting. Upon receipt of a complete permit application and after a thorough evaluation and review, APHIS will make a decision on whether or not to authorize the planting of flowering stecklings in seed production fields in late winter/early spring; planting of sugar beet seed for root crop production in spring; planting of seeds for direct seeding (flowering) for seed production in seed production fields in late summer/early fall; and the planting of non-flowering stecklings in seed production fields in late summer/early fall. Exact planting dates would vary dependent upon geographic location and local conditions. Subsequent seasons would follow a similar permitting scheme until APHIS completes the court-mandated EIS and makes a determination on whether or not to grant nonregulated status to H7-1 sugar beet. It is anticipated that the process for completing the EIS may take until the end of May, 2012 to complete.

Enforcing Permit Conditions. An applicant's compliance with APHIS permit conditions and notification requirements would be carried out using the following approaches.

Seed Production

- H7-1 beet seed producers (permit holders) would assign a responsible person pursuant to 7 CFR 340 to oversee the permit for beet seed production; this individual would oversee the performance of the sugar beet seed growers under the permits. The responsible person, likely an agronomist, would oversee the standard procedures of seed production and would monitor and assess compliance with the conditions assigned by the APHIS permit. Total acreage for all seed production permits is estimated to cover approximately 3000-5000 acres.
- APHIS will inspect the seed production fields to ensure their compliance with all mandatory permit conditions and such inspection(s) will be completed prior to any possible pollen shed.

Root Production

- H7-1 beet processors (usually a cooperative) (permit holder) would assign a responsible person pursuant to 7 CFR 340 to oversee the permit for beet root production; this individual would oversee the performance of the processor's sugar beet growers under the permits. The responsible person, likely an agronomist, would oversee the standard procedures of sugar beet production and would monitor and assess compliance with the conditions assigned by the APHIS permit. These employees advise growers on agronomic issues and also visit growers and assess conditions of the beet root crop. Under the permits for root production, the responsible person must oversee effective control of bolters, and would ensure that this permit condition and all other conditions were met.

- For the root crop production, APHIS will require third party inspections/audits. Permit holders will procure the third party inspectors/auditors. However, the third party inspectors/auditors will be trained by APHIS officials and will be working on APHIS' behalf, being responsible for submitting reports to APHIS. A large number of the root production fields will be inspected by the third party inspectors, sufficient to give statistically significant conclusions ($p=0.05$) on overall compliance. In addition, APHIS personnel will also inspect select fields following its standard practice. Total acreage for all root production permits is estimated to cover approximately 1 – 1.4 million acres.
- The third party auditor would review all grower records on file with the permit holder (the processor/cooperative) and submit field inspection reports to APHIS. APHIS will carefully examine the field inspection reports to ensure compliance with all permit conditions. The permit will specify that activities conducted by growers may be either audited or inspected by APHIS or third party auditors or both. APHIS will provide detailed inspection forms for the information to be supplied by processor/growers, and the subsequent records will be made available to APHIS/BRS for audit. Growers under the direction of the Cooperative/Processor must keep records of these compliance activities and make them available to APHIS and/or third party auditors upon request. APHIS will carefully examine a representative sample of cooperative/processor records to ensure compliance with the Agency's permit conditions.

Import and Movement under Notification

Site visits by APHIS inspectors will also involve monitoring and assessing compliance with regulations for seed and beet movement, such as secure storage sites, allowable containers and vehicle loading levels (transporting beets) when used in the movements.

Uniformity of Assigned Conditions. All permit conditions identified under Alternative 2 would be required and applicable to all permit applications that APHIS may receive for H7-1 sugar beet production. Details of the respective assigned permit conditions for each of the specific production systems (non-flowering steckling production, seed production from flowering stecklings or directly from seed, and root production) are described below.

Evaluation of Permit Application for Consistency with the Environmental Assessment*.* Upon receipt of a complete permit application or notification, and prior to issuing the permit or acknowledging the notification, APHIS will evaluate and make a determination about whether the permit application or notification corresponds with all of the required conditions and provisions as described in the final EA and, if so decided, in any subsequent final decision and FONSI. In addition, APHIS will review the applicant's SOP for adhering to the requirements set forth in 7 CFR Part 340. As part of this evaluation and review process, APHIS will prepare a separate decision document for each permit application which is approved to document that the approval and issuance of the permit is consistent with all of the required conditions and provisions and within the scope of the final EA. This decision document will be made available to the public. If APHIS determines that approving the permit is not consistent with any final EA (for example, there are some environmental impacts resulting from the permit which were not considered in the final EA), then APHIS will supplement or revise the final EA, prepare an additional EA, or prepare an EIS, as appropriate, before approving such permit, or will deny the permit.

Information for Non-GE Beta Seed Producers Regarding Male Fertile H7-1 Seed Production Locations.

7 CFR § 340.4 for "release into the environment" permits provides, among other things, that "[i]f there are portions of the application deemed to contain trade secret or confidential business information (CBI)" then applicants may label said information as CBI and, if APHIS concurs, it will treat it as such. Under Part 340's traditional regulatory and commercial practices, most permit applicants consider the particular location of the field releases to be confidential business information (CBI) and expect that APHIS, under applicable federal laws, will treat them as such.

APHIS has a record of the location of each field release. APHIS is provided an address, GPS coordinates, and a diagram of the site. On March 9, 2000, APHIS formally announced the APHIS policy to allow GE crop field trial location as CBI. For each permit application, companies need to justify their confidentiality claims by means of a justification letter. APHIS considers that the precise location of environmental releases can be validly claimed as CBI and may be excluded from public review for several important reasons. Many biotechnology producers expend millions of dollars on research and development to develop a commercially viable genetically modified plant product. Any disclosure of a biotech company's research (whether from a direct disclosure, industrial espionage or through reverse engineering of the product) would allow competitors and others to profit from a producer's expensive, laborious research. Revelation of environmental release sites would provide the opportunity for competitors or others to pilfer the sites for, among other reasons, purposes of industrial espionage and/or reverse engineering. Even the methods used by biotech producers to comply with APHIS regulatory requirements, such as confinement measures, may be proprietary, and revealing environmental release locations might reveal that CBI as well.

Additionally, field releases of some GE plant products represent an especially attractive target for commercial or personal theft. Stolen regulated GE seeds or plants can be propagated and grown by anyone with a rudimentary knowledge of farming practices. If such regulated products are stolen, they can be grown without regulatory oversight and used illegally. Such action could lead to the introduction of regular traits not intended for food and feed to illegally enter into the food and feed supply. Additionally, in the past ten to fifteen years there have been violent attacks of universities, government laboratories, farms, and other private industry facilities involved with genetically modified organisms. As a result many individuals working in the field of biotechnology have fears about their personal safety. In certain instances, the names of responsible parties and the locations of field trials as claimed CBI have been accepted by APHIS to protect individuals from harassment, mitigate civil unrest, and facilitate voluntary corporate and business compliance with APHIS's regulatory program.

In order for APHIS to protect the CBI specific site locations of any seed production permits, APHIS has decided that in reference to any seed permits, APHIS will set up a toll-free number which growers of non-GE *Beta* seed crops may use to request from APHIS the approximate distances from the nearest male fertile H7-1 seed crop to their non-GE *Beta* seed crop. Upon calling this number, the caller shall certify to APHIS that the caller is a grower of non-GE *Beta* seed crops or intends to grow non-GE *Beta* seed crops. APHIS shall provide to the caller the approximate distance from the nearest male fertile H7-1 seed crop location to the caller's location of a non-GE *Beta* seed crop.

a. Mandatory Permit Conditions Imposed on Seed Production

Under this Alternative, the following mandatory permit conditions would be imposed on plantings of H7-1 sugar beets intended for seed production via permit conditions where the seed producer (permit holders) will acknowledge and adhere to these mandatory conditions:

1. Planting of H7-1 sugar beets is not allowed in the state of California and the following counties in Washington State: Clallam, Clark, Cowlitz, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, Pacific, Pierce, San Juan, Skagit, Skamania, Snohomish, Thurston, Wahkiakum, and Whatcom.
2. A four-mile separation distance shall be maintained between male *fertile* H7-1 sugar beets and all other commercial *Beta* seed crops (i.e., table beets, Swiss chard) US wide.
3. An inventory of H7-1 male *fertile* planting locations shall be provided to APHIS within two weeks of planting.

4. A four-mile separation distance shall also be maintained between male *sterile* H7-1 sugar beets and all other commercial *Beta* seed crops US wide. During flowering, fields shall be scouted for male sterile H7-1 plants that shed pollen and such plants shall be destroyed.
5. A visual identification system, such as labeling, that accompanies the regulated material (e.g. basic seed, stock seed, stecklings, and commercial seed) throughout the production system, is required.
6. A companion seed-lot based tracking and tracing system that is fully auditable shall be maintained. Records must be retained for five years.
7. Other than non-GE *Beta* seed material used in the production of hybrid-seed, all H7-1 material shall be physically separated from non-regulated material to prevent commingling at all points throughout the production process.
8. Planting, cultivation, and harvesting equipment shall be cleaned to prevent H7-1 stecklings or seed from being physically transferred out of production areas or mixed with non-GE *Beta* material by inadvertent means.
9. All unused H7-1 stecklings shall be treated as regulated articles until devitalized and discarded.
10. All H7-1 seed and steckling material shall be moved in contained transport systems to avoid inadvertent release into the environment. Vehicles or movement containers shall be thoroughly cleaned after transport and any regulated material recovered shall be devitalized.
11. Sexually compatible varieties (e.g. chard/red beet) cannot be planted or produced in the same location (the same field) as H7-1 in the same growing year.
12. Planting/cultivating/harvesting equipment that might be used in chard/red beet seed production shall not be used for regulated GE material in the same growing year.
13. Measures to force same year sprouting of H7-1 seed left in production fields are required. Any seed which sprout from such leftover seed shall be destroyed. Fields shall be monitored for three years and any volunteer beet plants shall be destroyed. If the same land is used for crop cultivation during the three-year volunteer monitoring period, that crop shall be visually distinct from sugar beets or the fields left fallow.

14. A management plan shall be submitted and followed. The management plan will set forth best practices for oversight of the movement, transportation, and confined field production of H7-1 seed. The management plan shall include, but not be limited to, required resources, training of relevant personnel, monitoring of growers, record keeping, and verifying compliance with the permit conditions. The applicant shall also provide the SOPs that will be utilized to conduct the field trials and comply with the permit and permit conditions.
15. No H7-1 seed shall be cleaned or processed in any processing facility that also cleans and processes red beet or Swiss chard seed.
16. Interstate movement of H7-1 sugar beet stecklings and seed may only be authorized with a movement notification or permit consistent with regulations described in 7 CFR 340.
17. The applicant shall ensure that all site cooperators/growers have received the permit conditions and are trained in all the processes and procedures.
18. The applicant shall maintain records of all the activities authorized under the permit to demonstrate adherence to 7 CFR 340, the permit, and the permit conditions. These records shall be made available to APHIS/BRS.

b. Mandatory Permit Conditions Imposed on Root Production

Under this Alternative, the following mandatory permit conditions would be imposed on H7-1 sugar beets intended for root production via permit conditions where the cooperatives (permit holders) will acknowledge and adhere to these mandatory conditions:

1. Planting of H7-1 sugar beets is not allowed in the state of California, and the following counties in Washington State: Clallam, Clark, Cowlitz, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, Pacific, Pierce, San Juan, Skagit, Skamania, Snohomish, Thurston, Wahkiakum, and Whatcom.
2. Applicants shall ensure that root crop fields are surveyed to identify and eliminate any bolters before they produce pollen or set seed. Fields shall be surveyed every 3-4 weeks beginning April 1. Applicants shall ensure that field personnel maintain records of removal of bolters.

3. Applicants shall randomly choose a statistically representative sample of fields and conduct inspection for bolters. If bolters are identified, field personnel shall be notified immediately and those bolters must be removed. Applicant shall notify APHIS/BRS within 48 h after finding bolters, with the location and action taken by the field personnel. The applicant shall maintain all records of inspection and bolter removal and records must be made available to APHIS/BRS and/or to authorized third party inspectors/auditors upon request. APHIS will provide an inspection form to be used to capture this data.
4. Planting/cultivating/harvesting equipment that might be used in chard/red beet production shall not be used or shared for regulated GE material in the same growing year.
5. Trucks used for the movement of root crop from field to storage/processing shall be loaded in a manner to minimize loss of beets during transport or equipped with a retaining device.
6. During transport, chain of custody and records shall be maintained. Records shall be made available to APHIS/BRS and/or to authorized third party inspectors/auditors upon request.
7. Root crop fields shall be monitored for three-year following harvest and volunteer plants destroyed. If the same land is used for crop cultivation during the volunteer monitoring period, that crop shall be visually distinct from sugar beets or the fields left fallow.
8. The applicant shall ensure that all site cooperators/growers have received the permit conditions and are trained in the all processes and procedures.
9. The applicant shall maintain records of all the activities authorized under the permit to demonstrate adherence to 7 CFR 340, the permit, and the permit conditions. These records shall be made available to APHIS/BRS and/or to authorized third party inspectors/auditors upon request.
10. APHIS inspections and/or third party inspections/audits will be required to ensure that sugar beet producers comply with the requirements under 7 CFR 340, the permit, and the permit conditions. Records of audits shall be made available to APHIS/BRS for review upon request.

3. **Alternative 3 - Partial Deregulation of Event H7-1 Sugar Beets (Seed/Root)**

The petitioner requested APHIS to grant "partial deregulation" or similar administrative action to authorize the continued cultivation of H7-1 sugar beets subject to the conditions proposed by APHIS to the Court in the lawsuit challenging its determination of non-regulated status of H7-1 sugar beets. The supplemental request that APHIS received from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 (75 FR 62365-62366, Docket No. APHIS-2010-0047), pursuant to the regulatory scheme of 7 CFR Part 340, did not clearly explain what the petitioners mean or envision by a "partial deregulation." The petitioner did not identify any specific mechanism(s) that would be used to impose the conditions, which parties would be subject to the conditions, or how compliance with the conditions would be ensured.

APHIS has interpreted this petition to mean that Monsanto/KWS is requesting that H7-1 sugar beets would no longer be regulated under 7 CFR Part 340 provided that they are cultivated under the conditions that APHIS proposed to the Court. APHIS further interprets the request to mean that Monsanto/KWS would be the responsible party for overseeing implementation and monitoring of conditions for cultivation of H7-1 sugar beets. Under this alternative, APHIS would grant the petition for partial deregulation, APHIS would no longer regulate H7-1 sugar beets under 7 CFR Part 340, and the cultivation of H7-1 sugar beets would be allowed under conditions imposed by Monsanto/KWS through technology stewardship agreements, contracts or other legal instruments. These instruments would be established between Monsanto/KWS and each seed company, cooperative or any other entity that wished to cultivate H7-1 sugar beets. Monsanto/KWS would be responsible for overseeing compliance of contractual agreements. H7-1 sugar beet seeds (including stecklings) could be harvested, processed, stored, transported and sold in commerce; and H7-1 sugar beet roots could be harvested, stored, processed, transported and sold as sugar, so long as the Monsanto-imposed conditions were followed.

Under this Alternative, Monsanto/KWS would establish conditions similar to the following conditions APHIS proposed to the Court:

1) *Roundup Ready® Sugar Beet-Free Zone*

The planting of RRSB is prohibited in the entire State of California and in the State of Washington in the following counties west of the Cascades: Clallam, Jefferson, Grays Harbor, Island, Pacific, Mason, Thurston, Lewis, Cowlitz, Clark, Whatcom, Skagit, Snohomish, King, Pierce, Skamania, San Juan, Kitsap, and Wahkiakum Counties.

2) *A Coexistence Zone for Beta Seed Crop Production in the Willamette Valley in Oregon*

a. All parties to this action who grow *Beta* seed crops in the Willamette Valley must adhere to a four-mile isolation distance between RRSB seed crops and other *Beta* seed crops.

b. All parties to this action who grow *Beta* seed crops in the Willamette Valley must follow the Willamette Valley Specialty Seed Association (WVSSA) pinning procedures.

3) *Disclosure of Information Regarding Male Fertile RRSB Seed Crops.*

All growers of RRSB male fertile seed crops must provide locations with GPS coordinates to APHIS/BRS of any RRSB male fertile seed crops in the United States planted pursuant to a partial deregulation. Information regarding any plantings pursuant to a partial deregulation must be provided to APHIS within one week after the completion of planting of any RRSB male fertile seed crops. Within 60 days after the planting is completed pursuant to a partial deregulation, APHIS/BRS shall set up a toll-free number that growers of non-GE *Beta* seed crops may use to request from APHIS/BRS the approximate distances from the nearest RRSB male fertile seed crop to their non-GE *Beta* seed crop.

Upon calling this number, the caller shall certify to APHIS/BRS that the caller is a grower of non-GE *Beta* seed crops or intends to grow non-GE *Beta* seed crops at an existing location in the United States. APHIS/BRS shall only provide to the caller the approximate distance from the nearest RRSB male fertile seed crop location to the caller’s non-GE *Beta* seed crop.

4) *Measures to Prevent Mixing of Conventional Sugar Beet Seed and RRSB.*

RRSB seed producers shall follow protocols to ensure that mechanical mixing of material containing the RRSB trait and non-GE *Beta* seeds does not occur. Those protocols shall include:

a. A visual identification system for RRSB material (basic seed, stock seed, transplants (stecklings), and commercial seed) that accompanies seed material throughout the production system to delivery to ultimate purchaser;

b. A companion seed-lot based tracking and tracing system that is fully auditable;

c. Requirements for physical separation of RRSB material at all points in the seed production process from non-GE *Beta* material;

d. Requirements for monitoring, treating, and cleaning of all planting, cultivation and harvesting equipment to prevent RRSB seed, pollen or stecklings from being physically transferred out of production areas by inadvertent means;

e. Requirements for disposal of all unused RRSB stecklings by returning unused stecklings to the nursery field of origin and subsequent destruction through standard agricultural practices (i.e. physical destruction with tillage and chemical destruction in the subsequent crop);

f. Requirements for contained seed transport from field to cleaning facility, vehicle cleaning after transport of RRSB seed before use for other purposes, and devitalization of RRSB material derived from cleaning vehicles or processing facilities;

g. Prohibition on grower production of a RRSB seed and chard/red beet seed production on the same location/premises in the same year;

h. Prohibition on RRSB seed grower use or sharing of planting/cultivation equipment that might be used in a non-GE *Beta* seed production in the same growing year;

i. Prohibition on RRSB seed grower use of the same combine to harvest RRSB and non-GE *Beta* seed in the same year;

j. Provisions to force same-year sprouting of any RRSB seed left behind in production field for removal and destruction; plus 3-year monitoring of fields thereafter, along with removal and destruction of any beet plants;

k. Employee training in all aspects of points “a” through “j” above;

l. No RRSB seed shall be cleaned or processed in any processing facility that also cleans and processes red beet or Swiss chard seed;

m. Record-keeping to document compliance of points “a” through“l” above.

5) *Control of Any Bolters in the RRSB Root Crop Fields.*

All RRSB root crop growers must have contractual measures in place that require RRSB root crop growers to survey, identify, and eliminate any bolters in their root crop fields before they produce pollen or set seed.

6) *Control of Any Bolters in Harvested RRSB Root Crop in Outdoor Storage.*

All sugar beet processors or cooperatives that use RRSB must have measures in place to survey, identify, and eliminate any bolters in outdoor storage before they produce pollen or set seed.

7) *Third Party Audit for Compliance.*

APHIS will require third party audits to ensure that RRSB producers comply with requirements in paragraphs 2) and 4) above. APHIS expects that AMS (Agricultural Marketing Service) USDA, will be the third party auditor using its AMS-USDA Process Verified Program.

Preferred Alternative – Partial Deregulation – Combination of Alternatives 2 and 3

The petitioners requested APHIS to grant partial deregulation or similar administrative action to authorize the continued cultivation of H7-1 sugar beets subject to the conditions proposed by APHIS to the Court in the lawsuit challenging its determination of non-regulated status of H7-1 sugar beets. The supplemental request that APHIS received from Monsanto/KWS to amend the petition for non-regulated status submitted in 2003 (75 FR 62365-62366, Docket No. APHIS-2010-0047), pursuant to the regulatory scheme of 7 CFR Part 340, did not clearly explain what the petitioners meant or envisioned by a partial deregulation. The petitioners did not identify any specific mechanism(s) that would be used to impose the conditions, which parties would be subject to the conditions, or how compliance with the conditions would be ensured.

However, in response to APHIS' request for comments on its draft EA (Docket No. APHIS–2010–0047), the public (i.e., beet sugar cooperative, financial institution, employee of a sugar company) expressed interest and support for a partial deregulation alternative that included mandatory conditions imposed by APHIS. These conditions were clearly outlined and described under alternatives 2 and 3 and formed the basis for the conditions that would be imposed on the movement and environmental release of H7-1 sugar beets under the preferred alternative. Furthermore, Monsanto/KWS submitted additional information during the public comment period that expanded upon what the petitioners meant by partial deregulation and re-asserted that a deregulation in part with conditions could be implemented using the same type of conditions already discussed in the draft EA. Specifically, petitioners clarified that the conditions required for cultivating and handling H7-1 sugar beets under the deregulation in part with conditions would be articulated in that deregulation in part decision; implemented by seed companies, grower cooperatives and growers; and enforced through seed companies and grower cooperatives, respectively, under the direct oversight of APHIS. Furthermore, the petitioners clarified that the regulatory mechanism for imposing such conditions under the partial deregulation could be carried out through APHIS administered compliance agreements similar to APHIS' oversight of permits. The petitioners also identified that they will, for education and emphasis, place all of the APHIS-imposed conditions in its Technology Use Guide (TUG), which is implemented through Monsanto Technology Stewardship Agreements (grower agreements), to reinforce the measures imposed by APHIS as conditions of the partial deregulation.

APHIS reviewed this additional information as well as the other public comments regarding a partial deregulation of H7-1 sugar beets. Based on APHIS' analysis and evaluation of all of the proposed partial deregulation approaches, APHIS has determined that it is appropriate to have a partial deregulation alternative that partially deregulates H7-1 sugar beets by combining aspects of Alternative 2 in regards to seed production activities and a modification of Alternative 3 in regards to root production activities. Under this partial deregulation alternative, APHIS would *deny* the supplemental request for partial deregulation with regard to H7-1 sugar beet seed production activities and such seed production activities would remain regulated pursuant to Part 340; however, pursuant to and in compliance with 7 CFR 340.6, APHIS would grant the supplemental request with regard to partially deregulating the H7-1 root production activities as long as certain specific mandatory conditions are complied with by anyone desiring to conduct H7-1 sugar beet root production activities. Under the Preferred Alternative, the H7-1 sugar beet seed production activities would remain a regulated article subject to all of the procedural and substantive requirements of 7 CFR 340. Under the Preferred Alternative, APHIS would partially grant the supplemental request by partially deregulating the H7-1 sugar beet root production activities but with enforceable mandatory conditions that must be followed in order to be granted a partial deregulation for H7-1 sugar beet root production activities. APHIS has evaluated the supplemental petition and has concluded that H7-1 sugar beet root production activities, when conducted under specific mandatory conditions required and enforced by APHIS, is unlikely to pose a plant pest risk (USDA-APHIS 2011). Therefore, APHIS has determined that H7-1 sugar beet root production activities carried out under this interim action, if conducted under these mandatory conditions, should not be subject to the procedural and substantive requirements of 7 CFR Part 340 for the duration of this interim action. If, however, commercial root production activities are not conducted pursuant to these mandatory conditions, the APHIS Administrator has the regulatory authority and discretion to once again make such root production activities subject to regulation under 7 CFR Part 340.

The administrative action that APHIS would take on seed production activities under the Preferred Alternative largely adopts the regulatory scheme as described in alternative 2 of the draft and final EA. That is, APHIS would authorize the environmental release and movement of H7-1 sugar beet seed crops and seed production activities under APHIS permits or notifications in accordance with 7 CFR Part 340. As a result, importation and interstate movements of H7-1 sugar beet seed crops would be authorized under notifications that meet performance standards or under APHIS permits in accordance with conditions imposed by APHIS; and the environmental release (planting) of H7-1 sugar beet seed crops would be authorized under APHIS permits in accordance with conditions imposed by APHIS.

The administrative action that APHIS would take on root production activities largely adopts the partial deregulation process as described in alternative 3 of the draft and final EA. That is, APHIS would partially deregulate H7-1 sugar beet root crop if grown under specific conditions. In alternative 3, APHIS would grant the petition for partial deregulation and H7-1 sugar beets would no longer be subject to the procedural and substantive requirements of 7 CFR Part 340, and the cultivation of H7-1 sugar beets would be allowed under conditions imposed by Monsanto/KWS through technology stewardship agreements, contracts or other legal instruments. Under the Preferred Alternative, APHIS would also partially deregulate root production if grown under specific conditions, consistent with the conditions described in Alternative 3. In the Preferred Alternative, however, APHIS would authorize root production activities and impose those conditions directly through compliance agreements. Additionally, Monsanto/KWS will also be enforcing these conditions through their technology stewardship agreements, contracts or other legal instruments.

Since publishing the draft EA, APHIS has completed a Plant Pest Risk Assessment and has determined that H7-1 sugar beet root production activities carried out under this interim action, if conducted under mandatory conditions, do not pose a plant pest risk and, therefore, should not be subject to the procedural and substantive requirements of 7 CFR Part 340. Therefore, APHIS does not see the need to issue permits and impose the permit requirements under Part 340 for sugar beet root production activities.   A compliance agreement is a regulatory mechanism to authorize actions under the PPA. The compliance agreements would authorize root production activities under the PPA and impose the conditions that must be followed for the partial deregulation. Compliance agreements are well established in APHIS as an effective and efficient regulatory mechanism to authorize activity under the PPA and maintain regulatory oversight of those activities.

The Preferred Alternative is similar to the "Event H7-1 Sugar Beet Seed Production under APHIS Permit/Partial Deregulation for Root Production" alternative that was rejected from further consideration by APHIS in the draft EA. As specified in the draft EA, APHIS determined that this alternative was not appropriate because APHIS had not completed an assessment of potential plant pest risks to support the deregulation of H7-1 sugar beet. This alternative has now been considered in detail in the final EA for the following reasons:

1. Since releasing the draft EA for public comment, APHIS has completed a Plant Pest Risk Assessment (PPRA) of the H7-1 sugar beet root crop grown under specific mandatory conditions and APHIS has concluded that H7-1 sugar beet root crop, when grown for commercial root crop production and under specific mandatory conditions, does not pose a plant pest risk. As identified above, the public has expressed interest and support for a partial deregulation alternative that included conditions imposed by APHIS. APHIS received comments specifically requesting APHIS to allow production of sugar beets under compliance agreements. Based in part on this request, APHIS decided to consider in detail and fully analyze an alternative that includes APHIS using compliance agreements as an administrative mechanism to impose conditions on H7-1 sugar beet root crop and root production activities.

2. As identified above, Monsanto has submitted information that expanded upon what the petitioner meant by partial deregulation. This information clarified that petitioners intended APHIS deregulating H7-1 sugar beets in part with conditions. The petitioners provided a description of methodology for implementing partial deregulation that articulated the use of compliance agreements for overseeing the production of H7-1 sugar beets. Based in part on this additional information provided by the petitioners, APHIS

has decided to consider in detail and fully analyze an alternative that includes APHIS using compliance agreements as an administrative mechanism to impose conditions on H7-1 sugar beet root crop and root production activities.

Because the Preferred Alternative incorporates and adopts the key components of Alternatives 2 and 3 and considering that decision to use compliance agreements to impose mandatory conditions represents a sensible step that was suggested by commenters, the Preferred Alternative is a logical outgrowth of Alternatives 2 and 3. The draft EA fully evaluated and analyzed the potential environmental impacts of all of the specific aspects of Alternatives 2 and 3. Thus, the potential environmental effects of the specific aspects of Alternatives 2 and 3 that are now incorporated into the Preferred Alternative were previously analyzed in the draft EA..

These mandatory conditions, that must be followed and complied with in order for the root production activities to be considered partially deregulated under the Preferred Alternative, would be enforced and required pursuant to written APHIS compliance agreements authorized under the PPA, and would impose certain mandatory conditions on the movement and environmental release of the H7-1 sugar beet root crop and root production activities. These legally binding and enforceable compliance agreements would specify the mandatory conditions for partial deregulation of the root production activities and would formalize and impose the mandatory conditions under which the root crop and root production activities would be considered partially deregulated – not subject to the procedural and substantive requirements of 7 CFR Part 340 for the duration of the interim action. APHIS would employ these required compliance agreements to impose and enforce the mandatory conditions on the import, movement or environmental release of the root crop and root production activities and the compliance agreements would be a formal, written, and signed agreement between APHIS and a person who wants to import, move, and/or do an environmental release in conjunction with the H7-1 sugar beet root crop production activities [note that movement and the environmental release includes the entire production cycle of H7-1 sugar beet root crop – referred to collectively as all the "root production activities"; and the terms person, import, or move have the meanings as they are so defined in the Plant Protection Act (PPA), as amended].

Under the Preferred Alternative, the compliance agreements would be enforced under the authority of the PPA and 7 CFR Part 340. If APHIS determines that any of the mandatory conditions of the partial deregulation set forth in the compliance agreements are not complied with, APHIS may revoke, withdraw or otherwise cancel the conditional partial deregulation for the commercial root crop production activities. Further, APHIS may use the full range of PPA authorities to seek, as appropriate and necessary, criminal and/or civil penalties, and to take remedial measures including seizure, quarantine, and /or destruction of any root crop or root production activity in violation of the mandatory conditions of the partial deregulation.

APHIS has decided that the imposed and mandatory conditions associated with the partial deregulation of the H7-1 sugar beet root crop and root production activities, which will be formalized in compliance agreements, are appropriate and prudent safeguards to effectively minimize the likelihood of any potentially significant environmental impacts. Furthermore, APHIS has determined that the mandatory conditions imposed pursuant to the partial deregulation of the H7-1 sugar beet root crop and root production activities will help ensure that the implementation of this interim regulatory action (The Preferred Alternative) will not result in any environmental impacts which may significantly affect the quality of the human environment. Moreover, APHIS has likewise determined that the implementation of this preferred alternative with its mandatorily imposed conditions will help ensure that no potentially harmful economic or marketing impacts noted by the Court will occur during the interim until APHIS can complete its Environmental Impact Statement and make a determination on whether or not to grant full nonregulated status to H7-1 sugar beets. Under this preferred alternative, the *mandatory* conditions and restrictions would be consistent with the conditions that APHIS had previously proposed to the Court in litigation challenging the 2004 deregulation of H7-1 sugar beets. H7-1 sugar beets could be harvested, processed, stored, transported, processed and sold in commerce, subject to these conditions. Actions taken by APHIS under this preferred alternative would be an interim action only that is limited in scope and duration, and would neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS for a determination decision for a Petition for a full deregulation of H7-1 sugar beets.

APHIS is aiming to complete the EIS by May 28, 2012, but unforeseen conditions may affect the specific completion date. This interim, conditional, and partial deregulation of the H7-1 sugar beet root crop and root production activities along with the interim Part 340 permitting of the H7-1 seed crop, which would not be partially deregulated, will remain in effect through December 31, 2012, to allow the harvesting and processing of the 2012 commercial root crop and seed crop unless APHIS issues a Final EIS, Record of Decision, and Determination decision for a Full Deregulation of H7-1 sugar beets before those harvest are completed in 2012. If APHIS makes a determination decision, after completion of the EIS, to fully deregulate H7-1 sugar beet, the Record of Decision for that EIS for full deregulation will supersede and replace this partial deregulation FONSI, if it occurs prior to termination date of the interim action, which is December 31, 2012.

APHIS is making sure that any action it may take in response to the request for partial deregulation of H7-1 sugar beets is an interim action, which is limited in scope and duration, and would neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS.

Seed Production Activities - APHIS Permits and Notifications

The environmental release (planting), interstate movement and importation of H7-1 sugar beets associated with seed production activities would be authorized under APHIS permits in accordance with conditions imposed by APHIS. APHIS would authorize the environmental release and movement of H7-1 sugar beet seeds and stecklings under APHIS permits and notifications in accordance with 7 CFR Part 340. APHIS would impose conditions consistent with conditions proposed to the Court and those requested by the supplemental petition. Permits issued and notifications acknowledged under this alternative would be an interim action that is limited in scope and duration, and would neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS.

Permit Program. APHIS' permitting and notification process for the environmental release and movement of H7-1 sugar beets associated with seed production activities would be carried out in accordance with 7 CFR Part 340. As specified in 7 CFR Part 340.4, applicants must request permits for a field release (planting) in advance of the proposed planting date. Required data for the permit would include the responsible person, description of the regulated article and differences between it and the non-modified parental crop, locations and distribution of the regulated article, size of the field release site(s), confinement procedures and safeguards employed, and methods to dispose of residues or reproductive materials. For movement of sugar beet seeds or stecklings, quantity of the regulated H7-1 article would be identified in the applications. APHIS will provide States and Tribes, where the release is planned as appropriate, copies of its review of permit applications. AHPIS will review these applications for permit and specific permit conditions assigned by APHIS to each permit would prevent the escape, dissemination and persistence of the regulated article and greatly limit the risk of any potential for inappropriately introducing or disseminating H7-1 sugar beets into the environment.

Importation or interstate movement of H7-1 sugar beet seed or stecklings would occur under an APHIS permit or acknowledged notification. H7-1 sugar beets seed or stecklings could be imported or moved interstate under notifications acknowledged by APHIS-BRS as long as they meet the requirements found in §340.3 "Notification for the introduction of certain regulated articles." These include §340.3 (c)(1) "Performance standards for introductions under the notification procedure" which require shipment in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment. Permits for importation and interstate movement would meet the requirements identified in 7 CFR 340.4, 340.7 and 340.8, including specific permit conditions assigned by APHIS that would prevent inadvertent release of H7-1 sugar beets into the environment.

APHIS maintains a website, http://www.aphis.usda.gov/biotechnology/status.shtml, which automatically updates information about the status of a permit application on the next weekday morning after such information is inputted into the system. Information about APHIS's receipt of a permit can be obtained by anyone accessing the APHIS website and searching for information about the status of a permit. APHIS will use this website to inform the public in a timely manner on the status of all permit applications for H7-1 sugar beets. In addition, due to the anticipated public interest in these permits, APHIS will post a CBI redacted version of each permit application upon receipt and permit upon issuance to the APHIS e-FOIA Reading Room: http://www.aphis.usda.gov/foia/foia_reading_room.shtml.

Scope. Permits with specific permit conditions could be issued for each of the following sugar beet production systems in the states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming: non-flowering steckling production and seed production from flowering stecklings or directly from seed. The environmental release of H7-1 sugar beets would be limited to sites that have been in agricultural production for a minimum of 3 years. In addition, importation and interstate movement of seed and steckling shipments within and into the US would require a notification acknowledged by APHIS. For each type of sugar beet production system for which APHIS receives an application, APHIS could issue a permit to any organization, association, corporation, institution or any other entity that is in the business of growing and/or producing H7-1 sugar beets. This includes, but is not limited to seed companies producing H7-1-derived sugar beet seed. These entities then would allow farmers/transport drivers to plant and/or move H7-1 sugar beets under their APHIS issued permit or acknowledged notification. Because of the logistical impossibilities of dealing with the large number of potential individuals involved in growing and transporting H7-1 sugar beets, APHIS does not envision issuing permits to individual farmers or transport drivers.

APHIS has knowledge of four seed companies (American Crystal Sugar Company, Betaseed, Inc., SESVanderhave Sugar Beet Seeds, and Syngenta Seeds, Inc.) that produce H7-1 sugar beet seed, either directly or through a seed production cooperative (West Coast Beet Seed). APHIS could issue permits to any of these four seed companies for steckling and direct seed production activities upon receipt and review of a completed permit application. All growers and the locations of their H7-1 sugar beets would be identified in the permits issued to the seed company.

Chronology of Permitting. Upon receipt of a complete permit application and after a thorough evaluation and review, APHIS will make a decision on whether or not to authorize the planting of flowering stecklings in seed production fields in late winter/early spring; planting of seeds for direct seeding (flowering) for seed production in seed production fields in late summer/early fall; and the planting of non-flowering stecklings in seed production fields in late summer/early fall. Exact planting dates would vary dependent upon geographic location and local conditions. Subsequent seasons would follow a similar permitting scheme until the termination date of the interim action described above.

Enforcing Permit Conditions. An applicant's compliance with APHIS permit conditions would be carried out using the following approaches.

Seed Production

1. H7-1 beet seed producers (permit holders) would assign a responsible person pursuant to 7 CFR 340 to oversee the permit for beet seed production; this individual would oversee the performance of the sugar beet seed growers under the permits. The responsible person, likely an agronomist, would oversee the standard procedures of seed production and would monitor and assess compliance with the conditions assigned by the APHIS permit. Total acreage for all seed production permits is estimated to cover approximately 3000-5000 acres.

2. APHIS will directly inspect the seed production fields to ensure compliance with all mandatory permit conditions and such inspection(s) will be completed prior to any

possible pollen shed. APHIS' will use the standard inspection process that it uses for inspecting permits under 7 CFR Part 340.

Import and Movement under Notification

Site visits by APHIS inspectors will also involve monitoring and assessing compliance with regulations for seed and steckling movement, such as secure storage sites, allowable containers and vehicle containment devices when used in the movements.

Uniformity of Assigned Conditions. All mandatory permit conditions identified under this Alternative would be required and applicable to all permit applications that APHIS may receive for H7-1 sugar beet associated with seed production activities. Details of the respective assigned permit conditions for each of the specific production systems (non-flowering steckling production, seed production from flowering stecklings or directly from seed) are described below. As indentified above, APHIS will post a CBI redacted version of each permit upon issuance to the APHIS e-FOIA Reading Room: http://www.aphis.usda.gov/foia/foia_reading_room.shtml.

Evaluation of Permit Application for Consistency with the Environmental Assessment. Upon receipt of a complete permit application or notification, and prior to issuing the permit or acknowledging the notification, APHIS will evaluate and make a determination about whether the permit application or notification corresponds with all of the required conditions and provisions as described in the final EA and, if so decided, in any subsequent final decision and FONSI. In addition, APHIS will review the applicant's SOP for adhering to the requirements set forth in 7 CFR Part 340. As part of this evaluation and review process, APHIS will prepare a separate decision document for each permit application which is approved to document that the approval and issuance of the permit is consistent with all of the required conditions and provisions and within the scope of the final EA. This decision document will be made available to the public upon issuance in the APHIS e-FOIA Reading Room: http://www.aphis.usda.gov/foia/foia_reading_room.shtml. If APHIS determines that approving the permit is not consistent with any final EA (for example, if there are environmental impacts resulting from the permit which were not considered in the final EA), then APHIS will supplement or revise the final EA, prepare an additional EA, or prepare an EIS, as appropriate, before approving such permit, or will deny the permit.

Information for Non-GE Beta Seed Producers Regarding Male Fertile H7-1 Seed Production Locations.

7 CFR § 340.4 for "release into the environment" permits provides, among other things, that "[i]f there are portions of the application deemed to contain trade secret or confidential business information (CBI)" then applicants may label said information as CBI and, if APHIS concurs, it will treat it as such. Under Part 340's regulatory and commercial practices, most permit applicants consider the particular location of the field releases to be confidential business information (CBI) and expect that APHIS, under applicable federal laws, will treat them as such.

APHIS has a record of the location of each field release. APHIS is provided an address, GPS coordinates, and a diagram of the site. On March 9, 2000, APHIS formally announced the APHIS policy to allow GE crop field trial location as CBI. For each permit application, companies need to justify their confidentiality claims by means of a justification letter. APHIS considers that the precise location of environmental releases can be validly claimed as CBI and may be excluded from public review for several important reasons. Many biotechnology producers expend millions of dollars on research and development to develop a commercially viable genetically modified plant product. Any disclosure of a biotech company's research (whether from a direct disclosure, industrial espionage or through reverse engineering of the product) would allow competitors and others to profit from a producer's expensive, laborious research. Revelation of environmental release sites would provide the opportunity for competitors or others to pilfer the sites for, among other reasons, purposes of industrial espionage and/or reverse engineering. Even the methods used by biotech producers to comply with APHIS regulatory requirements, such as confinement measures, may be proprietary, and revealing environmental release locations might reveal that CBI as well.

Additionally, field releases of some GE plant products represent an especially attractive target for commercial or personal theft. Stolen regulated GE seeds or plants can be propagated and grown by anyone with a rudimentary knowledge of farming practices. If such regulated products are stolen, they can be grown without regulatory oversight and used illegally. Such action could lead to the introduction of regulated traits not intended for food and feed to illegally enter into the food and feed supply. Additionally, in the past ten to fifteen years there have been violent attacks of universities, government laboratories, farms, and other private industry facilities involved with genetically modified organisms. As a result many individuals working in the field of biotechnology have fears about their personal safety. In certain instances, the names of responsible parties and the locations of field trials as claimed CBI have been accepted by APHIS to protect individuals from harassment, mitigate civil unrest, and facilitate voluntary corporate and business compliance with APHIS's regulatory program.

In order for APHIS to protect the CBI specific site locations of any seed production permits, APHIS has decided that in reference to any seed permits, APHIS will set up a toll-free number which growers of non-GE *Beta* seed crops may use to request from APHIS the approximate distances from the nearest male fertile H7-1 seed crop to their non-GE *Beta* seed crop. Upon calling this number, the caller shall certify to APHIS that the caller is a grower of non-GE *Beta* seed crops or intends to grow non-GE *Beta* seed crops. APHIS shall provide to the caller the approximate distance from the nearest male fertile H7-1 seed crop location to the caller's location of a non-GE *Beta* seed crop.

Mandatory Permit Conditions

Under this Alternative, the following mandatory permit conditions, which are additional conditions that APHIS is imposing beyond those required under 7 CFR § 340.4, would be imposed on plantings of H7-1 sugar beets intended for seed production activities via permit conditions where the seed producer (permit holders) will acknowledge and adhere to these mandatory conditions:

1. Planting of H7-1 sugar beets is not allowed in the state of California and the following counties in Washington State: Clallam, Clark, Cowlitz, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, Pacific, Pierce, San Juan, Skagit, Skamania, Snohomish, Thurston, Wahkiakum, and Whatcom.

2. A four-mile separation distance shall be maintained between male *fertile* H7-1 sugar beets and all other commercial *Beta* seed crops (i.e., table beets, Swiss chard) US wide.

3. An inventory of H7-1 male *fertile* planting locations shall be provided to APHIS within two weeks of planting.

4. A four-mile separation distance shall also be maintained between male *sterile* H7-1 sugar beets and all other commercial *Beta* seed crops US wide. During flowering, fields shall be scouted for male sterile H7-1 plants that shed pollen and such plants shall be destroyed.

5. A visual identification system, such as labeling, that accompanies the regulated material (e.g. basic seed, stock seed, stecklings, and commercial seed) throughout the production system, is required.

6. A companion seed-lot based tracking and tracing system that is fully auditable shall be maintained. Records must be retained for five years.

7. Other than non-GE *Beta* seed material used in the production of hybrid-seed, all H7-1 material shall be physically separated from non-regulated material to prevent commingling at all points throughout the production process.

8. Planting, cultivation, and harvesting equipment shall be cleaned to prevent H7-1 stecklings or seed from being physically transferred out of production areas or mixed with non-GE *Beta* material by inadvertent means.

9. All unused H7-1 stecklings shall be treated as regulated articles until devitalized and discarded.

10. All H7-1 seed and steckling material shall be moved in contained transport systems to avoid inadvertent release into the environment. Vehicles or movement containers shall be thoroughly cleaned after transport and any regulated material recovered shall be devitalized.

11. Sexually compatible varieties (e.g. chard/red beet) cannot be planted or produced in the same location (the same field) as H7-1 in the same growing year.

12. Planting/cultivating/harvesting equipment that might be used in chard/red beet seed production shall not be used for regulated GE material in the same growing year.

13. Measures to force same year sprouting of H7-1 seed left in production fields are required. Any seed which sprout from such leftover seed shall be destroyed. Fields shall be monitored for three years and any volunteer beet plants shall be destroyed. If the same land is used for crop cultivation during the three-year volunteer monitoring period, that crop shall be visually distinct from sugar beets or the fields left fallow.

14. A management plan shall be submitted and followed. The management plan will set forth best practices for oversight of the movement, transportation, and confined field production of H7-1 seed. The management plan shall include, but not be limited to, required resources, training of relevant personnel, monitoring of growers, record keeping, and verifying compliance with the permit conditions. The applicant shall also provide the SOPs that will be utilized to conduct the field trials and comply with the permit and permit conditions.

15. No H7-1 seed shall be cleaned or processed in any processing facility that also cleans and processes red beet or Swiss chard seed.

16. Interstate movement of H7-1 sugar beet stecklings and seed may only be authorized with a movement notification or permit consistent with regulations described in 7 CFR 340.

17. The applicant shall ensure that all site cooperators/growers have received the permit conditions and are trained in all the processes and procedures.

18. The applicant shall maintain records of all the activities authorized under the permit to demonstrate adherence to 7 CFR 340, the permit, and the permit conditions. These records shall be made available to APHIS/BRS.

Root Production Activities – Not Considered a Regulated Article under 7 CFR 340 with Compliance Agreement Conditions/Restrictions

Pursuant to and in compliance with 7 CFR § 340.6, H7-1 sugar beet root crop, when grown under specific mandatory conditions imposed by APHIS, would not be subject to the procedural and substantive requirements of 7 CFR 340 for the duration of this interim action. The H7-1 sugar beet root crop and root production activities would be considered partially deregulated provided that there is compliance with mandatory conditions on the environmental release and movement of the H7-1 sugar beet root crop. These mandatory conditions would be enforced and required pursuant to APHIS compliance agreements authorized under the PPA, and would restrict the movement and environmental release of the H7-1 sugar beet root crop and root production activities. The compliance agreement system, outlined below, for root crop production and root production activities is comparable in rigor and enforceability to the permitting scheme. Like the requirements imposed on permittees, the compliance agreement system requires the responsible parties to give APHIS notice of the locations of the crops, to agree to APHIS oversight, and to be subject to suspension, revocation, and possibly civil and/or criminal penalties in the event of noncompliance.

Compliance Agreements. Any person who wants to import, move, and/or do an environmental release in conjunction with the H7-1 sugar beet root crop (root production activities) must first contact APHIS-BRS at Regulatory Operations Programs in Riverdale, MD at (301) 734-5301 and enter into a compliance agreement in advance of the shipment (import/movement) and/or planting (environmental release) of H7-1 sugar beets (seeds and roots) associated with the H7-1 sugar beet root crop production activities. These required compliance agreements will be formal, written, and signed agreements between APHIS and a person who wants to import, move, and/or do an environmental release in conjunction with the H7-1 sugar beet root crop. For the environmental release of H7-1 sugar beets associated with the root crop production activities, any organization, association, corporation, institution or any other entity that is in the business of growing and/or producing H7-1 sugar beets [i.e. sugar beet cooperatives or processors] must first request and then enter into a signed compliance agreement in advance of the proposed planting date. Required information for the compliance agreement will include: identifying the responsible party, contact information, location of the environmental release(s), and total number of acres to be planted. For the movement and/or importation of H7-1 sugar beets associated with the root crop production activities, any organization, association, corporation, institution or any other entity that is in the business of growing and/or producing H7-1 sugar beets [i.e. seed company, sugar beet cooperatives or processors] must first request and then enter into a signed compliance agreement in advance of the movement and/or importation. Required information for the compliance agreement includes: identifying the responsible party, contact information, and point of origin and final destination(s).

Due to the anticipated public interest in these compliance agreements, APHIS will post a CBI redacted version of each compliance agreement upon issuance to the APHIS e-FOIA Reading Room: http://www.aphis.usda.gov/foia/foia_reading_room.shtml.

Scope. Compliance agreements with mandatory conditions and restrictions can be issued for the environmental release (planting) of H7-1 sugar beets associated with root production activities in the states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming; and for the importation and interstate movement of H7-1 sugar beets associated with root production activities (seeds and roots) within and into the US. The environmental release of H7-1 sugar beets will be limited to sites that have been in agricultural production for a minimum of 3 years. APHIS can issue a compliance agreement to any organization, association, corporation, institution or any other entity that is in the business of growing and/or producing H7-1 sugar beets. This includes, but is not limited to seed companies producing H7-1-derived sugar beet seed, and sugar beet cooperatives or processors. These entities will then enter into a compliance agreement with APHIS on behalf of all its members/farmers. Because of the logistical impossibilities of dealing with the huge number of potential individuals involved in growing and transporting H7-1 sugar beets, APHIS does not envision issuing compliance agreements to individual farmers or transport drivers.

APHIS has knowledge of four seed companies (American Crystal Sugar Company, Betaseed, Inc., SESVanderhave Sugar Beet Seeds, and Syngenta Seeds, Inc.) that produce H7-1 sugar beet seed, either directly or through a seed production cooperative (West Coast Beet Seed), and nine grower-owned processors, including American Crystal Sugar Company, Michigan Sugar, Minn-Dak Farmers Cooperative, Sidney Sugars Incorporated, Snake River Sugar Company, Southern Minnesota Beet Sugar, Spreckels Sugar Company, Western Sugar Cooperative, and Wyoming Sugar Company in the US, with a tenth, Rogers Sugar Company, located in Alberta, Canada. One company, Spreckels Sugar, is in California. As specified in the mandatory conditions and restrictions indentified below, H7-1 derived sugar beets cannot be grown in California and certain counties in Washington State.

Chronology of Compliance Agreements. Upon receipt of a request to enter into a signed compliance agreement in conjunction with the H7-1 sugar beet root crop and after a thorough evaluation and review, APHIS will make a decision on whether or not to authorize the planting of H7-1 sugar beet seed in root production fields in the spring. Exact planting dates would vary dependent upon geographic location and local conditions. Subsequent seasons would follow a similar compliance agreement system until APHIS completes the court-mandated EIS and makes a determination on whether or not to grant nonregulated status to H7-1 sugar beet or until the last date of the harvesting and processing of the 2012 commercial root crop. It is anticipated that the process for completing the EIS may take until the end of May, 2012 to complete.

Enforcing Compliance Agreements. The oversight of APHIS compliance agreements would be carried out using the following approaches.

- Prior to planting H7-1 sugar beets, any person who wants to do an environmental release in conjunction with the H7-1 sugar beet root crop shall have a signed compliance agreement in place that identifies the responsible party, contact information, location of the environmental release(s) (county/state), total number of acres to be planted and applicable restrictions that will be followed to ensure confinement.

- Prior to moving H7-1 sugar beets, any person who wants to import and /or move seed or roots in conjunction with the H7-1 sugar beet root crop shall have a signed compliance agreement in place that identifies the responsible party, contact information, point of origin and final destination(s), and applicable restrictions that will be followed to ensure confinement.

- Within 28 days after planting of H7-1 sugar beet root crops under the compliance agreement, the responsible person shall provide APHIS a report that includes at least one GPS coordinate for the release site and the actual acreage planted.

- APHIS will conduct direct inspections to ensure that persons importing, moving, and/or doing an environmental release (planting) in conjunction with the H7-1 sugar beet root crop comply with all conditions and restrictions identified in the compliance agreements.

- For the root crop production activities, APHIS will require third party inspections. Beet processors (usually a cooperative) will propose at least two third party inspectors to APHIS. After evaluating their credentials and suitability, APHIS will notify the cooperatives whether it believes those third party inspectors are qualified and approves them. The cooperatives will be responsible for procuring the third party inspectors. Upon the procurement of the third party inspectors, APHIS officials will train them. The third party inspectors will work on behalf of APHIS and will schedule inspections according to APHIS' instructions. They will submit inspection reports directly to APHIS and APHIS will work directly with the inspectors if the reports require more information. A large number of the root production fields will be inspected by the third party inspectors, sufficient to give statistically significant conclusions ($p=0.05$) on overall compliance. Total acreage for all root production is estimated to cover approximately 1 – 1.4 million acres.

- For the root crop production activities, APHIS will require third party audits to review grower records. Beet processors (usually a cooperative) will procure the third party auditors and, like the third party inspectors, they will be vetted by APHIS prior to their procurement. The third party auditors will be trained by APHIS officials and will work on APHIS' behalf including being responsible for submitting reports to APHIS. The third party auditors will review all grower records on file and submit field inspection reports to APHIS. Records of audits shall be made available to APHIS/BRS for review upon request. APHIS will carefully examine the field inspection reports to ensure compliance with all conditions and restrictions identified in the compliance agreement.

- Activities conducted by growers to comply with compliance agreement conditions and restrictions may be either audited or inspected by APHIS or third party auditors or both. APHIS will provide detailed inspection forms for the information to be supplied by processor/growers, and the subsequent records will be made available to APHIS/BRS for audit. Growers must keep records of these compliance activities and make them available to APHIS and/or third party auditors upon request. APHIS will carefully examine a representative sample of these records to ensure compliance with all conditions and restrictions identified in the compliance agreement.

- Responsible persons who are operating under a compliance agreement will be required to notify APHIS immediately of any instance of noncompliance with the conditions in the compliance agreement. The responsible person shall describe the incident, the date it occurred, the location and contact information of the grower and field personnel associated with the incident.

- For importation and interstate movement, APHIS inspections and/or third party inspections/audits will be required to ensure that persons importing and/or moving H7-1 sugar beet seeds or roots in conjunction with the H7-1 sugar beet root crop comply with all conditions and restrictions identified in the compliance agreements. APHIS will carefully examine these records to ensure compliance with all conditions and restrictions identified in the compliance agreement.

- In the event of a finding of noncompliance or violation of the terms of a compliance agreement, APHIS may revise, suspend, revoke, or otherwise withdraw the compliance agreement and/or the partial deregulation of any and all root crop grown under the compliance agreement. APHIS may also, at its discretion, use the full range of PPA authorities to seek, as appropriate, criminal and/or civil penalties, and to take remedial measures including seizure, quarantine, and/or destruction of any H7-1 sugar beet root crop production that is found to be in violation of the conditions set forth in the compliance agreements.

Uniformity of Conditions and Restrictions. Conditions and restrictions identified in the compliance agreement would be required and applicable to all persons utilizing this partial deregulation authority. These mandatory conditions imposed and required pursuant to the partial, ***conditional***, deregulation of the root crop, would be enforced and required pursuant to APHIS compliance agreements authorized under the PPA. Details of the specific conditions and restrictions are described below.

Evaluation of Compliance Agreement for Consistency with the Environmental Assessment. Prior to issuing the compliance agreement, APHIS will evaluate and make a determination about whether the compliance agreement corresponds with all of the required conditions and provisions as described in the final EA and, if so decided, in any subsequent final decision and FONSI. As part of this evaluation and review process, APHIS will prepare a separate decision document for each compliance agreement that is approved to document that the approval and issuance of the compliance agreement is consistent with all of the required conditions and provisions and within the scope of the final EA. This decision document will be made available to the public upon issuance in the APHIS e-FOIA Reading Room: http://www.aphis.usda.gov/foia/foia_reading_room.shtml. If APHIS determines that approving the compliance agreement is not consistent with any final EA (for example, there are some environmental impacts resulting from the compliance agreement which were not considered in the final EA), then APHIS will supplement or revise the final EA, prepare an additional EA, or prepare an EIS, as appropriate, before approving such compliance agreement, or will deny the compliance agreement request.

Mandatory Conditions/Restrictions Imposed on Root Production Activities

Under this Alternative, the following mandatory conditions and restrictions will be imposed on H7-1 sugar beets intended for root production via a compliance agreement:

1. Planting of H7-1 sugar beets is not allowed in the state of California, and the following counties in Washington State: Clallam, Clark, Cowlitz, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, Pacific, Pierce, San Juan, Skagit, Skamania, Snohomish, Thurston, Wahkiakum, and Whatcom.

2. Root growers shall ensure that root crop fields are surveyed to identify and eliminate any bolters before they produce pollen or set seed. Fields shall be surveyed every 3-4 weeks beginning April 1. Root growers shall ensure that field personnel maintain records of their field observations and removal of bolters. Reports where bolters are not observed must be maintained as well. Root growers shall notify APHIS/BRS within 48 hours after finding bolters, with the location and action taken by the field personnel. Root growers shall maintain all records of inspection and bolter removal and records must be made available to APHIS/BRS and/or to authorized third party inspectors upon request.

3. Third party inspectors procured by beet processors (usually a cooperative) shall randomly choose a statistically representative sample of fields and conduct inspection for bolters.

If bolters are identified, field personnel shall be notified immediately and those bolters must be removed. APHIS will provide an inspection form to be used to capture this data.

4. Planting/cultivating/harvesting equipment that might be used in chard/red beet production shall not be used or shared for regulated GE material in the same growing year.

5. Root crop fields shall be monitored for three-year following harvest for volunteers and any volunteer plants must be destroyed. If the same land is used for crop cultivation during the volunteer monitoring period, that crop shall be visually distinct from sugar beets or the fields must be left fallow. Records of observations must be maintained and provided to APHIS/BRS or third party auditors upon request.

6. All root crop growers and field personnel must receive all conditions and restrictions identified in the compliance agreements and must be trained in the all processes and procedures necessary to comply with the terms of the agreement.

7. Root growers shall maintain records of all the activities being carried out under the compliance agreements to demonstrate adherence to the mandatory conditions and restrictions. These records shall be made available to APHIS/BRS and/or to authorized third party inspectors/auditors upon request.

Mandatory Conditions/Restrictions Imposed on Importation and Interstate Movement

Under this Alternative, the following mandatory conditions and restrictions would be imposed on the interstate movement and importation of H7-1 seeds and roots associated with root production activities via a compliance agreement:

1. The Responsible party shall ensure that all personnel have received all conditions and restrictions identified in the compliance agreements and are trained in the all processes and procedures necessary to comply with the terms of the agreement.

2. The Responsible party shall maintain records of all the activities being carried out under the compliance agreements to demonstrate adherence to the mandatory conditions and

restrictions. These records shall be made available to APHIS/BRS and/or to authorized third party inspectors/auditors upon request.

3. During transport, chain of custody and records shall be maintained. Records shall be made available to APHIS/BRS and/or to authorized third party inspectors/auditors upon request

4. Trucks used for the movement of root crop from field to storage/processing shall be loaded in a manner to minimize loss of beets during transport or equipped with a retaining device.

5. Sugarbeet seeds shall be transported in a sealed plastic bag, envelope, or other suitable container (primary container) to prevent seed loss.

6. The primary container for transporting seeds shall be placed inside a sealed secondary container that is independently capable of preventing spillage or loss of seed during transport.

7. Each set of containers (primary and secondary) for transporting seeds shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength. Each container shall clearly identify that the seed contents within shall only be used for the planting of sugar beet root crop.

8. The shipping containers for transporting seeds shall be transported in enclosed trucks or trailers with closed sides.

D. Alternatives Considered but Rejected from Further Consideration

APHIS assembled a comprehensive list of alternatives that might be implemented in the decision process for this EA. The agency individually evaluated each alternative on the basis of legality, environmental safety, efficacy, and practicality to identify which alternatives would be further considered during the decision process. Based on this evaluation, APHIS rejected a number of alternatives. In the interest of transparency, these alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. No Event H7-1 Sugar Beet Seed Production/Partial Deregulation for Root Production

APHIS considered taking no further actions to authorize the movement or environmental release of H7-1 sugar beets for seed production and granting the petition request for partial deregulation of H7-1 sugar beets for root production. Under this alternative, environmental releases of H7-1 sugar beet associated with seed production would be prohibited and APHIS would partially deregulate root production under conditions imposed by APHIS. H7-1 seed could be imported from outside the US but that would be the only source for such seed and most likely foreign H7-1 seed would not provide an adequate supply for root production in the U.S. APHIS determined that this alternative is not appropriate because seed producers would not have any control over seed production and could not guarantee adequate seed supply for root production actions.

2. Partial Deregulation of Event H7-1 Sugar Beet Seed Production/No Root Production

APHIS considered granting the petition request for partial deregulation of H7-1 sugar beets for seed production and considered taking no further actions to authorize the movement or environmental release of H7-1 sugar beets for root production. Under this alternative, APHIS would deregulate seed production under conditions imposed by APHIS and all importation, interstate movements, and environmental releases (i.e. plantings) of H7-1 sugar beets for root production would be prohibited. With only H7-1 seed production allowed in the U.S., the only use for such seed would be for exportation. No seed could be used for root production in the U.S. APHIS determined that this alternative is not appropriate since it has no reasonable application for the sugar beet production cycle in the US. Moreover, APHIS has not completed an assessment of what could be the potential plant pest risks from H7-1 sugar beet seed production to support the deregulation of H7-1 sugar beets for seed production. Until such time that a PPRA is completed for H7-1 sugar beets, APHIS cannot remove H7-1 sugar beets from 7 CFR Part 340 regulatory oversight.

3. Partial Deregulation of Event H7-1 Sugar Beet Seed Production/Root Production Regulated under APHIS Permit

APHIS considered granting the petition request for partial deregulation of H7-1 sugar beets for seed production and regulating H7-1 sugar beet root production under 7 CFR Part 340. Under this alternative, APHIS would partially deregulate seed production and would have the regulatory option of issuing or denying permits or notifications for all importation, interstate movements, and environmental releases (i.e. plantings) of H7-1 sugar beets for root production. APHIS determined that this alternative is not appropriate. Though APHIS has concluded that the conditional production of H7-1 sugar beet root crop is unlikely to pose a plant pest risk (USDA-APHIS 2011) APHIS has not completed an assessment of what could be the potential plant pest risks from H7-1 sugar beet seed production or root production without restriction to support the deregulation of H7-1 sugar beets. Until such time that a PPRA is completed for fully deregulated H7-1 sugar beet, APHIS cannot remove H7-1 sugar beet seed production from 7 CFR Part 340 regulatory oversight. APHIS would also have to complete a NEPA analysis for the partial deregulation of the seed production of H7-1 sugar beets.

E. Affected Environment

The following issues have been identified as areas of concern requiring consideration in this environmental assessment. These issues were developed based upon possible impacts raised by the Court and possible impacts indentified in the Notice of Intent APHIS published in the *Federal Register* on May 28, 2010 seeking public input on issues and alternatives the Agency should consider in preparation of an EIS for deregulating H7-1 sugar beets. The areas of the proposed environmental release include agricultural lands located within the primary sugar beet production states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming and the interstate movement and importation of H7-1 sugar beets within and into the US.

1. Biological Resources

Beta vulgaris as a crop species. Sugar beet (*Beta vulgaris* L.), a member of the family Chenopodiaceae, is a relatively modern field crop, having been developed in Europe in the late 1800s. Sugar beets were derived directly from fodder beets which are commonly grown for livestock feed. Fodder beets, as well as the vegetable crops table (red) beet and Swiss chard, are all members of this same species (OECD, 2001). For the purpose of this discussion, we will refer to these four crops collectively as beets. We will also use the term “vegetable beets” to collectively refer to table (red) beets, Swiss chard and leaf beets.

Beets are native to the Mediterranean region and have been grown for their tops and roots since Greek and Roman times. All cultivated beets are biennial and require two years to complete their life cycle. During the first year, beets grow as a rosette and in the case of sugar beet and table beet develop a swollen storage root. In the second year, the energy contained in the storage root is utilized to produce a seed stalk, completing the life cycle. Exposure to a period of cool temperatures and long nights, referred to as vernalization, triggers the transition from the vegetative to reproductive phases of growth. Flowering begins in late May and can last 3-4 weeks. The tall seed stalk may produce hundreds of flowers, each flower releasing a large quantity of wind borne pollen. The female flowers can remain receptive for more than two weeks (Kockelmann and Meyer, 2006). A complex system of self-incompatibility promotes cross pollination. The fruits, sometimes referred to as seed balls, are multiple (multigerm) such that each usually contains from 2-4 true seeds (Milford, 2006).

While beets are biennial, all of the agricultural commodities produced from beets are grown as summer annuals. That is, they are harvested during the first year of growth prior to vernalization and flowering. In contrast, beet seed production requires the completion of the natural biennial life cycle. The agricultural commodities of beet are all vegetative, and in a majority of cases farmers do not produce their own seed for subsequent crops.

Sugar beets (cultivation to end use). Beet seed production is a highly specialized operation primarily due to the biennial nature of the plant. The most essential climatic requirement is mild winters, cool enough to induce vernalization, yet not so cold as to cause freezing damage.

The US is among the world's largest sugar producers. Unlike most other sugar producing countries, the US has both large and well-developed sugarcane and sugar beet industries. Since the mid-1990s, sugarcane has accounted for about 45% of the total sugar produced in the US, and sugar beets for about 55% of production. Since 1961, planted sugar beet acreage has fluctuated within the range of 1.1 million (low in 1982) to 1.6 million (high in 1975) (USDA NASS, 2010a). Annual cash receipts for sugar beets in the US in the past few years have been as much as $1.5 billion (USDA ERS, 2009b). Sugar beets are produced primarily in the northern tier of states from Michigan west to Washington. The 11 sugar beet producing states in order of production are: MN, ND, ID, MI, MT, NE, CA, CO, WY, OR and WA. Sugar beets are grown for the purpose of processing them into sugar and transportation costs of the bulky crop limit profitable production to approximately 100 miles from one of the 22 US beet sugar processing facilities. The five US sugar beet production regions are discussed in detail below in the Affected Environment section.

While sugar beets have been adapted to a very wide range of climatic conditions, they are primarily a temperate zone crop produced in the Northern Hemisphere at latitudes of 30 to 60°N.

In these regions the sugar beet plant will grow until harvested or until growth is stopped by a hard freeze. Sugar beets primarily grow tops above ground until the leaf canopy completely covers the soil surface in a field, about 70 to 90 days after planting. Optimal daytime temperatures are 60 to 80°F for the first 90 days of growth. Regions with long day length are most suitable for sugar beet growth. The most favorable environment for producing a sugar beet crop from 90 days after emergence to harvest is bright, sunny days with 65 to 80°F temperatures followed by night temperatures of 40 to 50°F. These environmental conditions maximize yield and quality in a sugar beet crop. Sugar beets are successfully produced under irrigation in areas with very low rainfall and in regions relying on natural rainfall (Cattanach et al., 1991).

Commercial sugar beet production starts with high quality hybrid seed. Production of hybrid sugar beet seed is facilitated by several genetic factors including cytoplasmic male sterility (CMS). Two parental lines are required to produce the hybrid: a male-sterile (CMS) female line from which the seed will be harvested and a male line which produces the pollen that fertilizes the female parent. The CMS female lines are incapable of pollen production, ensuring that any seed produced will be hybrid. The male lines are fully fertile and referred to as pollinators. The CMS female parent is itself a single cross produced by pollinating a CMS line with an unrelated maintainer line referred to as an O-type (Bosemark, 2006).

In 2009-2010, nearly 95% of the US sugar beet seed crop was glyphosate tolerant, and 78.6% was produced with the glyphosate-tolerance trait (H7-1) on the CMS (male sterile) female parental line. In seed production fields where the H7-1 trait is carried by the female parent, the pollen producing parent produces 100% conventional sugar beet pollen. In most fields, no CMS plants will produce pollen. Occasionally a rare individual will be capable of releasing pollen, however seed production fields are routinely inspected prior to pollen release to identify and rogue (remove) these rare individuals to eliminate inadvertent pollination.

The majority of sugar beet pollen dispersal comes from commercial seed production. However, a small percentage of sugar beet pollen dispersal comes from seed increases of the parental lines when producing the stock seed required for the commercial seed production. In order to increase stock seed of H7-1 female (CMS) lines, the male parent of these crosses necessarily produces H7-1 pollen.

The female parent of a sugar beet hybrid is also monogerm, meaning that each fruit contains only a single seed. The monogerm trait allows farmers to precision plant their sugar beet seed, eliminating the need for thinning the stand. While breeding the multigerm male pollinators is rather straightforward, developing the female seed parents is highly complex since the required genes for CMS and the monogerm trait are all recessive (Bosemark, 2006). Because of the number of specialized traits that must be combined, the development of a new female parental line takes from 10-12 years, about twice as long as required to develop a new male parent line.

In addition to the specialized genetic traits required for hybrid seed production, sugar beet breeders focus on developing new hybrids with high yield, high sugar, and adequate disease resistance. The primary diseases that impact US sugar beet production are *Cercospora* leaf spot, *Rhizoctonia* root rot, *Aphanomyces* root rot, rhizomonia and beet curly top virus. The level of resistance required for each disease varies by production region and the disease resistance profile is what distinguishes the regional varieties. This regional variation in variety needs is further discussed below in the Affected Environment section.

Sugar beet variety development is a competitive, technological, and expensive multi-year activity. Seed companies develop varieties with the combination of agronomic and quality traits desired by both growers and processors. As described in the Affected Environment section below, each sugar company conducts official variety trials in order to generate a list of approved varieties, and growers are obligated to grow only varieties that appear on this list. In order to achieve full approval, new varieties must be tested in the official trials for three years and must generate data that meets or exceeds the specific criteria established by each company's seed committee. These approved variety lists are updated annually with new varieties added to those that were approved in previous years. Although seed policies vary by region, the seed companies are generally obligated to "enter" approved varieties in the official trials in order to maintain approval for unlimited sales. When sales of a given variety decline, the seed company must decide whether or not it is worth the cost of the official trial entry fees needed to support the declining market share of that specific variety. The variety approval systems are designed to enforce continuous improvement such that the life span of any given variety in the market is relatively short.

Sugar beet seed production. Because sugar beet is a biennial, sugar beet seed production must be initiated two years prior to the year the seed will be planted by sugar beet farmers. The parent lines are planted in the summer of year one, the hybrid seed harvested in the summer of year two and finally the seed is planted by farmers in the spring of year three. This means sugar beet seed providers need to forecast sales two years in advance in order to produce the product mix desired by their customers. Often this requires taking risks producing new varieties that may or may not achieve the desired approval in the sugar company official trials. For example, a seed company may choose to produce seed of a new variety that has performed well in two years of official trials. If that same variety performs poorly in the third year of official trials, the variety will not achieve approval and the seed that was produced cannot be sold.

Sugar beet seed is produced by either one of two methods: the direct-seeded method or the steckling (transplant) method. Stecklings are carrot-sized roots that have been vernalized. In the direct-seeded method, the male and female parents are planted in strips in the same field. Prior to pollination, the female rows are rogued to remove any fertile plants. Seed mixture and volunteers are the main sources of rogue fertile plants in the female rows. After the males have completed pollinating the CMS females, the male rows are destroyed in order to prevent any seed from maturing on the pollen parent. Once the hybrid seed has ripened, the female plants are cut into swaths for additional seed drying before threshing several days later.

When the steckling (transplant) method is used, the seed of the parental lines is planted in a steckling nursery where fall growth and vernalization occur. These relatively small roots are then transplanted to seed production fields in January and February. While the steckling method of seed production is more expensive, it provides an additional opportunity for seed companies to flexibly manage product inventory, as well as allowing for increased production when stock seed is limited. Historically, the vast majority of US sugar beet seed was produced by the direct-seeded method, however there has been an almost complete shift to the steckling method during the last decade.

Root production. Seed selection is the first critical decision made by the sugar beet grower.   As a cooperative member, a grower has a contract to deliver sugar beet from a specified number of acres. As discussed above, sugar beet varieties that are not approved cannot be delivered to the processor for sugar production because they do not meet the standards set forth by the processor.

Growers select the varieties that they expect will provide the highest return per acre. In most cases, these are the ones with the best data in the official variety trials. However some growers have specific needs for high levels of disease resistance and may choose a variety with enhanced disease resistance. In addition to choice of variety, growers purchase seed by size. Size choices include small, medium, large, extra large and pelleted. The size fractions result from the natural variability in a beet seed production field. Some growers have planting equipment (e.g. plate planters) which requires a specific seed size. Pelleted seed is the result of a specialized seed treatment process that makes the seed round by adding a coating of 2-300% by weight. Pelleting also allows the incorporation of fungicides or insecticides that might otherwise be phytotoxic to the seed. The non-pelleted seed is typically film coated with color and fungicide resulting in less than 100% buildup by weight.

Due to unpredictable emergence rates, sugar beet growers historically over-seeded and then thinned their fields to a proper stand. This thinning operation is dependent on hand labor. With today's high quality monogerm seed, most growers plant to stand. That is, they plant an amount of seed which emerges to the ideal plant population such that no thinning is required. The shift to planting to stand has greatly reduced the hand labor needs in sugar beet production.

Because it takes about two months for sugar beet foliage to cover the rows, early season weed control is a critical component of optimizing sugar beet production. Prior to the introduction of herbicide tolerant sugar beet hybrids, sugar beet farmers typically employed a combination of tillage, hand labor and chemical weed control, requiring multiple passes through the field with equipment. Some of the herbicides that have been most widely used in sugar beet production can cause crop injury to the sugar beet crop when applied at full label rates. Alan Dexter, extension weed scientist at NDSU, developed a system of micro-rates in order to minimize the probability o crop injury (Dexter, 1994). The micro-rate system involves multiple applications of less than labeled rates of herbicides, and was widely adopted in all US sugar beet producing regions.

The objectives of seedbed preparation are to manage crop residue (the leftover vegetative matter from the previous crop), minimize erosion, improve soil structure, and eliminate early season weeds. Tillage, which can be done in fall and spring, can help improve soil structure and eliminate early weeds, but tillage can also increase erosion. No-till, strip tillage in previous crop residues, and other conservation tillage systems require more planning and better management (Cattanach et al., 1991). In addition to the reduced tillage methods, no-till productions systems do not have any associated tillage and weed control is entirely through chemical means. A survey conducted in 2000, before H7-1 sugar beets became available, found that use of conventional tillage for sugar beet production varied by region from 64-96% of acreage (not including California where data was insufficient). Because weeds can be effectively controlled with glyphosate applications, the adoption of H7-1 sugar beets has significantly reduced the amount of tillage needed to produce a sugar beet crop (NRC, 2010; Duke and Cerdeira, 2007; Wilson, 2009).

Planting and harvesting times. In all regions except the Southwest (California), sugar beet root crops are planted in early spring (March through May, depending on latitude and location) and harvested in fall (September through November, also varying with regions) (McDonald et al., 2003; Mikkelson and Petrof, 1999; Michigan Sugar Company, 2010b). In the Imperial Valley in California, sugar beets are planted in September and October and harvested from April to July (California Beet Growers Association, 1999).

Sugar beet harvest is highly coordinated and organized by the beet sugar processors. Growers are assigned to deliver some small fraction of their production, typically about 10%, during the pre-pile period. This allows the processing facilities to start producing sugar before the full crop is ready for harvest. When full harvest begins in October, growers harvest around the clock until all of the sugar beets have been delivered to the piling sites. If temperatures get either too warm or too cold, the sugar processor will temporarily stop the harvest to prevent the delivery of poor quality sugar beets which are prone to spoilage.

Crop rotations. Sugar beets tend to be grown with other crops in three- to five-year rotations. Crop rotation results in improved soil fertility, fewer problems with diseases, and improved yield and quality of beets. The impact of certain soil borne diseases, nematodes (parasitic, microscopic worms) and weeds are minimized through crop rotations (Mikkelson and Petrof, 1999; USDA ERS, 2009b; Hirnyck et al., 2005). The crop rotations in each of the five regions vary with the mix of rotational crops available to the sugar beet grower (Table 1). More than half of all sugar beet acres are rotated to a grass crop; either corn or small grains, allowing use of herbicide modes of action that control all dicot (dicotyledonous) plants. Dry beans, soybean and potatoes are the most common dicot crops that follow sugar beets and MN is the only state where the dominant rotation is to soybeans. Nationally, just over one third of sugar beet acres are followed by a soybean crop in the following year (Table 1).

Table 1. **Rotational crops following US sugar beet production and an estimation of rotational crops as Roundup Ready® crops (all acreages are expressed as 1000 acres)**

A	B	C	D	E	F	G	H	I	J	K
State	**Total Sugar Beet Acres[1]**	**Major Crops That Follow Sugar Beet In Rotation[2]**	**Total Acreage of Rotation Crop in States[1]**	**Percent of Rotational Crop Rotated Following Sugar Beet[3]**	**Rotational Crop Acres Following Sugar Beet[2]**	**Percent Rotational Crop of Total Sugar Beet[4]**	**Percent Roundup Ready® Rotational Crop Option[5,6]**	**Acreage of Roundup Ready® Rotational Crop Option[7]**	**Percent of Sugar Beet Acres Preceding Major Rotations[8]**	**Estimated Percentage of Roundup Ready® Crops as Major Rotations[9]**
CA	**50**	Barley	130	7.7%	10	20%	NA	0		
		Dry Beans	92	5.4%	5	10%	NA	0		
		Durum	95	10.5%	10	20%	NA	0		
		Oats	260	3.8%	10	20%	NA	0		
		Spring Wheat	530	2.8%	15	30%	NA	0		
			Total: 1,107		**Total: 50**			**Total: 0**	**4.52%**	**0%**
CO	**44**	Barley	85	5%	4	10%	NA	0		
		Corn	1200	3%	31	70%	52%	16		
		Dry Beans	92	8%	7	15%	NA	0		
		Potato	78	3%	2	5%	NA	0		
			Total: 1,455		**Total: 44**			**Total: 16**	**3.02%**	**1.10%**
ID	**212**	Alfalfa	730	1.5%	11	5%	50%	6		
		Barley	730	4.4%	32	15%	NA	0		
		Corn	190	3.2%	6	3%	52%	3		
		Dry Beans	95	4.2%	4	2%	NA	0		
		Spring Wheat	530	30.0%	159	75%	NA	0		
			Total: 2,275		**Total: 212**			**Total: 9**	**9.32%**	**0.40%**
MI	**180**	Corn	2,250	5.2%	117	65%	52%	61		
		Dry Beans	270	6.7%	18	10%	NA	0		
		Soybean	2,050	2.2%	45	25%	91%	41		

Table 1. Rotational crops following US sugar beet production and an estimation of rotational crops as Roundup Ready® crops (all acreages are expressed as 1000 acres)

A	B	C	D	E	F	G	H	I	J	K
State	**Total Sugar Beet Acres[1]**	**Major Crops That Follow Sugar Beet In Rotation[2]**	**Total Acreage of Rotation Crop in States[1]**	**Percent of Rotational Crop Rotated Following Sugar Beet[3]**	**Rotational Crop Acres Following Sugar Beet[2]**	**Percent Rotational Crop of Total Sugar Beet[4]**	**Percent Roundup Ready® Rotational Crop Option[5,6]**	**Acreage of Roundup Ready® Rotational Crop Option[7]**	**Percent of Sugar Beet Acres Preceding Major Rotations[8]**	**Estimated Percentage of Roundup Ready® Crops as Major Rotations[9]**
			Total: 4,570		**Total: 180**			**Total: 102**	**3.94%**	**2.23%**
MN	**505**	Barley	210	23.8%	50	10%	NA	0		
		Soybean	7,200	4.9	354	70%	91%	322		
		Spring Wheat	2,000	5.1%	101	20%	NA	0		
			Total: 9,410		**Total: 505**			**Total: 322**	**5.37%**	**3.42%**
MT	**58**	Barley	1,200	2.4%	29	50%	NA	0		
		Corn	65	21.5%	14	25%	52%	7		
		Dry Beans	27	33.3%	9	15%	NA	0		
		Spring Wheat	3,750	0.2%	6	10%	NA	0		
			Total: 5,042		**Total: 58**			**Total: 7**	**1.15%**	**0.14%**
ND	**265**	Barley	1,600	2.5%	40	15%	NA	0		
		Corn	1,230	3.3%	40	15%	52%	21		
		Durum	2,100	0.6%	13	5%	NA	0		
		Soybean	2,670	4.0%	106	40%	91%	96		
		Spring Wheat	6,900	1.0%	66	25%	NA	0		
			Total: 14,500		**Total: 265**			**Total: 117**	**1.83%**	**0.81%**
NE	**57**	Corn	8,400	0.3%	29	50%	52%	15		
		Dry Beans	185	11.9%	22	40%	NA	0		
		Winter Wheat	1,650	0.4%	6	10%	NA	0		
			Total: 10,235		**Total: 57**			**Total: 15**	**0.56%**	**0.15%**
WY	**40**	Barley	90	24.4%	22	55%	NA	0		
		Corn	80	12.5%	10	25%	52%	5		
		Dry Beans	32	12.5%	4	10%	NA	0		
		Sugar Beet	40	10%	4	10%	95%	2		

Table 1. Rotational crops following US sugar beet production and an estimation of rotational crops as Roundup Ready® crops (all acreages are expressed as 1000 acres)

A	B	C	D	E	F	G	H	I	J	K
State	Total Sugar Beet Acres[1]	Major Crops That Follow Sugar Beet In Rotation[2]	Total Acreage of Rotation Crop in States[1]	Percent of Rotational Crop Rotated Following Sugar Beet[3]	Rotational Crop Acres Following Sugar Beet[2]	Percent Rotational Crop of Total Sugar Beet[4]	Percent Roundup Ready® Rotational Crop Option[5,6]	Acreage of Roundup Ready® Rotational Crop Option[7]	Percent of Sugar Beet Acres Preceding Major Rotations[8]	Estimated Percentage of Roundup Ready® Crops as Major Rotations[9]
			Total: 242		**Total: 40**			**Total: 7**	**16.53%**	**2.89%**
Overall	**1,411**	Alfalfa	730	1.5%	11	0.8%	50%	6		
		Barley	4,045	4.6%	186	13.2%	NA	0		
		Corn	13,415	1.8%	247	17.5%	52%	128		
		Dry Beans	793	8.7%	69	4.9%	NA	0		
		Durum	2195	1.0%	23	1.6%	NA	0		
		Oats	260	3.8%	10	0.7%	NA	0		
		Potato	78	2.6%	2	0.1%	NA	0		
		Soybean	11,920	4.2%	505	35.8%	91%	460		
		Spring Wheat	13,710	2.5%	347	24.6%	NA	0		
		Sugar Beet	40	10%	4	0.3%	95%	2		
		Winter Wheat	1,650	0.4%	6	0.4%	NA	0		
State Totals			**Total: 48,836**		**Total: 1,411**			**Total: 596**	**2.89%**	**1.22%**

Legend:
NA denotes not applicable.
1 Acreage planted of the specific crop is based on 2002 planting data (USDA-NASS, 2003).
2 Rotated crops and acreage following sugar beet production are based on communications from individual local experts, i.e., university agronomists, USDA-ARS and Monsanto field personnel.
3 Column E obtained by dividing Column F by Column D and multiplying by 100.
4 Column G obtained by dividing Column F by Column B and multiplying by 100.
5 Roundup Ready® rotational crop penetration rates for corn and soybean are based on 2007 plantings (USDA-NASS, 2007); penetration rates for alfalfa are assumed to be 50% for the purpose of this assessment to represent potential future plantings.
6 Roundup Ready® rotational crop penetration rates for corn and soybean are based on 2007 plantings (USDA-NASS, 2007); penetration rates for sugar beet are assumed to be 95% for the purpose of this assessment to represent potential future plantings.
7 Column I obtained by multiplying Column F by Column H.
8 Column J obtained by dividing Column B by Column D Total and multiplying by 100.
9 Column K obtained by dividing Column I Total by Column D Total and multiplying by 100.

Bolting. As described above, sugar beet is a biennial plant that produces an enlarged root the first year and then flowers in the second year. However, sugar beets will occasionally bolt (produce a seed stalk that may ultimately flower) in their first year of production (Darmency et al., 2009). Much effort has gone into developing sugar beet varieties that resist bolting, and today's varieties show little bolting (OECD, 2001).

For bolting to occur, the plants first require exposure to temperatures around 40 to 42F (others report 34 to 39F in the four to five leaf stage; conditions are variety-dependent), followed by exposure to increasing day length (12 hours or more). Varieties differ in their sensitivity to bolting, with easy bolting lines requiring only a few to 1000 hours of exposure to low temperatures, while bolting-resistant lines may require 2000 hours or more. Beets can de-vernalize when exposed to high temperatures (OECD, 2001).

Bolting depletes the root of simple sugars, translocating this stored energy into the above-ground biomass, making the root woody and worthless as a source of sugar. Bolters are easily detected since they are much taller than the rest of the crop. The woody roots that result from bolters can damage harvesting and processing equipment (Ellstrand, 2003). For these reasons, growers remove bolters. Because bolters are rare and require several weeks to develop flowers, stewardship can be 100% successful in eliminating any small probability of pollen shed.

In the Imperial Valley in California, sugar beets are planted in September, grow through the winter months, and are harvested the following April through June. Bolting occurs more frequently in the Imperial Valley than in the other US sugar beet regions where sugar beet is planted in the spring and harvested in the fall. If the winter in the Imperial Valley is unusually cold and harvesting is delayed, some bolters can develop (California Beet Growers Association, 1998; Bartsch et al., 2003).

Beet sugar processing co-products and their end uses. In addition to producing refined sugar, beet sugar processing generates two valuable agricultural co-products: sugar beet pulp and beet molasses. When entering the factory, sugar beet roots are washed and sliced into strips called cossettes. The sugar is extracted from the cossettes by diffusion in hot water and the remaining dry matter is wet sugar beet pulp. Dried sugar beet pulp is produced by pressing the water out of the wet pulp, which is then sold as shreds or pellets for livestock feed. These are high quality feeds due to their high energy and high fiber content (Harland et al., 2006). The second co-product, beet molasses, is the dark liquid remaining after all of the sugar has been crystallized from the diffusion juice. In contrast to molasses derived from sugar cane which has some food uses, beet molasses is used exclusively for livestock feed, mainly as a source of energy. It is also sprayed onto dried beet pulp shreds or pellets to enhance palatability. While livestock feed is the primary use for beet molasses, it is also used as a feedstock for yeast production and chemical manufacturing (Southern Minnesota Beet Sugar Cooperative, 2010).

Multiple countries that regulate the importation of biotechnology-derived crops and derived products have granted regulatory approval to H7-1 sugar beets for food and feed uses, including Japan, Canada, Mexico, European Union, South Korea, Australia, New Zealand, China, Colombia, Russian Federation, Singapore, and the Philippines (FSANZ, 2005; Monsanto KWS 2007; Berg, 2010). These diverse regulatory authorities have all reached the same conclusion, that food and feed derived from H7-1 sugar beets are as safe and healthy as food and feed derived from conventional sugar beets.

The CFIA (Canadian Food Inspection Agency) approved H7-1 sugar beets for livestock feed in 2005. As summarized in Decision Document DD2005-54, the CFIA "determined that this plant with a novel trait (PNT) and novel feed does not present altered environmental risk nor does it present livestock feed safety concerns when compared to currently commercialized sugar beet varieties in Canada" (CFIA, 2005). The European Food Safety Authority (EFSA) has also concluded that food and feed from H7-1 sugar beets are as safe as food and feed from conventional sugar beets (EFSA, 2006). In response to EFSA information requests, Monsanto/KWS conducted a 90-day toxicity study, feeding processed pulp to rats, which did not indicate any adverse effects. The GMO Panel reported additional studies of sugar beet pulp to sheep, also with no adverse effects (EFSA, 2006).

Vegetable Beets (cultivation to end use). In the USDA database, "beets" include table beets, Swiss chard, and spinach beets (grown for the leaves). In this document, these non-sugar beet crops are referred to collectively as vegetable beets. In 2007, the most recent year for which published data are available; 8,412 acres of beets were harvested in the US, on 2,744 farms, for an average of three acres per farm. Approximately 63% of the acreage was for processed beets, and the rest for the fresh market (USDA NASS, 2010b). The total value of vegetable beet production in 1999, the most recent year for which USDA has data available, was approximately $7 million. Based on the most recent year for which USDA has both harvested acreage and production value data (1997), the average value of vegetable beet production per acre was approximately $720, which would be roughly $1,000 in 2010, adjusted for inflation (USDA NASS, 2010b).

Production practices for vegetable beet seed are quite similar to those for sugar beet seed production discussed above; the following discussion is focused on those aspects that are different. All of the vegetable beet seed grown in Washington, where over 90% of US table beet seed is grown, where over 90% of the seed is grown, is produced by the steckling (transplant) method; the direct seeded method is not used. Due to increasing problems with beet mosaic virus, the Skajit Valley beet seed growers agreed to discontinue the use of the direct seeded method (Navazio, 2010).

The stock seed is planted in mid-June, much earlier than for sugar beet seed production. In October, the stecklings are topped, windrowed, and covered with soil (soil mulch) to prevent freezing during the winter. They are transplanted to production fields in March or April, and the seed is harvested in August or September (du Toit, 2007). Other than the timing of certain field activities, the production practices are essentially the same as those for sugar beet seed. The most notable difference is the windrowing and soil mulching of the stecklings.

Production of organic vegetable beet seed is also quite similar to the production of conventional vegetable beet seed, differing mainly by the type of inputs and the methods used for weed and pest management. Organic seed growers generally control weeds by mechanical means (hand weeding and cultivation). Because the average field size is relatively small, some organic seed growers will store their stecklings in a root cellar or an outdoor pit.

Vegetable beet crops are grown for either roots or leaves or both. Production of vegetable beet roots is quite similar to sugar beet root crop production discussed above. Vegetable beets for the fresh market are harvested from 40-80 days after planting, depending on market type (round, cylindrical, etc). Beets destined for processing are planted and harvested later (Schrader and Mayberrry, 2003). Some of the same herbicides are used in sugar beet and vegetable beet production; however the post harvest intervals would in general be less for vegetable beets.

Organic vegetable beet crop production would again be quite similar, with inputs and weed and pest management methods as the main differences.

Production practices for leaf beet crops (Swiss chard and spinach beets) do not differ appreciably from root production of vegetable beets. Beets are cool season vegetables and can be planted throughout the growing season in cooler climates. In Arizona, Swiss chard is grown in the fall (University of Arizona, 2001). Mature leaves are hand harvested about 50- 60 days after planting and this harvest can continue for up to a year. Weed control in Swiss chard is challenging because there are fewer registered herbicides than for beet root crop production; sethoxydim is the only herbicide registered for post-emergence application in Swiss chard (University of Arizona, 2001).

a. Gene Flow

Gene flow. Gene flow has been defined as the "incorporation of genes into the gene pool of one population from one or more populations" (Futuyma, 1998). Gene flow is a basic biological process in plant evolution and in plant breeding, and itself does not pose a plant pest risk (Bartsch et al., 2003; Ellstrand, 2006), but does so when specific genes with plant pest potential are incorporated into a cultivated plant

Hybridization. In plant biology, when gene flow occurs between individuals from genetically distinct populations and a new plant is formed, the new plant is called a hybrid (Ellstrand, 2003). Hybridization is usually thought of as the breeding of closely related species resulting in the creation of a plant that has characteristics different from either parent. Usually this occurs through deliberate human efforts; however, it can also occur indirectly from human intervention, or in nature. For example, when plants are moved to a new environment (with or without human intervention), they may hybridize with plants of a closely related species or subspecies in that new location.

For natural hybridization to occur between two distinct populations, the plants from the two populations must flower at the same time, they must be close enough so that the pollen can be carried from the male parent to the female parent, fertilization must occur, and the resulting embryo must be able to develop into a viable seed that can germinate and form a new plant (Ellstrand, 2003).

Introgression. Hybridization may occur in one generation, but in most cases, does not continue on its own. If it does, and stable new populations result, the process is called introgression. For introgression to occur, hybridization of offspring with the parental types (backcrossing) must occur several times. Because hybrids of distantly related species may not produce viable seed, introgression is much less common than hybridization. For example, in studies done with canola and a weedy relative, backcrossing from the hybrids to the weeds occurred at one-hundredth to one-thousandth the rate of the original hybridization (Stewart, 2008). Nevertheless, when weed species are introduced to new areas, there is the potential that those introduced plants may hybridize with other closely related species. Novel hybrids therefore may be created. In addition, novel hybrids may be created through back-crossing (i.e. introgression) with parent species which may change the native species with non-native genetic material. Invasive weeds can result from hybridization events, which mix genetic material potentially producing a wide array of genotypes. Some of these genotypes may exhibit increased invasive properties (USDA ARS, 2008).

Characteristics that favor natural hybridization between two populations when the above requirements are met include (Mallory-Smith and Zapiola, 2008):

- Presence of feral populations (domestic populations gone wild) and uncontrolled volunteers
- Presence of a high number of highly compatible relatives
- Self-incompatibility
- Large pollen source
- Large amounts of pollen produced
- Lightweight pollen
- Strong winds (wind pollinated)
- Large insect populations (insect pollinated)
- Long pollen viability

1) Gene Flow from Sugar Beet to Sugar Beet

Sugar beets and other members of the species *B. vulgaris* are self-incompatible; that is, fertilization does not occur between the male and female parts on the same plant. Self-incompatible plants must outcross with genetically unrelated individuals for fertilization to occur, wherein the pollen from the male part of one plant lands on the sticky stigma within the flower of the female part of another plant.

Sugar beets are largely pollinated by wind (Mallory-Smith and Zapiola, 2008; OECD, 2001). The potential for longer-distance gene flow increases with higher wind speeds (Mallory-Smith and Zapiola, 2008). Depending on wind conditions, wind-borne sugar beet pollen has been measured to travel at least 4,500 meters (2.8 miles) (OECD, 2001). Gliddon (1994) assumed that the airborne pollen movement can occur at distances up to 8 km. However, as discussed in the Affected Environment section, the vast majority of the pollen does not travel these great distances, and the very small amount that does is unlikely to pollinate another plant.

Successful wind-pollinated flowering plants must produce large amounts of pollen: the chances of any single wind-blown pollen grain landing on and being held by the stigma of another plant are very small. Pollen occurs in "clouds": scientists have estimated sugar beet pollen production at one billion pollen grains per plant (Schneider, 1942; OECD, 2001). There is great competition within this cloud for the limited available ovules (only one per flower), and the stray pollen from another source has extremely limited opportunity for success. In a large, densely planted area such as a seed production field, pollination is much more likely from the pollen cloud within the field than from stray pollen from another field (Westgate, 2010; Hoffman, 2010a). Most of the pollen is diluted during long-distance pollen dispersal because pollen incoming to a field is overwhelmed by the concentration of local pollen.

The viability of sugar beet pollen is influenced by characteristics of the pollen and environmental conditions such as relative humidity and exposure to sun (UV irradiation) (Aylor, 2003). The viability of sugar beet pollen, like most pollen sources, is known to decline rapidly with age and exposure to environmental stresses. Sugar beet pollen has been successfully stored when desiccated to 12% water content and stored at extremely low temperatures in liquid nitrogen (minus 321F) (Hecker et al., 1986). Under normal field conditions, the pollen does not survive wetting by dew or remain viable for more than a day (http://www.pedz.unimannheim.de/daten/edz-bn/eua/02/28.pdf).

Sugar beet pollen dispersal. Many studies have been done to measure distances over which cross-pollination may occur in *Beta* species, with a range of results (Bartsch et al., 2003; Chamberlain, 1967; Darmency et al., 2009; Darmency et al, 2007; Fenart et al., 2007). Darmency et al. (2009) summarized a literature review of studies on pollen flow in sugar beet (Table 2, values reported in meters converted to feet).

Darmency et al. (2009) noted that the experiments “were hardly comparable because the experimental design varied widely.” Darmency et al. (2009) also found that nearly all fertilization from a pollen source occurs nearest the source field (within about 0.3 miles). Additional references not included in the summary table provide information about distance pollen has travelled, but these observations are not actual hybridization events, which, as discussed previously, is a different issue. Darmency et al. (2009) did not report how many, if any, of these studies used isolated bait plants rather than groups of receptor plants that would be producing their own pollen cloud, which, as discussed above, could make a substantial difference (i.e., the percentages of pollination by an outside source are much smaller with competition). Also, in their own experiments, even when the pollen reached the target plant and hybridization did occur, Darmency et al. (2009) found a large drop in cross pollination rates, with approximately 40% at the source dropping to one percent at around 1,000 feet from the source. From these studies, it is clear that outcrossing frequencies at one mile (5,280 feet) are likely to be quite small. In the next section, Gene Flow from Sugar Beets into Vegetable Beets, additional analysis of the likely distance of gene flow using models is presented, giving further support for the validity of four miles as adequate for confinement of pollen from genetically engineered sugar beets.

Table 2. Gene Flow (% outcrossing) in Sugar Beet.

Authors	Outcrossing at Maximum dispersal distance (in ft)
Alibert et al (2005)	2.1% at 700
Archimowitsch (1949)	0.3% at 2,000
Bateman (1947)	0.07% at 62
Brants et al (1992)	8% at 250
Dark (1971)	0.1% at 100
Darmency et al (2007)	1.3% at 920
Madsen (1994)	0.31% at 250
Saeglitz et al (2000)	40% at 660
Stewart and Cambell (1952)	10% at 50
Vigouroux et al (1999)	1.2% at 50

Note: The maximum dispersal was "the highest rate at the farthest distance to which hybrids were found in the study".

Detecting cross pollination between GE and non GE sugar beet. Although most varieties of sugar beet contain the H7-1 trait, there are still some conventional sugar beet varieties being produced. For example, all varieties tailored for the Imperial Valley or produced for export to Europe lack the H7-1 trait. In most cases, the GE and non GE sugar beet will be visually indistinguishable. To avoid cross-contamination seed companies follow best management practices for GM seed production. The protocol (Loberg, 2010) "includes requirements for monitoring, within a three-mile radius of any Roundup Ready® field, and removal of any volunteer seedlings for a minimum of five years or until no volunteers are observed, whichever is later; a color tagging and traceability system for visual identification of any GM material; best practices for production, including equipment monitoring, treatment and cleaning procedures for crop production equipment; seed cleaning, storage, shipping container and screenings disposal requirements; grower guidelines; record keeping; inspections; training, and a continual review and improvement process." West Coast Beet Seed contracts also require seed growers to diligently control volunteer plants after RR sugar beet seeds are harvested by tilling and monitoring fields.

Testing can also be used to ensure that an undesired trait is not incorporated into basic or certified seed and widely disseminated into the marketplace. For the situation where the GE crop and the conventional or organic crop are physically indistinguishable, methods other than visual inspection have been developed to ensure that the GE trait has not been incorporated into the conventional or organic crop. Based on the awareness that past incidences of low-level presence have happened despite precautions, quality control measures have been introduced in seed operations to confirm the genotype of the selections. Among the best practices for seed handling (permit condition 4) include quality control measures used to verify that GE and proprietary traits are absent, as well as to confirm that the desired traits have been integrated into the next generation.

Removal of unwanted traits from a breeding line. Although rare, it is possible that in the coexistence area H7-1 sugar beet will pollinate conventional sugar beet, Swiss chard or table beet. This does not mean that the conventional line will permanently carry the RR trait. The frequency of cross pollination under a four mile isolation zone is likely to be no greater than 0.01% to 0.1% (see rationale in section, Gene Flow from Sugar Beet to Vegetable Beet), and it is straightforward to eliminate these seeds from the line. One strategy that might be used is a non-destructive test in which seeds from the line are sown, grown into plants, and the plants tested.. Plants that test positive are discarded so seeds are only collected from the plants that test negative for the trait, in this case H7-1. In this way elimination of the trait can be accomplished in a single generation. In the case of crosses between sugar beet and chard or table beet, it is likely that the progeny of the cross will be visibly distinct and can be rogued by physical appearance alone.

Testing based on biochemical analysis of plant genotypes can also be done to assure GE free status (see later discussion in this EA). A number of cost effective tests are available to detect the H7-1 trait. Inexpensive strip tests (about $2-4/assay) are available that allow non-invasive field testing (outside of the laboratory) of the sample (Neogen, 2010). These strips have a sensitivity that allows the detection of one H7-1 seed in 1000 in a matter of minutes by relatively unskilled personnel. For the H7-1 trait, a validated polymerase chain reaction (PCR) assay is available which costs about $200-300/assay and can detect about one H7-1 seed in 10,000 seeds (http://www.genetic-id.com).

Stander (2010) describes how to increase the efficiency and reduce the cost of testing by pooling samples. For example, if a grower had a target level of 1,000 plants to advance to the next generation, and the initial test suggested an outcrossing level of 1 in 3000, the grower might screen a subpopulation of 15 groups of 100 plants each. Fagan (2010) commented that pooling into 50 plants/pool would give better results. This could be done using several flats of seedlings in a greenhouse, divided into 30 groups of 50 seedlings.

To conduct the testing, leaves from each of the plants would be collected, with the leaves from the 50 plants in a single group being combined to form a bulk sample. The bulk samples, representing each of the several groups, would each then be tested with the strip test. If one of the groups tested positive, the entire group would then be discarded, and the plants in the remaining groups would then be vernalized and transplanted into the field to produce seed. In the example case, it would be very unlikely that more than one or two groups would test positive for the unwanted trait and very likely the grower would have at least 1000 plants that had been confirmed negative for the trait to advance to the next generation.

2) Gene Flow from Sugar Beet to Vegetable Beet

Vegetable beets grown in the US include red table beets, spinach (or leaf) beets, and Swiss chard. All are highly compatible with sugar beets.

Modeled sugar beet pollen dispersal. As discussed in this Affected Environment section, sugar beet pollen is transported primarily by wind. Gene flow from cross-pollination depends on dispersal distance of pollen grains, their viability, the environment, and the presence of competing pollen at recipient plants (Rognli et al., 2000). Dispersal distance is influenced by the characteristics of the pollen (size, weight and shape), climate conditions such as wind speed, direction, and turbulence, topography, pollen source field size, and architectural features of the plant such as height (Aylor, 2003; Jackson and Lyford, 1999). Westgate (2010) considered these parameters in modeling pollen dispersal from nearby sugar beet fields to the organic *Beta* production field of a Plaintiff's declarant who believed his fields would be cross-pollinated by H7-1. The nearest H7-1 field was 6.9 miles away. Using conservative assumptions and modeling conditions for the three days during the "pollen shed" period when wind conditions were most likely to result in cross-pollination (June 22, 23, and 27), the modelers obtained the following results for likelihood of outcrossing: June 22, $2x10^{-5}$% (1 seed in 4.9 million); June 23, $9x10^{-8}$% (one seed in 1.1 billion); and June 27, $4.5x10^{-7}$% (1 seed in 222 million). The risk of any successful pollination in these circumstances is highly unlikely. Based on Darmency's observation (Darmency et al., 2009) that nearly all fertilization from a pollen source (99.9%)

occurs within the first 500 m (about 0.3 miles), Hoffman 2010 concluded that the 4-mile isolation distance (as articulated in permit condition 2) “to isolate unlike sexually compatible crops such as Swiss chard, table beets and sugar beets is more than 12 times the distance needed to reduce cross-pollination between RRSB and Swiss chard to 0.1% (1 seed in 1000) in a worst case scenario without competition from a local pollen source” (Hoffman, 2010a). As described in the Affected Environment section local pollen production will effectively out-compete distant pollen sources reducing the likelihood of cross pollination even further. He conservatively estimated that the level of gene flow at 4 miles to be lower than at 0.3 miles by over an order of magnitude, or less than 0.01% (1 seed in 10,000 seeds). A plant geneticist and research leader of the sugar beet research unit at the USDA ARS Crop Research Laboratory, concurred with Hoffman’s analysis and conclusion (Panella, 2010). Carol Mallory-Smith, PhD, professor in the Department of Agriculture at Oregon State University in the Willamette Valley, concluded that the “proposed restrictions (permit conditions including a four-mile isolation distance) will provide significant safeguards to protect *Beta* species seed producers while the EIS is being conducted” and that the risk of gene flow would be “extremely low” (Mallory-Smith, 2010).

Detecting cross pollination between sugar beets and non sugar beet Beta species. When sugar beet pollen fertilizes a non-sugar beet *Beta* species plant such as Swiss chard or table beet, the resulting seed produces a visually distinct hybrid off-type of that *Beta* species plant.

Half of the genes in the seed come from sugar beet and half of the genes come from the other *Beta* species. If a cross pollination event occurred between H7-1 sugar beet and a chard or table beet variety, the progeny would not just have the H7-1 trait, but would also have half of its genes from chard or table beet. This hybrid off-type is a highly undesirable plant because it will most likely produce intermediate characteristics that diminish the quality of the desired plant. For the external appearance, the hybrid off-type will not be Swiss chard, sugar beet, or table beet but a mixture of the two parental characters at varying proportions depending on dominant-recessive nature of each character. A Swiss chard producer will reject a Swiss chard-sugar beet hybrid off-type because it will have undesirable flavor and shape. It will produce a plant that produces more roots at the expense of the shoot. Similarly, the sugar beet producer will reject this hybrid off-type because it will produce low levels of sugar in the root and may not have desirable disease resistance characteristics. The sugar beet-table beet hybrid off-type will be rejected by the table beet producer because the color will be less intense, the root larger and more irregular, and it will have inferior taste characteristics. Coexistence measures in the Willamette Valley have been designed to minimize the amount of visible off-types formed between sexually compatible species and varieties.

Seed companies growing sugar beets in the Willamette Valley monitor for off-types in the commercial seed by growing out a sample of seed and observing the appearance of the resulting plants. Seed companies have indicated a very low level of off-types in sugar beet crops, and one seed company reports that its latest "observation plots did not produce any off-types" (Lehner, 2010). Customers (i.e., growers of commercial sugar beet root crops) have likewise indicated that after inspecting the millions of plants grown in variety trials conducted over several years, "the number of chard or red beet off-types were so small as to be, for all intents and purposes, not quantifiable." (Grant, 2010; Berg, 2010; Hofer, 2010). Seed companies regularly perform grow out tests to determine if there are any issues with off-types (Lehner, 2010; Hovland, 2010). Red table beet off-types in sugar beet fields could occur due to nearby backyard gardeners growing red table beets, or might occur from open pollinated red table beet fields upwind from sugar beet fields (Anfinrud, 2010). In an open pollinated field, every plant sheds pollen (Stander, 2010). Thus an acre of open pollinated red table beets would produce more pollen than an acre of hybrid sugar beet fields, where only one-fourth to one-third of the plants produce pollen (Westgate, 2010). The Willamette Valley Specialty Seed Association pinning guidelines and isolation distances require four-mile isolation distances between open pollinated red beet and sugar beet fields, in order to limit red beet off types in sugar beet fields and vice versa (Stander, 2010)

The organic grower mentioned in the litigation has tested his organic chard seed using a PCR test capable of detecting 0.01% GE content (Morton, 2010a,b). That seed has been tested each year since 2007 and to date has not detected the presence of any H7-1 sugar beet. (Hoffman, 2010a; Morton, 2010a,b; Stearns, 2010).

In May 2009, an incident was reported involving H7-1 steckling disposal that raised questions regarding one sugar beet seed company’s stewardship and disposal requirements for those materials (Roseboro, 2009). Stecklings are sugar beet roots that may be transplanted into hybrid sugar beet fields. In or around May 2009, the Pro Bark garden store in Corvallis, Oregon procured a quantity of peat moss from Betaseed. Betaseed had used the peat moss to transport a shipment of sugar beet stecklings, and after the shipment had been transplanted, some quantity of stecklings remained in the peat moss. After Pro Bark obtained the peat moss Pro Bark mixed it with potting soil and offered it for sale as a fertile soil mixture. Betaseed learned that the mix was being sold and that it contained some stecklings, and at that point, Pro Bark's records indicated that it had sold portions of the mixture to thirty customers located in the Corvallis and Albany area. Betaseed repossessed the portion of the mixture that had not been sold. Betaseed personnel visited twenty of the thirty customers who had purchased portions of the mixture and removed any stecklings or steckling fragments found in the mixture. The owner of Pro Bark contacted seven additional purchasers and requested that they inspect for and destroy any stecklings in the potting mix they had purchased (Lehner, 2010)

Betaseed reported that the stecklings found in the mixture after repossessing it were not likely to survive and produce pollen. Most of the stecklings were fragmented, rotting or dead. Also, because a large percentage of Betaseed hybrid sugar beet fields in the Willamette Valley in 2009 had the H7-1 gene only on the non-pollinating female plant (the Affected Environment section), the shipment of stecklings that Betaseed had transported in the peat moss was composed of less than 5% H7-1 male pollinators. Therefore, according to Betaseed, the chances that any steckling in the peat moss was intact, alive and a male H7-1 pollinator were remote. In addition, given the time of year when the fertile mixture was sold (May), cross-pollination would have been very unlikely even if the stecklings had been able to produce pollen. Stecklings are normally planted in Jan and Feb so that they flower in May and June. Stecklings planted in May would be expected to flower in the late summer if they flowered at all. Betaseed subsequently revised its Standard Operating Procedures (SOPs) to provide for proper disposal of the peat moss in which it transports stecklings (Lehner, 2010).

Now stecklings that are removed from the nursery, but are not used, are destroyed or securely disposed. The prevailing method is returning unused stecklings to the nursery field of origin and subsequent destruction through standard agricultural practices (physical destruction with tillage and chemical destruction in the subsequent crop) (Loberg, 2010).

3) Gene Flow from Sugar Beet to Weed Beets

Plants that are native to a particular area or ecosystem are those that are not introduced by humans, but occur at those locations without human intervention.

Figure 1. All CA counties with *Beta* records
Source: Consortium of California Herbaria, 2008

Non-native beets fall into one of three categories: wild plants, weeds and feral beets. Non-native wild beets are those that that were never cultivated, and grow on their own outside of an agricultural/horticultural setting. Weeds, discussed in the Affected Environment section of this EA, included unwanted plants in an agricultural/horticultural setting. Feral beets are those that were originally domesticated, but have escaped cultivation and grow on their own

***Native Uncultivated and Weed Beets and Overlaps with Sugar Beet Root Production*.** No native members of the genus *Beta* are found in North America (USDA, 2010a; Mansfeld, 1986). Thus, all of the *Beta* species in North America, both cultivated and uncultivated, were introduced through human intervention from outside the continent

The USDA reports two *Beta* species in the US: *Beta procumbens* and *Beta vulgaris*. Some researchers (Bartsch and Ellstrand, 1999; Bartsch et al., 2003) consider *Beta macrocarpa* as a separate species; however, USDA ARS reports that the designation was changed in 2000 to *B. vulgaris* ssp. *macrocarpa* (USDA ARS, 2010). *Beta procumbens* can be artificially crossed with sugar beet (*B. vulgaris* spp.), but the plants usually die at the seedling stage (OECD, 2001). In any case, *B. procumbens* in the US has been identified only in Pennsylvania, where sugar beet is not currently commercially grown (USDA ARS, 2010). Sugar beet hybridizes with all *B. vulgaris* subspecies, including *B. vulgaris* ssp. *macrocarpa*. The hybrids are all annuals, flowering in the first year and producing little or no root or sugar yield (Messéan, 2009).

There is some scientific disagreement about the compatibility of sugar beet and *B. vulgaris* ssp. *macrocarpa* (referred to hereafter as *B. macrocarpa*, the terminology in all sources except USDA ARS, 2010). OECD reports that *B. vulgaris* and *B. macrocarpa* are fully compatible and the resulting hybrids are vigorous and fertile (OECD, 2001). In contrast, Dr. R.T. Lewellen, a USDA, ARS geneticist who has worked with sugar beet at the USDA/ARS Salinas Research Station for many years has done research on *B. macrocarpa* and has concluded that it does not outcross readily to sugar beet. This is because *B. macrocarpa* usually bolts and flowers too early to cause a risk of hybridization with sugar beet. Additionally, any hybrid of sugar beet and *B. macrocarpa* would possess several genetic factors that pose a challenge to the plants' survival in nature. For example, the hybrid would be mostly pollen sterile and would have disturbed genetic ratios and growth habit.

Other researchers have also found that hybridization between *B. macrocarpa* and sugar beet is relatively rare because the flowering times usually do not overlap (Bartsch et al., 2003; McFarlane, 1975). In addition, based on genetic studies, Bartsch and Ellstrand (1999) report a "strong genetic differentiation between *B. vulgaris* and *B. macrocarpa*, which supports the notion that the latter is a separate species" and find it "remarkable" that hybridization between the two "is still possible".

Sugar beets have been grown in the Imperial Valley since 1932 (Spreckels Sugar, 2009). As noted above, the earliest dated collected *Beta* specimen is from 1938; however, Bartsch and Ellstrand reference observations of uncultivated wild beets in the Imperial Valley from 1928 (Bartsch and Ellstrand, 1999). When Bartsch and Ellstrand did their research in 1998 and found evidence of introgression between *B. macrocarpa* and *B. vulgaris* in two percent of the *B. macrocarpa* tested, sugar beets had been grown in the Imperial Valley for 66 years.

Uncultivated wild beets in California. The USDA/ARS has 13 *B. vulgaris* var.*maritima*[4] and 7 *B. vulgaris* ssp. *macrocarpa* collected specimens in its National Plant Germplasm System, all

[4] Specimens were originally identified as *Beta vulgaris ssp. maritima*

DEFINITIONS

Ecosystem – *the complex of a community of organisms and its environment.*

Species *– group of organisms all of which have a high degree of physical and genetic similarity, generally interbreed only among themselves, and show persistent differences from members of allied groups of organisms.*

Introduction *- intentional or unintentional escape, release, dissemination, or placement of a species into an ecosystem as a result of human activity.*

Native species – *with respect to a particular ecosystem, a species that, other than as a result of an introduction, historically occurred or occurs in that ecosystem.*

Sources: Executive Order 13112 – Invasive Species (1999); USDA National Agricultural Library, 2010.

donated in 1985 by J.S. McFarlane of the USDA ARS Salinas, California office. The two *B. vulgaris* ssp. *macrocarpa* samples with collection information included were both from the Imperial Valley; one was collected from a sugar beet field in 1968; collection information for the other was not noted (USDA ARS, 2010). The Consortium of California, which keeps a database of 16 herbaria (collections of plant specimens) throughout the state, documents 172 *Beta* accessions from 15 counties, collected between 1896 and 2006 (counties shown in Figure 1) (Consortium of California Herbaria, 2008).

Forty of the specimens are designated *B. macrocarpa*, 19 as *B. vulgaris* ssp. *maritima*, one simply as *Beta*, and the rest are designated *B. vulgaris*. Seventeen of the accessions are from Imperial County: fourteen of these are designated *B. macrocarpa*, one is designated *B. vulgaris*, and one was originally identified as *vulgaris* and later corrected to *macrocarpa*. Imperial County collection dates ranged from 1938 to 1998 (Consortium of California Herbaria, 2008). Calflora's database includes herberbia records, plus other documented or recorded observations. California counties with records of *B. vulgaris* or *B. macrocarpa* are shown in Figure 1, along with sugar beet production areas (shown as blue dots).

There have been a number of hypotheses regarding the origin of the California uncultivated wild beets, including that at least some of them are wild (feral) sugar beets (Johnson and Burtch, 1959). However, based on genetic analysis, Bartsch and Ellstrand (1999) concluded that the uncultivated wild beets in California have two independent and primary genetic origins, one from European *B. macrocarpa* (the uncultivated wild beets found in the Imperial Valley and on the Channel Islands) and one from European *B. vulgaris* (beets from all other areas in California where uncultivated wild beets are found). They found that what they termed the *B. macrocarpa* of the Imperial Valley and the Channel Islands were, with the exception of one population, “genetically identical with a Spanish *B. macrocarpa* from the Mediterranean area of Cartagena” (Bartsch and Ellstrand, 1999). The single exception was a population in the Imperial Valley of *B. macrocarpa* that showed genetic similarities with *B. vulgaris,* which led them to conclude that the sugar beet (a subspecies of *B. vulgaris*) had introgressed with *B. macrocarpa* (Bartsch and Ellstrand, 1999). Bartsch and Ellstrand concluded that the other uncultivated wild beets in California are descended from cultivated Swiss chard and red table beets, European sea beets, and hybridized populations among these (Bartsch and Ellstrand, 1999).

Weed beets. Beets (genus *Beta*) generally are not weeds: there are no *Beta* species included in the Weed Science Society of America’s (WSSA) list of 3,488 weeds (WSSA, 2010a). No *Beta* species are included among the 1,553 weeds in the USDA database of invasive and noxious weeds (USDA, 2010b).

Weed beets in European sugar beet production. We discuss the problem of weed beets in European production fields because it is a concern in Europe and may raise questions about whether the same issues may occur in the US, and, if so, what impact the use of H7-1 sugar beet would have. Weed beets have been a serious problem in European sugar beet production since the 1970s (May, 2001; Desplanque et al., 2002; Ellstrand, 2003). In 2000, some sugar beet fields in the EU were growing more weeds than beets (Ellstrand, 2003). Weeds of the same or closely related species as the crop can present special problems. Their seeds and young plants may be indistinguishable, and they will have very similar responses to herbicides. Unlike sugar beets, the weed beets flower in the first year, and produce many seeds. Because they are the same species, any herbicide that is effective on the weed beet will also damage or destroy the sugar beet. Thus, the weed beets must be manually removed, and the grower often does not discover that the weed beets are not sugar beets until they bolt. The weed beets form a seed bank that can persist for years. While weed beets and native sea beets grow in many parts of Europe, the weed beets in the production fields apparently do not originate from weeds near the production fields. In the 1990s, the problem was traced to hybridization of weed beets with the sugar beets grown in seed production areas (Ellstrand, 2003). Sugar beet and sea beet (*B. vulgaris* ssp. *maritima*) hybridize freely and the resulting progeny are fully fertile. Sugar beet and sea beet also share a common flowering period. Sugar beets are grown in many parts of Europe, but seed production occurs mainly in the temperate climate regions of southwest France and northeast Italy, where weed beets are also present (Bartsch et al., 2003).

While the sugar beets and weed beets introgress with each other, and the weed beets and the native sea beets that grow along much of the Atlantic European and the Mediterranean also introgress with each other, in a century of sugar beet production, gene flow from sugar beets has not altered the genetic diversity of wild sea beets in the region, including in the seed production areas (Bartsch et al., 2003).

In the US, the only reports of weed beets as a problem have been in sugar beet production in the Imperial Valley (Lewellen et al., 2003; Bartsch et al., 2003; Lilleboe, 2009). The weed beet situation in the Imperial Valley is very different from that in Europe. The weed beets in Europe originated from seed production fields, where the sugar beet plants and nearby wild beets all flower at the same time, and the resulting hybrids apparently contaminated the seed supply. Thus, the European weed beets in sugar beet root production fields originated from the inadvertent planting of the weed beet seeds along with the sugar beet seeds. In the Imperial Valley, the weed beets are *B. macrocarpa*, which were present in the Imperial Valley before the introduction of sugar beets, and have coexisted with sugar beets since 1938 with very little hybridization (Bartsch and Ellstrand, 1999; Bartsch et al., 2003). At the present time, no sugar beet seed is produced in California (Hoffman, survey of seed producers, 2010) and the possibility of further hybridization would thus depend solely on bolters from established root crop plants, likely a rare event.

***Feral crops*.** Based on available data, de-domestication has occurred in only a few crops. These feral crops are of minor importance compared with other weeds (Gressel, 2005). In North America, the feral plants that cause much of the economic damage are imported horticultural plants; for example, Japanese privet (*Ligustrum japonicum*), Japanese honeysuckle (*Lonicera japonica*) and kudzu (*Pueraria lobata*) (Gressel, 2005).

Scientists from Oregon State University report that there are no feral sugar beet crops in the US (Mallory-Smith and Zapiola, 2008). As discussed in the Affected Environment section, in California, the only sugar beet growing state with documented beet populations (as opposed to the isolated reports from a few other locations), genetic assessment of uncultivated wild beets has not supported the conclusion that any of these beets are feral crops.

Based on this information, and the poor competitive characteristics of sugar beets, we have concluded that the existence of feral sugar beet crops in the US is unlikely, and any that might exist are negligible.

b. Weed Management

Weed management issues for sugar beet production:

The focus of this EA is to assess the direct impacts of the H7-1 sugar beet on the resources in the environment where the crop is grown. APHIS also assesses indirect impacts, such as the use of glyphosate on this crop, for which the variety was designed. The weed management issues, common to all types of sugar beet production are compared to any differences arising from use of glyphosate, and the issues analyzed are summarized here.

1. No competitive advantage has been shown to be conferred by the H7-1 transformation, and its descendants are not weedy
2. Sugar beet is a poor competitor with weeds, and at least 12 weeds are significant problems for growers
3. Herbicides are used by virtually all sugar beet growers; no single herbicide is effective on all weeds, and some herbicides used with conventional beets are toxic to the beets.
4. Weed control in conventional sugar beets is complex, requiring several applications of tank mixed herbicides along with hand weeding or cultivation.
5. Glyphosate has been used with 95% of sugar beet production, but accounts for only 1% of total glyphosate used in US agriculture.
6. Glyphosate –resistant weeds account for 5% of the herbicide resistant weed biotypes, while ALS herbicides account for 31%.
7. Glyphosate is designated an EPA Group E herbicide (evidence of non-carcinogenicity) and environmentally of lesser risk than many other herbicides.
8. Development of glyphosate resistance will be inhibited by grower awareness, available strategies to avoid it and financial incentives to reduce it.

9. Development of resistance is not unique to glyphosate but is faced by growers for every herbicide
10. Resistance hasn't developed by gene flow, but by selection acting on existing genes.
11. About 6% of total major crop acreage may have some level of glyphosate tolerant weeds.
12. Continuous cropping is the source of most resistance, not the 3-5 years crop rotations required for sugar beet production.
13. Volunteer sugar beet roots do not easily survive winters, and elimination is an invariant practice among growers.
14. Glyphosate treatment resulting in manganese deficiency only occurs in limited situations and evidence is conflicting.
15. Disease susceptibility of H7-1derived varieties are within the range of variation found in conventional varieties.

Sugar beets and weeds. The sugar beet plant is a poor competitor against weeds, especially from emergence until the sugar beet leaves shade the ground. Emerging sugar beets are small, lack vigor, and take approximately two months to shade the ground. Thus, weeds have a long period to become established and compete. To avoid yield loss from weed competition, weeds need to be controlled within four weeks after sugar beet emergence and weed control needs to be maintained throughout the season (Cattanach et al., 1991; California Beet Growers Association, 1999; McDonald et al., 2003; Mikkelson and Petrof, 1999).

Uncontrolled weeds that emerge with the crop may cause from 30 to 100 percent yield losses (California Beet Growers Association, 1999; Sprague, 2007). While yield losses are the major concern, weeds also create other problems. Late-season weeds can hinder harvesting operations. For example, infestations of wild mustard can cause loss of small beets during harvesting. Many weed species host plant pests including curly top virus, sugar beet cyst nematode and insects such aphids. High levels of weed control are essential for profitable sugar beet production (California Beet Growers Association, 1999; Mikkelson and Petrof, 1999; Mesbah et al., 1994). Prior to adoption of H7-1 sugar beets, growers regularly used multiple chemical herbicides to attempt to control weeds. (Cole, 2010; Kniss, 2010; Wilson, 2010; Hoffman, 2010a, b).

Some scientists, for example Ellstrand (2006), have raised the question of "unintended crop descendents from transgenic crops." Ellstrand states "The possibility of unintended reproduction by transgenic crops has raised questions about whether their descendents might cause problems. These problems have fallen into two broad categories: first, the direct feral descendents of the crops may prove to be new weeds or invasive plants, and second, that unintended hybrids between transgenic crops and other plants could lead to certain problems." This section discusses the weediness properties of H7-1 sugar beet, and addresses the concern of direct descendents of the crop that "may prove to be new weeds or invasive plants." Hybridization has been discussed in other sections.

H7-1 was allowed environmental releases in North America from 1998 to 2003 and in Europe from 1998 to 1999. In these trials, no differences were observed between H7-1 lines and non-transgenic lines with respect to the plants' ability to persist or compete as a weed (Schneider and Strittmatter, 2003; USDA APHIS, 2005). In these evaluations, APHIS considered data relating to plant vigor, bolting, seedling emergence, seed germination, seed dormancy and other characteristics (USDA APHIS, 2005).

In a separate evaluation, the Canadian Food Inspection Agency (CFIA), whose responsibilities include regulation of the introduction of animal food and plants (including crops) to Canada, reached the same conclusion about the weediness potential of H7-1 compared with non-transgenic sugar beet. In 2005, the CFIA authorized the "unconfined release into the environment and livestock feed use of the sugar beet H7-1" (CFIA, 2005). In its evaluation of H7-1, CFIA "determined that germination, flowering, root yield, susceptibility to plant pests and diseases typical to sugar beet and bolting percentage were within the normal range of expression of these traits currently displayed by commercial sugar beet hybrids" (CFIA, 2005). The CFIA reached the following conclusions (CFIA, 2005): No competitive advantage was conferred to these plants, other than that conferred by tolerance to glyphosate herbicide. Resistance to Roundup® agricultural herbicides will not, in itself, render sugar beet weedy or invasive of natural habitats since none of the reproductive or growth characteristics were modified.

The above considerations, together with the fact that the novel traits have no intended effects on weediness or invasiveness, led the CFIA to conclude that the H7-1 sugar beet has no altered weed or invasiveness potential compared to currently commercialized sugar beet.

Thus, the potential for H7-1 to become a weed or invasive plant was determined to be no greater than conventional sugar beets. Neither sugar beets nor other *Beta* species plants are considered a weed issue in any state other than California.

1) Sugar Beet and Weed Management.

The USDA Agricultural Research Service (ARS) has identified the following weeds as problem weeds in sugar beets that have previously prevented production of maximum yields to conventional crops: kochia (*Kochia scoparia)*, pigweed (*Amaranthus* spp*.)*, common lambsquarter (*Chenopodium album)*, nightshade (*Solanum* spp*.)*, common mallow (*Malva neglecta)*, cocklebur *(Xanthium strumarium)*, barnyardgrass (*Enchinochloa crus-galli)*, foxtail (*Setaria)*, wild millet (*Panicum miliaceum)*, wild oats (*Avena fatua)*, sowthistle (*Sonchus* L*.)*, Canada thistle (*Cirsium arvense)*, nutsedge (*Cirsium arvense)*, and dodder (*Cuscuta* L*.)* (USDA ARS, 2008). Most of these weeds, along with others, are present throughout the US sugar beet growing regions (Table 7). Weeds are classified as annual or perennial. An annual is a plant that completes its life cycle in one year or less and reproduces only by seed. Annuals are further classified as broadleaf or grass. Perennials are plants that live for more than two years. They may reproduce by seeds, rhizomes (underground creeping stems) or other underground parts.

Kochia (*Kochia scoparia)*, an annual broadleaf plant, is a member of the Goosefoot family, the same family as sugar beet. Weeds in the same family as a crop often thrive in the same growing conditions.

Pigweed (*Amaranthus* spp*.)* is a broadleaf annual that is a weed problem in many crops. There are several species; redroot pigweed is most common (UC IPM, 2010).

Common lambsquarter (*Chenopodium album)* is an annual broadleaf in the same family as sugar beets. With its rapid growth and large size it quickly removes soil moisture (McDonald et al., 2003).

Nightshade (*Solanum* spp*.)* is a broadleaf annual that grows 6-24 inches tall (McDonald et al., 2003).

Common mallow (*Malva neglecta)* and **cocklebur** *(Xanthium strumarium)* are widespread broadleaf annuals.

Barnyardgrass (*Enchinochloa crus-galli,* **foxtail** (*Setaria),* **wild millet** (*Panicum miliaceum)* and **wild oats** (*Avena fatua)* are annual grasses.

Sowthistle (*Sonchus* L.*)* is a perennial plant that reaches a height of 3 to 7 feet and reproduces by seed and underground roots.

Canada thistle (*Cirsium arvense)* is a perennial that reproduces by seeds and underground roots and grows 2-5 feet tall. The roots extend several feet deep and some distance horizontally. Canada thistle is the most prevalent and persistent non-grass weed in Minnesota, and is the number one noxious weed in Colorado. It is a problem weed in all growing regions. (Durgan, 1998; Colorado Department of Agriculture, undated; McDonald et al., 2003).

Nutsedges (*Cyperus* spp*.)* are among the most problematic weeds of agriculture in temperate to tropical zones worldwide. They are difficult to control, often form dense colonies, and can greatly reduce crop yields. Nutsedges reproduce primarily by rhizomes (UC IPM, 2010).

Dodder (*Cuscuta L.)* is an annual parasitic weed that grows only by penetrating tissues of host plants to obtain water and nutrients. Each plant produces thousands of seeds that can remain dormant in the soil for years (UC IPM, 2010).

Velvetleaf (*Abutilon theophrasti*) is a broadleaf annual that grows 2-7 feet tall (McDonald et al., 2003; USDA 1999).

Ragweeds (*Ambrosia spp.*) are annual broadleaf weeds that can be very competitive with crops.

Other non-herbicide weed management practices. In addition to crop rotation and tillage, discussed above, growers of conventional sugar beets have other non-herbicide means to manage weeds. Narrow row widths (22-24 inches) are commonly used for quicker canopy closure (Cattanach et al., 1991; McDonald et al., 2003; Mikkelson and Petrof, 1999). Because glyphosate tolerant sugar beet crops do not require in-crop tillage, the H7-1 sugar beet growers have been switching to narrow-row production. With narrower rows, glyphosate-tolerant sugar beets can achieve canopy closure earlier in the growing season, depriving weeds of sunlight and therefore retarding late season weed growth (Wilson, 2010). Growers also use weed-free seed. Additionally, nearly all growers scout their fields for weeds (Ali, 2004).

Other non-herbicide approaches have been suggested to manage difficult weeds and these methods require that the biology of the weeds be well-understood (Vencill et al. 2011). To target possible weakness in the ability of some weed seeds to germinate, cover crops can be grown to shade the seeds that have high light requirements (Vencill et al. 2011). Weeds with inability to emerge from deep soil depths may be susceptible to deep tillage. Other cultural practices may be employed if these weed requirements are sufficiently understood.

Use of Herbicides to Control Weeds

Herbicides are used by virtually all sugar beet growers. In 2000 approximately 98% of planted acres received one or more herbicide applications (Ali, 2004). Herbicides may be applied before the crop emerges from the ground (pre-emergence) or after (post-emergence). Pre-plant incorporated (PPI) herbicides can be mixed in with the soil before planting. In selecting a herbicide and application method, a grower must consider, among other factors, whether the herbicide is registered for use on the crop, the potential adverse effects on the crop, residual effects that may limit crops that can be grown in rotation, effectiveness on expected weeds, and cost. Herbicide use is not regulated by APHIS but regulated by EPA under FIFRA, and EPA has granted glyphosate reduced risk status (Schneider and Strittmatter, 2008).

Herbicide mode of action. Herbicides are chemicals that move into a plant and disrupt a vital process. They are classified according to their mode of action, which is the overall manner in which the herbicide affects a plant at the tissue or cellular level. Most herbicides bind to, and thereby block the action of, a specific enzyme.

The Weed Science Society of America (WSSA) has classified herbicides by group number, based on their mode of action. As shown in Table 3, herbicides commonly used with sugar beet include group numbers 1, 2, 3, 4, 5, 8, and 9 (Tranel, 2008; Dexter et al., 1994; Ross and Childs, undated):

Group 1 herbicides inhibit the action of the enzyme ACCase

Group 2 herbicides inhibit the action of the enzyme ALS

Group 3 herbicides inhibit cell division (mitosis inhibitors)

Group 4 herbicides mimic the plant growth hormone auxin and cause uncontrolled cell growth (synthetic auxins)

Group 5 herbicides inhibit photosynthesis

Group 8 herbicides inhibit a single key enzyme involved in fatty acid synthesis

Group 9 herbicides inhibit the action of the enzyme EPSPS

Weed control with conventional sugar beets. Conventional sugar beet growers use a variety of weed management practices as discussed above including a variety of herbicides. Though there are hundreds of commercial herbicides; only a fraction are appropriate for use with sugar beet (Table 3).

Table 3. Herbicide Applications to Sugar Beet Acres in the US, 2000[1]

Agricultural Chemical (Herbicide)	Trade Name (typical)	WSSA Mode of Action Group No.	Acreage Treated (%)	No. of Applications per Year	Rate per Application (lb/appli./ac)	Rate per Acre (lb/ac)	Total Applied per Year (1,000 lb)
Clethodim	Select	1	46	2.5	0.04	0.11	77
Clopyralid	Stinger	4	74	2.8	0.03	0.09	102
Cycloate	Ro-Neet	8	5	1.0	1.84	1.84	139
Desmedipham	Betanex	5	94	2.8	0.07	0.18	270
EPTC	Eptam	8	6	1.0	2.61	2.64	230
Ethofumesate	Nortron	8	37	2.1	0.06	0.14	82
Glyphosate	(Several)	9	13	1.1	0.39	0.43	86
Phenmedipham	Betamix	5	80	2.6	0.05	0.14	170
Pyrazon	Pyramin	HRAC Group C1	6	1.0	0.82	0.85	76
Quizalofop, ethyl	Assure II	1	10	1.6	0.04	0.06	9
Sethoxydim	Poast	1	11	1.7	0.19	0.33	56
Trifluralin	Treflan HFP	3	5	1.0	0.65	0.66	55

Triflusulfuronm ethyl	Upbeet	2	83	2.7	0.008	0.02	29

[1] 1.565 million acres were planted in the US in 2000. All values are averages. Source: National Agriculture Statistics Service (www.usda.gov/nass); www.weedscience.org; www.hracglobalcom.

Table 4 summarizes the effectiveness of the herbicides on important sugar beet weeds as identified by USDA ARS. As the table shows, no single herbicide is effective on all weeds. Some herbicides can be mixed together and applied at the same time (tank-mixed). For conventional sugar beets, glyphosate can be applied only pre-emergence. Blank cells indicate no data were available for that source.

Table 4. Effectiveness of Herbicides on Major Weeds in Sugar Beets.

Herbicide	Broadleaves						Grasses				Perennials			Parasite
	Kochia	Pigweed	Nightshade	Cocklebur	Common lambsquarter	Common mallow	Wild oats	Barnyardgrass	Wild millet	Foxtail	Sowthistle	Nutsedge	Canada thistle	Dodder
Pre-plant incorporated														
Ro-Neet														
MI Sugar	P	G	F	P	F			G		G	N	G	N	
NDSU	P	F-G	F-G	P	F-G	F-G	F-G	G		G-E			N	
U of ID	P	E	G	P	E	P	F	G		G	P	F	P	P
Pre-emergence														
Nortron														
MI Sugar	F	G	G	F	G			P		F	N	P	N	
NDSU	F-G	G-E	F-G	P	P-F	P	F-G	P		F-G			N	
U of ID	F-G	G-E	F-G	P	G-E	P	F	G		G	G	P	P	P
Pyramin														
MI Sugar	P	G	G	P	E			P		P	N	N	N	
U of ID	P	G-E	F-G	P	G	P	P	P		P	P	P	P	P
Eptam														
NDSU	F	F-G	F-G	P	F-G	F-G	G	G-E		G-E			N	
U of ID	F	F-G	F-P	P	G	P	F-G	G		G	F	F	P	P
Post-emergence														
Nortron														
MI Sugar	-	F	G	P	F			P		F	N	N	N	

Pyramin														
MI Sugar	-	F	F	P	F			N		N	P	N	P	
Betamix														
MI Sugar	F	G	F	F	E			P		F	N	N	N	
NDSU	F	G	F-G	P-F	G	P	N	P		F			N	
U of ID	P-F	G-E	F-G	F	E	P	P	P-F		F	E	P	P	P
Betanex														
NDSU	P-F	G-E	F-G	P	G	P	N	P		P			N	
Upbeet														
MI Sugar	-	F	F	F	P			P		P	N	N	P	
NDSU	P-E	F	F	N	P	G	N	N		F-G			N	
U of ID	G	G-E	G	F	G	F	P	P		P	G	P	P	P
Stinger														
MI Sugar	N	P	F	E	P			N		N	G	N	G	
NDSU	N	P	F-G	E	P-F	P	N	P		P			G-E	
U of ID	P	P	F-G	E	F	P	P	P		P	G	P	E	P
Progress (a mixture of Betamix plus Nortron)														
MI Sugar	F	G	G	F	E			P		F	N	N	N	
NDSU	F-G	G	G	F	G-E	P	N	P		F-G			N	
Assure II/Select (Assure II only for U of ID)														
MI Sugar	N	N	N	N	N			G		E	N	N	N	
NDSU	N	N	N	N	N	N	E	E		E			N	
U of ID	P	P	P	P	P	P	G-E	E		E	P	P	P	P
Poast														
MI Sugar	N	N	N	N	N			E		E	N	N	N	
U of ID	P	P	P	P	P	P	G-E	E		E	P	P	-	P
Glyphosate														
MI Sugar	G	E	G	E	G			E		E	-	F	G	
NDSU	F-E	E	P-G	E	P-E	P-G	G-E	E		E			G-E	
Select														
U of ID	P	P	P	P	P	P	G-E	E		E	P	P	P	P
Treflan HFP														
U of ID	F	G	P	P	F-G	P	F	G		G	P	P	P	P

E= excellent, G = good, F = fair, P = poor, N = no effect
Blank cells mean no data were available for that source.
Sources: MI Sugar: Michigan Sugar (2009); NDSU: Stachler and Zollinger (2009); U of ID: Morishita (2009).

Current practices for weed control in conventional sugar beets include tillage, pre-plant incorporation of grass and broadleaf herbicides, and in-crop use of grass and broadleaf herbicide tank mixtures (Dexter and Luecke, 2003; Dexter and Zollinger, 2003; WSSA, 1994). Each of these practices has limitations. Tillage and pre-plant incorporation of herbicides are associated with narrow windows of application, which is based on a specific weed size or crop stage (Baker et al., 1982; Baker and Johnson, 1979; Campbell and Janzen, 1995; Fawcett, 1995). Additionally, herbicide effectiveness is influenced heavily by soil pH, target weed size, crop size, air temperature, and irrigation practices. Moreover, many of the currently applied herbicides leave soil residues, whose persistence can impact crop rotation options in subsequent seasons (Dexter and Zollinger, 2003; WSSA, 1994).

Conventional weed control options are complex due to the need for several applications of multiple tank-mixed herbicides to achieve long-term, broad-spectrum weed control. As an example, a common practice in sugar beet production is to use “micro-rates” of herbicides (Dexter and Zollinger, 2003). This is accomplished by tank mixing multiple herbicides at reduced rates in combination with an oil additive. The components of the tank mixture may include Betanex (desmedipham), Betamix (phenmedipham + desmedipham), Nortron (ethofumesate), Upbeet (triflusulfuron methyl), Stinger (clopyralid) and also Select (chlethodim) if grasses are present. A minimum of three applications is recommended, beginning at the cotyledon growth stage and followed by weekly applications of this herbicide mixture. The intent of the micro-rate program is to lower overall herbicide costs and reduce the potential for crop injury.

A member of the Minn-Dak Farmers Cooperative, who farms about 1,100 acres of sugar beets annually, described his conventional weed control system (Mauch, 2010):

> “Prior to planting Roundup Ready® sugar beet, my herbicide regimen for conventional beet seed was very complicated and labor intensive. Pre-emergence, I used a combination of Eptam (which is very toxic to the sugar beet) and RoNeet (which is very expensive). Approximately two weeks after the beet plants emerge, I started spraying a mix of BetaMix, Betanex, UpBeet, Nortron and Stinger and adjunctives to make the herbicides stick better to the crops. This would be sprayed four times (approximately

> once a week). Even after spraying several times, there were still weeds and I then needed to hire manual labor to hoe and pull out the weeds."

This description of the complexity of conventional weed control is similar to that provided by researchers evaluating weed management in sugar beets (Odero et al., 2008). Odero et al. (2008) evaluated 20 different weed treatment alternatives for conventional sugar beets and found that the following treatment yielded the highest net economic return: PPI treatment with Nortron (ethofumesate), followed by three micro-rate treatments of a tank mixture of Betamix (phenmedipham + desmedipham) and Nortron (ethofumesate), followed by Outlook (dimethenamid-P); with hand-hoeing following each herbicide application. Other researchers have also found that a combination of herbicides plus hand hoeing is required to effectively control weeds in conventional sugar beets (Dexter and Luecke, 2003).

Hand-weeding is necessary in many situations; however, it is cost-prohibitive as a replacement for herbicides. USDA data shows that in 2000, conventional sugar beet growers spent an average of $94.28/acre for all chemicals (insecticides, herbicides, fungicides, etc.) (Ali, 2004). Five-year studies of the cost of hand-weeding sugar beet at the University of California – Davis, as reported by the California Beet Growers Association, found that the cost of hand weeding was between $260 to over $650 per acre (California Beet Growers Association, 1999). Using the midyear of 1996 as the base year, this is equivalent to approximately $373 to $914 per acre in 2010 dollars, or approximately three to seven times what sugar beet growers spent on all chemicals. More recently, scientists in Wyoming have found that net returns for optimal herbicide application combined with hand weeding are more than twice the net returns for hand weeding alone (Odero et al., 2008).

Glyphosate. Glyphosate, an effective non-selective herbicide, was first introduced as an herbicide under the trade name of Roundup® by Monsanto in 1974. Glyphosate is a systemic, post-emergence herbicide widely used on both agricultural and nonagriculture sites (Cerdeira and Duke, 2006).

Glyphosate has a substituted glycine, the simplest amino acid. The glyphosate molecule has a methylphosphono group bonded to the nitrogen atom of the amino group of glycine, as denoted in Figure 2 below.

At normal temperatures, glyphosate is a white crystalline substance that is not volatile (is not likely to vaporize at normal pressure) and is highly soluble in water. Glyphosate salts serve as the source of the active ingredient *N*-(phosphonomethyl) glycine. To improve handling, performance, and concentration, the glyphosate acid is formulated as a salt compound. Several salts of glyphosate are currently marketed. The term Acid Equivalent (a.e.) refers to the weight of the glyphosate acid, which is herbicidally active, while the term Active Ingredient (a.i.) is the weight of the glyphosate acid plus the salt.

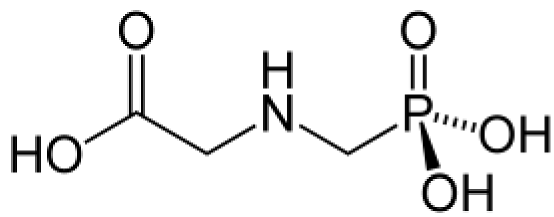

Figure 2. Molecular structure of glyphosate

Herbicide formulations in liquid form are generally considered trade secret. One formulation of glyphosate, Honcho®, has a tallow amine surfactant (Monsanto, 2007). This and other surfactants (surface action agents that are soluble in organic solvents and water), such as polyethoxylated tallowamine (POEA), are added to the herbicide formulations to increase leaf penetration.

As listed on the Roundup® Herbicide label, Roundup® Original MAX®, Roundup® WeatherMAX®, and Roundup® Ultra MAX II® products contain 48.8% of the potassium salt of glyphosate, equivalent to 4.5 lbs of glyphosate equivalents per gallon (540 g glyphosate/L). The product is to be applied over-the-top (e.g., spot treatment, broadcast ground application) for pre-plant, pre-emergence, and post-emergence weed control.

Use of Glyphosate with Roundup® Tolerant (H7-1) Sugar Beet

On sugar beet, according to the Roundup® herbicide label, no more than six pounds of glyphosate acid equivalents/acre may be legally applied per year. Of those six pounds, no more than 3.7 pounds can be applied pre-emergence, no more than two pounds can be applied from emergence to the eight leaf stage, and no more than 1.55 pounds can be applied between the eight leaf stage and canopy closure. No glyphosate applications may be made after 30 days prior to harvest. For post emergent applications, up to four sequential applications of glyphosate can be made with 10 days between applications. For each application no more than 1.125 pounds ae/acre may be applied post emergence prior to the eight leaf stage and no more than 0.77 pounds ae/acre may be applied after the eight leaf stage (Table 5). Typically RRSB growers use 2-3 applications of glyphosate a year at a rate of 0.75 pounds/acre, totaling 1.5-2.25 pounds/acre (Khan, 2010). Assuming an average use of 1.89 lbs/acre, we estimate that slightly over 1,975,000 pounds of glyphosate were used on RRSB in 2010 (Table 6).

Table 5. Glyphosate Use on Sugar Beet
Maximum Glyphosate Application Rates

	lbs ae/acre	lbs ae/acre/ application
Combined total per year for all applications	6	
Total preemergence applications	3.7	
Total of all applications made from emergence to 8-leaf stage	2	1.125
Total of all applications made between 8-leaf stage and canopy closure	1.55	0.77

Table 6. Glyphosate Use on Roundup Ready Crops

Glyphosate usage						
RR crops	lbs/acre[1]	RR adoption[2]	total acres x 1 million[3]	RR acres x 1 million	lbs x 1000	% of total
Corn	0.95	0.7	87.9	61.5	58454	25.1
Cotton	1.89	0.78	10.9	8.5	16069	6.9
Soybean	1.36	0.93	79	73.5	99919	42.9
Canola	1.125	0.9	1.5	1.4	1519	0.7
Sugar beet	1.89	0.95	1.1	1.0	1975	0.8
Estimated glyphosate use on "other" applications[4]						
1997 agricultural uses (non RR ready)					36000	15.5
1999 home and garden					6500	2.8
1999 industry commercial government					12500	5.4
Total all uses					232935	

[1]corn, cotton, soybean glyphosate rates from Benbrook (2009), canola rate from Berglund (2007)
[2]http://www.ers.usda.gov/Data/BiotechCrops/;
http://www.nytimes.com/2010/08/10/science/10canola.html, accessed 9.8.10
[3]2010 acres from NASS (http://www.nass.usda.gov, accessed Sept 8, 2010)
[4]from Kiely et al. (2004)

Based on the published glyphosate use rates for other glyphosate tolerant crops (Benbrook, 2009; Berglund, 2007) and the acreage planted in 2010 obtained from NASS, we estimated the amount of glyphosate used on the other major glyphosate tolerant crops (Table 6). We were unable to find recent statistics on glyphosate uses outside of glyphosate tolerant crops so have assumed that these uses have stayed relatively constant over the last decade and use agricultural data from 1997 before the widespread adoption of herbicide tolerant crops. Our estimate of the total glyphosate used in 2010 is about 233 million pounds of which 0.8% was used for weed control on glyphosate tolerant sugar beet. The glyphosate used on RRSB accounts for less than 1% of the US total and less than one third that used by gardeners and homeowners. Normal fluctuations in the acreage planted to corn or soybean represent larger potential glyphosate use than what is used on the entire sugar beet crop. Accordingly, the amount of glyphosate used on RRSB represents a small fraction of the total glyphosate use in the US.

In-crop applications of glyphosate can be made from crop emergence up to 30 days prior to harvest. This flexibility is preferred by growers because it allows a wider window of application, with the timing based on weed pressure, rather than on crop stage. The broad spectrum of weed control offered by glyphosate (Table 4) reduces the need for tank mixing with additional herbicides. However, the use of other herbicides in combination with or in sequence with glyphosate may be recommended under specific conditions to address select weed pressures and/or weed herbicide-resistance issues.

Monsanto's Technology Use Guide (TUG) (Monsanto, 2010) provides specific weed control recommendations for H7-1 sugar beet. The TUG recommends the use of "mechanical weed control/cultivation and/or residual herbicides" with H7-1 sugar beets, where appropriate, and "additional herbicide modes of action/residual herbicides and/or mechanical weed control in other Roundup Ready® crops" rotated with H7-1 (Monsanto, 2010).

2) Herbicide Resistance

Herbicide resistance is "the inherited ability of a plant to survive and reproduce following exposure to a dose of herbicide normally lethal to the wild type" (WSSA, 1998). In the mid-1950s, Harper (1957) theorized that annual, repeated use of any herbicide could lead to shifts in weed species composition within a crop-weed community. Similarly, Bandeen et al. (1982) suggested that a normal variability in response to herbicides exists among plant species and tolerance can increase with repeated use of an herbicide. To simplify, herbicide resistance in weeds is a result of natural selection. Plants of a given species are not all identical, but are made up of "biotypes" with various genetic traits. Biotypes possess certain traits or characteristics not common to the entire population. Herbicides, that suppress or kill weeds, exert selection pressure on weed populations. When an herbicide is applied, surviving plants, those that had reduced sensitivity to the herbicide, have a competitive reproductive advantage with progeny more likely to possess the same or superior herbicide resistance. With repeated application of the same herbicide and no other herbicide or weed control practice, the resistant biotypes can become the dominant biotype in that weed community. As of June 27, 2010, 341 herbicide resistant weed biotypes have been reported to be resistant to 19 different herbicide modes of action worldwide (Heap, 2010). Glyphosate-resistant weeds account for 5% of the herbicide resistant biotypes while weeds resistant to herbicides that inhibit acetolactate synthase (ALS) account for 31% of the herbicide resistant biotypes and Figure 3 (Wilson, 2010a).

Figure 3 shows the increase in herbicide resistant biotypes with time. Among the herbicides commonly used in conventional sugar beet, Assure II, Poast, and Select are ACCase inhibitors; Upbeet is an ALS inhibitor; Treflan HFP is a dinitroaniline; Stinger is a synthetic auxin, and glyphosate is a glycine. Figure 3 shows only the number of confirmed resistant biotypes. The total extent and distribution of resistant biotype varies widely.

Certain herbicide families have been classified according to their risk of resistant weed development. Beckie (2006) lists acetolactate synthase (ALS) and acetyl CoA carboxylase (ACCase) inhibiting herbicides as “High” risk for resistance development, while glyphosate is considered a “Low” risk herbicide for the development of herbicide resistant weeds. ALS and ACCase inhibiting herbicides are commonly used in conventional sugar beet production, and weeds resistant to these two herbicide groups are widely distributed across sugar beet growing regions of the U.S. (Kniss, 2010). Because glyphosate is a low risk herbicide, Kniss has suggested that glyphosate tolerant sugar beets can help delay resistance to these high risk herbicides (Kniss, 2010):

> “In fact, glyphosate resistant sugar beet adds to the diversity of herbicide modes of action in many sugar beet crop rotations because it introduces a new mode of action (glyphosate) into the rotation with non-glyphosate-resistant crops, that tend to rely heavily upon acetolactate synthase (“ALS”) inhibitors. ALS inhibiting herbicides pose a far greater risk of developing weed resistance than does glyphosate. By adding glyphosate to their crop rotations, growers of glyphosate resistant sugar beet actually decrease the likelihood of developing resistance to ALS inhibitors, just as the use of other crops and alternative modes of action in rotation with GR sugar beet reduce the likelihood of glyphosate resistant weeds.”

Use of herbicides with different modes of action, either concurrently or sequentially, is an important defense against weed resistance (WSSA, 2010b). According to the WSSA “Use of a single product or mode of action for weed management is not sustainable. Some of the best and most sustainable approaches to prevent resistance include diversified weed management practices, rotation of modes of action and especially the use of multiple product ingredients with differing modes of action" (WSSA, 2010b).

The WSSA reports higher levels of awareness among growers regarding the need to minimize the potential for development of glyphosate resistance: "In a market research study that surveyed 350 growers in 2005 and again in 2009, in response to the question, 'are you doing anything to proactively minimize the potential for resistance to glyphosate to develop,' 67% said yes in 2005 and 87% said yes in 2009" (WSSA, 2010b). "In a 2007 survey of 400 corn, soybean and cotton growers, resistance management programs were often or always used by 70% or more of all three grower groups" (WSSA, 2010b).

There is widespread information available from universities and other sources regarding glyphosate resistance. Public universities (e.g. North Dakota State University, University of Minnesota), herbicide manufacturers (i.e. www.weedresistancemanagement.com, www.resistancefighter.com) and crop commodity groups (i.e. National Corn Growers Association, American Soybean Association) have internet web sites with information on prevention and management of herbicide resistance. An example of information provided by public universities is Dr. Don Morishita, a weed scientist at the University of Idaho, who advises sugar beet growers on weed resistance management strategies (Dumas, 2008). The Sugar Industry Biotech Council provides weed resistance resources on its website. Monsanto includes information on weed resistance management practices in its Technology Use Guide that is mailed annually to all licensed growers. The sugar beet industry associations also hold annual meetings where weed resistance management practices and other stewardship measures are included as part of the proceedings. Sugar beet growers and processors have established funds to support research and extension activities on weed resistance. Cooperatives (e.g., Western Sugar, public comments on Draft EA) sponsor grower meetings at multiple locations in their growing regions to provide every grower the opportunity to discuss industry issues and learn about new research developments. Researchers from Colorado, Nebraska, and Wyoming, in cooperation with Monsanto, are developing region-specific technology usage guides to address weed management in cropping rotations that include sugar beet. Guides will provide regional and weed specific (kochia, common lambsquarters and pigweed) recommendations for … sugar beet, therefore enhancing the benefits of crop and herbicide rotations."

Sugar beet growers in particular have strong financial and practical interests in managing weeds effectively to reduce the development of herbicide resistance in order to maximize yield potential. Sugar beets are a high-value crop, and competition from weeds for moisture and light can negatively impact yields and the overall value of the crop. The development of glyphosate-resistant weeds harms the economic return per acre for the individual farmer and the entire sugar beet industry (Cole, 2010).

As such, strategies and recommendations to delay the development of glyphosate-resistant weeds have been developed for H7-1 sugar beets (Monsanto, 2010). Specifically, the TUG recommends the use of "mechanical weed control/cultivation and/or residual herbicides" with H7-1 sugar beets, where appropriate, and "additional herbicide modes of action/residual herbicides and/or mechanical weed control in other Roundup Ready® crops" rotated with H7-1 (Monsanto, 2010). In addition to the financial incentive to follow these recommendations, all Roundup Ready technology users, including sugar beet growers, are contractually obligated through the Monsanto Technology Stewardship Agreement to follow the TUG.

When a grower encounters a biotype that is resistant to an herbicide he is using, the grower must use an alternate method of weed control. Management practices that can be used to retard the development of resistance, such as those routinely used by sugar beet growers, include herbicide mixtures, herbicide rotation, crop rotation, altered planting dates, and increased cultivation. Vencill et al. (2011) further recommend increasing seed sanitation measures, inhibiting seed movement, scouting fields and supplemental control of weed escapes. These authors further advocate using "labeled herbicide rates during labeled application timings" and "discouraging the use of reduced rates and deviating from the recommended application timings."

Inherently Herbicide-tolerant Weeds. Not all weed species respond the same to every herbicide mode of action. Instead, a weed species can have a natural tolerance to a particular mode of action, and if a grower employs only that mode of action, over time, the naturally tolerant species will overtake other weed species in that area. This is often referred to as a shift in the weed population. This is another important reason that growers should use multiple products and methods to control the full spectrum of weeds in a field.

Since the beginning of widespread use of herbicides, weed shifts have been a recurrent issue. When 2,4-D (predominantly a broadleaf herbicide) began to be broadly used, grassy weeds began to be prevalent, for example, in corn crops, and required additional tillage for control of new weeds (see review in Vencill, et al., 2011). Atrazine as well has caused new weed shifts (Vencill et al., 2011). These herbicides are not rendered either herbicide obsolete, but evolving resistant weeds and shifts of weeds have required addition of other herbicides integrated with tillage.

Table 7 summarizes the major sugar beet weeds in terms of resistance to herbicide groups used in sugar beets for the states where sugar beets are grown commercially. A weed is listed for a state when herbicide resistance has been confirmed. The table does not show the extent of the weeds with the noted resistance; this would vary widely. Refer to Figure 3 for the distribution by herbicide mode of action.

Table 7. Major Sugar Beet Weeds with Resistance to Herbicide Groups used in Sugar Beets[1]

California

Species	Common Name	Year[2]	Herbicide Mode of Action
1. *Echinochloa crus-galli*	Barnyardgrass	2000	ACCase inhibitor
2. *Echinochloa crus-galli*	Barnyardgrass	2000	fatty acid synthesis inhibitor.

Colorado

Species	Common Name	Year	Herbicide Mode of Action
1. *Aramanthus retroflexus*	Redroot pigweed	1982	photosystems II inhibitors
2. *Kochia scoparia*	Kochia	1982	photosystems II inhibitors
3. *Kochia scoparia*	Kochia	1989	ALS inhibitors
4. *Avena fatua*	Wild Oat	1997	ACCase inhibitors

Idaho

Species	Common Name	Year	Herbicide Mode of Action
1. *Kochia scoparia*	Kochia	1989	ALS inhibitors
2. *Avena fatua*	Wild Oat	1992	ACCase inhibitors
3. *Avena fatua*	Wild Oat	1993	fatty acid synthesis inhibitor.
4. *Kochia scoparia*	Kochia	1997	synthetic auxins
5. *Aramantus retroflexus*	Redroot pigweed	2005	photosystems II inhibitors

Michigan

Species	Common Name	Year	Herbicide Mode of Action
1. *Chenopodium album*	Lambsquarters	1975	photosystems II inhibitors.
2. *Amaranthus tuberculatus*	Tall waterhemp	2000	ALS inhibitors

3. *Amaranthus powellis*	Powell Amaranth	2001	photosystem II inhibitors
4. *Amaranthus powellis*	Powell Amaranth	2001	ureas and amides
5. *Amaranthus retroflexus*	Redroot Pigweed	2001	photosystems II inhibitors.
6. *Chenopodium album*	Lambsquarters	2001	ALS inhibitors
7. *Amaranthus hybridus*	Smooth Pigweed	2002	ALS inhibitors
8. *Abutilon theophrasti*	Velvetleaf	2004	photosystems II inhibitors
9. *Solanum ptycanthum*	E Black nightshade	2004	photosystems II inhibitors
10. *Solanum ptycanthum*	E Black nightshade	2004	photosystems II inhibitors
11. *Kochia scoparia*	Kochia	2005	ALS inhibitors
12. *Setaria faberi*	Giant Foxtail	2006	ALS inhibitors

Minnesota

Species	Common Name	Year	Herbicide Mode of Action
1. *Chenopodium album*	Lambsquarters	1982	photosystems II inhibitors
2. Abutilon *theophrasti*	Velvetleaf	1991	PI
3. *Amaranthus retroflexus*	Redroot Pigweed	1991	PI
4. *Avena fatua*	Wild Oat	1991	ACCase inhibitors
5. Amaranthus tuburculatus	Tall Waterhemp	2007	glycine, ALS, PI
6. Ambrosia trifida	Giant ragweed	2006	glycine, ALS inhibitors, PI
7. *Kochia scoparia*	Kochia	1994	ALS inhibitors
8. *Xanthium strumarium*	Common cocklebur	1994	ALS inhibitors
7. *Setaria faberi*	Giant Foxtail	1996	ALS inhibitors
9. *Setaria viridis* (*var. robusta-alba Schreiber)*	Robust White Foxtail	1996	ALS inhibitors
10. *Setaria viridis* (*var. robusta-alba Schreiber)*	Robust White Foxtail	1999	ACCase inhibitors
11. *Setaria lutescens*	Yellow Foxtail	1997	ALS inhibitors
12. *Ambrosia trifida*	Giant ragweed	2006	glycines
13. *Amaranthus tuberculatus*	Tall waterhemp	2007	glycines

Montana

Species	Common Name	Year	Herbicide Mode of Action
1. *Kochia scoparia*	Kochia	1984	photosystems II inhibitors
2. *Kochia scoparia*	Kochia	1989	ALS inhibitors
3. *Avena fatua*	Wild Oat	1990	fatty acid synthesis inhibitor.
4. *Avena fatua*	Wild Oat	1990	ACCase inhibitors
5. *Kochia scoparia*	Kochia	1995	synthetic auxins
6. *Avena fatua*	Wild Oat	1996	ALS inhibitors
7. *Avena fatua*	Wild Oat	2002	ACCase inhibitors

Nebraska

Species	Common Name	Year	Herbicide Mode of Action
1. *Amaranthus tuberculatus*	Tall waterhemp	1996	photosystem II inhibitors

North Dakota

Species	Common Name	Year	Herbicide Mode of Action
1. *Kochia scoparia*	Kochia	1987	ALS inhibitors
2. *Setaria viridis*	Green Foxtail	1989	mitois inhibitors
3. *Avena fatua*	Wild Oat	1991	ACCase inhibitors
4. *Kochia scoparia*	Kochia	1995	synthetic auxins
5. *Avena fatua*	Wild Oat	1996	ALS inhibitors
6. *Kochia scoparia*	Kochia	1998	photosystems II inhibitors
7. *Amaranthus retroflexus*	Redroot Pigweed	1999	ALS inhibitors
8. *Solanum ptycanthum*	E.Blk.Nightshade	1999	ALS inhibitors

Oregon

Species	Common Name	Year	Herbicide Mode of Action
1. *Avena fatua*	Wild Oat	1190	ACCase inhibitors
2. *Avena fatua*	Wild Oat	1990	mitosis inhibitors
3. *Kochia scoparia*	Kochia	1993	ALS inhibitors
4. *Amaranthus retroflexus*	Redroot Pigweed	1994	photosystems II inhibitors.

Washington

Species	Common Name	Year	Herbicide Mode of Action
1. *Kochia scoparia*	Kochia	1989	ALS inhibitors
2. *Avena fatua*	Wild Oat	1991	ACCase inhibitors
3. *Amaranthus powellis*	Powell Amaranth	1992	photosystem II inhibitors
4. *Sonchus asper*	Spiny Sowthistle	2000	ALS inhibitors

Wyoming

Species	Common Name	Year	Herbicide Mode of Action
1. *Kochia scoparia*	Kochia	1984	photosystems II inhibitors
2. *Kochia scoparia*	Kochia	1996	ALS inhibitors

[1] *Heap, I, 2010.*
[2] *Year resistance was first reported*

Herbicide resistance is not a unique or new phenomenon. The development of weeds resistant to a particular herbicide mode of action is an issue that growers have faced for decades. As with other herbicide modes of action, not all weeds respond the same to glyphosate, and some species naturally vary in their tolerance to the herbicide.

Glyphosate Use and Potential Development of Herbicide Resistant Weeds. Glyphosate is a nonselective, foliar-applied, broad spectrum, burndown, pre- and post-emergent herbicide. It operates by binding to a specific enzyme (EPSPS) in plants interfering with an essential metabolic process. Because this enzyme is present in nearly all plants but absent in all animals, and glyphosate binds to this enzyme and does not appear to bind to other targets, it is highly specific (Cole, 2010).

There is no evidence that glyphosate resistance in problematic weeds resulted from the movement of genetic material from the glyphosate resistant crops into the weeds. Glyphosate resistance arose in those weeds arose as a consequence of natural selection resulting from the selective pressures of frequent glyphosate use.

Currently in the US, there are three known mechanisms of developed glyphosate resistance in plants. The first is through an exclusion mechanism in which glyphosate is either prevented from moving to growing cells or from reaching the target protein. The second mechanism, gene amplification, is an increase in enzyme gene copies in the plant leading to higher levels of resistance to glyphosate (Gaines et al., 2010). The third mechanism involves a mutation in the *epsps* gene (Baerson et al., 2002; Wakelin and Preston, 2006; Jasiniuk et al., 2008).

While glyphosate has been used extensively for over three decades, there are relatively few cases of developed resistance compared to many other herbicides especially considering the substantial amount of glyphosate-treated acreage worldwide (approximately 1 billion acres) and the total number of weeds that the herbicide controls (glyphosate is registered to control over 250 weeds). In the US, there are ten weed species with glyphosate-resistant biotypes in certain areas of the country and a total of 19 weeds with evolved glyphosate resistance worldwide (Heap, 2010). Of these 19 weeds, 10 may have evolved resistance from use of glyphosate in glyphosate resistant crops. The other nine glyphosate resistant weed species have developed resistance from the use of glyphosate in applications where glyphosate resistant crops were not used. The evolution of glyphosate resistant weeds is the result of selective pressures of glyphosate use and is not specific to the adoption of glyphosate resistant crops.

In 2009, approximately 135 million of the 173 million acres of corn, soybeans and cotton in the US were planted with an herbicide tolerant variety, with the most common tolerance trait being glyphosate tolerance (USDA NASS, 2009). It has been estimated that about 6% of the total planted corn, soybean and cotton acres in the US have some level of weeds resistant to glyphosate (WSSA, 2010b).

Evolution of glyphosate resistant weeds have occurred most commonly in continuous cropping systems such as in vineyards, orchards, roadways, or where glyphosate resistant corn and soybean are planted without rotation. In one case, a glyphosate resistant weed, common water hemp, evolved in a two-crop rotation where glyphosate resistant corn was rotated with glyphosate resistant soybean (Kniss, 2010). To date, there are no known cases where a glyphosate resistant weed has arisen in a three-crop rotation.

Sugar beet is a crop susceptible to many diseases, nematodes, and insects. By contractual agreement with sugar beet cooperatives, sugar beet growers are prohibited from planting sugar beets in the same field more frequently than once every three years. In some sugar beet growing regions (including Oregon, Washington, Idaho) sugar beet will be the only GR crop grown in the rotation. In other growing regions (Colorado, Montana, Wyoming, Nebraska, Northern North Dakota, and Northern Minnesota) there will always be at least one non-GR crop in the rotation. Southern Minnesota and Michigan may include farms that grow GR crops in all rotations.

Crop rotation is a known effective strategy for managing herbicide resistant weeds because it facilitates the use of different herbicide chemistries and creates different field conditions that favor certain weed species over others. Thus the different cultural conditions of the crop rotation such as planting date, harvest date, tillage practices, irrigation practices, fertilization practices, available herbicide chemistries etc.) reduce the potential for herbicide resistant weed to develop even where only glyphosate resistant crops are grown.

Finally, because herbicide resistance is a heritable trait, it takes multiple growing seasons of herbicide use for herbicide tolerant weeds to emerge and become the predominant biotype in a specific area (Cole, 2010). Researchers have concluded that even if growers completely relied on only one herbicide, it is likely to take at least five years for a herbicide resistant weed population to develop (Kniss, 2010; Beckie, 2006; Neve, 2008; Werth et al., 2008). Crop monitoring and follow up by academic and industry weed scientists in cases of suspected resistance are important parts of all herbicide resistance stewardship programs.

3) Sugar Beet Volunteer Control

Volunteers are plants from a previous crop that are found in subsequent crops. Volunteers are often considered a type of weed, not because the volunteer plants have any other inherent weedy characteristics, but simply because the volunteer plants are growing in an area where they are not wanted and might interfere or compete with other planting activities. For many cropping situations, growers often choose to apply herbicide to fields when rotating from one crop to another to avoid competition from both weeds and volunteer plants. In most crops, volunteers grow from seeds left in the field after harvest. If sugar beet bolters are allowed to go to seed in certain more temperate climates, the seed may sprout and cause volunteers in later years in fields planted to other crops. Additionally, groundkeepers are a type of volunteer derived from vegetative tissue (small roots) left in the field after harvest, which can grow in the next season if not controlled.

In most parts of the US where sugar beets are grown, beet roots would not be expected to survive the winter, so groundkeepers would be of little concern (Panella, 2003). The only areas where sugar beet roots might overwinter is in the Imperial Valley of California where H7-1 sugar beet is not grown. Cattanach, *et al.* (1991) focused on production in the northern plains and upper Midwest (including North Dakota and Minnesota), reported that sugar beets could not survive the winter in these areas. Any sugar beet that survives can be reservoirs for beet diseases and good management practices dictate that they be removed (Kaffka, 1998).

Since sugar beet seed plants are prone to shattering during seed harvest, control of volunteers in seed production fields was and remains an essential component of production practices developed to maximize seed purity. WCBS has detailed requirements in its protocol (Appendix 3) for post-harvest field management. After harvesting, the fields are shallow tilled and irrigated to promote sprouting of shattered seeds .Fall plowing is not allowed by WCBS. Any remaining seed that sprouts are destroyed by herbicides or other means. All equipment is cleaned according to WCBS procedures before it can leave the fields. Fields used for growing H7-1 are inspected by WCBS “for a minimum of five years or until no volunteers are noted (Appendix 1). Betaseed has similar requirements (Lehner, 2010)

Monsanto’s Technology Use Guide (Monsanto, 2010) provides specific weed control recommendations for H7-1 sugar beet. The TUG recommends the use of “mechanical weed control/cultivation and/or residual herbicides” with H7-1 sugar beets, where appropriate, and “additional herbicide modes of action/residual herbicides and/or mechanical weed control in other Roundup Ready® crops” rotated with H7-1 (Monsanto, 2010).

4) Effects on Micronutrient Availability due to Glyphosate Use

There are reports that glyphosate resistant soybean varieties require supplemental manganese to reach their yield potential compared to conventional varieties (Gordon, 2007) and that by extension, other glyphosate resistant crops would suffer micronutrient deficiencies. Zobiole et al. (2010) reported that glyphosate applications decreased Mn and other nutrient concentrations in RR soybean varieties. They also reported significant reductions in shoot and root biomass due to glyphosate applications which according to Hartzler (2010) is not normally observed. Hartzler suggested that the differences seen in the aforementioned study were due to other genetic differences because the effect was not confirmed in subsequent investigations (Hartzler, 2010). Differences in manganese absorption, accumulation, and availability between glyphosate treated and non treated glyphosate resistant soybean has been observed in only a limited number of conditions (Bott et al., 2008) or not at all, (Rosolem et al., 2009; Nelson, 2009). Monsanto conducted studies in 2008 and 2009 that tested any manganese-glyphosate effects on soybean. The research was carried out with three soybean varieties planted over seventeen locations in multiple states. The studies had various treatment regimes (including timing and application rates) of glyphosate and manganese foliar treatments, as well as untreated controls. The findings of those studies showed no significant differences in post-application leaf concentration of manganese for glyphosate applications within a manganese foliar treatment regime for either variety; that yield did not differ significantly among varieties, manganese treatment rates or glyphosate applications, and that the manganese concentration in seed likewise exhibited no significant difference in manganese concentrations for glyphosate applications within a manganese foliar treatment regime (Murdock, 2010). Thus the evidence in support of an effect of glyphosate or the glyphosate resistance gene is weak and conflicting in soybean. To our knowledge there is no sugar beet specific evidence suggesting an effect of glyphosate or the glyphosate resistance gene on manganese deficiency.

5) Disease and Pest Susceptibility Changes due to Glyphosate Treatment

The issue of increased disease susceptibility due to glyphosate treatment has been raised for both conventional and glyphosate resistant plants in a number of different crop plants (Duke and Cerdeira (2007). Research conducted by in greenhouse studies suggested the possibility that

Roundup® Ready sugar beets treated with glyphosate may have more sensitivity to *Rhizoctonia solani*, and *Fusarium oxysporum*, both serious diseases of sugar beets (Larson et al., 2006). This study looked at two glyphosate resistant cultivars and four fungal isolates. Of the eight possible combinations of cultivar and isolate, they observed the glyphosate effect three times. In this experiment, the glyphosate effect was dependent on the variety and the pathogen. Because the effect is variety dependent, the relevance of these results is questionable especially as the two varieties used in the experiment were not based on the H7-1 event that is in commercial use. Furthermore, the results could not be confirmed in field studies (Larson, 2010).

In trials conducted from 1998 to 2002, qualitative and quantitative data addressing disease susceptibility and overall agronomic performance of H7-1 were collected to assess possible effects from introduction of the *CP4 epsps* gene cassette. As summarized below, information collected from these trials indicate that H7-1 does not alter sugar beets susceptibility to diseases and pests. Experience in production fields since 2007 supports this conclusion.

During the 2000 and 2001 growing seasons, quantitative data was collected from variety trials at Betaseed nurseries for comparison of varieties with H7-1 to conventional varieties for relative resistance to four common sugar beet diseases: *Cercospora* leaf spot, *Aphanomyces* root rot, *Rhizoctonia* root rot, and curly top virus. In these trials, results of season-long testing for disease susceptibility from one to three varieties with the H7-1 event were compared with four conventional varieties. The results indicated that the disease susceptibility of the H7-1 varieties was within the range of the conventional varieties (Schneider and Strittmatter, 2003).

Ninety-eight separate Monsanto/KWS field trials were conducted in the US from 1998 to 2002 which included comparative evaluation of susceptibility to the four diseases evaluated in the nursery (Schneider and Strittmatter, 2003) which are the major diseases of economic importance affecting sugar beet production in the US (Schneider and Strittmatter, 2003e). At all but six trial locations there were no differences observed between the H7-1 varieties and the conventional comparators. At one trial site increased susceptibility to powdery mildew was noted while at three other sites decreased susceptibility was noted. At two trial sites increased susceptibility to *Cercospora* leaf spot was also noted. Given the interactions between the environment, the genetic backgrounds of the cultivars used and some inherent genetic variability between sugar beet varieties, these results are not unexpected and do not indicate an increased pest risk.

Additional field trials were conducted with H7-1 in Europe in 1998 and 1999 and monitored for several diseases and nematode worms. No diseases or nematode symptoms were reported in any of the trials for either H7-1 or conventional control sugar beets (Schneider and Strittmatter, 2003).

c. Animals

It is important to reiterate that EPA is responsible for regulation of pesticides (this includes both insecticides and herbicides) under FIFRA.[5] FIFRA requires that all pesticides be registered before distribution, sale, and use, unless exempted by EPA regulation. Prior to the approval of a new pesticide or a new use of that pesticide (including a change in pesticide application rates and/or timing) and before reregistering an existing pesticide, EPA must consider the potential for environmental effects and make a determination that no unreasonable adverse effects to the environment will be caused by the new pesticide, new use or continued use.

To make this determination, EPA requires a comprehensive set of environmental fate and ecotoxicological data on the pesticide's active ingredient (US 40 CFR Part 158). EPA uses these data to assess the pesticide's potential environmental risk (exposure/hazard). The required data include both short- and long-term hazard data on representative organisms that are used to predict hazards to terrestrial animals (birds, nontarget insects, and mammals), aquatic animals (freshwater fish and invertebrates, estuarine and marine organisms), and nontarget plants (terrestrial and aquatic).

Glyphosate is practically nontoxic to slightly toxic to birds, freshwater fish, marine and estuarine species, aquatic invertebrates and mammals and practically nontoxic to honey bees (which are used to assess effects on nontarget insects in general); (EPA 1993). Glyphosate has a low octanol-water coefficient, indicating that it has a tendency to remain in the water phase rather than move from the water phase into fatty substances; therefore, it is not expected to accumulate in fish or other animal tissues.

Mammals - Non-ungulates. Rodents and other non-ungulates can cause mild damage to sugar beet fields in the summer especially when the soil is dry. The Southern Great Plains subregion

[5] 7 USC §136 et seq.

includes growing areas in western Nebraska, southeastern Wyoming and northeastern Colorado, primarily in the valley of the Platte River and its tributaries. All Great Plains sugar beet production requires irrigation (Mikkelson and Petrof, 1999; Thomas and Hein, 2000; McDonald et al., 2003). Farrow irrigation appears to deter rodents (Virchow and Hygnstrom, 1991). Upper Mid-western and the Great Lakes regions that do not use any additional irrigation use commercially available deterrents to combat any rodent or rabbit problem.

Mammals - Ungulates. The main food use of sugar beet is for the extraction of sucrose from sugar beet roots as described in the Affected Environment section of this EA describing sugar beet root processing. The leafy sugar beet "tops" are usually left in the field, but they may occasionally be fed to ruminant animals as silage (Bonnette, 2004). Deer can often be a problem after the planting of stecklings because they prefer the delicate growing leaves of the plant. Commercial deterrents are often used to protect stecklings before they are re-planted in sugar beet fields (personal comm., B. Doley).

Avians**.** Sugar beet fields can be important for raptors such as hawks and owls because they provide good shelter for small rodents around field edges. Over-wintered sugar beet fields are excellent cover and food sources (insects) for nesting pheasants (Kaffka, 1996).

Reptiles**.** Sugar beet fields can be important for snakes as well as raptors because they provide good shelter for small rodents around field edges (Kaffka, 1996).

Amphibians and Fish. Amphibians and fish are not directly impacted by the growth of the sugar beet plant in that they do not use sugar beet for food or shelter. Indirectly, the herbicides currently used on conventional sugar beets can affect amphibians and fish in waterbodies adjacent to or downstream from, the treated field, and might include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers.

The glyphosate end-use products used in agriculture contain a surfactant to facilitate the uptake of glyphosate into the plant (Ashton and Crafts, 1981). Depending on the surfactant used, the toxicity of the end-use product may range from practically nontoxic to moderately toxic to fish and aquatic invertebrates (US EPA, 1993). For this reason, the 1993 Glyphosate RED stated that some formulated end-use products of glyphosate needed to be labeled as “Toxic to fish” if they were labeled for direct application to water bodies. Due to the associated hazard to fish and other aquatic organisms, glyphosate end-use products that are labeled for applications to water bodies generally do not contain surfactant, or contain a surfactant approved for direct application to water bodies.

Insects and Nematodes - Damage-causing. Due to geographic variability in weather, growing conditions, climate, insect and disease susceptibility, sugar beet varieties are developed for localized use. As described in the Affected Environment section sugar beet company selection committees in each region establish a list of approved varieties based on coded variety trials, which are designed to give an unbiased evaluation of the genetic potential of all sugar beet variety entries while other variables (stand, fertility, moisture levels, etc.) are kept constant. The impact of certain soil borne diseases, nematodes (parasitic, microscopic worms) and weeds are minimized through crop rotations (Mikkelson and Petrof, 1999; Hirnyck et al., 2005; USDA ERS, 2009b). Sugar beet seeds can also contain coatings (dressings) of insecticide and fungicide according to the geographic area and customer needs. Processing of seed involves polishing, sorting by size, pelleting, treatment with fungicides and insecticides required by certain customers, coloring, packaging and shipping to growers in sealed packages.

The sugar beet root maggot is the most destructive insect pest of sugar beet in Minnesota, North Dakota, and Idaho and secondarily in Nebraska, Colorado, Montana, and Wyoming. Approximately 49% of U.S. sugar beet acreage is infested at economic levels (USDA ARS, 2010). The organophosphates terbufos, phorate, and chlorpyrifos, and the carbamate aldicarb are the mainstay control and applied at planting (USDA ARS, 2010). Other destructive insects found in the US include: False root knot nematodes (*Nacobbus aberrans*), Beet cyst nematode (*Heterodera schachtii*), symphylids (*Scutigerella Immaculata*), millipedes (*Blaniulus guttulatus* and *Brachidesmus superus*), wireworms (*Agriotes lineatus*) cutworms and other caterpillars (*Agrotis* spp, *Euxoa* spp., *Peridroma saucia*, *Crymodes devastator*, *Amathes cnigrum*, *Feltia ducens*) and lygus bugs (*Lygus elisus, L. hesperus*) (Dewar and Cooke, 2006).

Insects and Nematodes - Non-target Insects. The insecticides and herbicides currently used on sugar beets can not only affect terrestrial insects (target pests and non-target insects), but also affect waterborne insects in waterbodies adjacent to or downstream from the treated field, and might include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers (see the Affected Environment section for a list of herbicides currently used on sugar beets).

d. Microorganisms

Disease Causing Microbes. As with insects and nematodes, the geographic variability in weather and growing conditions, and varietal differences influence disease susceptibility from region to region. For example, sugar beets in California that are over-wintered in the field have problems with Beet Curly Top Virus (BCTV) which is spread by the beet leaf hopper (*Circulifer tenellus*). Insecticide use to combat the beet leaf hopper and crop rotation help with BCTV infection. Likewise, one of the most important root diseases in sugar beet production is Aphanomyces root rot, caused by the soilborne oomycete *Aphanomyces cochlioides* (Harveson, 2007). This fungus occurs infrequently in the far west states but can be a problem in other regions, such as southern Minnesota and the Red River Valley of North Dakota and Minnesota. Over the last decade, this pathogen has become an important part of a root disease complex (including Rhizoctonia root rot and Rhizomania) and has been demonstrated to be widely distributed throughout western Nebraska and other areas of the Central High Plains. Chemical control is only possible as a seed treatment (dressing) with hymexazol (Harveson, 2007).

Non Disease-causing Microbes. There is little information in peer-reviewed journals about the effects of herbicides and insecticides on the resident soil microbes that do not cause disease.

e. Plants

The affected environment for growing sugar beet plants can generally be considered the agroecosystem (managed agricultural fields) plus some area extending beyond the intended plantings that might be affected by agricultural operations. Plants, extraneous to the crop, which grow in planted fields can be considered weeds and are dealt with in a separate section in this document. Plants not growing in a field amongst the sugar beets would be considered in this section. These plants could be in ditches, hedge rows, fence rows, wind breaks, yards, etc. These plants could be annuals, biennials or perennials. Regardless of the agricultural operation, these plants are likely to be impacted, both positively and negatively, by agricultural operations. Fertilizers and/or water may run off into adjacent lands, resulting in increased plant growth outside the agroecosystem. Negative impacts on adjacent land can occur from increased dust deposition on leaves, herbicide drift, etc

2. Socioeconomic Impacts

a. Sugar Production in the US: Contribution of Beets to Sugar Market

Approximately 55% of the U.S. domestic sugar production comes from sugar beets (Colacicco, 2010), with an estimated value of $3.23B. About 75% of US refined sugar is sold in bulk to food manufacturers, with the remainder packaged and sold to consumers. The bulk sugar is primarily used in the baking, confectionary, dairy and beverage industries. Sugar beets were planted on 1.186M A in 2010, nearly the same figure as in 2009 (USDA NASS, 2010b). From 1990 through 2002, sugar beet planting exceeded 1.4M acres, but has been below that figure since then. Some of the reduced acreage can be attributed to higher yields.

Sugar beets contain from 13-22% sucrose. Sugar beet pulp and molasses are processing co-products used as feed supplements for livestock. These products provide required fiber in rations and increase the palatability of feeds. The molasses co-product is used as a feedstock in the alcohol, pharmaceuticals, and bakers' yeast industries (Cattanach et al., 1991).

Refined sugar from sugar beets is the product of a multi-year cycle and involves beet seed suppliers, sugar beet growers, sugar beet processors, sugar users and consumers (Colacicco, 2010). As part of that process, beet seed suppliers plant the commercial sugar beet seed crop in the fall of Year One, which produces the commercial seeds harvested in the fall of Year Two. The commercial seed is processed over the winter and sold to sugar beet growers who plant it in the spring. Sugar beet growers harvest the beet root in the fall of Year Three and deliver them to beet processing facilities owned by the beet processors. Beet sugar is extracted by beet processors beginning in the fall of Year 3 and throughout Year Four. The sugar produced from these beets is purchased by food manufacturers and consumers (Colacicco, 2010).

b. Principal Companies and Cooperatives

Sugar beet production, more than most field crops, requires close coordination between the grower and the processor. The crop is of little value without a processor to extract the sugar, and a sugar processing facility cannot stay in business without a reliable supply of beets (Kaffka and

Hills, 1994). While a type of syrup can be made on a small scale, home garden production of sugar would be impractical; processing cannot be duplicated successfully in a home kitchen (California Beet Growers Association, 1998). Sugar beets are 75% water and expensive to transport long distances (Michigan Sugar Company, 2010a). For economic reasons, sugar beets are typically grown within 60 miles of a processing facility, but may be grown up to 100 miles away (Western Sugar Cooperative, 2006). Locations of the 22 processing facilities in operation in 2010 are shown in Figure 5. While existing facilities have been upgraded, no new currently operating processing facilities have been built in the US since 1975. An estimated cost for an average-sized new facility in 1991 was $100 million (Cattanach et al., 1991). The cost would be substantially higher today due to inflation and other factors.

Sugar beet production and processing in the US is done almost entirely by grower-owned cooperatives. The cooperatives own the processing facilities and the sugar beet farmers are members of the cooperatives. The members own shares of stock that require them to grow a specified acreage of beets in proportion to their stock ownership in the cooperative and guarantee processing for their beets. US companies are summarized by regions below. Cooperatives are owned by growers who are principally family farmers. According to the 2007 US Census of Agriculture, over 4,000 farms grow sugar beets (USDA ERS, 2009b).

Michigan Sugar Company, the third-largest sugar beet processor in the US, processes all the sugar beets in the Great Lakes region, as well as beets from Ontario, Canada. The cooperative has over 1,000 grower-shareholders who grow sugar beets on 150,000 acres each year. The sugar beets are processed into sugar at four factories in Bay City, Sebewaing, Caro and Croswell. The cooperative employs 450 year-round and 1,200 seasonal employees, generates nearly $400 million in direct economic activity annually in the local communities in which it operate, and annually produces nearly one billion pounds of sugar (Michigan Sugar Company, 2010b).

Three cooperatives operate in the Upper Midwest, American Crystal Sugar, Minn-Dak Farmer’s Cooperative and Southern Minnesota Beet Sugar Cooperative. American Crystal Sugar Company, the largest beet sugar producer in the US, is owned by approximately 3,000 shareholders who raise 500,000 acres of sugar beets in the Red River Valley of Minnesota and North Dakota. The company operates five sugar processing facilities in the Red River Valley: three in Minnesota (Crookston, East Grand Forks and Moorhead) and two in North Dakota

(Drayton and Hillsboro). American Crystal also operates a sugar beet processing facility in eastern Montana at Sidney, under the name Sidney Sugars Incorporated. American Crystal's fiscal year 2009 Red River Valley crop averaged 25.4 tons per acre with 17.6% sugar content. In 2009, the company produced approximately 3 billion tons of sugar and 681,000 tons of agri-products (molasses and pulp) (American Crystal Sugar Company, 2009). Minn-Dak Farmers Cooperative, with 450 shareholders, operates a processing facility in Wahpeton, in the far southeast corner of North Dakota. Minn-Dak also operates a yeast factory, which utilizes the molasses co-product from sugar beet processing (Minn-Dak Farmers Cooperative, undated). The Southern Minnesota Beet Sugar Cooperative has approximately 600 shareholders who farm 120,000 acres, and operates a processing facility near Renville, Minnesota (Southern Minnesota Beet Sugar Cooperative, 2010).

The Western Sugar Cooperative, with 135,000 acres and five factories, processes most of the Great Plains sugar beet. Processing facilities are in Fort Morgan, Colorado; Billings, Montana; Scottsbluff, Nebraska; and Lovell and Torrington, Wyoming. Wyoming Sugar Beet Company, LLC is not a cooperative, but works through the Washakie Farmers Cooperative to acquire beets for its plant in Worland, Wyoming (Boland, 2003).

The Amalgamated Sugar Company LLC processes all of the sugar beets produced in ID, OR and WA. Amalgamated is owned by Snake River Sugar Company, a grower-owned cooperative, and is headquartered in Boise, Idaho with processing plants in Paul, Twin Falls, and Nampa, Idaho (Snake River Sugar Company, 2009).

Spreckels Sugar Company, a subsidiary of Southern Minnesota Beet Sugar Cooperative, operates a sugar beet processing facility in Brawley, California, in the Imperial Valley. Yields in the Imperial Valley are higher than anywhere else in the US, averaging approximately 40 tons per acre (Spreckels Sugar, 2009).

The sugar beet seed industry is another essential component of US beet sugar production. All US sugar beet seed is produced, processed and marketed by four private entities. The American Crystal Sugar Company produces seed that is marketed to its grower owners in the Red River Valley, while Betaseed, Syngenta and SESVanderHave develop products to serve all of the US beet seed markets. These latter three companies are all owned by larger seed companies who together encompass the majority of the global beet seed business. As discussed above, these four seed providers deliver genetic products that meet the demands of both sugar beet farmers and beet sugar processors, and they need to forecast product demand at least two years in advance of sales. There is a multi-year cycle starting with planting commercial seed production and ending with processed sugar sold to consumers and food manufacturers. Therefore, disruptions in the seed production phase can potentially impact all phases of this multiyear cycle.

c. Regional Production of Seed and Roots

Seed Production Regions: Vegetable Beet and Sugar Beet

Vegetable Beet Seed Production. The most comprehensive data currently available for vegetable seed production is from the USDA Farm Service Agency (FSA).However, the FSA does not distinguish between organic and conventional production. Also, FSA does not include leaf beet seed production, which is apparently minor. According to data from the USDA FSA, red table beet seed was grown on approximately 1,130 acres in 2009, with 92% grown in Washington State, 7% in Oregon and 1% in California; and Swiss chard seed was grown on approximately 166 acres in 2009, with 51% grown in Washington State and 49% in California. Based on FSA data, there are no counties where both Swiss chard and table beet seed are grown, and only one county, in the Willamette Valley, where both sugar beet seed and table beet seed are grown. In that county the FSA data lists only two table beet seed fields. The total FSA-reported red table beet seed production in Oregon is approximately 79 acres (Stankiewicz Gabel, 2010). There is also some Swiss chard seed production in the Willamette Valley of Oregon (Morton, 2010a,b) with as many as six growers (Hake, public comments on Draft EA). Additional vegetable seed and sugar beet seed production in proximity are also found in the Rogue River Valley Region of Oregon (Oregon Crop Map, http://www.hort.purdue.edu and public comments on Draft EA).

Based on older USDA published data, 95% of US red table beet seed production (650 to 700 acres) occurs within the small-seeded vegetable seed production area of western Washington State that includes Skagit, Island and Snohomish counties (Figure 5) (duToit, 2007). These data do not exactly match the FSA data because they are for different years, and planting practices change from year to year.

Neither sugar beet root crops nor sugar beet seed crops are grown in the part of western Washington where the majority of the US vegetable beet seed production occurs. The sugar beet root crop produced in Washington State is hauled about 300 miles to the nearest processing facility in Nampa, ID. In 2008, only Washington one county, Benton, reported sugar beet production (1,600 acres) (USDA NASS, 2010b). Benton County is in the Columbia Basin on the east side of the Cascade Range. There is no reported production of vegetable beet seed in the Columbia Basin.

The estimated value of the table beet seed produced in western Washington is $5.5M. Based on average production costs of $1500/A (du Toit, 2007), the net return for table beet seed production exceeds $6000/A. The price premium on organic seed, the difference in price between conventional and organic seed, is also difficult to estimate. Comparing the price of organic vs. conventional seed of four varieties of vegetable beets available from Johnny's Selected Seeds gives a range of 17-54% for the premium on organic seed.

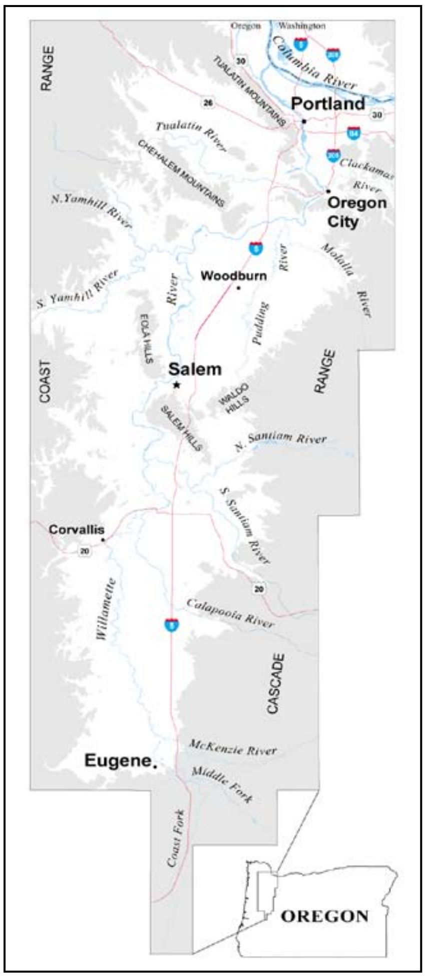

Figure 4. Willamette Valley
Source: Givler and Wells, 2001

Sugar Beet Seed Production. All US production of commercial sugar beet seed takes place in Oregon and Washington. This production was historically concentrated in the Willamette Valley of Oregon, however in the past decade a secondary production area has developed in central Washington and there is also some minor production in OR east of the Cascade Range.

At least 95% of Oregon sugar beet seed production (equal to 70% or more of the total US production), is in the Willamette Valley, located between the Coast Range and the Cascade Range (Figure 4) (Stankiewicz Gabel, 2010). The valley is over 100 miles long. The climate is cool enough for winter vernalization but warm enough for most roots to survive an average winter. Summers are very dry, producing ideal conditions for seed harvesting. Beet seed fields are planted in August or September, vernalized over the winter, and then the plants produce a seed stalk (bolt) in spring. Seeds are harvested in late July to early August.

Commercial sugar beet seed in the US is produced, processed and marketed by four private entities. These are:

1. American Crystal Sugar Company is a grower-owned cooperative based in Moorhead, MN, which markets seed to its shareholders in the Red River Valley.
2. Betaseed, Inc, based in Shakopee, MN, is a wholly owned subsidiary of the German seed company KWS.
3. Syngenta Seeds, Inc., with sugar beet seed operations based in Longmont, CO, is a division of Syngenta.
4. AG. SES Vanderhave Sugarbeet Seed, based in Fargo, ND, is a subsidiary of the French company Florimond Desprez SES.

There are two commercial beet seed production entities in the Willamette Valley: West Coast Beet Seed (WCBS) and Betaseed. West Coast Beet Seed, based in Salem, OR, is a cooperative, producing seed for its member companies which include American Crystal Sugar, Syngenta and SESVanderHave. Betaseed has seed production and processing facilities based in Tangent, OR. While there is some degree of overlap, the seed production operations of these two seed producers are geographically separated with Betaseed located in the southern and southeastern fringes of the Willamette Valley, and WCBS producing seed to the north in the Salem area.

With its unique growing conditions, the Willamette Valley is used for seed production of a wide variety of crops, including vegetable beet seed. In addition to seeds, many vegetables are also grown in the valley. It is a major area for production of “most temperate vegetables, herbs and vegetable seeds” (Mansour, 1999). Because high quality and seed purity are important to many growers, and because the valley is the site of varied seed production, sugar beet seed production companies have worked cooperatively to develop and implement protocols to maintain seed purity and quality. Most seed companies in the Willamette Valley, including both WCBS and Betaseed, belong to the Willamette Valley Specialty Seed Association (WVSSA) and follow the guidelines for isolation and minimum separation distances between fields (Appendix 1). WCBS and Betaseed have both developed explicit standard operating procedures (SOPs) and grower guidelines that are intended to minimize and/or eliminate the possibility of pollen movement between seed fields as well as of inadvertent seed mixing (Appendix 1).

Currently, the WVSSA implements pinning procedures and isolation guidelines for seed production within the Willamette Valley. Pinning procedures identify the geographic location of production fields by placing pins and flags on a map. This is used to establish isolation distances between seed production fields. Additionally, WCBS and Betaseed have instituted protocols and management practices to further maintain the integrity of seed.

Regional Availability of Non GE Sugar Beet Seed. Due to the two year production cycle, the majority of conventional seed varieties and seed available for the 2011 crop year originated prior to 2007. Consequently, some approved varieties, including the genetic traits of those seed, and the inventory of some conventional seed now available were based on production decisions made many years ago (Meier, 2010). Certain seed producers have not engaged in new varietal development for conventional sugar beet since 2006/2007. It is reasonable to assume that some processors may not have conventional seed on their current approved variety list for planting, while others still list some conventional seed varieties. Colacicco (2010) stated that domestically-produced conventional sugar beet seed is in short supply because domestic seed companies have reduced production of conventional beet seed in recent years. Should H7-1 sugar beet seed be unavailable, at least some sugar beet growing regions in the US may experience a shortfall of sugar beet seed for planting.

Only sugar beets grown from approved varieties can be utilized by growers for sugar beet production. The processor seed committee will establish a list of approved varieties from which growers may select. Once a variety has been approved for commercial production by the processor seed committee, the seed producer produces the seed in the quantities projected to be sold to the processor's growers. Seed suppliers must predict years in advance the likely demand for new varieties. If a seed supplier over predicts likely demand, the excess seed may be inventoried for a period that does not exceed the viability of the seed.

The approved varieties have undergone extensive multi-year planting trials to determine how well each variety tolerates exposure to particular diseases and pests known to infest the growing region, particular growing conditions such as exposure to particular weather conditions, and the variety's ability to deliver acceptable yields per ton and sugar content.

The approved variety list denotes sugar beet varieties that may be delivered to the processor for sugar production. As a cooperative member, a grower has a contract to deliver sugar beet from a specified number of acres. Sugar beet varieties that do not make the approved variety lists cannot be delivered to the processor for sugar production because they do not meet the standards set forth by the processor. A grower is not permitted by the processor to plant a sugar beet variety not on the approved list.

When H7-1 sugar beet was deregulated in 2005, the industry began production of H7-1 sugar beet seed. The majority of conventional seed varieties and seed available for the 2011 crop year originated prior to 2007. Consequently, some approved varieties, including the genetic traits of those seed, and the inventory of some conventional seed now available were based on production decisions made many years ago. Certain seed producers have not engaged in new varietal development for conventional sugar beet since 2006/2007. Some processors have no conventional seed on their current approved variety list, while others still list some conventional seed varieties. At least some sugar beet growing regions in the US would experience a shortfall of sugar beet seed to plant. Colacicco (2010) also stated that domestically-produced conventional sugar beet seed is in short supply because domestic seed companies have reduced their production of conventional beet seed in recent years.

Sugar beet seed produced outside the US may not be suitable for commercial production in the US, and this lack of suitability varies by region. For example, some European varieties may perform well in the Red River Valley, the market with the least severe disease pressure. However it would be difficult to source varieties with enough *Cercospora* resistance for production in Michigan, and no European varieties could provide the curly top resistance required for production in Idaho. Furthermore, due to concerns about importing the weed beet problem from Europe, some sugar processors (e.g. American Crystal Sugar) have policies which prohibit the use of seed not produced in North America. Regional availability of conventional sugar beet seed for planting the 2011 sugar beet root crop is discussed in further detail in the Environmental Consequences section below.

Sugar Beet Isolation Distances. While sugar beet seed is generally not certified, the Oregon Seed Certification Service (OSCS) standards for certified seed and the corresponding isolation distances are reported here, as additional data points on what to expect in seed purity from a given isolation distance. The OSCS has set the following standards for those items for certified sugar beet seed (OSCS, 1993):

- Pure seed, minimum: 99.00%
- Other crops, maximum: 0.10%
- Inert matter, maximum: 1.00%
- Weed seed, maximum: 0.10%

Minimum isolation distances required for certified seed are as follows:

- From sugar beet pollen of similar ploidy or between fields where male sterility is not used – 2,600 ft (0.49 mile)
- From other pollinator or genus *Beta* that is not a sugar beet – 8,000 ft (1.5 mile)

The maximum specified OSCS required isolation distance, for “stock” seed which has a maximum allowable concentration of “other crop” seed of 0.00%, is 10,200 ft (1.9 miles) from other, non-sugar beet *Beta* species (OSCS, 1993).

All growers of commercial specialty seed in the Willamette Valley are members of the WVSSA (Loberg, 2010). This includes all commercial companies producing seed of sugar beets or vegetable beets. The isolation distances required by WVSSA between H7-1 sugar beets and vegetable beets is 1.1 miles further than the maximum required OCCS isolation distance for stock seed discussed above.

The Non-GMO Project Working Standard, sponsored by leading players in the organic industry (including Whole Foods Markets), specifically permits crops to be verified “non-GMO” despite the presence of a low level of GMO content—0.25% for GE sugar beet seed in other *Beta* seed crops (Non-GMO Project, 2010) and 0.9% in organic food and feed.

As discussed above, all sugar beet seed planted by US sugar beet growers is produced in Oregon and Washington (Anfinrud, personal communication; Loberg, personal communication; Miller, personal communication). There is no production of commercial sugar beet seed in other states. However, small quantities of breeder's seed is produced in AZ, CO, ID, MN, OR and WA.

Root and Vegetable Production Regions: Vegetable Beet and Sugar Beet

Vegetable Beet Crop Production. There is very little overlap between major areas of vegetable beet production and sugar beet root crop production. Over half of the 2007 acreage of vegetable beets (59%) was in two states, New York and Wisconsin, where sugar beets are not grown. California harvested 979 acres of vegetable beets in 2007. All California counties with five or more harvested acres reported are in the coastal region. Sugar beets are grown only in Imperial County in California. Oregon harvested 425 acres of vegetable beets, but no vegetable beet production was reported in the two Oregon counties with sugar beet root crops; however, some vegetable beet crops are grown in the Willamette Valley. One county in Colorado (Larimer), and one county in Michigan (Lapeer), reported both sugar beet and vegetable beet harvests. No more than seven acres of vegetable beets were harvested in any single Minnesota county. Harvested vegetable beet acreage for all other sugar beet producing states in 2007 was ten acres or less each (Montana, Idaho, Nebraska, North Dakota, and Wyoming) (USDA NASS, 2010b). Although there is little overlap in major production areas, based on USDA FSA (Farm Service Agency) data, vegetable beet crops and sugar beet crops can sometimes be found growing in adjacent fields (Stankiewicz Gabel, 2010).

California is the only state for which organic vegetable beet production data are publicly available. In USDA's reports, red table beets and Swiss chard are included in the "other vegetable" organic category. California accounts for 76% of "other" organic vegetable production within the sugar-beet producing states, and there is very little or no organic production of red table beets, Swiss chard, or leaf beets in the four major sugar beet production states (MN, ND, MI and ID) (USDA, 2010c).

Sugar Beet Root Crop Production. US sugar beet acreage has changed little over the past 50 years (since 1961), ranging from a low of 1.1M A in 1982 (slightly less than the 2008 acreage) to a high of 1.6M A in 1975. Table 8 shows planted sugar beet acreage for the past six years. While there have been changes within individual states, the overall range is small.

Table 8. Sugar Beet Acres Planted 2005 to 2010

Location	2005	2006	2007	2008	2009	2010
California	44,400	43,300	40,000	26,000	25,300	25,000
Colorado	36,400	42,100	32,000	33,800	35,100	29,800
Idaho	169,000	188,000	169,000	131,000	164,000	169,000
Michigan	154,000	155,000	150,000	137,000	138,000	147,000
Minnesota	491,000	504,000	486,000	440,000	464,000	445,000
Montana	53,900	53,600	47,500	31,700	38,400	42,400
Nebraska	48,400	61,300	47,500	45,200	53,000	46,000
North Dakota	255,000	261,000	252,000	208,000	225,000	227,000
Oregon	9,800	13,100	12,000	6,700	10,600	11,000
Washington	1,700	2,000	2,000	1,600	---	---
Wyoming	36,200	42,800	30,800	29,700	32,400	32,000
US Total	1,299,800	1,366,200	1,268,800	1,090,700	1,185,800	1,174,200

Source: USDA NASS, 2010b

As discussed above, sugar beet production is highly structured, vertically integrated, and centered on production facilities that are grower owned. To maintain a healthy industry, production cannot fluctuate significantly from year to year; a certain level of production is needed to support the major investment of a processing facility, and a processing facility has limited capacity. Barring some unusual disruption in the industry, large fluctuations from year to year would not be expected. Figure 5 shows the five major US sugar beet producing regions, along with 2008 production by county. Total sugar beet production by state for the five production regions is summarized in Table 9.

Table 9. US Sugar Beet Production, 2009-10

Region/State	1,000 short tons	Percent of US Total
Great Lakes		
Michigan	3,318	
Total	3,318	11
Upper Midwest		
Minnesota	10,641	
North Dakota	4,796	
Total	15,437	52
Great Plains		
Colorado	963	
Montana	1,001	
Nebraska	1,294	
Wyoming	678	
Total	3,936	13
Northwest		
Idaho	5,591	
Oregon	395	
Total	5,986	20
Southwest		
California	886	
Total	886	3

Source: USDA ERS, 2010

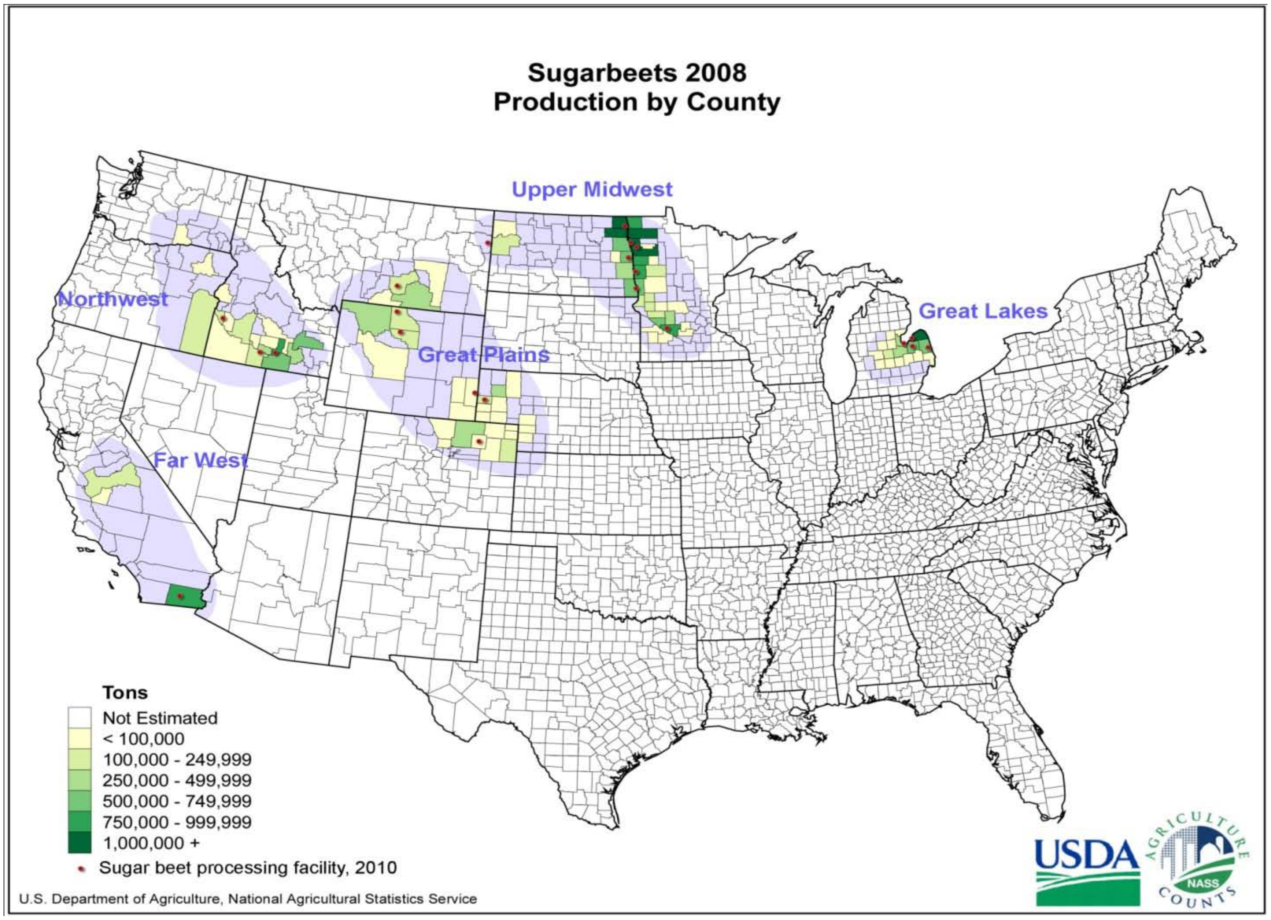

Figure 5. Sugar Beet Production Areas in 2008 and Processing Facilities, 2010.

Great Lakes sugar beet production, now entirely in Michigan, occurs in the flat area around Saginaw Bay. The Great Lakes region also includes Ohio, where sugar beets were last produced in 2004. Michigan sugar beets are generally not irrigated and the varieties must have a high level of resistance to *Cercospora* leaf spot. Sugar beets are also grown in Ontario and then trucked to MI for processing.

The Upper Midwest is the largest sugar beet production region in the US, with the majority of this production in the Red River Valley. The Red River, flowing north into Canada and forming most of the ND-MN border, is all that remains of glacial Lake Agassiz which dried up 10,000 years ago, leaving a broad, flat valley with highly fertile soils. The Minnesota River Valley, another broad, flat glacial valley that crosses southern Minnesota to the south of the Red River Valley, is also a large production area. Irrigation is uncommon in the Red River/Minnesota River Valleys (Ali, 2004). A moderate level of resistance to *Cercospora* leaf spot is required to achieve variety approval in the Red River Valley, while Southern Minnesota requires a high level of resistance. Rhizomania can also be a problem in the Upper Midwest, but rarely as severe as in the irrigated regions to the west.

The northern Great Plains production sub-region includes areas in northern Wyoming and southern Montana. The major sugar beet growing areas in the Northern Great Plains are the sandy loam soils along the Yellowstone River and its tributaries (Mikkelson and Petrof, 1999). There is another, much smaller Northern Great Plains production area along the Montana border of North Dakota, in the valley of the Yellowstone River and its tributaries. The Southern Great Plains production sub-region includes growing areas in western Nebraska, southeastern Wyoming and northeastern Colorado, primarily in the valley of the Platte River and its tributaries. All Great Plains sugar beet production requires irrigation (Thomas et al., 2000; Mikkelson and Petrof, 1999; McDonald et al., 2003). The Great Plains region previously included New Mexico and Texas, where sugar beets were last harvested in 1997. Variety approval in the Great Plains region requires a moderate level of resistance to beet curly top virus. Resistance to rhizomania is also essential.

Most production in the Northwest region is in the sandy loam soil of the Snake River Valley in Idaho. This area also requires irrigation (Traveller and Gallian, 2000). In addition, production occurs in south central Washington, east of the Cascade Mountains. Variety approval in the northwest region requires a high level of resistance to beet curly top virus. Resistance to rhizomania is also essential.

The only remaining sugar production in the Southwest region is in the Imperial Valley of California at the far southern end of the state, where the only sugar processing plant in California is located. Production occurred in the Central Valley (near the middle of the state) through 2008; however, the last processing plant in this area closed that same year. As recently as the 1990s, nearly 30% of sugar beet production was in the Central Valley; there were also small areas of production in coastal counties in the past (California Beet Growers Association, 1998).

US production for the 2009/2010 season (harvested in 2009 and processed in 2009/2010) is shown in Table 9. In 2010, sugar beet was planted on 1.2 million acres (USDA ERS, 2010).

Of the sugar beet root crop planted in the spring of 2009, 95% was reported to be H7-1 sugar beet seed. This is also the same for the sugar beet root crop planted in the spring of 2010, and harvested in the fall of 2010. This represents 98% of the sugar beet root crop outside of California, where, as discussed in Affected Environment (Regional Production of Seed and Roots), H7-1 has not been grown (Colacicco, 2010). The harvesting of the 2010 root crop will began between late August and early September. By late August, most of the crop would be contracted for sale (Colacicco, 2010).

The domestic sugar market is closely managed by USDA's sugar program and therefore, not governed solely by supply and demand. USDA controls domestically produced sugar through the Flexible Sugar Marketing Allotment Program, and controls foreign imports through the raw and refined sugar tariff-rate quotas (TRQs). Unlimited amounts of refined sugar can be imported under a high duty of 16.3 cents per pound and raw sugar of 15.36 cents per pound. Under section 156 of the Federal Agriculture Improvement and Reform Act of 1996, as amended by the Food Conservation, and Energy Act of 2008 (the Farm Bill), and the Harmonized Tariff Schedule of the United States (HTS), USDA is required to establish a range of acceptable market conditions, which means maintaining a price floor in potentially oversupplied situations by removing surplus supply, and maintaining "adequate supply" in potentially undersupplied market situations (Colacicco, 2010). The minimum raw and refined sugar prices that the sugar program must support are the levels that would cause sugar beet and sugarcane processors to forfeit their sugar that was put up as collateral under the USDA sugar nonrecourse loan program. Sugar nonrecourse loans support raw cane sugar prices at 21 cents per pound and refined beet sugar prices at 24 cents per pound. The nonrecourse loans support price because forfeiting the sugar collateral completely extinguishes the borrower's debt, thus sugar beet and sugarcane processors are assured of getting at least the USDA loan proceeds for their sugar. Loan collateral forfeiture also removes surplus sugar out of the market because the government is limited by the Farm Bill in its sugar disposal options (Colacicco, 2010).

At the other end of the range, the objective of maintaining "adequate supply" (as described in the Farm Bill) or "adequate supply at reasonable prices" (described in HTS) requires USDA to increase supply under tight markets, which will make domestic prices lower than they would otherwise be. However, there is no maximum sugar price strategy stipulated in federal law, as there is a minimum sugar price. Under the Flexible Sugar Marketing Allotments Program, the sugar beet processors are guaranteed a market share of 46% of the domestic market. If the sector cannot fulfill its quota, USDA is required to increase imports to maintain adequate supply (Colacicco, 2010).

d. Choice of Varieties Available to Sugar Beet Growers

As discussed above, the seed varieties that sugar beet growers may choose is limited to varieties on the company's approved variety list. Each company has a seed committee that develops the policies and procedures for the conduct of the official trials as well as the rules for determining which varieties achieve approval. These seed committees are typically composed of a mix of growers, company employees and board members. Since nearly all of the beet sugar processing capacity is now grower-owned, the board members on the seed committees are also growers. While the variety approval systems were developed before much of the industry shifted to cooperative ownership, this change in ownership has not significantly altered the variety approval policies. In other words, the grower-owners clearly recognized the value delivered by the variety approval systems in terms of both grower and company profitability. While the number of approved varieties varies from year to year, the average sugar beet grower has the ability to choose among 10-20 different approved varieties.

When H7-1 varieties were in an advanced state of development, official variety trials were conducted in two parallel sets of trials, one with conventional varieties and one with H7-1 varieties. This was necessary because of the difference in weed management protocols for each variety. Effectively, the official variety trials were evaluating weed management systems in addition to variety performance *per se*. Once H7-1 varieties were commercially available, the proportion of H7-1 varieties in the official variety trials steadily increased. With the exception of California, all new entries in the 2009 official variety trials were H7-1 varieties. Since there were no new conventional varieties to test, there was no longer any need to conduct the parallel official trials.

The H7-1 sugar beet trait was adopted faster than any other biotech trait had ever been adopted (ISAAA, 2010). US sugar beet farmers rapidly adopted this trait because of the clear advantages: easier, cheaper weed control and higher yields (Kniss et al., 2004). As seed of the new H7-1 varieties became available, demand for seed of conventional varieties declined steeply.

Despite the clear production advantages derived from growing H7-1 varieties, there are a few reasons why some sugar beet farmers might prefer to plant seed of conventional (non-GE) varieties. These include: (1) the need for specialized disease resistance not yet available in H7-1 varieties; (2) the cost of the technology fee included in the price of H7-1 seed; and (3) a preference for non-GE varieties and/or a desire not to use GE varieties.

Varieties with specialized disease resistance (i.e., specialty varieties) are available in all sugar beet production regions, and due to the length of the breeding cycle, many of these specialty varieties are still offered only as conventional (non GE) seed. In terms of sugar yield, the performance of specialty varieties is typically well below that required for full variety approval, however in situations with high disease pressure, these varieties often are the best economic choice for the grower.

Prior to the launch of H7-1 varieties, the technology fee that sugar beet growers could afford to pay was estimated to be about $50/A (Burgener et al., 2000). In a more recent economic analysis, Dillen et al. (2009) estimated the technology fee at 88 Euros/ha, quite similar to the $50/A estimate. The current technology fee on H7-1 sugar beet seed exceeds $100/unit of seed. A unit contains 100,000 seeds and can plant anywhere from 1-4 A depending on seed spacing and row width. Therefore, the current technology fee can also exceed $100/A. When buying seed for a large farm, some growers might balk at this large technology fee, and instead may choose to plant conventional varieties.

In early 2009, the American Crystal Sugar Company (ACSC) Seed Committee exempted approved conventional varieties from continued variety testing (Niehaus, personal communication). Since the seed industry was no longer entering these older varieties in the official trials, this policy change was enacted to allow these varieties to continue to be sold without testing fees assessed to the seed companies. Based on this decision, there were 31 conventional varieties available to ACSC growers in 2010, but only 7 of these were tested in the 2009 official variety trials. While seed of all 31 varieties may not have been available, ACSC growers have had the choice of a wide range of both conventional and H7-1 varieties. Judging from estimates of the amount of conventional seed available in other growing regions for the 2011 growing season, such a large choice of conventional seed may be exceptional.

e. Coexistence of GE and Conventional Crops

Coexistence of different varieties of sexually compatible crops has long been a part of agriculture, especially in seed production, where large investments are made in developing new varieties and high seed purity levels are required by the Federal Seed Act implementing regulations (7 CFR 201).   The aspect of coexistence most relevant to this document is that related to specific methods of crop production. In this context, coexistence refers to the "concurrent cultivation of conventional, organic, and genetically engineered (GE) crops consistent with underlying consumer preferences and choices" (USDA, 2008). The differences among these crops that are particularly relevant to coexistence in this EA are in the types of breeding methods (sometimes referred to as "genetic modifications") that are associated with each of the three types of crops.

"Genetic engineering" is defined by APHIS regulations as "the genetic modification of organisms by recombinant DNA techniques" (7 CFR 340.1). While there are many ways to genetically modify a crop, the APHIS definition of GE crops applies only to those developed using rDNA techniques, which are among the more modern breeding methods.

Organic crops are those produced in accordance with the requirements of USDA's National Organic Program (NOP), which establishes uniform standards and a certification process for those producing and handling food products offered for sale as "organically produced." The NOP defines certain "excluded methods" of breeding that cannot be used in organic production, describing them as "means that are not possible under natural conditions or processes" (7 CFR Subtitle B Chapter 1 Part 205). Along with genetic engineering, three other modern breeding techniques are specified as "excluded methods" in the regulations. Thus, a certified organic grower cannot intentionally plant seeds that were developed by these specific excluded methods. However, because "organic" is based on process and not product, the mere presence of plant materials produced through excluded methods in a crop will not jeopardize the integrity of products labeled as organic, as long as the grower follows the required organic production protocol. APHIS is not aware of any grower or seed producer that has lost organic certification due to inadvertent transmission of genetic material from a genetically engineered crop.

"Conventional crops" are simply those that are neither GE nor organic. They may be commodity crops (mass produced), or they may be identity preserved, with some characteristic tailored for a specific end user. Identity-preserved usually refers to a "specialty, high-value, premium or niche market" (Massey, 2002). One type of identity preserved product that has been produced since the introduction of GE crops is "non-GE;" however, there are no mandatory standards governing the use and/or marketing of "non-GE" products (USDA, 2008).

Farmers who want to maximize their profitability must decide whether the higher prices (premiums) they may receive for organic or identity-preserved crops are sufficient to offset the added managerial costs of producing these crops. As researchers have noted, "Although yields on organic farms are sometimes less than those of conventional systems, price premiums make it an attractive option for growers looking for specialized markets and a higher-value product" (Ronald and Fouche, 2006).

It is USDA's position that all three methods of agricultural production described above can provide benefits to the environment, consumers, and the agricultural economy (Smith, 2010a). Since the time GE crops were introduced in the US in the mid-1990s, organic markets have grown and expanded (Smith, 2010a).

The USDA Advisory Committee on Biotechnology and 21st Century Agriculture who reported that "coexistence among the three categories of crops is a distinguishing characteristic of US agriculture, and makes it different from some other parts of the world," expressed its belief that US agriculture supports coexistence, and recommended continued government support of coexistence (USDA, 2008). Among the Committee's findings:

- The US is the largest producer of GE crops in the world.
- The US is one of the largest producers of organic crops in the world.
- The US is one of the largest exporters of conventionally-grown, identity preserved, non-GE crops in the world.
- Some US farmers currently are producing a combination of organic, conventional, and GE crops on the same farm.

Among the coexistence-enabling factors the Committee identified are the existing "legal and regulatory framework that has enabled different markets to develop" without foreclosing the ability of "participants in the food and feed supply chain to establish standards and procedures (e.g., not setting specific mandatory adventitious presence (AP) thresholds and having process-based rather than product-based organic standards)." At the same time, development of practices and testing methods that allow for voluntary thresholds has also enabled coexistence (USDA, 2008).

As APHIS has previously observed, "studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) demonstrated that GE and non-GE crops are coexisting with minimal adverse economic effects" (Gealy et al., 2007; Brookes and Barfoot, 2003; Brookes and Barfoot, 2004(a) and (b), and Walz, 2004). In addition, "the agricultural markets and local entities have addressed coexistence through contractual arrangements, management measures, and marketing arrangements. This market-based approach to coexistence has created economic opportunities for all kinds of producers of agricultural products."

f. Cost of Maintaining and Producing GE-Free Organic Vegetable Beet Seed

All seed companies conduct quality analyses on their seed products before they are sold. The Federal Seed Act requires that all agricultural seeds in commerce have labels that state specific information, such as the percent pure seed, percent germination and percent weed seed. Regardless of the crop, routine quality assurance is integral to the marketing of high quality seed products. Along with the introduction of GE crops in the past 15 years, there has been a parallel development of technology to evaluate seed lots for GE presence. For crop species in which GE traits have been commercialized, most seed companies have incorporated routine GE testing as a standard component of quality control.

The available tests for GE detection include DNA tests, protein tests and bioassays. The DNA tests require laboratory expertise and are typically conducted by seed testing firms, while the protein tests and bioassays are typically conducted by the seed producer. The DNA tests are the most accurate with costs dependent on the level of detection desired by the customer. For example, SGS MWSS (Brookings, SD) offers trait testing of a 10,000 seed lot for $250, with a limit of detection of 0.05% (Brix-Davis, personal communication). The protein tests are typically lateral flow strips, commonly referred to as dipsticks, and can be conducted by non-scientists at a cost of about $10 per test. These strips provide qualitative results, however strip readers which generate semi-quantitative results are also available. The bioassay approach is not possible with all traits, but is easy to do with herbicide tolerance traits. For example, if an organic vegetable seed producer wanted to screen a seed sample for the H7-1 trait, a simple spray test could be conducted in a greenhouse by spraying seedlings with glyphosate. Screening of commercial seed lots requires an appropriate sampling strategy and most companies use the publicly available program Seedcalc to develop their sampling strategy. Seedcalc is available free online through the International Seed Testing Association (ISTA); the ISSTA website also contains other statistical tools for seed testing.

g. Applicant Costs

Permits. If permits are chosen for the federal action supporting sugar beet seed production, the applicants will need to make application to the USDA APHIS for permits. Under the Federal Paperwork Reduction Act, agencies report on the amount of time the public spends completing agency paperwork. APHIS last provided this information to the public in 2009 (OMB 0579-0085, 74 FR 46081). Based on this information it takes applicants an average of less than one hour to complete a BRS application. Applications for permits take more time and are estimated at about 5 hours. Time to complete and file reports is estimated at about 0.75 hours.

Record Keeping. Record keeping requirements would include keeping records of planting, harvesting, disease and pest incidence.

Audit and Inspections. The inspections would require presentation of records of the site visited, and SOPs used for production of the regulated sugar beets.

Partial Deregulation under Specified Conditions. APHIS would require that much the same details of compliance with permit conditions would also be required for conditional deregulation. The most important difference would be that these would have a different mechanism of inspection and compliance, which would be third party audits.

h. Availability of Alternative Herbicides

Herbicides are labeled for use on particular crops. EPA labels these herbicides with instructions for how to apply the herbicides on any particular crop. Tables 4 and 11 lists herbicides that have been used on beets.

The availability of herbicides is another factor that will likely affect a growers' decision to plant conventional sugar beet varieties. The advent of H7-1 sugar beets caused a decline in the use of certain herbicides that were used with conventional sugar beet crops. The manufacturers of these herbicides have reduced or ceased production. Should growers plant conventional seed, the herbicides may not be available unless the manufacturers ramp up production to meet anticipated demands. These decisions must be made far in advance of when the herbicides would be needed by growers of conventional sugar beets.

i. Consumer Preference for Non GE Sugar and other Non GE Foods

(i) ***Organic and Non GE Sugar***. Sugar (sucrose) can be derived from sources other than sugar beets. The most common is cane sugar, and for customers that desire sugar from only conventional, non GE sources, cane sugar is readily available since it supplies half of US domestic sugar production. Such cane sugar is marketed as "cane sugar" and can be easily distinguished from the sugar from other sources. Only one domestic cane sugar product is marketed as organic sugar, but many international sources of organic sugar are readily available to consumers. Sugar from conventional sugar beets grown in California is only marketed in 50 pound containers to the food industry (Spreckels Sugar website: http://www.spreckelssugar.com/). Corn is also used as a sugar source and when adjusted with fructose, is similar in ratios of sugars to that in beet or cane sugar and has similar taste. In addition there are other sweeteners (including honey) both natural and artificial, either nutritive or non-nutritive, that are used by consumers. With a variety of such sweeteners, there are numerous options for those desiring choices in sugar sources. APHIS is aware that seed for organic sugar beets is produced in the US (Seeds of Change, public comments received on Draft EA), but knows of no commercial of the beets that derive from such production.

(ii) ***The Organic Segment of the Food Industry*.** The organic sector is rapidly growing both in the European Union (EU) and the United States (Dimitri and Oberholtzer, 2005). Together, consumer purchases in these two regions made up 95% of the $25 billion in estimated world retail sales of organic food products in 2003 (Willer and Geier, 2005). In reporting the results of their annual manufacturer survey, the Organic Trade Association (2007) reports that US organic food sales were estimated to be $16.67 billion in 2006, up 22% from 2005 (see Table 9a).The Organic Trade Association (2007) notes that organic foods have shown consistent annual growth rates of 15 to 21 percent since 1997, when fairly comprehensive data were first available. Moreover, they report growth rate data based on historical surveys and interviews with long-time participants in the organic foods business to be similar at a nearly 20% annual increase since 1990. Organic food sales are projected to continue growing at the same pace through 2010 (Table 9a).

Table 9a. U.S. Organic Food Sales and Sales Growth Forecasts.

	Sales (Millions of $)			Annual Sales Growth Rates (%)		
Category of Food	2004	2005	2006	2004-2005	2005-2006	Forecasted Annual 2007-2010
Organic Dairy	1,731	2,140	2,668	24	25	20
Organic Meat	195	256	334	31	30	27
All Organic	12,460	13,831	16,673	11	22	18

Source: For 2005-2006, Organic Trade Association Manufacturers Survey (2007); For 2004, Organic Trade Association Manufacturers Survey (2006). Data rounded to the nearest integer value.

Organic production may be somewhat lagging behind the growth in demand; the Organic Trade Association (2006) indicated that 52% of respondent firms reported that a lack of dependable supply of organic raw materials has restricted their company from generating more sales of organic products. Willer et al. (2008) report that agricultural land under organic production systems represented 0.5% of all agricultural land in the United States in 2006, somewhat below the worldwide average.

There is evidence that consumer perceptions of organic food safety may be an important driver for consumer substitution of organic for conventionally produced food. In particular, Dimitri and Oberholtzer (2005) argue that changes in organic and conventional food demand are driven in part by "food scares." They note, for example, that mad cow disease (bovine spongiform encephalopathy (BSE)) considerably influenced the European organic livestock and dairy industry. Dimitri and Oberholtzer (2005) report that in response to news reports on BSE, many consumers substituted organic dairy and meat products (which consumers perceived as safer) for conventionally raised dairy and meat products. Dimitri and Oberholtzer (2005) report that other food scares that caused European consumers to substitute organic for conventionally produced food include episodes of contaminated chicken feed in Belgium in 1999, feed contaminated by dioxin in 2004, and more recently, carcinogenic food dyes in TV dinners in Ireland in 2005. Dimitri and Oberholtzer (2005) do not find evidence that U.S. consumers are as strongly affected by food scares.

Consumer Sensitivity to GE Content in Food. Demand for GE foods or for foods free of GE content is very difficult to estimate. In the case of European countries this is because most European major food retailers do not carry GE foods in response to consumer demand (Noussair et al. 2004). In the case of the United States, the absence of mandatory GE food identity-labeling makes demand estimation difficult. Most U.S. consumers are unaware of the prevalence of GE material in the U.S. food supply (Anderson et al., 2006; Hallman and Hebden, 2005; Thomson and Dininni, 2005). Hallman and Aquino (2003) found that only one-fourth of U.S. residents believed that they had ever consumed food containing GE ingredients. There seems to be no estimate available of consumer demand for GE-free food products (Noussair et al., 2004).

In the last decade, there have been a considerable number of attempts to identify consumer preferences regarding GE foods, in and outside the United States, most of them based on consumer surveys done under various conditions asking consumers to express their preferences under hypothetical situations. The results overwhelmingly show lack of information regarding GE foods and some resistance toward their consumption (Hallman and Aquino, 2003).

A number of studies have implemented experiments in which consumers actually get to choose among products and benefit from their choices. Lusk et al. (2004) developed a meta-analysis of 25 studies including 57 valuations of GE foods. Most of the studies analyzed are from the United States, a third are from Europe, and the remainder are from Asia, Canada and Australia. Seventeen of the studies are based on consumer surveys while eight are based on experiments. These studies report that the willingness to pay for GE-free foods was positive, implying that consumers were willing to pay more for these foods.

A number of other studies have investigated whether the resistance to GE foods and the lack of information regarding biotechnology are correlated. Chern and Rickertsen (2002) conducted a student survey in four countries (United States, Japan, Norway and Taiwan) and a national phone survey in the United States and Norway. Willingness to consume GE foods increased when it was explained that GE foods could include benefits such as the reduced use of pesticides. Bertolini at al. (2003) compared attitudes toward GE foods in the United States, Japan, and Italy in random surveys of food shoppers. They also found a positive impact of familiarity with GE technology on acceptance. On the other hand, Hallman and Aquino (2003) conducted a survey of a random sample of U.S. households and found out that improved information on GE food did not necessarily mean increased approval. Those most knowledgeable of genetic engineering tended to have more extreme opinions, in favor or against, than those less knowledgeable. Noussair et al. (2004) also found that prior beliefs regarding GE food had a stronger influence on consumer choice than information.

Studies also exist investigating how consumers value varying levels of GE content in their foods. In an experiment in France, where consumer surveys reveal very strong resistance to GE products, Noussair et al. (2004) found that 89% of consumers were willing to purchase a product with up to 1% GE content and 96% with up to 0.1% GE content. They also found that consumers differentiated between GE-free and 0.1% of GE-content. On the other hand, a nationwide study in the United Kingdom found that consumers did not distinguish between 0 and

0.5% GE levels in food and did not place a value in having products with 0% GE content as opposed to 0.5% (Rigby et al., 2004).

Over 40 countries have adopted some type of labeling regulations specifically for identifying GE food products (Guère et al., 2007).[6] In Europe, the main impact of GE identity labeling requirements has been the virtual disappearance of many GE food products, given that the cost differentials in production are small (since often GE ingredients are a minor share of total ingredients in products) and the risk of loss of market share is high given the perceived consumer resistance (Guère et al., 2007). In addition, to the extent that GE identity labeling requirements require segregation of GE and non-GE food products throughout the production process, this type of labeling may imply considerable costs (Noussair et al., 2004; Friesen et. al., 2003).

(a) United States

There is relatively little literature specifically assessing purchase motivations associated with GE foods in the United States. In their summary of 25 valuation studies relating to GE food, Lusk and Rozan (2005) found that U.S. consumers are more receptive to GE foods than their European counterparts, although a preference for non-GE foods remains, suggested by various estimates of willingness to pay for GE-free foods.

Lusk and Rozan (2005) attribute differences in GE product receptivity by consumers in France and the United States, partially to differences in information about GE foods and partially to different levels of trust in the sources providing information. While the United States showed greater knowledge of GE foods, there was also greater trust in the institutions delivering the information (food regulatory agencies, universities, and agribusiness).

Several studies have argued that even with the negative opinions Americans express about biotechnology in surveys, there has been little apparent effect on sales of food items that contain or are raised on GE ingredients or feeds (Fernandez-Cornejo and Caswell, 2006; Putnam, 2005).

What these studies reveal is that, despite a consumer preference for foods free of genetically engineered content, this preference does not necessarily translate into decreased sales of products

[6] Some of these regulations have not yet been implemented or only partially so.

potentially produced with genetically engineered material. This consumer behavior was observed in Europe as well (Marks et al., 2004).

Some suggest that the demand for food free of genetically engineered content can be found in the growth of the organic market. One of the unique attributes of organic foods, and one possible reason consumer demand for organic foods is increasing, is the intended absence of GE ingredients in the process of producing them (Anderson et al., 2006; Dhar and Foltz, 2005; Larue et al., 2004). However, the organic standard is broader than the absence of genetically engineered content, involving the prohibition of many substances commonly used in conventional agriculture and specific processes and procedures. Simultaneously, it is narrower than a GE-free concept, in the sense that is does not guarantee the absence of low-level presence of genetically engineered content when such presence is unintentional.

An indication that at least a segment of the organic market (sales) is sensitive to the presence of the genetically engineered content in organic products, even if unintended, is the recent development of a private certification standard with third-party verification and labeling, for products free of genetically engineered content (Non-GMO Project, 2010). Although this standard is also process based, it does require testing for a list of risk ingredients at specific points in the production chain, in contrast with NOP standards (Non-GMO Project, 2010). Notably, the Non-GMO Project sets thresholds for risk ingredients and does not employ a zero standard.

j. Restrictions/labeling Requirements by Some Countries on GE Products

The United States ranks among the leading producers of sugar (USDA ERS, 2010b). In 2009, sugar beets accounted for 57% of US sugar production, with 43% derived from sugar cane (Schumacher et al., 2010). Despite annual sugar production approaching 8 million metric tons (MT), total domestic production still falls short of yearly consumption. As a result, almost one-fifth of the sugar consumed in the United States is imported (USDA NASS, 2008; Baucum and Rice, 2009). Other leading importers of sugar are China, Russia, Japan, Malaysia, Indonesia, and the Republic of Korea (USDA FAS, 2007).

Due to high domestic demand and global trade restrictions/tariffs on sugar, the export market for US sugar is nominal; of the 7.8 million MT of combined cane and beet sugar produced in 2009 only 136,000 MT (1.7%) was exported (Schumacher et al., 2010; USDA FAS, 2009). For the past ten years the main export markets for US sugar have been Canada, Mexico, and Jamaica (USDA FAS, 2004; USDA FAS, 2007; Schumacher et al., 2010). Sugar beet pulp, a byproduct of the refinement process, is also dried and exported as a supplement for animal feed. Japan, Spain, Morocco, Ireland, and Canada accounted for 90% of beet pulp exports from 2000-2009 (USDA ERS, 2010b). Although the price of sugar is highly dependent on yearly supply and demand, US sugar exports have been relatively consistent over time, regardless of fluctuations in the global market.

3. Physical environment

a. Land Use

Acreage planted in sugar beets in the US has changed little over the past 50 years (since 1961), ranging from a low of 1.1 million acres in 1982 (slightly less than the 2008 acreage) to a high of 1.6 million acres in 1975 (USDA NASS, 2010c). Table 6 shows planted sugar beet acreage for the last six years. As discussed in the introduction, a small part of the sugar beet crop was derived from H7-1 in 2007, and by 2010, 95% of the planted crop was H7-1 derived. Immediately prior to the 13 August, 2010 District Court order, the exact acreage planted with the GE sugar beet in the 2009-2010 and following growing seasons is not known, but in the previous year had attained to 95% of total acreage. After widescale planting of H7-1-derived varieties, the planted US sugar beet acreage remained similar to the sugar beet acreage of 1961 and successive years.

Just as acreage has remained level for sugar beets, the sugar production industry (including the Federal sugar program structure) is organized to maintain stability, rather than emphasizing growth. Sugar beet production is highly structured, vertically integrated, and centered on sugar production facilities that are grower owned. To maintain a healthy industry, production cannot fluctuate much from year to year: a certain level of production is needed to support the major investment of a processing facility, yet the processing facility has limited capacity. A sugar beet grower is essentially bound to the local processing facility while the processing facility is bound to the local sugar beet growers. Total US sugar production is carefully controlled by allocations made through the Federal sugar program.

Crop data also provides no indication that the introduction and widespread adoption of GE crops in general has resulted in any substantial change to the total US acreage devoted to agricultural production. The acres in the US planted to principal crops, which include corn, sorghum, oats, barley, winter wheat, rye, durum, spring wheat, rice, soybean, peanuts, sunflower, cotton, dry edible beans, potatoes, canola, proso millet, and sugar beets, has remained relatively constant over the past 25 years (USDA NASS, 2010c). From 1983 to 1995, the average yearly acreage of principal crops was 328 million (USDA NASS, 2010c). Biotechnology-derived crops were introduced in 1996, (USDA ERS, 2009a) and in 2009, 319 million acres of principal crops were planted.

***Soils*.** A variety of soil types are suitable for sugar beet production. In dryland regions of production, and in regions of greater than 20 inches of rainfall, soil with high water holding capacities are desired (Cattanach et al., 1991). Otherwise, silty clay or silty loam soils, those with high clay content, or any soil varying between course-textured sandy to high levels of organic content are adequate (Cattanach et al., 1991). The practice of tillage (discussed in the next sections below (Air Quality and Climate Change and Surface and Ground Water Quality) also can affect the quality of soils because of the varying impacts of erosion on soil nutrient composition. With increased erosion following non-optimal grower practices, plant nutrients and organic material can be lost from soils.

b. Air Quality and Climate Change

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer. These agricultural activities individually have potentially adverse environmental impacts on air quality and climate and may be impacted by the actions proposed in this EA. Issues of concern include, but are not necessarily limited to, atmospheric emission of carbon dioxide, nitrogen oxide, sulfur oxide, and particulate matter. Both conventional and genetically engineered agricultural practices have the potential to directly and indirectly impact air quality and to contribute emissions which could lead to climate change.

Agricultural burning generates smoke that consists of particulate matter, including a complex mixture of carbon, tars, liquids, and different gases that are harmful to the human environment (US EPA, 2008a,b). Tillage contributes to the release of greenhouse gases (GHG) because of the loss of carbon dioxide to the atmosphere, and the exposure and oxidation of soil organic matter (Baker et al., 2005). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides. Nitrous oxide may also be released following the use of nitrogen fertilizer. Agriculture, including land-use changes for farming, is responsible for an estimated 17 to 32 percent of all human-induced GHG emissions. Herro (2008) proposes that if agriculture practices were modified, significant changes in the release of GHGs would be expected.

Pesticide Applications. Aerial application of pesticides may cause impacts to air quality from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel et al., 2008). Airborne chemicals may partition between gas and particle phase, be transported through wind, and then be deposited again by rainfall or particulate settling. Vogel et al. (2008), from measurements of pesticide content in four states, estimated that 2% of all applied agricultural chemicals are re-deposited via rainfall.

The air contamination caused by the persistence of pesticides in the atmosphere is an air quality issue that may be greatest within the immediate treatment area. Airborne pesticides can be removed from the air by rain, and deposited elsewhere. Sampling of pesticides in rainwater showed that pesticides used beyond the local watershed may nevertheless be well represented among the analytes, even in the intermediate and larger watersheds (Vogel et al., 2008). Whether pesticides are applied by ground or aerial spraying or by mechanical application to the plant surface, chemicals move to their intended and unintended targets through air, moving as droplets, dry particles or vapors (Carlsen et al., 2006; Cooter and Hutzell, 2002). The distance traveled depends upon their chemical and physical nature, method of application, and the atmospheric conditions at time of treatment. All these influence their concentration and ultimate fate (Carlsen et al., 2006).

Crops with herbicide tolerance such as H7-1 sugar beet may allow use of glyphosate, which is "more environmentally benign than the herbicides that it has displaced" (NRC, 2010; also see Fernandez-Conejo and McBride, 2002) or in some cases (such as corn) lower the quantities of herbicide used on herbicide tolerant crops compared to other crops (Fernandez-Conejo and McBride, 2002; Brookes and Barfoot, 2008; NRC, 2010). If broad spectrum herbicide can be sprayed directly without consequence to the crop, this decreases the need for applications of multiple specialized products for weed control. With the use of glyphosate tolerant crops, many growers use only glyphosate as the herbicide both for preplant ("burndown") and "over the top" spray applications. Also, the herbicide glyphosate is not considered a volatile or persistent chemical and therefore is less likely to have issues of drift or diffusion as compared to other herbicides.

***Tillage and Particulates*.** The USDA Economic Research Service defines conservation tillage as cultural operations that maintain at least 30% cover of the soil surface by plant residue at the time of planting (Anderson and Magleby, 1997). Conservation tillage can encompass a range of management practices, from no-till to ridge- and strip-till cultivation to minimum tillage systems that restrict equipment traffic to dedicated zones. Special tillage field equipment can often perform the equivalent functions of several standard implements, reducing the necessity for multiple passes through the field. No-till is defined by USDA ERS (Anderson and Magleby, 1997) to be those practices that do not disturb more than one-third the row width, and thus leave substantial crop residues on the surface of the planted field. Implementing conservation tillage practices can lead to both economic and production quality benefits, as well as having positive environmental impacts (www.nrcs.usda.gov). Tillage contributes to the release of GHG because carbon is lost as carbon dioxide to the atmosphere, and because soil organic matter is exposed and subsequently is oxidized (Baker et al., 2005).

Conservation tillage practices have seen increased use throughout the United States in recent years, especially in the Midwest where wind and water erosion are more problematic concerns. The percentage of conservation tillage managed land in the United States increased from 26% in 1990 to 41% in 2004 (Sandretto and Payne, 2006). Tillage, which can be done in fall and spring, can help improve soil structure and eliminate early weeds, but tillage can also increase erosion. Conservation tillage systems require more planning and better management (Cattanach et al., 1991).

Before H7-1 sugar beets were available, a survey conducted in 2000 found that use of conventional tillage for sugar beet production varied by region from 64% of acreage in the Red

River Valley in the Upper Midwest to 96% of acreage in the Northwest (California was not included because there was too little data; Ali, 2004). In the same survey, growers in the Red River Valley reported using reduced tillage on only 16% of sugar beet acres and mulch tillage on 20% (Ali, 2004).

Recent studies by North Dakota State University have found that since the introduction of H7-1, strip tillage is a viable option for sugar beet production that reduces fuel and fertilizer costs and susceptibility to wind erosion (Overstreet et al., 2009). A member of the Minn-Dak Farmers Cooperative, who farms about 1,100 acres of sugar beets annually, has found that instead of three post-emergence tillage trips across the fields, with H7-1 he now needs “little to no tillage post-emergence” (Mauch, 2010). Because weeds can be effectively controlled with glyphosate applications, H7-1 sugar beets are usually grown with less tillage (NRC, 2010; Duke and Cerdeira, 2007; Wilson, 2009).

In Northwest Idaho, prior to glyphosate tolerant sugar beets conventional tillage was essential for weed control, minimizing soil erosion and improving soil structure (Ali, 2004; Traveller and Gallian, 2000). Since the introduction of H7-1, some farmers have switched to strip tillage and have reported reduced fuel and labor costs and reduced wind erosion (Lilleboe, 2008). Researchers in Idaho found that while conventional tillage was necessary for weed control with conventional beets, the practice has little to no benefit with glyphosate-tolerant sugar beets (Miller and Miller, 2008). In Red River Valley trials, cultivation (conventional tillage) with H7-1 beets caused stand reduction, and yield loss in two soil types (American Crystal Sugar, 2009).

In much of the Great Plains region, conventional sugar beets were cultivated using conservation tillage systems. However, deep tillage, used to improve drainage, was utilized to help reduce the risk of soil borne diseases (mainly the beet necrotic yellow vein virus causing rhizomania) (McDonald et al., 2003). Farmers in the Great Plains have reported that strip tilling and H7-1 have “been a great marriage,” with strip tilling resulting in reduced wind erosion, reduced irrigation requirements, along with fuel and time savings (Lilleboe, 2010).

Michigan Sugar Company recommends conservation tillage practices to help control erosion resulting from strong early spring winds in the Great Lakes region (Michigan Sugar Company, 2009). However, with the introduction of H7-1 this growing region has the option of implementing varying methods of reduced tillage systems.

Tilling can introduce soil particulates into the air. One analysis determined that soil was found to be the source of 38% of total particulates (Jimenez et al., 2005). In some cases, most particulates arise from soil (Madden et al., 2008) and conservation tillage can reduce these by 85%. Consequently, dust production may be reduced by both limiting the number of passes through a field and by changing key soil properties. These changes include increasing water-holding capacity and aggregate stability, both improved by accumulation of soil organic matter typical of no-till production. Additionally, reduced tillage can potentially limit loss of carbon dioxide to the atmosphere by preventing exposure and oxidation of soil organic matter (West and Post, 2002).

***Nitrogen Fertilizer*.** Agriculture, including land-use changes for farming, is responsible for an estimated 17 to 32 percent of all human-induced GHG emissions (Herro, 2008). Massive overuse of fertilizers is the biggest contributor to these emissions within the industry. More than half of all fertilizer applied to fields ends up in the atmosphere or local waterways each year. The equivalent of 2.1 billion tons of carbon dioxide in the form of nitrous oxide, a GHG almost 300 times more potent than carbon dioxide, is emitted because of fertilizer use (Herro, 2008).

c. Surface and Ground Water Quality

Tillage and Water Conservation. Use of conservation tillage compared to use of conventional tillage in many soils may allow 10 to 40% greater water infiltration into soils (Hoeft et al., 2000a,b). Crop residues established by conservation tillage on soil surfaces slow water run-off, increase porosity by increasing numbers of wormholes and by means of remnants of crop residue, and reduce evaporation through the insulating ability of surface mulches. Conservation and strip till techniques also reduce soil erosion by 90% on highly erodible lands (Zhou et al., 2009) and no till can reduce run-off volume 35 fold compared to conventional tillage (Gregory, et al., 2005).

Irrigated and Non irrigated Production. From a USDA survey (Ali, 2004) about 40% of US sugar beet acres are irrigated. Great Plains States and Northwest States are both almost completely irrigated, while Michigan and Red River Valley sugar beet fields are not typically heavily irrigated. In three states, Michigan, North Dakota, and Colorado, water is derived fairly equally from surface and ground water (USDA NASS, 2007). In Minnesota and Nebraska, irrigation water comes predominantly from groundwater sources. In Idaho, Montana, Oregon, Washington and Wyoming, irrigation water is derived predominantly from surface water sources.

Agriculture contributes to several types of chemicals in water resources. These include nitrogen and phosphorus along with various pesticides that can lead to eutrophication and other deleterious consequences for varied bodies of water. Areas of concern are ground water and aquifers where nitrogen levels are either approaching or have exceeded the maximum contaminant level (10 mg L-1) (Klocke et al., 1999). In areas, such as Nebraska, where soybean and corn are grown in rotation and where ground water is a principle source of water for human consumption, this can be a critical issue. In other areas, surface water movement of contaminants is of concern, and agricultural tile drainage systems have been shown to be a source of nitrate entering streams and rivers (Randall and Mulla, 2001). In areas where water retention in fields is high, periodically impeding crop production, such subsurface drainage systems are commonly employed (Hoeft et al., 2000a,b).

***Fertilizer Application*.** Sugar beet growers are encouraged to have sufficient soil nitrogen to attain maximal sugar content, with premiums paid for higher than average content (Michigan Sugar Company, 2010a,b). However, excessive nitrogen can injure beets, reduce sugar content, and juice purity. Previous crops can also affect the total amount of nitrogen that should be applied to the new beet crop (Michigan Sugar Company, 2010a,b).

4. Human Health

a. Consumer Health and Safety

Allergenicity and Toxicity of Sugar Beet. Allergens can be derived from many sources: animal hair, pollen, insect bites, dust mites, plants, pharmaceuticals, and food. Approximately 20,000 allergens have been identified. Most allergens in food are high molecular weight proteins and are rather resistant to gastric acid and digestive enzymes (GMO Safety, 2010). Most plant allergens come primarily from pollen and are classified as environmental (Luoto, 2008).

Sugar beet pollen can illicit an allergic response and is considered to be an occupational hazard in the sugar beet greenhouse setting in Sweden (Luoto, 2008). Sugar-beet seed has been reported to induce allergy symptoms in sensitized individuals, predominantly in occupational settings such as the animal feed industry and farms (Steinman, 2008).

Several high molecular weight proteins have been isolated from sugar beet leaf tissue that have homology to class I and IV chitinases (Berglund, 1995; Nielsen, 1997) and to non-specific lipid transfer proteins (Nielsen, 1996). While these proteins have not been implicated in specific reactions to sugar beet, they have the potential to cause an allergic response in a sensitized individual.

Development of New Tolerances for Glyphosate when used with Glyphosate Tolerant Crops. On February 20, 1998, EPA issued a notice announcing the filing of two pesticide petitions (2E4118 and 7F4886) for increasing glyphosate tolerances in multiple crops by Monsanto Company (63 FR 8635). This notice included a summary of the petition prepared by Monsanto. There were no comments received in response to the notice of filing.

On April 14, 1999, EPA issued a final rule that increased the tolerance levels for isopropylamine salt of glyphosate or the monoammonium salt of glyphosate in or on barley, grain; barley, bran; beets, sugar, dried pulp; beets, sugar, roots; beets, sugar, tops; canola, meal; canola, seed; grain crops (except wheat, corn, oats, grain sorghum, and barley); and legume vegetables (succulent and dried) crop group (except soybeans). The residues from treatment of sugar beets and canola include residues in or on sugar beet and canola varieties which have been genetically altered to be tolerant of glyphosate (64 FR 18360).

EPA evaluated the toxicity data as well as the relationship of the results of the studies to human risk. The toxicological profile was summarized in the Final Rule. The EPA evaluated toxicological end points for acute toxicity as well as short and intermediate-term toxicity and found no toxicological endpoint attributed to a single dose. EPA's Reference Dose (RfD) for glyphosate includes a 100-fold safety factor above the NOAEL from a rabbit developmental study. No evidence carcinogenicity was found and EPA has classified glyphosate as a Group E chemical. Risk assessments (including aggregate risks for the safety for the US population, especially in infants and children) were conducted that analyzed acute and chronic exposures from food and feed uses, drinking water and non-dietary exposure.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ‘‘safe.’’ Section 408(b)(2)(A)(ii) defines ‘‘safe’’ to mean that ‘‘there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.’’ This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ‘‘ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.’’

Consistent with section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information in support of increasing glyphosate tolerances. EPA had sufficient data to assess the hazards of glyphosate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of (*N*-(phosphonomethyl) glycine) resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate on barley, bran at 20 ppm; barley, grain at 30 ppm; beets sugar, dried pulp at 25 ppm; beets, sugar, roots at 10 ppm; beets, sugar, tops at 10 ppm; canola, meal at 15 ppm; canola, seed at 10 ppm; grain crops (except wheat, corn, oats, grain sorghum, and barley) at 0.1 ppm; and legume vegetables (succulent and dried) group (except soybeans) at 5 ppm. The data evaluated by the EPA in the toxicity and risk assessments led to the increase in the tolerance levels for glyphosate because the agency was reasonably certain these glyphosate tolerance increases were “safe”.

APHIS-BRS has also reviewed the data supplied to EPA and is in agreement with EPA’s assessment that the increased glyphosate tolerances are “safe”. It has been twelve years since the EPA’s decision to increase glyphosate tolerances for the above crops and no new peer-reviewed data has demonstrated a need for re-assessment of the original decision.

FDA Consultation on Food Safety of Event H7-1 Sugar Beet. In response to the 1992 policy of the Food and Drug Administration (FDA) on foods derived from new plant varieties, Monsanto/KWS analyzed H7-1 sugar beets for compositional changes. The petitioners engaged the FDA in a consultation on both sugar beet brei (processed root) and tops. Compositional analyses evaluating carbohydrates, proteins, fiber, fat, sugars and eighteen amino acids (a total of 55 statistical comparisons) identified seven statistically different values compared with the near isogenic control line. All analyses fell within the range of values observed for both the near isogenic control line and conventional sugar beet varieties, providing additional evidence that H7-1 sugar beet does not exhibit unexpected or unintended effects. FDA agreed with the assessment of Monsanto/KWS that the brei and tops are not materially different in composition, safety, and other relevant parameters from sugar beet brei and tops currently on the market (Biotechnology Consultation Agency Response Letter BNF No. 000090). In addition, the enzyme EPSPS has received an Environmental Protection Agency tolerance exemption in all raw agricultural commodities (US EPA, 1996).

Event H7-1 in Roundup Ready® sugar beets. As discussed in the Environmental Affects section, EPSPS is a catalyst for a reaction necessary for the production of certain aromatic amino acids essential for plant growth and has a similar function in bacteria and fungi (for example, baker's yeast). While EPSPS is present in plants, bacteria and fungi, it is not present in animals; animals do not make their own aromatic amino acids, but rather obtain them from the foods they consume. Thus, EPSPS is normally present in food and feeds derived from plant and microbial sources (Harrison et al., 1996). There are variations in the genetic makeup (amino acid sequences) of EPSPS among different plants and bacteria. The EPSPS from *Agrobacterium* spp. strain CP4 that composes the H7-1 cassette in Roundup Ready® sugar beets is just one variant of EPSPS. A unique characteristic of the CP4 EPSPS is that, unlike EPSPS enzymes commonly found in plants, it retains its catalytic activity in the presence of glyphosate (Padgette et al., 1995; Schneider and Strittmatter, 2003; Bonnette, 2004).

Concentrations of Event H7-1 in Roundup Ready® sugar beets. In 1999, field trials were conducted at six distinct field locations distributed across Europe in the major sugar beet production areas. The H7-1 sugar beets were treated with a Roundup® agricultural herbicide. Samples of brei (root tissue processed using standard sugar beet industry methods) and top (leaf) tissues were collected and analyzed for levels of the CP4 EPSPS protein. On average, concentrations of the CP4 EPSPS protein on a fresh weight basis were similar in the leaf tissue (161 µg/g) and in the root tissue (181 µg/g). The range of mean levels of the CP4 EPSPS protein in top (leaf) tissue was 112 to 201 µg/g and in root (brei) were 145 to 202 µg/g across the sites (Schneider and Strittmatter, 2003).

Toxicity of CP4 EPSPS. Studies were conducted on mice, using CP4 EPSPS doses of 400, 100 and 40 milligrams (mg) of CP4 EPSPS per kilogram of body weight per day (mg/kg body wt –d). For a typical 0.03-kg mouse, the 400 mg/kg body wt/d dose equated to 12 mg CP4 EPSPS per mouse per day. The study was designed to reflect a 1,000-fold factor of safety on the highest possible human exposure to CP4-EPSPS, based on assumed exposures to soybean, potato, tomato and corn at the time the study was done (Harrison et al., 1996)[7]. The daily CP4 EPSPS content in the maximum mouse exposure was equivalent to the amount in approximately 160 pounds of H7-1 sugar beets. No treatment-related adverse effects were observed, and there were no significant difference in any measured endpoints between the CP4 EPSPS treated mice and the control group (Harrison et al., 1996).

There are two studies relevant to the mammalian digestibility of CP4 EPSPS. In the first study, the CP4 EPSPS protein was exposed to simulated gastric (stomach) and intestinal fluids that were prepared according to the US Pharmacopoeia (US Pharmacopeia, 1990). The half-life of the CP4 EPSPS protein was reported to be less than 15 seconds in the gastric fluid, greatly minimizing any potential for the protein to be absorbed in the intestine. The half-life was less than ten minutes in the simulated intestinal fluid (Harrison et al., 1996). The second study reported similar results (Bonnette, 2004).

Compositional analysis of H7-1 vs conventional sugar beets. A large body of scientific evidence that has been developed that supports the conclusion that food and feed derived from H7-1 sugar beets are as safe and healthy as food and feed derived from conventional sugar beets. The evidence has been evaluated and peer reviewed by panels of government scientists from the US, Canada, the European Union (EU), Japan, Australia, New Zealand, Mexico, South Korea, the Russian Federation, China, Singapore, Colombia and the Philippines, all of whom have

[7] Note that this was a theoretical exercise as no glyphosate tolerant potatoes or tomatoes are commercially grown.

approved, or recommended for approval, the use of products from H7-1 in their countries (FSANZ, 2005; Monsanto KWS, 2007; Berg, 2010). The composition of the hybrid lines containing H7-1 produced through conventional breeding were compared to the composition of the corresponding non-transgenic sugar beet control. The sugar beet H7-1 was found to be as safe and nutritious conventional sugar beets as discussed in the Environmental Consequences section of this EA (Bonnette, 2004).

These analyses included proximate values (crude ash, crude fiber, crude fat, crude protein and dry matter), carbohydrates, quality parameters, saponins (naturally-occurring antinutrients that have a bitter taste and can act as a deterrent to foraging), and eighteen amino acids. Quality parameters measured in root samples included percent sucrose, invert sugar, sodium, potassium and alpha-amino nitrogen. All analyses were conducted as a single analysis for the root (brei) and top (leaf) samples collected as three replica samples from each of five field trials sited. Fifty-five statistical comparisons were made with the control line, of which seven were found to be statistically different ($p<0.05$). Based on the statistical methods, three of these seven would have been expected based on chance. In all seven cases, the ranges for the statistically different components in H7-1 significantly overlapped or fell completely within the range of values observed for the control, the conventional reference varieties and for available published values from conventional sugar beet varieties (Schneider and Strittmatter, 2003).

b. Worker Safety

Effects of Glyphosate on Workers. According to the Reregistration Eligibility Decision (RED) document for glyphosate (US EPA, 1993), glyphosate is of relatively low oral and dermal acute toxicity. For this reason, glyphosate has been assigned to Toxicity Categories III and IV for these effects (i.e., Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). An acute inhalation study was waived by EPA because glyphosate is a non-volatile solid, and the studies conducted on the end-use product formulation are considered sufficient (US EPA, 1993). Expert toxicological reviews from US EPA (1993) and the World Health Organization (WHO, 2005) are in agreement that glyphosate does not pose any human acute exposure concerns for dietary exposures and thus negated the need to establish an acute reference dose.

With regard to subchronic and chronic toxicity, one of the more consistent effects of exposure to glyphosate at high doses is reduced body weight gain compared to controls. Body weight loss is not seen in multiple subchronic studies, but has at times been noted in some chronic studies at excessively high doses ≥ 20,000 ppm in diet (WHO, 2005). Other general and non-specific signs of toxicity from subchronic and chronic exposure to glyphosate include changes in liver weight, blood chemistry (may suggest mild liver toxicity), and liver pathology (USDA FS, 2003). Glyphosate is not considered a carcinogen; it has been classified by EPA as a Group E carcinogen (evidence of non-carcinogenicity for humans) (US EPA, 1993; US EPA 2004).

EPA has considered in its human health analysis the potential applicator and bystander exposure resulting from increased glyphosate use. Based on the toxicity of glyphosate and its registered uses, including use on glyphosate-tolerant crops, EPA has concluded that occupational exposures (short-term dermal and inhalation) to glyphosate are not of concern because no short-term dermal or inhalation toxicity endpoints have been identified for glyphosate (71 FR 76180, 2006).

Additional evidence to support the EPA conclusion can be found in the Farm Family Exposure Study, a biomonitoring study of pesticide applicators conducted by independent investigators (Acquavella et al., 2004). This biomonitoring study determined that the highest estimated bodily adsorption of glyphosate as the result of routine labeled applications of registered glyphosate-based agricultural herbicides to crops, including glyphosate-tolerant crops, was approximately 400 times lower than the Reference Dose (RfD) established for glyphosate. Furthermore, investigators determined that 40% of applicators did not have detectable exposure on the day of application, and 54% of the applicators had an estimated bodily adsorption of glyphosate more than 1000 times lower than the RfD (Acquavella et al., 2004).

Effects of Herbicides Other Than Glyphosate on Workers. Herbicides are used by virtually all sugar beet growers; in 2000 approximately 98% of planted acres received one or more herbicide applications (Ali, 2004). There are hundreds of commercial herbicides; only a fraction of that total can be appropriate for use with conventional sugar beet (Table 3). The acute oral and dermal toxicity for herbicides used on sugar beets are summarized in Table 10 below. Many of these herbicides do have a human health risk and are labeled accordingly as to what measures are needed to minimize the risk during handling and application on sugar beets. Table 11 lists the herbicides used in conventional sugar beet production, the label signal word from the EPA, and what measures are needed to mitigate exposure risks to humans.

Table 10. Herbicide Acute Toxicity (Oral and Dermal) for Use on Sugar Beets

Agricultural Chemical (Herbicide)	Trade Name (typical)	WSSA Mode of Action Group No.	Acute toxicity Oral (mg/kg) LD50	Acute Toxicity Dermal (mg/kg)
Clethodim*	Select	1	1630 (male rats) 1360 (female rats)	Non-irritant
Clopyralid**	Stinger	4	<50 (rats)	<200 (rats)
Cycloate**	Ro-Neet	8	2000-3190 (male rat) 3160-4100 (female rat)	>4640 (rats; non-irritant)
Desmedipham**	Betanex	5	3720 (rat)	2025-10,250 (rabbit)
EPTC*	Eptam	8	916-1630 (rats) 750-3160 (mice)	1460 – 10,000 (rabbits) 3200 (rats)
Ethofumesate**	Nortron	8	500-5000 (rats)	2000-5000 (rats)
Glyphosate*	(Several)	9	5600 (rats)	>5000 (rabbits, non-irritant)
Phenmedipham**	Betamix	5	>8000 (rats)	>4000 (rats, non-irritant)
Pyrazon**	Pyramin	HRAC Group C1	4200 (males) 2500 (males)	Non-irritant
Quizalofop, ethyl*	Assure II	1	1670 (male rats) 1480 (female rats)	Mild irritation
Sethoxydim*	Poast	1	3200-3500 (rats)	>5000 (rats; non-irritant)
Trifluralin*	Treflan HFP	3	3700->10,000	>5000 (rats; non-irritant)
Triflusulfuronmethyl**	Upbeet	2	500-5000 (rats)	2000-5000 (rats)

*Extension Toxicology Network, Accessed Aug, 2010; pmep.cce.cornell.edu/profiles/extoxnet/
**PAN Pesticide Database, Accessed Aug, 2010; pesticideinfo.org

Table 11. Alternative Herbicides for Weed Control in Sugar Beets - Label Comparison / Exposure Mitigation

Active Ingredient(s)	Product Brand	Label Signal Word	Sugar Beet PHI[a] (days)	Max. lb ai/acre (single appl.)	Max. lb. ai/acre (season)	Label Precautionary Statements / Special Directions / Other Information[b]	Applicator and Handler PPE[c] Required to Mitigate Exposure Risks
Glyphosate	Roundup WeatherMAX	Caution	30	1.125	6	Causes moderate eye irritation. Harmful if inhaled. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist. Do not store in steel. Several resistant weed biotypes confirmed in the U.S.	Long-sleeved shirt, long pants, shoes plus socks. When handling this concentrated product or its application solutions of 30% or greater, must also wear chemical-resistant gloves.
Clethodim[d]	Example Brands: Select 2 EC, CropSmart Clethodim, Albaugh Clethodim 2E, Micro Flo Clethodim 2EC	Warning	40	0.25	0.25	Causes moderate eye irritation. Harmful if swallowed. Avoid contact with eyes, skin or clothing. Environmental hazard statements for runoff and drift. "The use of this product may pose a hazard to the federally designated endangered species of Solano Grass and Wild Rice.". Warnings for repeated use leading to selection of resistant weed biotypes. Crop injury warnings. Physical hazard: Combustible.	Long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, protective eyewear. Do not reuse heavily contaminated clothing.
Clopyralid	Stinger	Caution	45	0.25	0.25	Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Warning for leaching to groundwater under certain conditions. Crop injury warnings for 1) use of treated plant material or manure from animals grazed in treated areas, as mulch or compost; and 2) spreading of treated soil. Up to 18-month rotation restrictions to many crops due to risk of injury; field bioassay	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, protective eyewear

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Active Ingredient(s)	Product Brand	Label Signal Word	Sugar Beet PHI[a] (days)	Max. lb ai/acre (single appl.)	Max. lb. ai/acre (season)	Label Precautionary Statements / Special Directions / Other Information[b]	Applicator and Handler PPE[c] Required to Mitigate Exposure Risks
						recommended. Physical hazard: Combustible.	
Cycloate	Ro-neet 6-E	Caution	NA; preplant incorporation	4	4	Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Environmental hazard statement for drift. Soil incorporation or soil injection required. Crop injury concerns dependent on soil type.	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks. Engineering controls required for dermal penetration and inhalation protection. In California: For mixers, loaders, applicators and other handlers 93 gallon limit for handling in any 21-day period.
Desmedipham[e]	Betanex	Caution	75	1.2	1.95	Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contamination of food and feedstuffs. This product contains the toxic inert ingredient isophorone. This product is toxic to fish. Environmental hazard statements for runoff and drift. Physical hazard: Do not store near heat or open flame. Sugar beet injury possible under many situations.	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, protective eyewear.

Table 11. Alternative Herbicides for Weed Control in Sugar Beets - Label Comparison / Exposure Mitigation

Active Ingredient(s)	Product Brand	Label Signal Word	Sugar Beet PHI[a] (days)	Max. lb ai/acre (single appl.)	Max. lb. ai/acre (season)	Label Precautionary Statements / Special Directions / Other Information[b]	Applicator and Handler PPE[c] Required to Mitigate Exposure Risks
Desmedipham/ phenmedipham	Betamix	Warning	75	1.2	1.95	Causes substantial, but temporary, eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. This product contains the toxic inert ingredient isophorone. This pesticide is toxic to fish and aquatic organisms. Drift and runoff...may be hazardous to fish and aquatic organisms. Physical hazard: Combustible. Sugar beet injury possible under many situations; evening applications recommended. Rotation restriction of 120 days for cereals.	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, protective eyewear. Do not reuse heavily contaminated clothing.
EPTC[f]	Eptam	Warning	NA for preplant incorporation or very early postemergence For Irrigation Water application: 49	4.6	6.1	Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through the skin or inhaled. Do not get in eyes or clothing. Avoid contact with skin. Avoid breathing vapor or spray mist. This chemical is toxic to mammals. Attention: This product contains a chemical known to the State of California to cause Birth Defects or other reproductive harm. May cause injury to stressed seedlings. Incorporation or soil injection required unless applied through irrigation.	Long-sleeved shirt, long pants, shoes plus socks. For exposure to the concentrate: chemical-resistant footwear, gloves and apron; protective eyewear. Additional PPE requirements for chemigation systems, dry bulk fertilizer impregnation and application, backpack or hand-held application

Table 11. Alternative Herbicides for Weed Control in Sugar Beets - Label Comparison / Exposure Mitigation

Active Ingredient(s)	Product Brand	Label Signal Word	Sugar Beet PHI[a] (days)	Max. lb ai/acre (single appl.)	Max. lb. ai/acre (season)	Label Precautionary Statements / Special Directions / Other Information[b]	Applicator and Handler PPE[c] Required to Mitigate Exposure Risks
Ethofumesate	Nortron	Caution	Not Specified	3.75	4	Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor or spray mist. Rotation restrictions of 6 to 12 months for crops other than sugar beets or ryegrass. Do not graze livestock on treated crops.	Long-sleeved shirt, long pants, waterproof gloves, shoes plus socks.
Pyrazon	Pyramin DF	Caution	0	7.3	7.3	Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing dusts or spray mists. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Do not contaminate water used for irrigation or domestic purposes. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Warning for leaching to groundwater under certain conditions. Significant crop injury warning statements, depending on soil moisture level, soil type (organic matter content, loam, sandy, etc.), and temperature at time of application, application method, and tank mix products. Plant back restrictions of 1 year for certain crops.	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks. Do not reuse clothing heavily contaminated with this product's concentrate.

Table 11. Alternative Herbicides for Weed Control in Sugar Beets - Label Comparison / Exposure Mitigation

Active Ingredient(s)	Product Brand	Label Signal Word	Sugar Beet PHI[a] (days)	Max. lb ai/acre (single appl.)	Max. lb. ai/acre (season)	Label Precautionary Statements / Special Directions / Other Information[b]	Applicator and Handler PPE[c] Required to Mitigate Exposure Risks
Quizalofop-p-ethyl	Assure II	Danger	45 days, except 60 days for feeding of tops	0.0825	0.17	Causes irreversible eye damage. Harmful if swallowed, inhaled, or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapor or spray mist. This product contains petroleum-based distillates. This pesticide is toxic to fish and invertebrates. Environmental hazard statements for drift and runoff. Rotation restriction of 120 days for crops not labeled. Need spray adjuvant added. Special precautions for spray tank clean out. Physical hazard: Combustible.	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus sock, protective eyewear. Do not reuse clothing heavily contaminated with this product's concentrate.
Sethoxydim[g]	Poast	Warning	60	0.47	0.94	Causes substantial, but temporary, eye injury. Do not get into eyes or on clothing. Harmful if swallowed. This product is toxic to aquatic organisms. Adjuvant addition required. Crop injury warnings. Multiple confirmed resistant weed biotypes.	Coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear for overhead exposure, chemical-resistant apron for cleaning, mixing, loading. Do not reuse clothing heavily contaminated with this product's concentrate.

Table 11. Alternative Herbicides for Weed Control in Sugar Beets - Label Comparison / Exposure Mitigation

Active Ingredient(s)	Product Brand	Label Signal Word	Sugar Beet PHI[a] (days)	Max. lb ai/acre (single appl.)	Max. lb. ai/acre (season)	Label Precautionary Statements / Special Directions / Other Information[b]	Applicator and Handler PPE[c] Required to Mitigate Exposure Risks
Trifluralin[h]	Treflan HFP	Caution	NA; one application between first true leaf and 6 inch stage	0.75	0.75	Causes moderate eye irritation, harmful if swallowed, prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid contact with eyes, skin, or clothing. Contains petroleum distillates. This pesticide is extremely toxic to freshwater marine and estuarine fish and aquatic invertebrates including shrimp and oyster. Environmental hazard statement for aerial drift. Soil incorporation required within 24 hrs of application. Crop injury warnings. Crop rotation restrictions ranging from 5 to 21 months. Confirmed multiple resistant weed biotypes.	Long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, protective eyewear. Do not reuse clothing heavily contaminated with this product's concentrate.
Triflusulfuron	UpBeet	Caution	60	0.03	0.08	Avoid contact with skin, eyes and clothing. In case of contact with eyes, immediately flush with plenty of water. Get medical attention if irritation persists. Resistant weed biotypes; multiple MOA resistance. Need spray adjuvant added. Special precautions for spray tank clean out. Requires tank mix with another herbicide for broad spectrum weed control.	Long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks.

NA indicates not applicable.

[a] PHI – Post Harvest Interval.

[b] All the herbicides in the table have a form of the following statement: "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when [cleaning equipment or] disposing of equipment washwaters (or rinsate). The text in bracket is excluded only for trifluralin and triflusulfuron. The text in parentheses is included for clethodim, cycloate, EPTC, pyrazon, and quizalofop-p-ethyl.

[c] PPE – Personal Protective Equipment.

[d] Based on recent clethodim tolerance action (67 FR 46893, Final Rule, July 17, 2002) percent-crop-treated market data necessary to refine chronic dietary exposure estimates; per label statement: concern for risks to endangered plant species.

[e] 1996 desmedipham RED: concern for Margins of Exposure (MOE) for dermal exposure to mixers and loaders; additional concern for applicator inhalation exposure to wettable-powder formulations requiring limits on application rate per acre and number of acres treated per day; low to moderate chronic risk to birds.

[f] 1999 EPTC RED ; 10x FQPA UF retained due to neurotoxic effects; developmental neurotoxicity study required; reversible Cholinesterase inhibitor; Tier 3 refinements using average residues and percent crop treated data for chronic dietary assessment; concern for risk to applicators and handlers from dermal and inhalation exposure; concern for risks to small mammals and non-target plants, including endangered species from run-off and spray drift.

[g] Based on sethoxydim tolerance actions (66 FR 51587, Final Rule, Oct.10, 2001), aPAD includes additional 3x FQPA UF for acute exposure to females 13+ yrs of age, due to fetal effects seen in rat developmental tox study; anticipated residues and percent-crop-treated data necessary to refine chronic exposure assessment.

[h] 1995 Trifluralin RED: concern for cancer risk to applicators, handlers and field workers; moderately to highly toxic to fish and aquatic invertebrates; chronic risk concern for birds due to evidence of egg cracking in avian study.

F. Environmental Consequences

This chapter provides information for making an informed decision on the potential effects that the identified alternatives may have on the human environment. The following analysis is based upon the information provided for each of the issues described in the Affected Environment and also takes into account cumulative impacts.

Monitoring and Compliance. Under Alternative 2, APHIS engages its full capacity to enforce the necessary conditions that will confine the regulated crop under its permitting program. In addition to APHIS' inspections, the mandatory permit conditions will require monitoring by the responsible person and also by third party auditors under APHIS supervision who will oversee that compliance conditions and requirements are conducted appropriately by assessing the records of the seed and root producers. Furthermore, another important part of meeting the requirements to monitor the fields and comply with the mandatory conditions is that each seed producer (and processor/cooperative) has agronomists who function to provide information about crop management and to advise field personnel or growers. A percentage of APHIS' compliance incidents are self-reported by the regulated community, and APHIS expects that this will continue for sugar beet growers. APHIS inspectors will also be assigned to visit the planting sites and observe whether permit conditions are being followed by the regulated party. Under the Plant Protection Act, if the regulated party fails to comply with the permit conditions, APHIS may seek, as appropriate and necessary, criminal and/or civil penalties and may take remedial measures to control the activity including seizure, quarantine, and /or destruction of plants. and

Under Alternative 3, the owner of the technology, Monsanto/KWS, and those producing seed expressing the technology, would establish the required conditions to maintain confinement of the H7-1 gene. Monsanto/KWS would also enforce compliance with the assigned conditions by means of stewardship agreements, contracts or other legal instruments. Mechanisms of monitoring the field production sites of the seed producers and processor/cooperatives (root production) for compliance would also be written to specify the roles of Monsanto/KWS and the roles of the seed and root producers. Finally, third party auditors should monitor production and compliance with the assigned conditions and the tasks specified in agreements or contracts. Monsanto would be responsible for establishing and assessing any penalties or other liabilities enforceable pursuant to the stewardship agreements, contracts or other legal instruments for those who have not complied with the agreed conditions.

Under the preferred alternative, APHIS engages its full capacity to enforce the necessary conditions that will confine H7-1 sugar beets under its permitting program and under compliance agreements. In addition to APHIS' inspections, mandatory permit conditions and mandatory compliance agreement conditions/restrictions will require monitoring by the responsible person and also by third party auditors under APHIS supervision who will oversee that compliance conditions and requirements are conducted appropriately by assessing the records of the seed and root producers. Furthermore, another important part of meeting the requirements to monitor the fields and comply with the mandatory conditions is that each seed producer and processor/cooperative has agronomists who function to provide information about crop management and to advise field personnel or growers. A percentage of APHIS' compliance incidents are self-reported by the regulated community, and APHIS expects that this will continue for sugar beet growers. APHIS inspectors will also be assigned to visit the planting sites and observe whether permit conditions and compliance agreement conditions/restrictions are being followed by the regulated party. Under the Plant Protection Act, APHIS may seek civil and/or penalties for failure to comply. In addition, APHIS may take if appropriate measures were not taken under the APHIS issued permit, pursuant to the Plant Protection Act, 7 USC 7712. Sec. 412, " the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, … if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States."

APHIS has extensive experience in issuing and enforcing permits pursuant to its part 340 regulations and compliance agreements similar to those described in the Preferred Alternative; accordingly, the actions proposed in the Preferred Alternative and the anticipated impacts of those actions are not novel or unprecedented.

*Importation and Interstate Movement of H7-1.*Under Alternatives 2, 3 and the Preferred Alternative, APHIS could authorize the importation or interstate movement of H7-1 sugar beets. Importation and movement of H7-1 sugar beet would not occur under Alternative 1.

Under Alternative 2, in accordance with 7 CFR Part 340, importation or interstate movement of H7-1 sugar beet would occur under an APHIS permit or acknowledged notification. H7-1 sugar beets could be imported or moved interstate under notifications acknowledged by APHIS-BRS as long as they meet the requirements found in §340.3 "Notification for the introduction of certain regulated articles", including §340.3 (c)(1) "Performance standards for introductions under the notification procedure" that requires shipment in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment. Permits for importation and interstate movement would meet the requirements identified in 7 CFR 340.4, 340.7 and 340.8 and specific permit conditions (*see* Alternatives section) that would prevent the dissemination of H7-1sugar beets into the environment.

For the time period of 2003 to August 2007, APHIS-BRS acknowledged 796 notifications and issued 195 permits for importation; 1,676 notifications and 295 permits for interstate movement; and 3,133 notifications and 20 permits for combined interstate movement and release. Of these 6,115 approvals, there were 102 reported incidents of noncompliance. Most of these incidents were due to the arrival or departure of material from an origin or destination not authorized in the permit or notification. The remainder consisted of 37 instances of unauthorized movement were due to a shipping insufficiency (lost in shipment, label or documents missing) and 5 instances of unauthorized release due to container failure in movement under notification. None of the five known releases resulting from container failure under notifications have had negative environmental consequences.

Considering the performance standards (packaging/handling requirements) and six specific requirements indentified in 7 CFR part 340.3 for a regulated article to be imported or moved interstate under notification, specific permit conditions that must be adhered to by the permit holder, permit requirements identified in 7 CFR 340.4, 340.7 and 340.8 for a regulated article to be imported or moved interstate, and the above review of past regulatory actions, APHIS-BRS considers the possibility of unintended exposure from importing or moving H7-1 sugar beet under Alternative 2 to be negligible to non-existent.

Conditions for movement of H7-1 sugar beets under Alternative 3 and the Preferred Alternative are similar to the permit conditions indentified under Alternative 2. Therefore impacts are expected to be similar to Alternative 2.

1. Biological resources

a. Environmental Effects on Gene flow

1) Gene Flow from Sugar Beet to Sugar Beet

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, no plantings of H7-1 sugar beet would be allowed by APHIS and therefore there would be no gene flow of the H7-1 trait to conventional sugar beet.

Alternative 2. Under Alternative 2, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Based on the fact that over 75% of the H7-1 trait is on male sterile lines and that isolation distances of at least four miles will separate any male fertile H7-1 lines from any other *Beta* species, negligible pollen movement (and thus, gene flow), if any, is expected into conventional sugar beet lines. Permit conditions also require following best practices for the seed industry which include tracking and inventory systems, cleaning of equipment, physical separation of H7-1 material from other non-GE *Beta* material, cleaning requirements for all planting, cultivation, and harvesting equipment, contained transport of seed and stecklings, protocols to control H7-1 volunteers and land use restrictions during the three-year monitoring period. These practices are expected to minimize any mixing of H7-1 sugar beet with conventional sugar beet lines. Seed companies routinely test conventional lines for the presence of GE and other traits for quality control purposes. Seed companies also have a vested interest in maintaining GE free conventional lines for their export markets in Europe.

Some parts of sugar beet seed production have no likely impacts on other *Beta* crops or other plants. APHIS intended to allow production of stecklings under APHIS permits by a categorical exclusion because APHIS could determine no impacts, but the District Court of Northern California decided that the permits assigned to sugar beet companies were not in compliance with his original decision. However, no attempt was made by the court to assess the lack of environmental impacts of steckling production. Stecklings derive from seed planted in early fall and are removed from the soil after production of plants with small roots. These plants are vegetative, since they are not yet vernalized and are not capable of producing seed or even pollen. Because the glyphosate resistant stecklings may be planted in mixed fields with non GE stecklings, glyphosate may not be applied to them for weed control. After uprooting, stecklings are then placed in storage and in the next season, transplanted into other fields before they complete development as reproductive plants.

Alternative 3. Under Alternative 3, plantings of H7-1 sugar beet would be authorized under conditions described in the Alternatives Considered section though Monsanto would establish conditions for production that are the same as those required by APHIS for responsible parties under permits, and would be responsible for all monitoring and compliance. Because the conditions are identical in Alternatives 2 and 3, the environmental consequences are the same.

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. As no H7-1 root production would be allowed under this alternative, there would be no possibility of gene flow to conventional sugar beet.

Alternative 2. Because sugar beets are harvested in the vegetative stage, before they flower, there is little potential for cross-pollination between root production fields. Cross-pollination, if it occurred could potentially result in adventitious (inadvertent) presence of genetic material from the crop in one field into a nearby crop's field. Scientists from Oregon State University report that for sugar beet "gene flow via pollen or seed in root production fields is generally not an issue" (Mallory-Smith and Zapiola, 2008). Messéan et al. (2009) concurs: "the potential for adventitious presence of GM material in non-GE sugar beet production is low through cross-pollination since the harvest is vegetative". The European Commission (EC, 2001) also assessed the potential for adventitious presence of H7-1 sugar beet at various stages of farm production. The Committee identified seed production as the major potential source of adventitious presence, with other sources, including planting, cultivation, cross-pollination, volunteers, harvesting and production all with no or minor potential contributions.

For both conventional and H7-1 commercial sugar beet production, all seed is purchased from either the cooperative or the seed supplier; root producers do not attempt to raise their own seed. The only sources of H7-1 pollen in production fields would be from uncontrolled bolters. If bolters occurred in two nearby fields, one with H7-1 and one with conventional sugar beets, and the bolters were not controlled and were allowed to flower, a conventional plant could potentially become fertilized with H7-1 pollen, and the resulting seeds may contain the H7-1 trait. This occurrence would not affect the conventional sugar beet crop because it would be harvested before these new resulting seeds grew into sugar beet plants. If the seeds germinated and the resulting plants survived the winter, which is unlikely in most sugar beet production areas, or the seeds survived the winter and germinated in the spring, the volunteer plants would appear in the conventional sugar beet farmer's next rotational crop, and (if they survived) would be treated as weeds, as described in Affected Environment section, and would be eliminated.

There is evidence that growers pay close attention to bolters. All growers that submitted declarations in the sugar beet litigation declared that bolters are easy to spot in their fields and if seen they would destroy them. There is no evidence to the contrary that we have seen. Any conventional sugar beet grower concerned about this occurrence could prevent it by controlling bolters in his sugar beet crop, which is normal stewardship for any sugar beet crop.

Bolters are rare. When they occur they are easily detected and there is a period of about 4-6 weeks where they can be removed before pollen is shed and 8-12 weeks before seeds are formed. Removal of bolters is a good management practice required by the cooperatives for managing both conventional and H7-1 sugar beets. Under Alternative 2, removal of bolters will be a permit condition required for all H7-1 sugar beets. To ensure compliance, a sampling of fields will be inspected by an outside party and records must be kept of bolters identified and removed. Given the rarity of bolters, the fact that they are easily spotted, there is over a four week period between emergence of the bolt and pollen release, and fields will be inspected for bolters, there is negligible opportunity for gene flow from H7-1 sugar beet to conventional sugar beet through pollen gene flow.

With the exception of California, which doesn't grow H7-1 sugar beet, all areas of commercial sugar beet production experience freezing temperatures over the winter. These cold temperatures are sufficient to kill any sugar beet roots that may have been left in the field thereby eliminating the possibility of gene flow from the root crop that is not harvested.

Currently, by mutual agreement among growers, cooperatives, processors and marketers, H7-1 sugar beets and conventional sugar beets are harvested, transported, stockpiled, processed and marketed without distinction in all areas; in California, H7-1 sugar beet has not been grown. Through the condition (Item 1) prohibiting planting of H7-1 in California, this status quo will be maintained. Based on all available information, we have concluded that there is essentially no organic sugar beet production in the US. Therefore, under Alternative 2, no impacts are expected resulting from mechanical mixing of H7-1 and conventional sugar beets.

The 22 sugar beet processing facilities in the US process a combination of H7-1 and conventional sugar beets. None processes organic sugar beets. No currently operating sugar beet processing facilities have been built in the US since 1975. Because a processing facility is required for sugar production, the 22 processing facilities account for all the beet sugar produced in the US Markets have been available for the sugar, beet pulp, molasses and other products (Kaffka and Hills, 1994; California Beet Growers Association, 1998; Western Sugar Cooperative, 2006; Michigan Sugar Company, 2010b; American Crystal Sugar Company, 2009; Minn-Dak Farmers Cooperative, undated; Snake River Sugar Company, 2009). All beets that are harvested are either destroyed by processing or spoilage thereby eliminating any further chance of gene flow. For all these reasons we conclude that the possibility of gene flow from the H7-1 root crop to the conventional root crop is non-existent and commingling of the two varieties is not an issue.

Alternatives 3 and the Preferred Alternative. Because the conditions of confinement are similar in Alternatives 2, 3 and the Preferred Alternative, the environmental consequences are the same.

2) Gene Flow from Sugar Beet to Vegetable Beet

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 sugar beet seed would not be produced so the possibility of gene flow of the H7-1 trait to vegetable beet seed would be nonexistent. Even in the absence of H7-1 crops, mechanisms to prevent gene flow will continue to be employed for conventional sugar beet and vegetable beet seed production especially in the Willamette Valley, where both coexist and measures are still needed to ensure that gene flow between vegetable beet and sugar beet is minimal in order to maintain varietal purity and avoid undesirable off-types. Isolation distances of four miles between open pollinated vegetable beets and hybrid sugar beets or three miles between hybrid vegetable and hybrid sugar beets are required for members of the Willamette Valley Specialty Seed Association. Historically, these isolation distances have been found to limit gene flow between vegetable beet and sugar beet to acceptable levels which were estimated to be less than one off-type in 10,000 seeds. In addition, Principles of Quality Assurance for sugar beet seed production have been set forth in an industry-endorsed Code of Conduct. The Sugar Beet Code of Conduct adopted by the beet group of the International Seed Federation (ISF) describes the measures the sugar beet seed industry has taken to deliver high quality varieties. The Code of Conduct document has been agreed to by Syngenta Seeds, SESVanderHave, Danisco Seed, Fr. Strube Saatzucht KG, A. Dieckmann-Heimburg, KWS (owns Betaseed), and affiliated companies.

Alternative 2. Under this alternative, H7-1 sugar beet seed would be produced under permit conditions. No gene flow is expected or less than detectable gene flow from H7-1 seed production to vegetable *Beta* seed crops are expected for the following reasons:

- The large majority of red beet (greater than 90%) and chard (greater than 99%) seed crops are grown in different geographic areas than are H7-1 sugar beets.
- Male *fertile* female parents carry the H7-1 trait on less than 25% of plants in seed production fields, and an isolation distance of 4 miles is expected to reduce cross pollination to non detectable levels. The conclusion that a 4-mile isolation distance would reduce the chances of cross pollination to undetectable levels is based on the following analysis:

1. Darmency's observation (Darmency, *et al.*, 2009) that nearly all fertilization from a pollen source (99.9%) occurs within the first 500 m (about 0.3 miles) in a worst case scenario without competition from a local pollen source.
2. The fact that each beet plant produces up to 1 billion grains of pollen and most remain in the immediate area so that local competition will substantially reduce the likelihood of cross pollination from more distant plants
3. The fact that the 4-mile proposed isolation distance is more than 12 times the distance needed to reduce cross-pollination between beet crops to 0.1%
4. Reliable PCR detection methods routinely have a limit of detection of 0.01% presence (1 seed in 10,000).
5. The combination of pollen competition and a twelve fold greater isolation distance would reduce cross pollination by at least one order of magnitude.

- Male *sterile* female parents carry the H7-1 trait in 75% of plants in sugar beet seed production fields Although APHIS establishes a 4-mile isolation for all GE sugar beet and vegetable beets, in the case of male *sterile* female sugar beets, evidence can be offered that no detectable cross pollination of vegetable beet crops with the H7-1 pollen would be likely at even 1 mile, which APHIS concludes from the following observations:
    1. H7-1 male *sterile* lines that produce pollen are very rare (Anfinrud 2010).
    2. To ensure that hybrid seed crosses proceed as intended, male *sterile* lines are rigorously inspected for pollen producers and if any are found, they are removed to prohibit inadvertent pollination.
    3. Even if some H7-1 pollen is produced, it would be highly diluted by the pollen from the non H7-1 pollen parents with the end result that the contribution of H7-1 pollen to the local pollen cloud is near zero.
    4. As discussed above, 99.9% of the pollen produced remains within 0.3 miles of the source. The pollen that drifts into a neighboring field comprises just a fraction of the pollen in the neighboring field. In other words, a major dilution of H7-1 pollen would occur in the neighboring field over a 1 mile distance.
    5. The two aforementioned dilution factors combined with an isolation distance of 1 mile significantly reduce the likelihood of a cross pollination below the level of detection of 0.01% presence (1 seed in 10,000).

- USDA is aware of studies that show that beet pollination can occur over distances as great as six miles in situations where there is little pollen competition and self incompatibility (Fenart 2007). The non GMO-Project working standard from Spring 2010 recommends five miles. Basing isolation distances on the greatest distance over which fertilization has been detected, however, is not relevant to commercial seed production because it is based on a worst case scenario. The experimental observations do not consider competition from the local pollen source, which can substantially reduce the likelihood of cross pollination. Nor do they consider the size of the pollen source relative to the pollen receptor. All commercial sugar beet operations, including H7-1 seed production, use cytoplasmic male sterility for their hybrid production, which produce less pollen than open pollinated fields commonly used for Swiss chard and table beet. Because hybrid fields are optimized for seed production, they are planted with 2-4 times as many female parents (pollen receiving and non- pollen producing plants) than male parents (pollen producing plants). Further, if the GE trait is located on the female parent, essentially all pollen produced in these fields is non-GE, and there is minimal risk of transferring the GE trait by cross pollination. However with increasing isolation distance fewer growers will be able to coexist in the valley. The Willamette Valley covers approximately 4000 square miles. A four-mile isolation distance means that each seed producer requires 50 square miles of valley. Similarly, isolation distances of five and six miles mean that each seed producer requires 78 and 113 square miles of valley, respectively. If the seed producers were optimally distributed and assuming there are no cities in the valley to take up land, the maximum number of *Beta* seed producers would be 80, 51, and 35 for 4, 5, and 6-mile isolation distances, respectively. While each isolation distance would be expected to reduce levels of cross pollination with the H7-1 trait below 0.01% (1 seed in 10,000), increasing the isolation distance would not eliminate the potential for unwanted gene flow but would substantially reduce the number of *Beta* seed growers in the valley. Therefore APHIS concludes that the four-mile isolation distance is adequate for maintaining non-detectable levels of gene flow while maximizing the number of growers in the valley.

- Disclosure requirements regarding male fertile H7-1 seed crops (Permit Condition 3) will enable any producer of vegetable beet seed to ascertain whether H7-1 pollen producers are located within four miles. Producers of red beet and chard can take account of those distances and take appropriate measures (to lay out their fields, scout for off-types, conduct genetic testing, or through other means discussed herein) if they are concerned about any level of risk. Site-specific modeling of outcrossing potential in one of the few vegetable beet seed fields known to be in proximity of sugar beet seed fields (6.9 miles away) predicted cross pollination rates of less than 0.0001% (one event in 1 million).

- Testing of the vegetable beet seed from one of the few vegetable beet seed fields in the Willamette Valley in proximity to sugar beet seed fields revealed no detectable cross pollination in any of the three years of testing (2007-2009) validating that the current isolation distances are working.

- The mandatory permit condition to prevent seed mixing which makes current seed and steckling production and handling practices required (described in the Affected Environment section), is expected to eliminate any admixture of H7-1 in vegetable beet seeds.

Removal of H7-1 trait from a Vegetable Beet Seed Crop. In the event that an undesired H7-1 trait was found within a vegetable beet seed crop, there are common procedures used in the seed industry that could be used to remove a transgene from seed stock. If a test for presence of the H7-1 gene in a vegetable beet line was positive (no evidence has been found that this has ever occurred) three methods might be used by the vegetable seed grower to remove the trait. To determine the level of possible admixture of seed with Roundup resistant traits, numbers of seedlings could be grown in flats, and leaves sprayed with a diagnostic concentration of glyphosate (Stander 2010). Most plants will display symptoms of herbicide injury (chlorosis); however H7-1 plants would be detected by lack of injury. Followup with PCR analysis if needed could be done to provide a more precise assessment of the level of admixture. Otherwise, the method could provide an easy and cost effective means to routinely test the seed supply for admixture.

One method of assuring an H7-1 free breeding stock would require coordination with a PCR provider and company that could assess for seed genetic purity, for example, Genetic Id Company (http://www.genetic-id.com/). The company would provide guidance on how to sample the seed and do so with a high degree of accuracy. One strategy might be to assess a subsample of seeds for the H7-1 event with PCR tests (one seed in 10,000 can be detected). The batch from which these seeds were sampled would be planted, seed harvested and then again subsampled for absence of H7-1 genes; the batch that had been screened twice with no H7-1 detected would be planted for seed production. Or, the second screen could be the herbicide application as noted in the first method above (Stander, 2010). The process would take two seed production cycles, or four years for vegetable beet seeds.

A similar approach to the previous method would be to divide the seed harvest into discrete units (sub-fractions) and then sample each unit with a PCR testing procedure for H7-1 presence (Fagan 2010; Stander, 2010). The necessary sample size would be based on a calculation based on the detection limit of the PCR test. All fractions without positive PCR would be bulked for sale as organic seed. The fractions which test positive can be discarded. Because acceptable seed batches would be determined from subsamples, overall precision would not be the same as that attained from sampling individual plants, but levels of adventitious H7-1 presence should be lower than detectable limits. This process could be accomplished at the end of a growing season, and before the start of the next, to ensure seed genotypic integrity.

A less expensive set of assessments could be performed with a lateral flow “strip test” which analyzes for the novel protein CP4 EPSPS expressed in H7-1. This is a qualitative assay that can be performed in the field. From a flat of candidate seedlings, single leaves could be removed and tested in bulk. If any flat tested positive for the protein, the flat would be discarded; those flats testing negative would be the source for GE-free seed (Stander, personal communication to John Cordts, 2010).

Maintaining Purity of Vegetable Beet Seed Traits Once seed is produced, a *g*rower typically will perform grow-out tests on a sample of the seed each year to confirm that the seed is producing plants without undesired off-types. Off-types might include unexpected H7-1 traits from sugar beet. The same genetic testing methods (identified in the Gene Flow from Sugar Beet to Sugar Beet Crop section above) for accurately addressing genetic seed purity can also address any inadvertent mixing of H7-1 and vegetable beets.

Removal of Unwanted Traits from Vegetable Beet Crops. Vegetable beet seed growers routinely rogue their seed production fields for off-types, including sugar beet/vegetable beet hybrids. These are often visibly distinct from the vegetable beet phenotypes (Stander, 2010; Navazio, 2010). The often types can be identified by morphological differences in shape and color of leaves and petioles, vigor, and root color and shape. A sugar beet/vegetable beet cross will display hybrid vigor and is often noticeably larger than the vegetable beet plants in the same field (Goldman, personal communication). As noted in the Gene Flow from Sugar Beet to Sugar Beet Crop section above, sensitive genetic techniques are able to accurately assess presence of the H7-1 trait.

If the grower is planning to save seed for next season, unwanted crosses between a sugar beet and vegetable beet plant can be eliminated by roguing all off-types; any previously hybridized plants will be removed before becoming parental types (Stander, 2010). As noted in the Gene Flow from Sugar Beet to Sugar Beet Crop section of Affected Environment above, sensitive genetic techniques are able to accurately assess presence of the H7-1 trait.

Based on the proposed mandatory permit measures, the expected frequency of cross pollination, would be less than the proposed non-GMO Project tolerance levels for sugar beet which is 0.25% occurrence and would achieve the ultimate aim of the project, namely, the production of vegetable beet seeds with non-detectable levels of H7-1 trait.

Alternative 3. Because the conditions are similar in Alternatives 2 and 3, the environmental consequences are the same.

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. As no H7-1 root production would be allowed under this alternative, there could be no gene flow of the H7-1 trait to vegetable beet.

Alternative 2. Under this alternative, H7-1 could be grown in all sugar beet production areas except California and certain counties in Washington State. In general, these areas do not overlap with the locations used for commercial production of vegetable beets. Furthermore, both sugar beet and vegetable beet are harvested before flowering so gene flow is expected to be non-existent.

There may be backyard gardeners who produce their own seed from their root crop. Even in such cases where these gardeners are in proximity to a sugar beet root field, the likelihood of cross pollination is negligible because the vegetable seed crop flowers at a different time of the year (early summer of the second year) than the sugar beet bolters (fall of the first year). As explained above in (H7-1 sugar beet to conventional sugar beet root production Alternative 2), it is extremely unlikely that any H7-1 root crops would produce pollen because of the mandatory permit conditions to remove bolters and even if they released pollen it would be too late to fertilize the seed crop. For these reasons, gene flow from the root crop to a back yard seed crop is expected to be non-existent.

There is a remote possibility that bolters from a sugar beet field may flower at the same time as bolters from a vegetable seed field. If these bolts are not removed, they could cross pollinate and produce seed that could shatter and result in progeny the following year. The mandatory permit conditions further reduce the potential for gene flow from H7-1 root crops to other *Beta* vegetable crops by requiring complete control of bolters. All H7-1 root crop growers will have measures in place that require them to survey, identify, and eliminate any bolters in their root crop fields before they produce pollen or set seed (Item 5). Therefore, no or negligible impacts from gene flow from H7-1 sugar beet root crops to other *Beta* vegetable crops would be expected under Alternative 2. Any grower of *Beta* vegetable crops who wanted to be certain of preventing cross pollination could do so by controlling bolters in his/her own vegetable crop fields. A volunteer H7-1 hybrid appearing in a subsequent crop resulting from cross pollination can be controlled using standard weed control practices (see Affected Environment section).

Alternatives 3 and Preferred Alternative. Because the conditions are similar in Alternatives 2, 3 and the Preferred Alternative, the environmental consequences are the same.

3) Gene Flow from Sugar Beet to Weed Beets

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternatives 1, 2, 3 and the Preferred Alternative. Except for isolated reports in Michigan and Oregon, all the known populations of non-native wild and weed beets in sugar beet root production states occur in California, where H7-1 sugar beets are not grown. As discussed in the Affected Environment section, *B. macrocarpa* weed beets are a weed issue in the Imperial Valley, the only major sugar beet production area in California (root and seed production). Even so, research in 1998 found only minor introgression between the sugar beets and *B. macrocarpa* after 66 years of coexistence in the Imperial Valley (Bartsch and Ellstrand, 1999). There is no commercial sugar beet seed production in California. H7-1 sugar beets are presently not grown in California and would not be permitted to be grown in CA under Permit Condition 1, Pennsylvania, a non sugar beet producing state, has a weedy beet population that is not sexually compatible with commercial beets. Scientists from Oregon State University report that there are no feral sugar beet crops in the US (Mallory-Smith and Zapiola, 2008). For these reasons, the likelihood of gene flow from H7-1 seed production to weedy or feral beets is non-existent under each of the three alternatives.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternatives 1, 2, 3 and the Preferred Alternative. As discussed in the Affected Environment section, California is the only sugar beet growing state with documented weedy beet populations that are sexually compatible with sugar beet. H7-1 sugar beets are presently not grown in California and under Alternatives 2 and 3 would not be permitted to be grown in CA under Permit Condition 1, Pennsylvania, a non sugar beet producing state, has a weedy beet population that is not sexually compatible with sugar beet. Given the economic constraints of sugar beet production such as need for nearby processing plants, it is not reasonably foreseeable that Pennsylvania would become a sugar beet producing state. Conditions required under both Alternatives 2 and 3 specifies that all bolters be identified and removed, if any of H7-1 beets are grown, an unlikely possibility for Pennsylvania. Scientists from Oregon State University report that there are no feral sugar beet crops in the US (Mallory-Smith and Zapiola, 2008). For these reasons, the likelihood of gene flow from H7-1 root production to weedy or feral beets is non-existent under each of the three alternatives.

b. Environmental Effects on Weed Management

1) Sugar Beet and Weed Management

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. The "no action" alternative would result in the need for sugar beet seed growers to revert back to use of herbicides and weed management practices used prior to nonregulated status for H7-1 sugar beet. The herbicides that were historically used on sugar beets are listed in Table 3. Additionally, and as noted elsewhere, tillage was a common practice prior to development of herbicide tolerant crops and would be expected to increase under this alternative. The environmental consequences of this reversion on the relatively small acreage devoted to growing sugar beet seed (3000-5000 acres per year) would be expected to be relatively small.

Alternatives 2 and 3. The sugar beet seed crop is estimated to comprise approximately 3000-5000 acres of plants. Given that this work consists of breeding and variety development, much of this acreage does not contain the GE glyphosate tolerance trait H7-1imparted by the *epsp*s gene[8]. Under these alternatives, herbicides historically used on sugar beet seed crops would be likely still be used and a relatively very small increase in glyphosate use may occur, possibly accompanied by a small decrease of other herbicides. Given the total size of these seed plantings, compared with the size of the commercial sugar beet root crop (approximately 1 million acres per year), as well as the acreage of Roundup Ready® crops grown across the country (over 100 million acres every year of corn, soybean, cotton, etc), the glyphosate used on this small acreage is negligible by comparison.

[8] The seed developed for the commercial root crop is almost exclusively hybrid seed and it is not necessary, nor even desirable, for both parents of that seed to have the GE *epsps* gene in order for the resulting plants to be glyphosate tolerant. Most growers have converted their breeding systems to use the *epsps* gene on the male sterile plants.

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. The "no action" alternative would result in the need for commercial sugar beet growers to revert back to use of herbicides and weed management practices used prior to nonregulated status of H7-1 sugar beet. The herbicides historically used on sugar beets are listed in Table 3. Additionally, and as noted elsewhere, tillage was a common practice prior to development of herbicide tolerant crops and would be expected to increase under this alternative. Under this alternative, the rates and volumes of glyphosate applications on sugar beet crops would likely return to the level of use that existed prior to the deregulation of H7-1 sugar beets (approximately 13% of acres based on year 2000 data). Growers would likely convert back to using a larger array of other herbicides. The herbicides used in conventional sugar beet systems generally have been found to have more potential for negative impacts on human and environmental health compared to glyphosate (USDA FS, 2003). The use of other herbicides may lead to increased hazards for field workers, as more hand labor is typically needed to remove weeds not effectively controlled by traditional herbicides, and those laborers would be more likely exposed to residues of more hazard herbicides.

Comparison of results from terrestrial and aquatic plant studies with predicted exposure from herbicide use suggests that several of the herbicides used in conventional sugar beet systems may have more adverse impacts than glyphosate on aquatic and terrestrial plant species (Tables 12-14). The herbicides noted in the tables (and as noted in the Affected Environment section) are selective herbicides that kill only particular groups of plants such as annual grasses, perennial grasses, or broadleaf weed species and reversion back to these weed management systems will require the use of more than one herbicide to achieve satisfactory weed control. EPA did grant glyphosate Reduced Risk status when used on sugar beets in 1999 (http://www.epa.gov/opprd001/workplan/completionsportrait.pdf). Other herbicides used on sugar beet farms do not have this status.

For non-target aquatic species, Tables 12, 13 and 14 provide summaries of the estimated exposure and hazard information for the traditional herbicides used in conventional sugar beet production, and present quantitative comparisons of the derived Risk Quotients. Exposure, defined as the EEC, was calculated for all products using the standard assumptions (assuming aerial application) of 5% drift of spray applied to a one-acre field onto water and 5% runoff from 10 treated acres into a one-acre pond six feet in depth. Herbicide treatments were based on the maximum single application rate taken from product labels. Hazard information (LC50 or EC50) for each active ingredient was taken from the EPA Ecotoxicology One-Liner Database (if available) or other EPA source documents and summarized in Tables 10 and 12, 13 and 14 as the upper and lower values from the range of values reported. Hazard information for the end-use formulated products is generally not readily available, thus this analysis is a comparison based solely on the active ingredients. Any label warnings and other available hazard and/or risk descriptions for non-target aquatic species are also included. The Risk Quotient is determined for each active ingredient by dividing the EEC by the hazard (LC50 or EC50) value.

Neighboring crops and plants potentially at risk from the use of glyphosate are also potentially at risk from the use of any other herbicide. Federal law requires pesticides to be used in accordance with the label. Because glyphosate binds strongly to soil particles, conservation tillage and no tillage practices, which greatly reduces soil runoff, provide additional assurance that the impact to aquatic plants are negligible. That assurance is not maintained under this alternative.

The labels for products containing desmedipham, phenmedipham, sethoxydim, clethodim and trifluralin include warnings of toxicity or adverse effects to fish, aquatic invertebrates, and/or aquatic plants. Risk Quotients that exceed the Trigger Value of 0.5 for aquatic animals and 1.0 for aquatic plants are highlighted in bold text in Tables 12, 13 and 14 as exceeding a Level of Concern, based on EPA Ecological Effects Rejection Analysis and Deterministic Risk Characterization Approach. Current sugar beet herbicide products containing triflusulfuron, trifluralin, and pyrazon are shown to exceed these Levels of Concern. As supported by the EPA designation of reduced risk for application of glyphosate to H7-1 sugar beet, glyphosate is a more environmentally preferred herbicide compared to other herbicides currently used in sugar beet production since glyphosate is generally less toxic and has more favorable degradation properties.

Alternative 2. None of the permit conditions anticipated under Alternative 2 specifically impact herbicide or weed management practices (with the exception of those aimed at controlling sugar beet itself – which will be addressed later in the section on Sugar Beet Volunteer Control). Alternative 2 is expected to result in the ability to continue use of glyphosate-based herbicide formulations in post-emergent applications (not to exclude pre-emergent and burndown uses) on relevant farms growing H7-1 derived glyphosate resistant sugar beet varieties in the permitted areas according to the conditions. This could result in some incidental glyphosate exposure to terrestrial and aquatic plants in the vicinity of H7-1 beet fields by spray drift. The EPA has concluded that glyphosate use on H7-1 sugar beet can be considered to pose reduced risk compared to other herbicides used for weed control in conventional sugar beets fields.[9]

Hundreds of millions of acres of other glyphosate tolerant crops have been treated with glyphosate for over ten years with minimal impact to adjacent non-target terrestrial plants. Because glyphosate binds strongly to soil particles and has minimal to no herbicidal activity after binding to soil, no effects on aquatic plants will result from surface water runoff from glyphosate use on H7-1 sugar beet when used in accordance with labeled directions. Conservation tillage and no tillage practices that are facilitated when glyphosate is used also have the potential to decrease surface water runoff and sedimentation which further benefits aquatic organisms, compared to Alternative 1.

Use of other herbicides labeled for use on sugar beets would likely decrease under this alternative. The adverse environmental impacts associated with the use of those herbicides would also be expected to decrease. Weed control would likely be more effective compared to conventional varieties such that hand weeding would be less needed or not needed. Additionally because field workers would not be exposed to more toxic herbicides while weeding, potential negative impacts to their health would be lower in Alternative 2 (Impacts of the Alternatives on Human and Animal Health are discussed more fully elsewhere in this Environmental Assessment).

[9] A reduced risk decision is made at the use level based on a comparison between the proposed use of the pesticide and existing alternatives currently registered on that use site. A list of decisions regarding Reduced Risk Status can be found at: http://www.epa.gov/opprd001/workplan/reducedrisk.html

Alternatives 3 and Preferred Alternative. The impacts on weed management in sugar beet root production are expected to be same as those above under Alternative 2. Conditions for sugar beet root production imposed under Alternatives 3 and the Preferred Alternative are similar to permit conditions proposed under Alternative 2 and likewise do not specifically impact weed management.

Table 12. Comparison of Potential Effects of Glyphosate and Sugar Beet Herbicides on Freshwater Aquatic Invertebrates

Active Ingredient	Max. lb/acre (single appl.)	EEC[1] (ppm)	Invertebrate EC_{50} (a.i.)[2] Range (ppm)		Invertebrate Risk Quotient[3] Range		Classification / Label Warnings
			low	high	worst	best	
Glyphosate	1.125	0.038	134	780	0.0003	0.00005	
Clethodim[4]	0.25	0.0084	20.2	NA	0.0004	NA	May pose hazard to federally designated endangered species of Solano Grass and Wild Rice
Clopyralid	0.25	0.0084	225	NA	0.00004	NA	
Cycloate	4.0	0.135	2.6	24	0.052	0.006	
Desmedipham	1.2	0.040	1.88	NA	0.021	NA	Toxic to fish.
EPTC	4.6	0.155	3.5	66	0.044	0.002	
Ethofumesate	3.75	0.126	64	294	0.002	0.0004	
Phenmedipham	0.6	0.020	3.2	14	0.006	0.001	Toxic to fish and aquatic organisms
Pyrazon	7.3	0.246	NA	NA	NA	NA	Drift and runoff may be hazardous to aquatic organisms
Quizalofop-p-ethyl	0.0825	0.0028	2.12[5]	6.4[5]	0.001	0.0004	Toxic to fish and invertebrates
Sethoxydim	0.47	0.016	78	NA	0.0002	NA	Toxic to aquatic organisms.
Trifluralin[6]	0.75	0.025	0.56	2.2	0.045	0.011	Extremely toxic to freshwater, marine and estuarine fish and aquatic invertebrates including shrimp and oyster
Triflusulfuron	0.03	0.0010	>960[7]	NA	<0.000002	NA	

NA = information not available or not applicable

[1] EEC refers to the Estimated Environmental Concentration, which assumes that a one-acre pond, six feet deep receives 5% drift from a one-acre field and 5% runoff from a 10-acre field.

[2] Aquatic Invertebrate EC_{50} values obtained from the EPA OPP Pesticide Ecotoxicity Database (http://www.ipmcenters.org/Ecotox/index.cfm) downloaded May 28, 2010, except as noted.

[3] Risk Quotient is EEC/EC_{50}. Risk Quotient **Bolded** if > 0.5 = Level of Concern [criteria from EPA Ecological Effects, Rejection Analysis]

[4] EC_{50} value is from a study using a 25.6% ai concentration.

[5] These values are for Quizalofop-ethyl, the 50/50 racemic mixture of R and S enantiomers. EPA considers the toxicity to animals comparable for the racemic mixture and Quizalofop-p-ethyl, the purified R enantiomer (Reg Review Summary document EPA-HQ-OPP-2007-1089, page 27. Studies are MRID 00128210 and MRID 00146951, respectively.)

[6] Toxicity values are from the Trifluralin Reregistration Eligibility Document, United States Environmental Protection Agency, April 1996.

[7] Aquatic Invertebrate EC_{50} value obtained from the EPA OPP Pesticide Ecotoxicity Database (http://www.ipmcenters.org/Ecotox/index.cfm) downloadedJanuary 24, 2008.

Table 13. Comparison of Potential Effects of Glyphosate and Sugar Beet Herbicides on Aquatic Plants (Algae and Duckweed)

Active Ingredient	Max. lb/acre (single appl.)	EEC[1] (ppm)	Aquatic Plant EC_{50} (a.i.)[2] Range (ppm)		Aquatic Plant Risk Quotient[3] Range		Classification / Label Warnings
			low	high	worst	best	
Glyphosate	1.125	0.038	0.8	38.6	0.048	0.001	
Clethodim	0.25	0.0084	1.34	>11.4	0.006	<0.0008	May pose hazard to federally designated endangered species of Solano Grass and Wild Rice
Clopyralid	0.25	0.0084	6.9	NA	0.001	NA	
Cycloate	4.0	0.135	NA	NA	NA	NA	
Desmedipham	1.2	0.040	0.044	>0.33	0.909	<0.122	Toxic to fish.
EPTC	4.6	0.155	1.36	41	0.114	0.004	
Ethofumesate	3.75	0.126	>2.76	>39	<0.046	<0.004	
Phenmedipham	0.6	0.020	0.19[4]	>0.32[4]	0.105	<0.063	Toxic to fish and aquatic organisms
Pyrazon	7.3	0.246	0.17	>4.6	**1.45**	<0.054	Drift and runoff may be hazardous to aquatic organisms
Quizalofop-p-ethyl	0.0825	0.0028	>0.082	>1.77	<0.035	<0.002	Toxic to fish and invertebrates
Sethoxydim	0.47	0.016	>0.27	>5.6	<0.060	<0.003	Toxic to aquatic organisms.
Trifluralin	0.75	0.025	0.0075[5]	>0.339[5]	**3.32**	<0.074	Extremely toxic to freshwater, marine and estuarine fish and aquatic invertebrates including shrimp and oyster
Triflusulfuron	0.03	0.0010	0.0028	0.123	0.35	0.008	

NA = information not available or not applicable.

[1] EEC refers to the Estimated Environmental Concentration, which assumes that a one-acre pond, six feet deep receives 5% drift from a one-acre field and 5% runoff from a 10-acre field.

[2] Aquatic EC_{50} values obtained from the EPA OPP Pesticide Ecotoxicity Database (http://www.ipmcenters.org/Ecotox/index.cfm) downloaded May 28, 2010, except as noted.

[3] Risk Quotient is EEC/EC_{50}. Risk Quotient **Bolded** if > 1.0 = Level of Concern [criteria from EPA Ecological Effects, Rejection Analysis].

[4] Aquatic EC_{50} values for phenmedipham are from the Reregistration Eligibility Decision for Phenmedipham, EPA-738-R-05-007, March 2005.

[5] Aquatic EC_{50} values for trifluralin are from the Reregistration Eligibility Decision for Trifluralin, EPA-738-R-95-040, April 1996

Table 14. Comparison of Potential Effects of Glyphosate and Sugar Beet Herbicides on Freshwater Fish

Active Ingredient	Max. lb/acre (single appl.)	EEC[1] (ppm)	Fish LC_{50} (a.i.)[2] Range (ppm)		Fish Risk Quotient[3] Range		Classification / Label Warnings
			low	high	worst	best	
Glyphosate	1.125	0.038	45	140	0.0008	0.0003	
Clethodim	0.25	0.0084	19	>33	0.0004	<0.0003	May pose hazard to federally designated endangered species of Solano Grass and Wild Rice
Clopyralid	0.25	0.0084	104	125	0.00008	0.00007	
Cycloate	4.0	0.135	4.5	7	0.03	0.02	
Desmedipham	1.2	0.040	1.7	6	0.024	0.007	Toxic to fish.
EPTC	4.6	0.155	11.5	27	0.013	0.006	
Ethofumesate	3.75	0.126	0.75	>320	0.168	<0.0004	
Phenmedipham	0.6	0.020	1.41	3.98	0.014	0.005	Toxic to fish and aquatic organisms
Pyrazon	7.3	0.246	NA	NA	NA	NA	Drift and runoff may be hazardous to aquatic organisms
Quizalofop-p-ethyl	0.0825	0.0028	0.17	10.72[4]	0.016	0.0003	Toxic to fish and invertebrates
Sethoxydim	0.47	0.016	170	265	0.00009	0.00006	Toxic to aquatic organisms.
Trifluralin[5]	0.75	0.025	0.041	2.20	**0.61**	0.011	Extremely toxic to freshwater, marine and estuarine fish and aquatic invertebrates including shrimp and oyster
Triflusulfuron	0.03	0.0010	<640	<760	>0.000001	>0.000001	

NA = information not available

[1] EEC refers to the Estimated Environmental Concentration, which assumes that a one-acre pond, six feet deep receives 5% drift from a one-acre field and 5% runoff from a 10-acre field.

[2] Aquatic LC_{50} values obtained from the EPA OPP Pesticide Ecotoxicity Database (http://www.ipmcenters.org/Ecotox/index.cfm) downloaded May 28, 2010, except where noted.

[3] Risk Quotient is EEC/LC_{50}. Risk Quotient **Bolded** if > 0.5 = Level of Concern [criteria from EPA Ecological Effects, Rejection Analysis]. Risk Quotients >0.1 result in classification for Restricted Use (http://www.epa.gov/oppefed1/ecorisk_ders/toera_risk.htm#Deterministic).

[4] This value is for Quizalofop-ethyl, the 50/50 racemic mixture of R and S enantiomers. EPA considers the toxicity to animals comparable for the racemic mixture and Quizalofop-p-ethyl, the purified R enantiomer (Registration Review Summary document EPA-HQ-OPP-2007-1089, page 26. Study is MRID 00128210).

[5] Toxicity values are from the Trifluralin Reregistration Eligibility Document, United States Environmental Protection Agency, April 1996.

2) Herbicide Resistance

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. The impacts of no production of seed for H7-1 derived varieties would be the same as those described below for "Root Production" in Alternative 1 except that much less acreage is affected.

Alternative 2. The impacts would be the same as those described below for "Root Production" in Alternative 2 except that much less acreage is affected. None of the permit conditions anticipated under Alternative 2 specifically impact herbicide resistant weed management practices (with the exception of those aimed at controlling glyphosate resistant sugar beet itself – which will be addressed in the section on Sugar Beet Volunteer Control).

Alternative 3. The impacts would be the same as those described below for "Root Production" in Alternative 2 except that much less acreage is affected. None of the conditions anticipated under Alternative 3 specifically impact herbicide resistant weed management practices (with the exception of those aimed at controlling glyphosate resistant sugar beet itself – which will be addressed in the section on Sugar Beet Volunteer Control).

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, there would be no effect of H7-1 on the potential for weeds to develop resistance to glyphosate, given that glyphosate use is minimal with conventional sugar beets. Growers would continue to use conventional weed control methods, including other herbicide modes of action, to the extent that such conventional herbicides are available and effective (see Affected Environment). The use of other herbicides could have consequences for development of further resistance to those herbicides, however as analyzed later in the

Cumulative Impacts section, most of the major sugar beet weeds in sugar beet producing states that have developed resistance to non-glyphosate based herbicides that are also used in sugar beet production were specifically first reported as infesting crops other than sugar beet. Notable exceptions where non-glyphosate herbicide resistant weeds are specifically reported as infesting sugar beet include kochia resistant to ALS-inhibitor herbicides and wild oats resistant to ACCase inhibitor herbicides.

As discussed above, glyphosate use in H7-1 sugar beet has proven to be an effective tool against weeds resistant to non-glyphosate herbicides, such as ALS-inhibitors and ACCase-inhibitors. If the planting of H7-1 sugar beets is substantially curtailed, a valuable tool for post-emergent herbicide resistant weed management (as well as pre-emergent, and burndown use) will be unavailable to sugar beet growers, and the impact of weeds resistant to other herbicides may increase, although the impact would likely be small relative to other crops since sugar beets are a relatively small crop (Kniss, 2010).

Alternative 2. Under Alternative 2, impacts, if any, with respect to the development of glyphosate-tolerant weeds in sugar beet crops are expected to be small for three reasons. APHIS does recognize the potential for H7-1 sugar beet to contribute to the development of glyphosate tolerant weeds (also a potential following use of any herbicide), but identifies existing strategies and procedures that will minimize the potential.

First, H7-1 sugar beets account for less than one percent of the acreage of glyphosate-tolerant crops grown in the US. Relative to other US glyphosate tolerant crops which are associated with development of some glyphosate resistant weeds, glyphosate tolerant sugar beets would likely be a small contributor to development of new ones (for reasons cited in 2 and 3 below). In sugar beet producing states, weeds specific to sugar beet production with glyphosate resistance have been rare (see Cumulative Impacts section). The presence of other glyphosate resistant weeds in sugar beet (probably arising from herbicide use in another herbicide tolerant crop) has been rare (see Cumulative Impacts Section). Glyphosate use in H7-1 sugar beet production grown under APHIS permit under Alternative 2 is not expected to increase beyond recent levels, as market penetration of H7-1 sugar beet has been already at 95% in 2010. Maximal rate of glyphosate use per season between crop emergence and canopy closure is limited by the EPA to 100 ounces per acre, so there are restrictions on glyphosate use that also constrain overapplication.

Second, glyphosate is a non-residual herbicide, which along with sugar beet-specific growing practices makes the possibility of new glyphosate-resistant weed populations emerging from sugar beet fields less likely. Sugar beet co-ops provide the grower-owners with detailed information about using preplant herbicides other than glyphosate, and strategies that should be adopted to prevent weed resistance in sugar beet fields (for example, see Ag Note #496 at American Crystal Sugar website). In Monsanto's Technology Use Guide (Monsanto 2010; mandatory for those who have signed the Monsanto Technology/Stewardship Agreement), growers are not advised to use glyphosate for preplant herbicide, but "Start with a clean field, using either a burndown herbicide application, residual herbicide or tillage" and encouraged to use a "residual herbicide labeled for sugarbeet…preplant, preemergence or posteemergence." Growers and producers of H7-1 sugar beet are motivated to prevent the emergence of glyphosate tolerant weeds, as these weeds could potentially reduce crop yields significantly. Although none of the permit conditions anticipated under Alternative 2 specifically impact herbicide resistant weed management practices (with the exception of those aimed at controlling glyphosate resistant sugar beet itself – which will be addressed later in the section on Sugar Beet Volunteer Control), H7-1 growers are legally required by Monsanto to follow Monsanto's Technology Use Guide (Monsanto, 2010). Crop rotations of three to five years (often required by farming co-ops) and for seed production, rotations of five to eight years (American Crystal Sugar, 2010) would make it less likely that new glyphosate-resistant weed populations will develop in sugar beets as a result of glyphosate use. As discussed in the Cumulative Impacts section, a variable percentage of the rotation crop will be a Roundup Resistant one (see Table 18), from a low in Idaho of 1.4% corn and 2.8% alfalfa (only 0.4% of these total Roundup Resistant crop in ID), to a high in Minnesota of 64% soybean (only 3.4% of MN soybean crop). In eight states, an average 32% of rotation crops following sugar beet will be Roundup resistant. When a rotation crop does not use herbicides of the same mode of action, or may require tilling, the likelihood of weed resistance developing on the field is lowered (Prather et al., 2000).

Finally, because herbicide resistance is a heritable trait, it takes multiple growing seasons of herbicide usage for herbicide resistant weeds to emerge and become the predominant biotype in a specific area (Cole, 2010). Researchers have concluded that even if growers completely relied on only one herbicide, it is likely to take at least five years for a herbicide-resistant weed population to develop (Kniss, 2010; Beckie, 2006; Neve, 2008; Werth, 2008). Crop monitoring and follow up by academic and industry weed scientists in cases of suspected resistance are important parts of all herbicide resistance stewardship programs.

Alternatives 3 and Preferred Alternative. The impacts would be the same as those described above for Root Production in Alternative 2. None of the conditions anticipated under Alternatives 3 and the Preferred Alternative specifically impact herbicide resistant weed management practices (with the exception of those aimed at controlling glyphosate resistant sugar beet itself – which will be addressed in the section on Sugar Beet Volunteer Control).

3) Sugar Beet Volunteer Control

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, glyphosate would still be effective to devitalize or remove any volunteer conventional sugar beet that emerges, as no glyphosate tolerant beets would be planted under this alternative.

Alternative 2. Under Alternative 2, the planting of H7-1 sugar beet would be allowed under APHIS permits, so glyphosate would not be an option for the control of those sugar beet volunteers that are derived from those plantings. As there are alternative methods for the removal of volunteer plants, such as other herbicides and physical removal or destruction, and these methods have been used by growers previously for the control of H7-1 derived volunteers, Alternative 2 does not represent a significant change from current agricultural practices.

As described earlier, in the Affected Environment section on Sugar Beet Volunteer Control, many protocols are available to control post-harvest sugar beet volunteers in sugar beet seed production fields, including H7-1 sugar beet production fields, and these methods would continue to be put into effect. Several permit conditions proposed under Alternative 2 are expected to ensure that the glyphosate resistant trait will not be unintentionally passed on to other sexually compatible plants. Additionally, glyphosate resistant H7-1 derived sugar beet seed or stecklings will not be dispersed outside of the production site and will not persist as volunteers or feral plants. Sugar beet plants do not survive winter conditions in most growing locations, so persistent volunteers or other feral populations are unlikely.

Alternative 3. The impacts would be the same as those described above for Seed Production in Alternative 2. The conditions anticipated under Alternative 3 include measures similar to the permit conditions under Alternative 2 that are expected to control volunteer or feral plants that express the glyphosate tolerant trait.

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. The analysis of this alternative is the same as that for Alternative 1, Seed Production above, except that the issue of volunteers in sugar beet root production fields is significantly reduced as the root crop plants are not in the ground long enough to produce the seeds that are the primary source of volunteers in subsequent crops. Volunteer plants produced directly from roots (known as groundkeepers) that might overwinter in the Imperial Valley of California, where H7-1 sugar beet is not grown, would be controlled, as needed, in a similar fashion as volunteers from seeds as described above in Alternative 1, Seed Production. As described earlier, in the Affected Environment section on Sugar Beet Volunteer Control, groundkeepers rarely occur in the northern plains and upper Midwest.

Alternative 2. The analysis of this alternative is the same as that for Alternative 2, Seed Production above, except that the issue of volunteers in sugar beet root production fields is significantly reduced as the root crop plants are not in the ground long enough to produce the seeds that are the primary source of volunteers in subsequent crops. Volunteer plants produced directly from roots (groundkeepers) would be controlled, as needed, in a similar fashion as volunteers from seeds as described above in Alternative 2, Seed Production. Permit conditions proposed under Alternative 2 that requires surveying and removal of bolters from root production fields planted to H7-1 derived varieties will ensure that H7-1 volunteer sugar beet root crops do not produce seeds that will pose a weed problem in rotation crops.

Alternatives 3 and Preferred Alternative. The analysis of this alternative is the same as that for Alternative 2, Root Production above. Conditions proposed under Alternative 3 and the Preferred Alternative that require surveying and removal of bolters from root production fields planted to H7-1 derived varieties are similar to those proposed under Alternative 2 and will ensure that H7-1 volunteer sugar beet root crops do not produce seeds that will pose a weed problem in rotation crops.

4) Effects on Micronutrient Absorption Due to Glyphosate

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternatives 1, 2, 3 and Preferred Alternative. As discussed in the Affected Environment section of this EA, there is conflicting evidence regarding whether the introduced glyphosate-resistance trait and/or glyphosate applications can lead to manganese deficiency in soybean. Even in the situations where manganese deficiency was observed in soybean, the deficiency was effectively corrected by foliar applications of manganese or addition of manganese to the soil with an acid-forming phosphorous-containing fertilizer (Camberato). Also, the field studies performed by Monsanto over multiple years and locations showed no significant difference in leaf manganese content. Regardless, farmers have many decades of experience dealing with manganese deficiency resulting from high soil pH, drought, or high organic soils and can alleviate the condition by either adjusting the soil pH, adding more manganese to the soil, or adding manganese by foliar sprays. If it turns out that glyphosate use is a factor that exacerbates manganese deficiency, the problem can be corrected with these same treatments. Furthermore, we are not aware of any evidence indicating that H7-1 sugar beets suffer manganese deficiency from glyphosate treatment. Impacts, if any, with respect to occurrence of manganese deficiency in sugar beets are expected to be negligible because an effect of glyphosate on manganese deficiency in sugar beet has not been demonstrated. Extension agents at Purdue and Iowa State Universities are not recommending changes to fertility regimes for growers raising glyphosate tolerant crops because it is not clear that glyphosate use causes micronutrient deficiency and because yield reductions can result from over fertilization. Rather they recommend treating manganese deficiency as is currently done by testing the soil and adding amendments as needed and inspecting plants for signs of deficiency and making foliar applications of manganese as appropriate. Consequently, it is not expected that growers of sugar beet will experience any differences in manganese deficiency under the three alternatives.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

The analysis of the alternatives for root production is the same as that for seed production.

5) Disease and Pest Susceptibility Changes Due to Glyphosate Treatment

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

<u>Alternative 1.</u> The impacts of glyphosate use on disease and pathogens associated with sugar beet are the same as those for Alternative 1 for Root Production below.

<u>Alternative 2.</u> The impacts of glyphosate use on disease and pathogens associated with sugar beet are the same as those for Alternative 2 for Root Production below, except that the affected area for impacts of seed production conditions is smaller.

<u>Alternative 3.</u> The impacts of glyphosate use on disease and pathogens associated with sugar beet are the same as those for Alternative 3 for Root Production below, except that the affected area for impacts of seed production conditions is smaller.

<u>Preferred Alternative</u>. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

<u>Alternative 1.</u> Under Alternative 1, H7-1 would not be produced, so there is no potential for the sugar beet crop to suffer from increased disease susceptibility to glyphosate use given that glyphosate use is minimal with conventional sugar beets. Alternative 1 may limit the amount of

sugar beet seed with disease resistance traits available for certain geographic areas. If seed with adequate disease resistance is not available, the sugar beet crop may be more susceptible to disease in those areas.

Alternative 2. Under Alternative 2, impacts, if any, with respect to occurrence of increased disease susceptibility in sugar beets are expected to be negligible because an effect of glyphosate on increased disease susceptibility in sugar beet has not been demonstrated. The evidence for a relationship between the glyphosate resistance gene, glyphosate use, and disease susceptibility of glyphosate tolerant sugar beet is not compelling. It should be noted that there is not just one variety of H7-1 sugar beet, but rather the H7-1 has been introduced into hundreds of varieties tailored for localized production regions. Nonetheless, the H7-1 has not been introduced into all varieties of sugar beet and there are some lines available that offer greater disease resistance than H7-1 derived sugar beet varieties (Larson, 2010). The difference in disease resistance is attributable to the presence and absence of genes that confer disease resistance, not the presence of a glyphosate tolerance trait.

Additionally, variety selection done by sugar beet producers may include disease resistance traits. Only the varieties that appear on the cooperatives' approved list in 2010 may be planted in 2010 (See, e.g., Gerstenberger Declaration). In order to appear on cooperatives' approved variety list, a seed variety must be entered into official variety trials, which compare trial varieties over at least two years against a set of benchmark varieties using criteria for purity, yield (both in tons per acre and sugar), and disease resistance. In addition, a Seed Committee which is responsible for evaluating and approving new seed varieties focuses on the disease resistance traits required for the particular growing region (Gerstenberger declaration). In other words, varieties must perform well in local multi-year field trials before they may be used for wide production. If a variety shows poor disease resistance characteristics in the presence of glyphosate, it will not appear on the approved list for planting that year. In this way, variety trials provide a management tool to mitigate any potential impacts of glyphosate effects on disease susceptibility of H7-1 derived varieties. Even if there were increased susceptibility to certain pathogens in some lines, all sugar beet varieties available for planting are evaluated for disease resistance in multiyear trials mitigates any possible increased susceptibility with glyphosate treatment.

Alternative 2, in which current traits associated with H7-1 derived seed are readily available, are more likely to lead to less disease in sugar beet production.

Alternatives 3 and Preferred Alternative. Because the conditions are similar in Alternatives 2, 3 and the Preferred Alternative, the environmental consequences are the same.

c. Environmental Effects on Animals

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, sugar beet seed producers can't transplant H7-1 stecklings into sugar beet production fields in late winter. It's possible that fields destined for hybrid seed production will remain fallow in which case there will be reduction of ground for rodents and rabbits. The lack of ground cover for these animals could have a cascading effect, reducing the food for snakes and raptors in the area. Leaving a field fallow (unplanted) can also increase the erosion of topsoil.

If farmers plant conventional sugar beets, , the use of traditional herbicides to control weeds in sugar beet fields may have increased impacts on animals that come in contact with these herbicides. Herbicides traditionally used in sugar beet seed crops to combat weeds are listed above with acute oral and dermal toxicities listed for each (Table 10).

Under this No Action Alternative, the potential for impacts to animal species may be greater than with Alternative 2 because of the return to greater use of additional herbicides, potentially with higher toxicities (See Table 10 and 11).

Alternatives 2 and 3. Alternative 2 and 3 are expected to result in continued glyphosate exposure to animal species within and adjacent to those sugar beet fields that use this herbicide through drift and direct contact, but would likely decrease animal exposure to other herbicides (USDA APHIS, 2009).

Based on the data available on glyphosate usage, chemical fate, and toxicity, glyphosate is not expected to pose an acute or chronic risk to the following categories of wildlife (US EPA, 1993):

- birds

- mammals
- terrestrial invertebrates
- aquatic invertebrates
- fish
- microorganisms

Under this alternative, impacts of herbicide use on animals could be reduced by the continued use of glyphosate on sugar beet seed production because of reduced exposure to other more toxic herbicides (USDA APHIS, 2009).

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, farmers will not be able to plant a sugar beet root crop in the spring of 2011. If farmers do not plant an alternative crop or do not have conventional sugar beets to plant at the beginning of the 2011 year, there could be a reduction of ground cover for wildlife that use these areas, including birds and small mammals (ie.rodents and rabbits). The lack of ground cover for these animals could have a cascading effect, such as reducing the food availability (prey) for predatory wildlife species such as snakes and raptors in the surrounding area. Leaving a field fallow (unplanted) could also increase the erosion of topsoil. Soil erosion could have impacts on aquatic animal species such as fish and aquatic invertebrates.

If farmers plant conventional sugar beets, the use of traditional herbicides to control weeds in sugar beet fields may have increased impacts on animals that come in contact with these herbicides. Herbicides traditionally used in sugar beet seed crops to combat weeds are listed above with acute oral and dermal toxicities listed for each (Table 10). Under this No Action Alternative, the potential for impacts to animal species may be greater than with Alternative 2 because of the return to greater use of additional herbicides, potentially with higher toxicities (See Tables 10 and 11).

Alternatives 2, 3 and Preferred Alternative. Alternatives 2, 3 and the Preferred Alternative are expected to result in continued glyphosate exposure to animal species within and adjacent to those sugar beet fields that use this herbicide through drift and direct contact and would likely decrease animal exposure to other herbicides (USDA APHIS, 2009).

Based on the data available on glyphosate usage, chemical fate, and toxicity, glyphosate is not expected to pose an acute or chronic risk to the following categories of wildlife: (US EPA, 1993)

- birds
- mammals
- terrestrial invertebrates
- aquatic invertebrates
- fish
- microorganisms

Under these alternatives, impacts of herbicide use on animals could be reduced by the continued use of glyphosate on sugar beet seed production because of reduced exposure to other more toxic herbicides (USDA APHIS, 2009).

a. Environmental Effects on Microorganisms

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, the potential for impacts to microbial species may be greater than with Alternative 2 because of the return to greater use of additional herbicides, potentially with higher toxicities.

Alternatives 2 and 3. Alternatives 2 and 3 are expected to result in continued glyphosate exposure to microbial species within and adjacent to those sugar beet fields through drift and direct and would likely decrease in exposure to other herbicides (USDA APHIS, 2009).

Microorganisms produce aromatic amino acids through the shikimate pathway, similar to plants. Since glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. However, field studies show that glyphosate has little effect on soil microorganisms, and, in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate (USDA FS, 2003).

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, the potential for impacts to microbial species may be greater than with Alternative 2 because of the return to greater use of additional herbicides, potentially with higher toxicities.

Alternatives 2, 3 and Preferred Alternative. Alternatives 2, 3 and the Preferred Alternative are expected to result in continued glyphosate exposure to microbial species within and adjacent to those sugar beet fields through drift and direct and would likely decrease in exposure to other herbicides (USDA APHIS, 2009).

Microorganisms produce aromatic amino acids through the shikimate pathway, similar to plants. Since glyphosate inhibits this pathway, it could be expected that glyphosate would be toxic to microorganisms. However, field studies show that glyphosate has little effect on soil microorganisms, and, in some cases, field studies have shown an increase in microbial activity due to the presence of glyphosate (USDA FS, 2003).

b. Environmental Effects on Plants

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, impacts associated with agriculture production systems that have been occurring for decades would continue to occur. Those impacts, both positive and negative, include those such as water/fertilizer/pesticide run off, pesticide spray drift, and increased/decreased growth of plants adjacent to sugar beet fields. These impacts are typical of those found in areas surrounding most agricultural operations and most are not unique to the growing of sugar beets.

Alternatives 2 and 3. Under Alternatives 2 and 3, impacts to plants outside H7-1 sugar beet seed fields would be similar to those identified in Alternative 1. Negative impacts associated with water/ soil/pesticide run off, however, could be less as growers could adopt low- or no-till practices associated with the use of glyphosate. Given that the scale of production of sugar beet seed fields is fairly small (3000-5000 acres), even these impacts would be expected to be small.

Preferred Alternative. Under the preferred alternative, plantings of H7-1 sugar beet would be authorized under specific permit conditions described in the Alternatives Considered section. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, impacts associated with agriculture production systems that have been occurring for decades would continue to occur. Those impacts, both positive and negative, include those such as water/fertilizer/pesticide run off, pesticide spray drift, and increased/decreased growth of plants adjacent to sugar beet fields. These impacts are typical of those found in areas surrounding most agricultural operations and most are not unique to the growing of sugar beets.

Alternatives 2, 3 and Preferred Alternative. Under Alternatives 2, 3 and the Preferred Alternative, impacts to plants outside H7-1 sugar beet root fields would be similar to those identified in Alternative 1. Negative impacts associated with water/ soil/pesticide run off, however, could be less as growers could adopt low- or no-till practices associated with the use of glyphosate.

2. Socioeconomic Environment

a. Environmental Effects on Sugar Production in the US: Contribution of Beets to Sugar Market

Since this analysis is focused on US sugar production, the impacts of the permit conditions on seed and root production cannot logically be separated and they are therefore discussed together. In alternative 1 we assume that H7-1 seed cannot be planted for either seed or root production, while for Alternatives 2, 3 and the Preferred Alternative we assume that H7-1 seed can be planted for both purposes, with appropriate conditions imposed by APHIS.

APHIS Conditions for Seed and Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

<u>Alternative 1.</u> Under this alternative, H7-1 is fully regulated and the entire 2011 root crop will need to be planted with conventional seed either currently on hand, harvested in the 2009/2010 seed crop or imported from Europe. Only a small fraction of the 2008/09 sugar beet seed production was conventional, and there is no evidence that this fraction would have significantly increased in the 2009/10 production cycle. The impacts of this alternative on US sugar production are a function of the following considerations: (1) the availability of conventional seed; (2) the relative yield potential of the available conventional seed; (3) the flexibility of sugar companies to allow growers to plant seed of unapproved varieties; and (4) the availability of the herbicides that are labeled for use with conventional sugar beet production.

The limited availability of conventional seed is expected to severely restrict plantings of sugar beets in 2011, reducing beet sugar production in 2012. Based on information provided by sugar beet seed producers and buyers, Colacicco (personal communication and Colacicco, 2010) estimates that prohibiting the planting of H7-1 sugar beet seed would result in a 37% reduction in sugar beet root crop acreage in 2011. Based on this estimate reduction in acres planted, the consequent reduction in beet sugar production in 2012 is estimated to be 1.6M tons (assumes unchanged yields and unchanged sugar recovery (Colacicco, personal communication and Colacicco, 2010) The economic impact of a reduction in beet sugar supply on grower incomes in 2011 and 2012 would be severe (USDA FSA, 2010). Manufacturers and consumers will have time to reduce their beet sugar use and manufacturing costs if a decision to prohibit H7-1 sugar beets is announced at least one year before it affects domestic supply. Colacicco (personal communication and Colacicco, 2010) estimates that U.S. demand for sugar could fall 1% due to the higher sugar costs in 2012.

One potential impact of a shift to older conventional varieties derives from the yield gap between H7-1 derived varieties and the older conventional varieties. As discussed above, beet seed breeders have shifted their variety development to focus on H7-1 products. Most of the conventional seed available for planting the 2011 crop would have been produced two or more years ago. In order to plant the entire 2011 sugar beet root crop with conventional varieties, the sugar processors may also need to at least temporarily relax their variety approval policies. That is, they may need to allow the planting of seed of varieties that are no longer approved, or perhaps were never approved. Since the variety approval systems ensure that all newly approved varieties produce more extractable sugar/ton than the older varieties, a crop produced with these older varieties can be expected to produce less extractable sugar/ton, which could further reduce the amount of beet sugar available.

The availability of conventional seed for planting the 2011 root crop would also vary significantly by production region such that the impact of seed shortages would be much greater on some sugar processors than on others. See below for a more detailed discussion of regional availability of conventional seed for planting the 2011 root crop.

The only available option for planting the entire 2011 sugar beet root crop with conventional seed would be to import seed from Europe. Such varieties would be relatively unadapted and expected to yield less than varieties developed for the US market. Regional differences in the viability of this option are discussed in detail below. Due to the possibility of importing Europe's weed beet problem along with the seed, this option could potentially have long term negative consequences on the US beet sugar industry.

The shortage of conventional seed is likely to impact sugar beet production in a similar fashion in 2012. However, accurate analysis of the impact requires knowledge of the amount and type of seed that is currently being produced during the 2010/2011 seed production cycle. Since the court has restricted the production of H-7 seed, seed producers may have chosen to produce some conventional seed. The impact of this alternative on the 2012 sugar beet root crop is a direct function of the level of risk that seed companies were willing to accept when they finalized their 2010/2011 seed production plans. Regardless, it is unlikely that there is adequate conventional seed in current production to plant the full 2012 root crop. Furthermore, the severe seed shortages forecast for 2011 are predicted to result in the closing of some beet sugar processing plants and some companies may not survive after a one year shutdown (Colacicco, personal communication and Colacicco, 2010). Regional impacts to beet sugar processors are discussed in detail below.

Under Alternative 1, H7-1 sugar beets cannot be grown and harvested in 2011 (providing sugar for FY 2012 sales) or 2012 (providing sugar for FY 2013 sales). Thus, beet processors would likely not be able to supply their normal market share of sugar during this period. Projected acreage planted to sugar beets would be reduced by 37% in 2011. Based on that estimate, the drop in area planted for sugar beet production would lower beet sugar production by an estimated 1.6 million tons in FY 2012 (lost acreage with unchanged yields and unchanged sugar recovery). The economic impact of a reduction in beet sugar supply on consumer costs in FY 2012 would be severe. However, the severity would be mitigated depending to the degree that sugar users respond by switching to non-sugar sweeteners. Since this impact will occur one and a half years from now, manufacturers will have time to adjust their formulas to reduce their sugar use and reduce manufacturing costs. FSA estimates that US demand will fall by only 1% due to the higher sugar costs because of shifting consumer preference for non-HFCS sweeteners (Colacicco, personal communication and Colacicco, 2010).

USDA provisions in the sugar program would be activated as market prices for sugar increased. Useful precedents that might predict the impacts on the sugar market of a decline in sugar production have occurred previously. Domestic refined sugar production was sharply reduced due to losses of cane refineries in 2005 (Hurricane Katrina damage to two refiners and Red River Valley early sugar beet crop failure; 2% of gross domestic sugar production) and 2008 (explosion at Imperial Sugar's Savannah, GA refinery; loss of 9% of domestic sugar production), and the sugar program allowed increased importation of cane sugar. Under this alternative, sugar users and consumers would not have access to the lower priced beet sugar contracted months earlier and would have to write new contracts, in a much tighter sugar market, with new suppliers. With total FY 2012 deliveries forecast at 10.1 million tons, users and consumers would pay an additional total of $1.6 billion for sugar in FY 2012, though they consume less due to higher sugar prices.

This alternative would cause greater disruption and harm to the US sugar market than the situation caused by the 2005 disruption (2% loss of domestic production) or the 2008 disruption (9% loss of domestic production) (Colacicco, personal communication and Colacicco, 2010). The likely reduction, 1.6 million tons, is five times larger than the loss of supply in FY 2006 and twice as large than the loss in FY 2008. Prices increased substantially in those years, but were never high enough to cause sugar to be imported off the world market at the high tariff rate of 16.3 cents per pound. Under this alternative, it is anticipated that world sugar would enter under a high tariff, and set the refined price in the US market. With the sudden shortage of sugar in the US market, the world refined sugar price would increase in order to divert sugar to the US from already contracted destinations (Colacicco (personal communication and Colacicco, 2010). Besides economic consequences for producers and growers, a termination of seed production for H7-1 (and a return to conventional seed) would produce additional impacts upon the sugar beet industry and consumers of US sugar.

Replacement of Sugar Beet with Imported Cane Sugar

Because US sugar cane refiners are expected to run at near full capacity in FY 2011, they will not have the capacity to refine imported raw cane sugar to replace the 1.6 million tons of beet sugar lost. Normally, USDA would increase the raw sugar tariff rate quota to alleviate domestic sugar shortages. However, in FY 2011, domestic needs for sugar would have to be filled by increasing refined sugar imports; however, this would be extremely challenging due to the limited world sugar processing capacity and the uncertain capability of foreign producers to supply refined sugar of the quality and packaging needed by US sugar users. In order to meet the 1.6 million ton shortfall, refined sugar imports would have to increase three-fold from of an average of 690,000 tons over the past three years. This increase in refined sugar imports may tax the current refined sugar distribution system. For example, the 1.6 million tons would require over 97,000 containers on at least 115 ships by the end of September 2012.

Impacts on Sugar Quality by Increasing Amounts of Imported Sugar

Even if sugar could be attained from the world market, USDA learned from the temporary loss of cane refineries in 2005 and 2008 that many US food manufacturers have difficulty using imported refined sugar due to the difference in product quality or packaging.

After the 2005 and 2008 events, a new business developed - liquefying and clarifying imported refined sugar for domestic use. This was required because domestic food companies would not use the crystallized imported sugar in its original packaging. This effort expanded domestic refined supplies at a cost, but only for users that could use liquid sugar. Most sugar users, i.e. food manufacturers, need crystallized sugar. Many domestic food manufacturing companies perform sugar processing plant inspections to ensure that the quality of sugar meets their specific requirements. With the tight supply in the world market, it would be difficult to secure the quality of sugar that US manufacturers require in the amounts that would be needed if an injunction is imposed on H7-1 sugar beets and beet sugar production is consequently substantially limited.

Impacts on Industrial Sugar Users and Packagers

Other impacts are also expected. Sugar users could expect a price increase of 24 percent. The stocks on the grocery shelves would likely be reduced due to the lack of supply and the higher cost of carrying sugar inventory. It is unlikely that the sugar users could immediately replace the lost beet sugar available for sale, so some sugar-containing product factories would have to close temporarily, shorting the market for sugar containing products and consumer packaged products. Food manufacturers rely disproportionately on beet sugar, as opposed to cane sugar, and therefore the supply of sugar products would be affected immediately. Under Alternative 1, costs of sugar for both industrial foods users and retail consumers would be substantially increased.

<u>Alternative 2.</u> Under this alternative, H7-1 is fully regulated. H7-1 seed could be planted for sugar beet root crop production under appropriate regulatory authorization from APHIS. There

would likely be no impact on US beet sugar production in 2011 or 2012. The seed conditions assigned would allow full production of beet sugar in the US, and avoid need for importing foreign sugar of marginal quality. Cane sugar in the US would not be needed to fill the US sugar requirements, since production would continue as before with adequate seed to plant H7-1 sugar beets.

Seed would have adequate agronomic properties suited to pests and local agricultural environments. Full production of sugar for the domestic market would be possible, and no additional imports would be necessary. If Alternative 2 were chosen, substantial increases in sugar prices would not occur as they would under Alternative 1, and the US would not need to purchase additional sugar on world markets

Alternative 3. Under this alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 seed and roots under APHIS requested conditions. The impacts of this alternative on the US sugar market are identical to those for Alternative 2 and the Preferred Alternative.

Preferred Alternative. The impacts of this alternative on the US sugar market are identical to those for Alternative 2 and 3.

b. Environmental Effects on Principal Companies and Cooperatives

Beet sugar processors need a dependable and consistent supply of beets in order to remain profitable and satisfy sugar delivery contracts. Ensuring the availability of adequate high quality sugar beet seed to plant the crop has always been of primary concern to beet sugar companies and this is the historical explanation for why all beet sugar companies once had internal seed divisions. Beet seed providers must estimate product demand at least three years ahead of sales. Since all sugar processors restrict growers to planting only approved varieties, sugar beet seed providers must take seed production risks if they wish to sell commercial seed in the first two years following variety approval.

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Seed of H7-1 may not be planted for any purpose.

While this alterative may impact beet sugar processors in future years, there will be an immediate impact on beet seed suppliers. One sugar beet seed company that predominantly supplies H7-1 seed to US growers does a $50-60 million business annually (Zeph, Syngenta, public comments on Draft EA) and would lose investments made in unneeded seed, research and development, trial participation and production and processing. Additionally, forecasting beet seed demand by variety is extremely challenging due to the long time frame required for seed production. Factoring in the uncertainty as to whether or not it will be possible to market H7-1 seed in the future, and whether or not conventional varieties will be in demand in the future, means that any seed production initiated in 2010 would include a significant level of risk.

Under Alternative 1, any seed production initiated in 2010, for harvest in 2011 and root production in 2012, would necessarily be limited to non-GE varieties. As discussed above, variety selection by sugar beet growers is limited to the varieties included on the list of approved varieties.

As the industry has transitioned to greater than 95% use of H7-1 seed, the frequency of non-GE varieties entered in official variety approval trials has approached zero. For example, in 2009 Betaseed only submitted conventional varieties to one seed committee outside of California (Miller, 2009). Therefore, the seed production options remaining to seed providers may be limited to the extent that they would not be able to satisfy the conventional seed requirements for the 2012 and 2013 sugar beet crops

All of the H7-1 commercial seed crop harvested in 2010, as well as that harvested in previous years cannot be sold until such time as H7-1 is again deregulated. Seed can be carried over from year to year, but seed quality declines each year in storage. This alternative directly impacts sugar beet seed providers by complicating their task of efficient inventory management. Due to the normal decline in seed quality over time, some of the H7-1 seed harvested in 2010, as well as any seed in inventory, may eventually need to be discarded. Conversely, if seed companies choose to produce seed of conventional varieties for the 2012 and 2013 root crops, this seed may also be unsalable if the varieties are not acceptable to the sugar companies or if there is a return to the use of H7-1 seed.

Alternative 2. Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. This alternative does not serve to eliminate the uncertainty facing the seed producers since they will still have no assurance that they will be able to sell the H7-1 seed to sugar beet growers in future years. Therefore, some negative impact on the seed companies, as well as their contract growers can be expected.

Because all of the seed that will be planted to produce the 2011 root crop has already been produced, this alternative does not impact the 2011 sugar beet root crop, and therefore will not impact the beet sugar processors in 2011. As discussed above, the impact on the 2012 sugar beet root crop is a direct function of the seed production choices seed companies have made and/or will soon make for the seed crop to be harvested in 2011. Since permits will be required, this alternative has some potential to impact seed producers in that they will be obligated to apply for the permits in an appropriate time frame and with accurate information. That is, if a seed producer were to submit untimely applications to APHIS, or to submit applications which require significant additional information or review under NEPA, the issuance of the permits could delay or preclude planting for the seed production. Additionally, seed companies that hire consultants to obtain APHIS permits may incur additional incremental costs.

Alternative 3. Under this alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 seed under APHIS requested conditions. The impacts of this Alternative on the beet seed companies and beet sugar processors are quite similar to those for Alternative 2, with slightly less uncertainty since APHIS permits would not be required. In summary, Alternative 1 will result in some degree of economic harm to the US beet *seed companies* because they have limited conventional seed available and face uncertainty of what seed will be needed for future seasons, but will have large impacts on at least some of the beet *sugar processors* in 2011. Potential impacts on the 2012 root crop and the processors require knowledge of the current seed availability and the seed crop. Alternatives 2 and 3 will also have minor impacts on US beet *seed companies*, because specialists to pursue APHIS permits will need to be hired.

Preferred Alternative. Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 sugar beets may not be planted and shortages of conventional seed will result in a significant reduction of sugar beet production and beet processing in late 2011, and a short supply of sugar for FY 2012 (Colacicco, personal communication and Colacicco, 2010). The lead time for producing new seed is two years. Because conventional seed comprised only 5% of planting in 2009 and 2010, adequate replacement for H7-1 seed is not available beginning in the spring of 2011 (see Affected Environment). Under this alternative, seed production would focus on providing for the longer term needs for H7-1 seed through the 2012 growing season or even later. Seed for both H7-1 and conventional varieties would need to be produced, given a need for preferred H7-1 varieties over the alternative conventional varieties, and given the uncertainty of the time frames for APHIS regulatory actions. If pursued, this double production of seed would increase costs, which eventually must be borne by seed users – beet growers. This increase in cost would continue until APHIS completed an EIS and made a new decision on the petition for nonregulated status.

The Director of Dairy and Sweetener Analysis at USDA's Farm Service Agency estimates that conventional seed supply would be sufficient for planting only 63% of present sugar beet acres in the spring of 2011 (Colacicco (personal communication and Colacicco, 2010). Beet processing would be highly impacted, and so consequently would the economics of co-ops and growers who own the processing facilities. Sugar beet processing factories and the surrounding communities would experience economic hardship if beet processing factories were limited because of the inability to plant H7-1 sugar beet seed and incomplete replacement by conventional beet seed.

Some flexibility has been shown historically for processors to adjust to changes in beet supply. Where a region had multiple sugar beet processing facilities, surplus beets have been shipped to other factories, even owned by other companies, when the need has arisen. At least one processor has closed a factory in the past as their beet acreage declined in order to maintain processing efficiency in their remaining factories. Nevertheless, beet processors would suffer significant costs to shutter a factory until an adequate beet seed supply is available. In the interim, fixed capital costs would have to be paid as well as salaries to retain company management and skilled factory labor.

Table 15. Seed Availability by Region

Region	Conventional seed required (units)	Conventional seed available (units)	% shortage
West region	199,152	88,465	55.58
East region	453,900	323,088	28.82
Total U. S.	653,052	411,553	36.98

A unit contains approximately 100,000 seeds.

Given that the current outlook through FY 2012 is already for high prices due to tight US and world supplies, a 37% reduction in domestic beet sugar supply incurred under Alternative 1 can be expected to highly motivate beet processors to consider alternatives to shutting down factories. For instance, beet processors might try to obtain their beet seed supply from foreign sources, knowing that the seed might not be geographically compatible and possibly contaminated with weed beet seeds. Beet processors would evaluate whether it is worth introducing the exotic weedy beets into their beet producing regions in order to save jobs and not idle factories. It is unlikely that beet processors will choose to import foreign, potentially contaminated seed knowing that once the weed beet seed is introduced, it will be difficult, if not impossible, to eradicate in a conventional sugar beet cropping system. Rather, beet sugar processors may prefer to idle factories for one or two years, if necessary, even knowing that restarting their factories and reinstating a qualified labor pool will be extremely costly and difficult.

Alternatively, beet processors might attempt to use raw cane sugar as an input into their processing operations to supplement the reduced beet tonnage. Several beet processors have experimented in recent years with importing high polarity Mexican raw cane sugar in this way, with varying degrees of success. Some found that transportation, dependability of delivery and quality issues made adopting this method cost prohibitive. Others were more satisfied with their cane refining experience and might import raw sugar to supplement their diminished beet sugar supply. It is assumed here that processors will rely on whatever conventional seed is available and either close or underutilize their factories.

Dr. Richard Sexton, an agricultural economist and an authority on agricultural cooperatives, recently conducted an investigation of economic impacts to growers and processors if H7-1 sugar beet seed was unavailable for planting in crop years 2011 and 2012. His results rely on direct interviews, and written surveys with each of the eight sugar beet processing companies, and a study of 2011 conventional seed availability. Sexton concludes that consequences from the unavailability of H7-1 sugar beet will be suffered unequally around the nation and likely permanently change the structure of the US sugar beet industry. He predicts that the factories most at risk for closing will be in those areas with the best options for alternative crops and that were the first to convert to GE seed due to severe weed conditions. Growers in those regions have changed their tillage practices and bought specialized equipment which is not compatible with a conventional sugar beet cropping system. In year one (2011) of the unavailability of H7-1 beet seed and faced with having to invest in new equipment versus planting alternative crops, Sexton's surveys indicate that these growers would most likely remove sugar beets from their rotations resulting in more than 430,000 acres moving into alternative crop production. In 2012, abandonment of acreage is reduced as adequate (by assumption) conventional seed becomes available. Loss of growers who abandon sugar beets due to the unavailability of planting H7-1 beet seed reduces factory throughput and increases average processing costs. Sexton predicts that the unavailability of H7-1 seed for two years, 2011 and 2012, would lead to the permanent closure of beet processors; six in the West region and two in the East region[10]. Sexton surmises

[10] The five regions defined earlier in the Environmental Assessment have been combined for this discussion into two regions due to disclosure issues. The West Region includes the Northwest and Great Plains regions. The East Region includes the Upper Midwest and Great Lakes regions. The South West is excluded from this section on economic impacts because only conventional seed is used there; hence, the unavailability of H7-1 beet seed would have no impact.

that because expansion of the beet industry is unlikely, importers and cane sugar refiners would be in a position to benefit from factory closures.

Sexton's analysis suggests that the unavailability of planting of H7-1 sugar beet seed in the spring of 2011 would have the following ramifications, which are mostly realized in 2012 as the crop is processed: 1) 8 of the 21 sugar beet processing plants would close; 2) sugar beet grower income would be reduced by approximately $253 million; and 3) sugar beet processor worker salaries would be reduced by about $138 million dollars due to a $80 million reduction in full-time payroll (1,463 jobs lost) and a $58 million reduction in seasonal payroll (2,127 jobs lost). Accounting for multiplier effects, which reflect the income lost to suppliers of goods and services to direct recipients of sugar beet processor payments, Sexton's analysis suggests the economic loss to local economies where sugar beets are grown and processed would be approximately $1.1 billion.

If the unavailability of H7-1 sugar beet seed prevents H7-1 beet seed from being planted in the spring of 2012, Sexton's analysis suggests the following losses would be realized (mostly in 2013 as the crop is processed): 1) a loss in grower variable profits of $282 million; 2) processor full-time and seasonal employment would be reduced by 1,570 workers; and 3) reduced salaries would amount to $56 million. Taking into account the multiplier effects, net revenue is estimated to be $964 million less than would be generated if H7-1 sugar beets were allowed to be planted in 2012. The losses attributed to the unavailability of H7-1 sugar beets in 2012 are smaller because Sexton assumes that adequate conventional seed is available in 2012.

Sexton's 2011 Regional Summary

For 2011, Sexton predicts that beet processors would use whatever conventional seed is available, then plant alternative crops to the remaining acres. Of the total $253 million farm income loss, $145 million is the estimated loss from growers using conventional, rather than H7-1 seed. The West region would suffer the greatest loss ($82 million), while the East region would suffer $63 million in losses. Total losses in income from switching to alternative crops ($108 million) would be felt most in the East region ($59 million), with $49 million in losses estimated for the West region.

The combined effect of plant closings and running factories at suboptimal capacities reduces full-time employment by 1,463 workers or $80 million in total payroll ($68 million loss in West region (1,238 full-time employees) and $12 million loss in the East region (225 full-time jobs). Seasonal employment falls by 2,127 workers, costing $58 million in wages ($35 million to the East region (1,284 seasonal jobs lost), $23 million in losses to the West region (843 seasonal jobs).

Total direct impacts from the unavailability of using H7-1 beet seed in 2011 are $391 million; $221 million in the West region and $170 million in the East region. Applying a 2.85 multiplier effect yields total direct and indirect impacts of $1.1 billion; $631 million to the West region, $483 million to the East region.

Sexton's 2012 Regional Summary

Assuming an ample supply of conventional beet seed is available for planting in 2012, Sexton estimates that acreage switched to alternative crops in 2011 drops by 25 percent. He estimates that acreage in conventional beet seed increases 40% from that in 2011. Sexton estimates that grower losses in variable profits will be $282 million. Of that, $30 million is due to switching to an alternative crop; $17 million to the West region, $13 million to the East region. The remaining $252 million is lost due to costs involved with switching to conventional seed; $137 million to the West region, $115 million to the East region.

With the unavailability of using H7-1 sugar beet seed continuing into 2012, Sexton estimates that beet processors would employ 493 fewer workers than they would if H7-1 beets were permitted, or $27 million in total payroll - all in the West region. Seasonal employment would fall by 1,077 workers; $18 million to the West region (668 seasonal jobs) and $11 million to the East region (409 seasonal jobs).

Total direct impacts from a ban on using H7-1 beet seed in 2012 are $338 million; $199 million to the West region and $139 million to the East region. Applying a 2.85 multiplier effect yields total direct and indirect impacts of $964 million; $568 million to the West region and $396 million to the East region.

Another study by the University of Idaho (2004) found that if sugar beet production and processing ceased in Idaho and alternative crops were planted instead, Idaho would lose over 3,000 jobs and farm incomes would decline (given lower returns to corn, wheat, and other production options based on 2004 projections). Sugar beet growers generally produce other crops since beets are grown in rotation, and their land would not remain idle; they have the equipment and expertise to produce other crops. The longer-term concern, however, is in terms of the impact on infrastructure, as some companies may not survive closing down for one season (Colacicco, personal communication and Colacicco, 2010).

Alternatives 2, 3 and Preferred Alternative. The USDA-required conditions specific to beet production, including control of bolters, and monitoring of crop areas for four years will have no impacts on beet processors, since these measures are already required by the cooperatives for their member/owners. Processors and growers would experience no shortage of seed for planting because the existing seed is adequate. Thus, beet processors would have a sufficient supply of sugar beets for processing. Alternatives 2, 3 and 4 provide for stable production of sugar beets so that processors can produce a full allotment of sugar. Under Alternatives 2 and the Preferred Alternative, responsibility for enforcing conditions such as removing bolting sugar beets and making records and chain of custody documents would be with the cooperatives/processors under APHIS oversight, while oversight under Alternative 3 would be established by contractual agreements between Monsanto/KWS and the cooperative or grower-owned company processors.

c. Environmental Effects on Regional Production of Seed and Roots

Vegetable Beet Seed

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated and may not be planted for any purpose. Since all sugar beet seed production would be limited to conventional varieties, any impacts on vegetable beet seed production would be the same as prior to the introduction of H7-1 sugar beets. For example, there has always been the potential for cross-pollination between vegetable beet and sugar beet seed production fields, but this potential has been successfully mitigated through seed association policies, in particular the rules for pinning of seed production fields (the mechanism for sharing information about location of *Beta* crops). Vegetable beet seed and sugar beet seed production have coexisted in Oregon for many years without major conflicts. For more information on this topic, see Affected Environment section for a thorough discussion of gene flow between these crops as well as Appendix 3 that describes the pinning rules used in the Willamette Valley of Oregon.

Alternative 2. Under this alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed.

As indicated above, most table beet seed (92%) is produced in Washington, and the majority of Swiss chard seed production is in Washington and California. The potential impacts of this alternative are limited to the 7% of table beet seed production which occurs in areas of the Willamette Valley of Oregon where H7-1 seed would be grown. These potential impacts derive from: (1) gene flow from H7-1 seed fields to vegetable beet seed fields; (2) gene flow from H7-1 volunteers following H7-1 seed production to vegetable beet seed fields; and (3) mixing of H7-1 seed with vegetable beet seed.

Even with the mandatory conditions in place, there remains a low probability that H7-1 pollen could reach a vegetable beet seed production field. Since conventional vegetable beet seed growers do not have zero tolerance for GE content in seed, this alternative has no impact. The only potential impact is that to organic vegetable seed producers whose customers may have a zero tolerance for GE. Only one grower who sells organic vegetable beet seed has been identified in the Willamette Valley. That grower produces chard seed on approximately 1-3 acres at the Western margin of the Willamette Valley. He has tested his organic chard seed using a PCR test capable of detecting 0.01% GE content during this period (Morton, 2010a,b). PCR tests over multiple years have found no indication of gene flow from H7-1 seed production (Hoffman, 2010a; Morton, 2010a,b; Stearns, 2010). The proposed permit conditions that increase the separation distances between male fertile H7-1 seed fields and other beet fields and require disclosure of such fertile pollen H7-1 fields would further reduce the chances that this grower would detect H7-1 in his seed harvest. APHIS will also require each seed company producing H7-1 seed to be subject to third party audits of compliance with the proposed standards to ensure that the measures were effective.

Furthermore, H7-1 hybrids only require one parent to carry the H7-1 trait; seed production in the Willamette Valley has been steadily shifting to use of H7-1 CMS (male sterile) female parents, so that those fields produce virtually no H7-1 pollen. Organic seed producers with a zero tolerance to GE seeds in this region could choose to market and sell seed with no risk of H7-1 pollen movement from such fields. Although some organic growers require zero content in seed, it should be noted that one organic community's consensus statement, the "Non-GMO Project Working Standard," does not require zero tolerance. Rather it proposes a tolerance for GE traits in verified Non-GMO seed of 0.25 percent. There is also no realistic prospect of mechanical mixing between vegetable beet seed with H7-1 seed because the two production processes are entirely separate. As discussed above, the seed is processed in different facilities than sugar beet seed, and no common equipment is used. The best practices proposed in the permit conditions include a number of requirements which further reduce the chance of any mixing of H7-1 seed and vegetable beet seed.

One grower (Morton, 2010a,b) has provided an estimated value of $15,000 for his annual production of organic Swiss chard seed. If his seed crop were unsalable as organic due to the zero tolerance of his customers to H7-1 trait in seed, then the economic harm could be as high as $15,000. However, he would still be free to market his seed crop as conventional, receiving instead approximately $10,000, and reducing the actual harm to the $5,000 derived from the organic premium.

<u>Alternative 3.</u> Under this alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 roots under APHIS requested conditions. The impacts of this Alternative on the US vegetable beet seed production would be identical to those for Alternative 2.

<u>Preferred Alternative</u>. Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

In summary, Alternative 1 is expected to have no impact on vegetable beet seed production. Although production of an H7-1 seed crop has an exceedingly low potential to impact producers of vegetable beet seed under current conditions, under Alternatives 2, 3 and the Preferred Alternative these impacts should be reduced to no or negligible impacts through the conditions proposed by APHIS.

Sugar Beet Seed

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated and may not be planted for any purpose. Therefore, only conventional sugar beet seed production could be initiated in 2010 and perhaps in 2011.

As discussed in Affected Environment section, the increased uncertainty as to whether or not either type (H7-1 or conventional) of seed harvest could be sold to sugar beet growers, this alternative is expected to significantly reduce the total US sugar beet seed production in the 2010/2011 seed production cycle. This acreage reduction will be a direct function of the level of risk seed companies are prepared to accept. Some of the beet seed farmers in the Willamette valley that normally grow sugar beet seed may need to seek out alternative crops which may not provide the same high level of economic return as sugar beet seed production.

Due to the increased level of risk involved in any sugar beet seed production, the four companies that produce sugar beet seed can all be expected to incur losses due to lost sales and/or discarded inventory.

Alternative 2. Under this Alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Under this Alternative, APHIS issues permits with conditions for the production of H7-1 seed. This Alternative would have minimal impact on the socioeconomic resources involved in US sugar beet seed production.

As discussed above, Alternative 2 has some potential negative impacts on seed producers due to the obligation to apply for APHIS permits in an appropriate time frame and with accurate information. Additionally, seed companies that hire consultants to obtain APHIS permits may incur additional incremental costs.

Alternative 3. Under this Alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 seed under APHIS requested conditions. The impacts of this Alternative on US sugar beet seed production would be quite similar to those for Alternative 2, with the exception of the potential impacts that derive from the obligation of seed companies to obtain APHIS permits.

Preferred Alternative . Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

In summary, Alternative 1 potentially impacts the socioeconomic environment of beet seed production by injecting a high level of future uncertainty around sugar beet seed production decisions during the next 18 months. This uncertainty will have some degree of negative economic impact on sugar beet seed producers as well as their contracted seed growers. In contrast, Alternatives 2, 3 and the Preferred Alternative are anticipated to have no or negligible impacts on sugar beet seed production.

Vegetable Beet Crops

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this Alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Since seed of H7-1 may not be planted for any purpose, there would be no possibility of the potential impacts that derived from H7-1 gene flow or from mixing of H7-1 seeds or roots with those of vegetable beets.

A reversion to planting conventional sugar beet seed would significantly increase the demand for the several herbicides that sugar beet growers relied on prior to the introduction of H7-1 sugar beets and which may also be used by vegetable beet growers. This increased demand could potentially impact vegetable beet growers in two ways: (1) increased prices for these herbicides; and (2) lack of availability of these herbicides due to diversion of product to sugar beet producing regions. Thus there would be small impacts on any vegetable beet production in 2011.

Alternative 2. Under this Alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Under this Alternative, APHIS issues permits with conditions for the production of H7-1 seed.

Whether grown for leaves or roots, vegetable beet crops are all harvested in their first year before they produce seed. As discussed above, there is virtually no overlap between sugar beet root crop production areas and major areas of vegetable beet crop production. Additionally, vegetable beet growers do not have zero tolerance for GE, limiting any potential impacts of H7-1 root crop production to producers of organic vegetable beet crops.

Potential impacts from H7-1 sugar beet root crop production on organic vegetable beet production derive from: (1) gene flow from H7-1 bolters to organic vegetable beet bolters; (2) H7-1 volunteers following H7-1 root crop production; and (3) mixing of H7-1 roots with roots of organic vegetable beets. Due to the generally non-overlapping production regions and the visual distinction between a sugar beet and a vegetable beet, each of these potential impacts is highly unlikely. There is no indication that this type of gene flow from H7-1 bolters to organic vegetable beet bolters has occurred since wide scale H7-1 sugar beet root crop production began in 2008. Furthermore, if an organic vegetable beet grower had bolters, that grower could eliminate any chance for gene flow by removing the bolters.

The permit conditions proposed by APHIS will essentially eliminate these potential impacts, primarily by requiring the complete removal of bolters in H7-1 root crop production fields. Gene flow cannot occur if the bolters never release pollen. Under the proposed permit conditions, all H7-1 root crop growers will have measures in place that require them to survey, identify, and eliminate bolters in their root crop fields before they produce pollen or set seed. Beet sugar processors and cooperatives would also be required to randomly inspect H7-1 root crop fields for bolters and notify the grower if any are detected.

Therefore, no or negligible impacts from gene flow from H7-1 sugar beet root crops to organic vegetable beet would be expected under Alternative 2. Among the sugar beet production areas, organic vegetable beet growers, who may sometimes save their own seed, are concentrated in

California where only conventional sugar beet is grown. The proposed GE-free zone formally precludes the growing of H7-1 sugar beets in California, where a significant organic vegetable beet crop is also produced, and further reduces the potential for any impact.

Alternative 3. Under this Alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 roots under APHIS requested conditions. The impacts of this Alternative on US vegetable beet production would be identical to those for Alternative 2.

Preferred Alternative. Under this Alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 roots under compliance agreement conditions/restrictions. The impacts of this Alternative on US vegetable beet production would be identical to those for Alternative 2.

In summary, Alternative 1 will is expected to have no more than a minor impact on vegetable beet crop production derived from lack of availability or increased cost of herbicides. Alternatives 2, 3 and the Preferred Alternative are anticipated to have no or negligible impacts on producers of vegetable beet crops.

Sugar Beet Roots

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Based on all available information, there is essentially no organic sugar beet production in the US. All commercial sugar beet grown in the US is processed into sugar at one of the 22 US beet sugar processing facilities, none of which process organic sugar beets. Organic sugar beet production is therefore not discussed below.

Alternative 1. Under this Alternative, H7-1 is fully regulated and seed of H7-1 may not be planted for any purpose. The impacts to sugar beet root crop production derive primarily from the predicted 37% shortage of conventional seed. The impact of this seed shortage on US beet sugar processors was discussed above in the Affected Environment section. If H7-1 seed is not available in 2011, at least eight beet processing facilities are expected to go idle (Sexton, 2010). If the H7-1 seed remains unavailable in 2012, these facilities would lead to permanent closure of numerous facilities, fully eliminating sugar beet production from two or three of the current sugar beet producing regions. This could lead to an expansion of the sugar beet acreage in the surviving regions and/or the absorption of beet sugar processing capacity from the failed regions. The root production conditions proposed in Alternative 1 (allowing no H7-1 derived varieties) would result in major financial impacts on sugar beet producers.

Alternative 2. Under this Alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Under this Alternative, APHIS issues permits with conditions for the production of H7-1 sugar beet roots

The permit conditions imposed by APHIS on sugar beet root crop production will increase the compliance costs incurred by beet sugar processors. Specifically, the condition requiring beet sugar processors to randomly inspect fields for bolters, along with the associated record keeping requirements, will likely result in additional costs due to the need for additional staff to conduct these activities.

Since permits will be required, this alternative has some potential to impact beet sugar processors in that they will be obligated to apply for the permits in an appropriate time frame and with accurate information. That is, if a beet sugar processor were to submit untimely applications to APHIS, or to submit applications which require significant additional information or review under NEPA, the issuance of the permits could delay the planting of the sugar beet crop. Delays in planting generally reduce final yields. Additionally, beet seed processors that utilize consultants to obtain APHIS permits may incur additional incremental costs.

Alternative 3. Under this alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 seed under APHIS requested conditions. The impacts of this alternative on US sugar beet crop production would be quite similar to those for Alternative 2, with the exception of the potential impacts that derive from the obligation of beet sugar processors to obtain APHIS permits.

Preferred Alternative. Under this Alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 roots under compliance agreement conditions/restrictions. The impacts of this Alternative on US sugar beet production would be similar to those for Alternative 2.

In summary, Alternative 1 is expected to result in dramatic changes to regional sugar beet production. Sugar beet production would cease in some current production regions, and could potentially increase in the surviving production regions. In contrast, Alternatives 2, 3 and the Preferred Alternative are anticipated to have no or negligible impact on the socioeconomic environment of sugar beet root crop production.

d. Environmental Effects on Choice of Varieties Available to Sugar Beet Growers

APHIS Conditions for Seed and Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Seed of H7-1 may not be planted for any purpose. This alternative impacts the socioeconomic environment of grower choice by limiting that choice to conventional varieties. The ability to purchase seed of the most productive varieties has been removed and in many cases, sugar beet growers will be forced to choose between growing less desirable conventional varieties or not growing sugar beets at all.

Alternative 2. Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. This alternative maintains the same level of choice of varieties that sugar beet growers have had from their processer, which may include both conventional and H7-1 derived varieties.

Alternative 3. Under this alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 seed under APHIS proposed conditions. The impacts of this alternative on the choice of varieties available to sugar beet farmers are identical to those for Alternative 2.

Preferred Alternative. Under this Alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 roots under compliance agreement conditions/restrictions. The impacts of this alternative on the choice of varieties available to sugar beet farmers are identical to those for Alternative 2.

In summary, Alternative 1 will restrict US sugar beet growers' choices about which varieties they can plant in 2011. Specifically, they will be prevented from choosing the H7-1 varieties that the majority of them would prefer to plant and may not have suitable conventional varieties to plant. In contrast, Alternatives 2, 3 and the Preferred Alternative will have no or negligible impact on the choice of varieties available to US sugar beet growers.

e. Environmental Effects on Coexistence of GE and Conventional Crops

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated and seed of H7-1 may not be planted for any purpose. Coexistence refers to the "concurrent cultivation of conventional, organic, and genetically engineered (GE) crops consistent with underlying consumer preferences and choices" (USDA, 2008). Under this alternative, coexistence would not occur since only conventional beet seed and organic beet seed could be legally produced.

Alternatives 2. Under this alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Under this alternative, APHIS issues permits with conditions for the production of H7-1 sugar beet roots.

Choices of GE or Organic Production for Growers. The proposed permit conditions described in the Alternatives Considered section are designed to promote coexistence for the three types of production. First, by creating a geographic isolation between nearly all the chard and table beet seed production and H7-1 production, it is expected that all the vegetable seed from these zones will meet the most stringent demands of the GE sensitive market. Second, gene flow into the vegetable beet crop seeds has never been detected and these conditions ensure that vegetable beets will continue to have undetectable levels of the H7-1 gene. Organic vegetable beet producers will coexist with other production systems and both growers and consumers will have clear choices for a preferred genetic background for vegetable beets. However, in a limited number of cases, some growers of sugar beet seed within a four-mile isolation zone of vegetable seed production may not be able to produce their crops on sites which they may have farmed previously. Third, in the limited area where sugar beet seed and vegetable seed production overlap, measures are proposed that are expected to keep cross pollination to non detectable levels.

APHIS establishes in this EA that the conditions proposed for growing H7-1 sugar beets are sufficiently rigorous to prevent any significant level of GE admixture to organic vegetable beet seed. If any admixture were to occur, substantial numbers of US buyers of organic produce have agreed to accept small quantities of admixture as nevertheless "organic" as long as the producers have followed all USDA required processes (*see* Non-GMO Project website). Any buyers who refuse to purchase organic products because of the possibility of genetic admixture, in the absence of actual genetic proof of such, are within their rights as buyers, but demonstrate the likely future arbitrariness in their future relationships with growers of organic seed. Legal definitions, and buyer definitions of "organic" do not prevent sales of crops with small genetic admixtures to be accepted in the marketplace, and APHIS cannot demonstrate any harms in the mere suggestion that some buyers may discriminate against potential (an unlikely one) for substantial admixture (*see* multiple public comments by vegetable seed producers, who rate perception of admixture by buyers as more important than actual numbers of admixed seeds in a vegetable beet seed sample).

The impacts of confinement measures are largely borne by the sugar beet seed producers but Alternative 2 would allow sugar beet production and the industry built around it to continue to operate at its previous level of economic activity. While many of the measures proposed in Alternative 2 are similar to industry standards in intensively farmed areas where both types of systems may exist (Willamette Valley), Alternative 2 goes beyond these standards in imposing conditions in new areas, requiring new geographic separation of *Beta* crops, and establishing mandatory compliance with standards that will be ensured by APHIS inspection and third party auditing. If concerned about the GE sensitive market, the vegetable beet seed producers in the area of overlapping production may decide to test their seeds to verify they meet their production standards. Accordingly, Alternative 2 is expected to increase the harmonious coexistence of GE sugar beet seed, conventional vegetable beet seed and organic vegetable beet seed production systems, although with some impacts on sugar beet seed producers in areas where both sugar beet and vegetable beet crops coexist. Alternative 1 would have far greater impacts on sugar beet producers than would Alternative 2 or 3.

Alternative 3. Under this alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 seed under APHIS proposed conditions. The impacts of this alternative on coexistence of the three types of beet seed production would be identical to those for Alternative 2.

Preferred Alternative . Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

In summary, Alternative 1 negatively impacts the socioeconomic environment of coexistence by prohibiting the production of GE sugar beet seed. In contrast, Alternatives 2, 3 and the Preferred Alternative serve to promote the coexistence of GE and organic beet seed production.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated and seed of H7-1 may not be planted for any purpose. Since H7-1 seed cannot be used to plant the sugar beet root crop, coexistence would not occur since only conventional beets and organic beets could be grown.

Alternative 2. Under this alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Under this alternative, APHIS issues permits with conditions for the production of H7-1 sugar beet roots.

As indicated in the Affected Environment section, there is little or no overlap of H7-1 root crop production and vegetable beet production. If there exist vegetable beet seed savers in the regions of sugar beet root crop production (none have been identified), the permit conditions proposed for removing bolters and related stewardship render the potential for genetic transmission from H7-1 negligible. Furthermore, the seed crop and bolters from the root crop do not overlap in flowering time. Therefore, this alternative would be expected to have no or negligible socioeconomic impacts on vegetable beet crops. Therefore, Alternative 2 serves to enhance the coexistence of GE sugar beet and organic vegetable beet crop production.

Alternative 3. Under this alternative, APHIS grants the petition request for partial deregulation, allowing planting the 2011 sugar beet root crop with H7-1 seed under APHIS proposed conditions. The impacts of this alternative on coexistence of the three types of beet crop production would be identical to those for Alternative 2.

Preferred Alternative. Under this Alternative, APHIS grants the petition request for partial deregulation, allowing production of H7-1 roots under compliance agreement conditions/restrictions. The impacts of this alternative on coexistence of the three types of beet crop production would be identical to those for Alternative 2.

In summary, coexistence would not occur under alternative one and is enhanced under Alternatives 2, 3 and the Preferred Alternative.

f. Environmental Effects on Cost of Maintaining and Producing GE-Free Organic Vegetable Beet Seed

Alternative 1. Under this alternative, H7-1 seed may not be produced for any purpose. Therefore, organic vegetable beet seed producers would not incur any costs in order to maintain GE-free seed stocks or to screen commercial seed production for GE presence.

Alternative 2, 3 and Preferred Alternative. In the case of organic seed production, the grower has two distinct considerations: (1) maintenance of GE-free seed stocks; and (2) minimizing the GE content of commercial seed products. All certified organic seed producers must have an organic system plan in place which includes how they will minimize GE presence in their seed production.   Therefore, any certified organic vegetable beet seed growers in Oregon have already considered and implemented appropriate methods to minimize the GE content in their products.

The best way to maintain GE-free seed stocks is to produce the seed stocks as a separate operation from the commercial production. For cross-pollinated crops, most seed companies produce stock seed with greater care and greater isolation than that used for commercial seed production. Since seed stock increases require much less land than commercial seed production, they are often placed in fields that are buffered by landscape features such as trees, increasing the level of purity obtained. Saving commercially produced seed for use as stock seed is ill advised since any reduction in purity is carried on to future generations of seed production. Screening all new seed stocks for GE content is the best way for organic seed producers to ensure that their commercial seed production is planted with GE-free seed. The costs and methodologies for screening were reviewed and discussed above in the Affected Environment section.

In the case of commercial seed, a sampling strategy (ex. Seedcalc) is required in order to conduct a trait screen.   The result of the trait screen is statistical. For example, the result may be 99% confidence that the GE content of the seed lot is less than 0.05%. It is not possible to conclude that any seed lot is 100% GE-free. However, since the NOP is process based, there is no legal requirement that any organic seed lot be tested for GE content; the NOP allows for low level GE presence in certified organic seed. In some cases the customers of the organic seed producer have zero tolerance for GE content. This is quite unfortunate since zero tolerance may be incompatible with coexistence between organic and GE seed producers. Any additional testing for GE content required by such customers is a component of the business relationship between the seed producer and the customer. Organic seed has a significant premium over conventional seed and such testing for GE content then becomes a required component of obtaining the premium. The cost to the seed producer is a function of the level of GE presence they wish to detect; a single $300 test will reveal GE presence above 0.5% with 99% confidence. To screen for lower levels of GE presence would not necessarily cost more, but would require a larger sample size to be submitted to the seed testing firm.

In summary, under alternative 1, organic vegetable seed producers would incur no additional costs to maintain GE-free seed stocks or to minimize GE presence in their commercial seed production. Under alternatives 2, 3 and the Preferred Alternative, organic seed producers would incur modest costs to maintain GE-free seed stocks and to screen commercial seed production for GE presence.

g. Environmental Effects on Applicant Costs

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under the No Action Alternative, all importation, interstate movements, and environmental releases of H7-1 sugar beets for seed or root production after August 13, 2010 would be prohibited so there would be no impact on applicant costs for permits.

Alternative 2. Similar to Alternative 3, certain conditions would be imposed by APHIS, but done with permits as opposed to a combination of administrative orders and other regulatory schemes. Under Alternative 2, growers would need to apply to APHIS for permits to grow either sugar beet seed crops or root crops. Time and expertise are needed to obtain APHIS permits, and some of the seed companies (and processors for beet production) would likely be first time customers for APHIS. In the event that the production conditions were made mandatory in the context of permits, record keeping for all critical procedures identified by APHIS' conditions would be needed. Because third party auditors would be required under the permits, a cost for the service would also be mandatory. Since Alternative 2 has the same practical impact on the affected parties as Alternative 3, its economic impact is identical.

Alternative 3. Under this Alternative, APHIS would grant partial deregulation of H7-1 sugar beet seed crops or root crops and Monsanto/KWS would provide monitoring and compliance to those technology users who agree to produce H7-1 and abide by the APHIS requested conditions of its production. Record keeping for all critical procedures identified by Monsanto/KWS would be needed and third party auditors would also be required, so that a cost for the service would also be mandatory.

Preferred Alternative. Under this alternative, APHIS issues permits with conditions for the production of H7-1 seed. Because the conditions are identical in Alternatives 2 and the Preferred Alternative, the environmental consequences are the same.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

The analysis of applicant costs would be the same as those corresponding to Alternatives 1, 2, 3 and the Preferred Alternative for Applicant Costs in Seed Production above.

h. Environmental Effects on Availability of Alternative Herbicides

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, most growers may decide to grow conventional crops, since Roundup tolerant sugar beets will not be available. A different set of production practices and herbicides will be needed. A survey of manufacturers regarding the availability of seven of the most important herbicides for conventional sugar beets was conducted. The survey revealed that for several herbicides, substantial shortages existed or lack of production was discovered. If production was to be restarted for some of those examined, up to 10 months may be needed. In other cases, a decision to produce the herbicide would need to be made on the basis of the likely size of the conventional crop. Because grower production of a conventional sugar beet crop or its possible size is uncertain, decisions to produce these herbicides would be uncertain. Some of these principle herbicides are also used in other crops (such as Stinger and Outlook), and beet sales are only a small part of a larger market, so these would be readily available to growers. Under Alternative 1, growers of conventional sugar beets in 2011 would find some herbicides unavailable that typically had been used in their regions. However, options for some sugar beet herbicide exist for growers, but may these may not have been assessed for use in specific areas, including details of rate, date of application or effectiveness. Herbicides unavailable for the 2011 growing season may be available for the 2012 season, subject to decisions of agricultural pesticide producers. Herbicide manufacturers may be incentivized to produce herbicide inventory at the expense of the sugar beet processors. If growers don't plant conventional sugar beet seed because varieties are unavailable or they choose to plant alternative crops, herbicide manufacturers may incur losses from excess inventory.

With a change to conventional seed, and to different herbicides, growers would need to use different spray application equipment to apply the herbicides. From public comments, many growers informed APHIS that they had sold this equipment, and would need to repurchase sprayers because their glyphosate sprayers were purchased for 'over the top' applications, not application between rows. Additionally, cultivators that had been previously used between rows would need to be purchased, since these had also been sold after the growers began to use Roundup Ready crops.

<u>Alternatives 2, 3 and the Preferred Alternative.</u> Under this alternative, growers would continue planting and producing H7-1 sugar beets. Glyphosate herbicide will be used for a major portion of weed control for these plantings. In contrast, choosing Alternative 1 will invoke uncertainties in herbicide supply and possibly concerns for the appropriateness of replacement herbicides in some regions. Based on the lead time needed for herbicide production, manufacturers may

already have committed to restarting or increasing herbicide production. If they have done so, they may incur losses from excess inventory if Alternatives 2, 3 and the Preferred Alternative are chosen. If the manufacturers have not recently decided to provide the formerly used herbicides for the conventional sugar beet production, herbicide manufacturers will not be impacted by Alternatives 2, 3 or the Preferred Alternative.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. The impacts of these conditions on herbicide availability are the same as those that are discussed for Alternative 1 in the Seed Production Conditions section above.

Alternatives 2, 3 and the Preferred Alternative. The impacts of these conditions on herbicide availability are the same as those that are discussed for Alternatives 2, 3 and the Preferred Alternative in the Seed Production Conditions section above.

i. Environmental Effects on Consumer Preference for Non-GE Sugar

APHIS Conditions for Seed and Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, no H7-1 sugar beets could be planted, and no sugar derived from these beets would be available. US domestic sugar would be in short supply and consumers would pay increased prices for sugar that was imported. Sugar from only conventional sugar (cane source) and organic would be available but subject to expected increased costs because of the shortage of beet-derived H7-1sugar (See Economic Issues: Sugar Marketing).

Alternatives 2, 3 and the Preferred Alternative. Under these alternatives, full production of domestic sugar allotments of beet sugar would be met, attaining to the levels adequate for US domestic supplies. For consumers that desire non GM or organic sugar, food suppliers exclusively use cane sugar is used (Pierson, 2010), since almost all sugar beets are GM (95%) and only a small amount of sugar is available from conventional beets (5%). Sugar beet processors do not segregate conventional and GM beets and beet sugar is never produced as organic (Pierson, 2010). No possibility exists for inadvertent mixing of sugar from GM beets and organic sugar from cane sources; cane and beet sugar are processed in plants that are separated by hundreds of miles. Sugar is distributed to the customers directly, including industrial and food packagers, and consequently, no mixing of processors products can occur (Pierson, 2010). Furthermore, there is currently no market in the US for organic sugar beets (Pierson, 2010), and in any event, sugar from conventional beets does not differ chemically or in any other way from the sugar from H7-1 beets (Hoffman, 2010a). Organic sugar derived from sugar cane may be imported into the US, and besides being grown under organic farming conditions, may also be processed without addition of chemicals if sold as "first crystallization" sugar (Willerton, 2008). Under this alternative, full availability of organic sugar will be maintained for consumers, offering a choice between GM and non GM or organic sugars. Under Alternative 1, although no change would occur in availability of organic sugar, the production of sugar for the remainder of the market would be highly impacted, with price increases for all sugar users and consumers and loss of business for growers and processors.

j. Environmental Effects on Restrictions/labeling Requirements by Some Countries on GE Products

APHIS Conditions for Seed and Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under this alternative, H7-1 is fully regulated pending the completion of the EIS required for deregulating this trait. Seed of H7-1 may not be planted for any purpose. Not allowing the planting H7-1 Roundup Ready® sugar beets will have a limited effect on US sugar exports; export of sugar and sugar byproducts will either decrease marginally or remain unchanged. Due to the lack of availability of non-GMO seed and the increased cost of weed control (see Affected Environment section), sugar production in the US is expected to dramatically decrease in 2011. With a decrease in US production, import of foreign sugar must increase to meet domestic demand. Currently the US imports one-fifth of its sugar, yet there is still a relatively constant export market for sugar and sugar byproducts (USDA ERS, 2010b; USDA NASS, 2008; Baucum and Rice, 2009). Exporters may choose to capitalize on increased domestic demand, and the increased price of sugar, by selling to local markets. However it is more likely, given the current import and export figures, that exporters will maintain existing trade obligations preserving current export projections.

With the deregulation of H7-1 there was concern that the domestic sugar industry would be negatively affected by trade restrictions on GE products. Some foreign countries restrict the import of genetically modified organisms or require labeling of products with GE content. Removal of genetically modified sugar beets from US production is unlikely to increase total sugar exports. Currently the primary export markets for domestic sugar, Canada and Mexico, both allow the import of GE sugar beet products without restriction (USDA FAS, 2004; USDA FAS, 2007; Schumacher et al., 2010), as do the European Union, Mexico, South Korea, Australia, New Zealand, Columbia, Russia, China, Singapore, and the Philippines (USDA APHIS, 2010; GM Crop Database, 2008). Prior to deregulation of H7-1, total US sugar production, was approximately 7.65 million MT (2000/2001 season) (USDA FAS, 2004). In 2000/2001 sugar exports totaled 113,000 MT, roughly 1.4% of total sugar production. In 2009, four years after deregulation of H7-1, total US sugar production was 7.8 million MT, of which 57% was beet sugar (Schumacher et al., 2010). Sugar exports in 2009 totaled 136,000 MT, or 1.7% of total production (Schumacher et al., 2010). Based on these figures there was a limited effect on export markets due to the deregulation of H7-1 sugar beets. Similarly the export of sugar beet pulp has also remained constant between 2000 (581,698 MT) and 2009 (453,140 MT) (USDA ERS, 2010b).

<u>Alternatives 2, 3 and the Preferred Alternative.</u> Under these alternatives, there would likely be no effect on the export of sugar beet products. As previously stated, US export of sugar is nominal, approximately 1-2% of total production, and has not changed significantly in 10 years. The main export markets for US sugar, Canada and Mexico, already allow the import of H7-1 sugar beets without restriction, as do three of the main sugar importing countries China, Japan, and Russia (USDA APHIS, 2010; GM Crop Database, 2008).

3. Physical Environment

a. Environmental Effects on Land Use

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, no plantings of H7-1 sugar beet would be allowed by APHIS. Since sugar beet growers can and do also grow other crops, those who would have grown H7-1 sugar beets would likely still use the land for agriculture production. A number of factors may influence this decision, including availability of herbicides for conventional sugar beets, availability and cost of specialty cultivating equipment, availability of desirable varieties of sugar beet or other crops, and the potential penalty or lost ownership shares in the cooperative for not growing sugar beets. In the short term, Alternative 1 could potentially result in a large decrease in sugar beet production though significant changes in land use would not be expected.

Growers do move their sugar beet crop to different locations on their properties as part of crop rotation strategies (see Production of Sugar Beets), but movement to new production sites is limited because co-ops or processors assign these grower allocations to members according to individual investments in the processing operation. Increasing allocations of sugar beet production and marketing authority to states and to "new entrants" requires federal application and approvals, and new production cannot exceed 1.67% of average US sugar production between 1998 through 2000 (Dean, 2006; 7 U.S.C. § 1359dd(b)(2)(H)). Requests for such increases may not be granted since the President of CCC (with appeal rights to an Administrative Law Judge) make these allocations, in consideration of existing producers whose allocations would need to be correspondingly reduced (CCC, 2005; 7 CFR PART 1435—Sugar Program).

Additionally, if growers decide to produce conventional sugar beets or other crops, as an alternative to H7-1 sugar beets, there is the increased probability that farmers would also determine to use methods of herbicide control that are more destructive to agricultural land compared to current practices. For example, if growers initiate more aggressive tillage practices for weed control, this could result in added erosion and nutrient leaching, which will in turn diminish the soil resources and land value (Sharpley, 1985). Growers may also opt to leave agricultural land fallow or the land may be used for non-agricultural purposes, depending on economic and other considerations.

Alternatives 2, 3 and the Preferred Alternative. Choices seed growers made over the previous three growing seasons would be unchanged with the authorized planting of H7-1 under these alternatives. The continued cultivation of H7-1 under these alternatives is not expected to change current patterns of land use nor is soil quality from cultivation of H7-1 expected to change.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. As discussed in Seed Production above, the current production regime, established mainly by producers, processors, and government regulatory agencies, cooperates to keep sugar production and acreage relatively stable from year to year. However, production of conventional sugar beet would be accompanied in some locations with conventional tillage, and the benefits of conservation tillage that are possible with a glyphosate tolerant sugar beet variety would be lost.

Alternative 2, 3 and the Preferred Alternative. The same conditions apply as in the impacts discussed in the Seed Production Conditions above. These Alternatives would not lead to increased sugar beet acreage beyond those already existing or alter where sugar beet is grown. Under Alternative 1, growers will produce conventional sugar beet and some would need to go back to increased tillage to control weeds. Soil quality under the No Action Alternative could decline and erosion could increase compared to Alternatives 2, 3 and the Preferred Alternative.

b. Environmental Effects on Air Quality and Climate Change

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, plantings of H7-1 sugar beet would not be allowed. An increase in the use of conventional tilling could be expected under Alternative 1, especially if growers would choose to plant conventional sugar beets which is likely. If growers do choose other crops or leave the land fallow, the effects on air quality would vary. Emissions related to global warming, ozone depletion, summer smog and carcinogenicity, among others, were found to be lower in glyphosate-tolerant crop systems compared to conventional crop systems (Bennett et al., 2004). Alternative 1 would be expected to have greater negative impacts on air quality and climate, if growers planted conventional sugar beets rather than H7-1 sugar beets. In a study of conventional compared to glyphosate tolerant sugar beets in Idaho, the genetically engineered sugar beets required fewer cultivation passes, fewer herbicide applications, and less fuel, with an estimated 38.6 pounds less of carbon dioxide released per acre (Hirnyck and Morishita, 2006). Therefore, Alternative 1 would be expected to have potentially greater impacts on air quality and climate than would Alternative 2 or 3, especially if growers planted conventional sugar beets rather than H7-1 sugar beets.

Alternatives 2, 3 and the Preferred Alternative. Under these Alternatives, growers who have produced H7-1 sugar beet seed in the past would very likely continue to plant H7-1 sugar beets. The use of H7-1 sugar beets may result in additional increases in conservation tillage, as discussed in the Affected Environment section because changing to conservation tillage (CT) practice has been a gradual process; CT often requires different management practices and often new planting and applicator equipment. Additionally, growers using glyphosate on H7-1 crops obtain more effective weed control with fewer herbicide applications compared to the conventional crop (Hirnyck and Morishita, 2006). The consequences of fewer field passes are reductions in greenhouse gases from farm machinery (Bennett et al., 2004). Therefore, Alternatives 2, 3 and the Preferred Alternative may lead to a small but positive impact on both air quality and climate relative to Alternative 1.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. The consequences of Alternative 1 on air quality and climate for root production are not different from those of seed production conditions above. Conventional sugar beet seed production would have greater likelihood of negative impacts on air quality and climate.

Alternatives 2, 3 and Preferred Alternative. The consequences of Alternative 2, 3 and the Preferred Alternative on air quality and climate for root production are not different from those of seed production conditions above, except the benefits would be larger, since acreage of sugar beet root production is much greater than that of seed production. Because of possible increases in conservation tillage and fewer passes with herbicide sprayers Alternative 2, 3 and Preferred Alternative would present positive benefits for climate and air quality.

c. Environmental Effects on Surface and Ground Water Quality

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, growers will likely plant conventional sugar beet to replace the glyphosate tolerant H7-1 derived varieties that is enjoined from production, or they may choose to grow other crops, and both decisions may result in indirect negative impacts on water quality. Herbicides used on conventional sugar beets are likely to cause more environmental concerns than does glyphosate (for impacts of these herbicides, see Weed Management section of Affected Environment; Monsanto/KWS 2010) Of eight herbicides used in sugar beet production cited in one Idaho study, glyphosate had the lowest Environmental Impact Quotient (Hirnyck and Morishita, 2006). Using a modeling program, this study also showed that two of eight sugar beet herbicides had a greater risk of leaching into groundwater, and five had a higher risk of runoff into surface waters. In another study using glyphosate tolerant soybeans, direct measurements have shown that runoff of glyphosate does not exceed health advisory levels or maximum contaminant levels while those of other herbicides used in soybean production may exceed those levels (Shipitalo, 2008). If conventional sugar beets replace the H7-1 derived varieties, herbicide runoff may increase concerns for environmental safety in surface waters.

Alternatives 2, 3 and Preferred Alternative. Glyphosate tolerant crops such as H7-1 which allow use of glyphosate as an herbicide facilitate the use of conservation tillage farming practices (USDA ERS, 2009a). Generally, the use of glyphosate tolerant crops has allowed a more effective and less costly weed control regime compared to other cropping systems (USDA ERS, 2009a; Gianessi and Carpenter, 1999).

The impact of conservation tillage (including no-till, ridge-till, and mulch-till) in controlling soil erosion and soil degradation is well documented (Edwards, 1995; Sandretto, 1997). By leaving substantial residues of plant matter on the soil surface, conservation tillage 1) reduces soil erosion by wind; 2) reduces soil erosion by water; 3) increases water infiltration and moisture retention; 4) reduces surface sediment and water runoff; and 5) reduces chemical runoff (USDA ERS, 2009a).

Glyphosate may potentially be found in surface water runoff when erosion conditions lead to the surface transport of particles. However, glyphosate tolerant crops typically lead to an increase in conservation tillage and no-tillage systems, which results in less mechanical disturbance of the soil during sugar beet cultivation, decreasing the loss of surface soil. Because of this, and the fact that glyphosate binds strongly to soil particles, no-tillage and conservation tillage are expected to further reduce any concerns of herbicide surface water runoff (Wiebe and Gollehon, 2006). Because of the adsorptive properties of glyphosate onto soil minerals, expectations are for only limited leaching of glyphosate in most soils, though sandy and high porosity soils may be exceptions (Borggaard and Gimsing, 2008). Adverse impacts to surface water or groundwater are not anticipated and the consequences of H7-1 planting are likely beneficial when compared to Alternative 1.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. No differences of impacts to water resources are expected from conditions assigned to root production than to seed production.

Alternatives 2, 3 and Preferred Alternative. No differences of impacts to water resources are expected from conditions assigned to root production than to seed production.

4. Human Health and Worker Safety

a. Environmental Effects on Consumer Health and Safety

APHIS for Conditions for Seed Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, conventional sugar beets would be grown instead of H7-1 sugar beets, and the alternative herbicides typically used on these would replace glyphosate. Potential impacts to consumers may be greater under Alternative 1 compared to Alternatives 2, 3 and the Preferred Alternative because of the use of herbicides with higher toxicities. Sugar beet seeds are not consumed and roots may contain translocated glyphosate, but extracted, purified sugar will not contain the herbicide. Therefore there would be no direct impacts of herbicides from consumer use or consumption. However, the indirect effects as discussed in Alternatives 2, 3 and the Preferred Alternative below are considered.

Alternatives 2, 3 and Preferred Alternative. Because these alternatives would allow planting of glyphosate tolerant sugar beets, APHIS considered the possibility of increased exposure to glyphosate. The general public is not at a high risk of exposure to substantial levels of glyphosate under typical use conditions (US EPA, 1993; USDA FS, 2003). According to the EPA Glyphosate Fact Sheet (1993) glyphosate is of relatively low oral and dermal acute toxicity and has been placed in Toxicity Category III for these effects (Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). The acute inhalation toxicity study was waived by EPA because glyphosate is nonvolatile and available adequate inhalation studies with end-use products show low toxicity.

The use of glyphosate herbicide does not appear to result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals. Under present and expected conditions of use, glyphosate herbicide does not pose a health risk to humans (US EPA, 1993).

Additionally, the nature of glyphosate residue in plants and animals is adequately understood, and studies with a variety of plants indicate that uptake of glyphosate from soil is limited. The material that is taken up is readily translocated throughout the plant. In animals, whether ingested or absorbed most glyphosate is essentially not metabolized and is rapidly eliminated in urine and feces. Enforcement methods are available to detect residues of glyphosate in or on plants. EPA conducted a dietary risk assessment for glyphosate based on a worst-case risk scenario, that is, assuming that 100% of all possible commodities/acreage were treated, and assuming that tolerance-level residues remained in/on all treated commodities. Based on the assessment, EPA concluded that the chronic dietary risk posed by glyphosate food uses is minimal (US EPA, 1993).

The addition of another glyphosate tolerant (GT) crop to agricultural production may lead to a greater chance that a GT crop, including GT sugar beets may be grown near other food crops.

This could lead to higher exposure to glyphosate in the diet of the general public because there would be a greater chance for glyphosate residue to reach food crops via spray drift.

Nonetheless, such increase risk of exposure to glyphosate residue will not result in increased risks to the general population because the current upper estimates of risk are based on highly conservative fruit and vegetable intake rates with an assumed high estimated amount of glyphosate residue. Glyphosate is registered for use as a direct application to weeds in several fruits and vegetables and tolerances are established in the consumable commodities of these crops. The current aggregate dietary risk assessment completed by EPA concludes there is no concern for any subpopulation regarding exposure to glyphosate, including the use on many fruits and vegetables and GT sugar beet (71 FR 76180, 2006). Moreover, the potential exists for decreases in the applications and subsequent residues of more toxic herbicides if GT sugar beet is deregulated.

Under Alternatives 2 and 3, potential impacts to consumers may be reduced because of the reduced use of herbicides with higher toxicities (USDA APHIS, 2009). Based on the scientific evidence provided in the Affected Environment section, food and feed derived from H7-1 sugar beets have been shown to be equivalent to food and feed derived from conventional sugar beets.

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, the potential for impacts to consumers may be greater than with Alternatives 2, 3 and Preferred Alternative because of the use of herbicides with higher toxicities. There would be no impacts from consumer use and consumption of H7-1 sugar beets and by-products. The main food use of sugar beet is for the extraction of sucrose from sugar beet roots through a process involving hot water extraction, followed by purification, evaporation, and centrifuge separation of sucrose crystals (granular sugar). Refined sucrose does not contain protein or other genetic material. There would be no risk from eating refined sugar from Roundup Ready® sugar beets. Aside from sugar, the other products from sugar beets (molasses and pulp) are not major consumer items and can easily be avoided by consumers who do not wish to be exposed to GE products. As discussed above, there is no detectable DNA in processed sugar; however, consumers who wish to avoid all products derived from GE crops can purchase cane sugar rather than beet sugar. While processed foods, the situation is similar to that for corn and soy products: even without H7-1, it would be very difficult for a consumer to avoid products derived from GE crops.

Alternatives 2, 3 and Preferred Alternative. Under these alternatives potential impacts to consumers may be reduced because of the reduced use of herbicides with higher toxicities (USDA APHIS, 2009). Based on the scientific evidence provided in the Affected Environment section, food and feed derived from H7-1 sugar beets have been shown to be equivalent to food and feed derived from conventional sugar beets.

b. Environmental Effects on Worker Safety

APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or Preferred Alternative

Alternative 1. Under Alternative 1, growers will plant conventional sugar beet varieties and use herbicides effective on these crops. The potential for impacts to field workers may be greater than with Alternatives 2, 3 and the Preferred Alternative because of the potential increase in the use of herbicides with higher toxicities (See Table 11).

Alternatives 2, 3 and Preferred Alternative. Under Alternative 2, 3 and the Preferred Alternative, field workers would be exposed to increased glyphosate and to decreased herbicides with higher toxicities (See Table 11) when compared to exposures under Alternative 1.

According to the RED document for glyphosate (US EPA, 1993), glyphosate is of relatively low oral and dermal acute toxicity. For this reason, glyphosate has been assigned to Toxicity Categories III and IV for these effects (i.e., Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). An acute inhalation study was waived by EPA because glyphosate is a non-volatile solid, and the studies conducted on the end-use product formulation are considered sufficient (US EPA, 1993). Expert toxicological reviews from US EPA (1993) and the World Health Organization (WHO, 2005) are in agreement that glyphosate does not pose any human acute exposure concerns for dietary exposures and thus negated the need to establish an acute reference dose.

With regard to subchronic and chronic toxicity, one of the more consistent effects of exposure to glyphosate at high doses is reduced body weight gain compared to controls. Body weight loss is not seen in multiple subchronic studies, but has at times been noted in some chronic studies at excessively high doses $\geq$ 20,000 ppm in diet (WHO, 2005). Other general and non-specific signs of toxicity from subchronic and chronic exposure to glyphosate include changes in liver weight, blood chemistry (may suggest mild liver toxicity), and liver pathology (USDA FS, 2003). Glyphosate is not considered a carcinogen; it has been classified by EPA as a Group E carcinogen (evidence of non-carcinogenicity for humans) (US EPA, 1993).

EPA has considered in its human health analysis the potential applicator and bystander exposure resulting from increased glyphosate use. Based on the toxicity of glyphosate and its registered uses, including use on glyphosate-tolerant crops, EPA has concluded that occupational exposures (short-term dermal and inhalation) to glyphosate are not of concern because no short-term dermal or inhalation toxicity endpoints have been identified for glyphosate (71 FR 76180, 2006).

Additional evidence to support the EPA conclusion can be found in the *Farm Family Exposure Study*, a biomonitoring study of pesticide applicators conducted by independent investigators (Acquavella et al., 2004). This biomonitoring study determined that the highest estimated bodily adsorption of glyphosate as the result of routine labeled applications of registered glyphosate-based agricultural herbicides to crops, including glyphosate-tolerant crops, was approximately 400 times lower than the Reference Dose (RfD) established for glyphosate. Furthermore, investigators determined that 40% of applicators did not have detectable exposure on the day of application, and 54% of the applicators had an estimated bodily adsorption of glyphosate more than 1000 times lower than the RfD (Acquavella et al., 2004). Use patterns and rates for glyphosate tolerant sugar beet are typical of most glyphosate agronomic practices. Therefore, the deregulation of glyphosate-tolerant sugar beet would not significantly increase the exposure risk to pesticide applicators.

Finally, the biomonitoring study also found little evidence of detectable exposure to individuals on the farm who were not actively involved in or located in the immediate vicinity of labeled applications of glyphosate-based agricultural herbicides to crops. Considering the similarity of the use pattern and application rates of the glyphosate products in this study compared to those registered for use on glyphosate-tolerant sugar beet and glyphosate-tolerant crops in general, bystander exposure attributed to the use of glyphosate on glyphosate-tolerant crops is expected to be negligible. Therefore, the use of currently registered pesticide products containing glyphosate in accordance with the labeling will not pose unreasonable risks or adverse effects to humans or the environment. In general, the herbicidal activity of glyphosate is due primarily to a metabolic pathway that does not occur in humans or other animals, and, thus, this mechanism of action is not directly relevant to the human health risk assessment. EPA considers glyphosate to be of low acute and chronic toxicity by the dermal route of exposure. Glyphosate is considered a Category IV dermal toxicant and is expected to cause only slight skin irritation (USDA APHIS, 2009).

APHIS Conditions for Root Production under Alternatives 1, 2, 3 or the Preferred Alternative

Alternative 1. Under Alternative 1, the potential for impacts to field workers may be greater than with Alternative 2 because of the potential increase in the use of herbicides with higher toxicities (See Table 11).

Alternatives 2, 3 and Preferred Alternative. Under Alternatives 2, 3 and the Preferred Alternative, field workers would be exposed increased glyphosate and reduced herbicides with higher toxicities (See Table 11) when compared to exposures under Alternative 1. For additional details, see Conditions for Seed Production above.

G. T&E Species

Potential Impact on Threatened or Endangered Species

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress, on behalf of the American people, passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the US Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal lists of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, in accordance with the ESA protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action “may affect” listed species or critical habitat. To facilitate APHIS’ ESA consultation process, APHIS met with the USFWS to discuss factors relevant to their effects analysis for petitions for nonregulated status and developed a process for conducting an effects determination (Appendix 4). This process is used by APHIS to assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

As part the environmental review process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis and if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

In following this process, APHIS evaluated the potential effects of approving the environmental release, importation and interstate movement of H7-1 sugar beet for both seed and root production on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas indentified in the Affected Environment section of the EA, APHIS obtained a list of TES species (listed and proposed) for each state where sugar beets could be approved by APHIS and grown for seed production and marketable roots from the USFWS Environmental Conservation Online System (ECOS) (http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp) (accessed September 3, 2010) (Appendix 2). These states included Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming. Although sugar beets are also grown in California, that state was not considered in this analysis because it is outside the geographic scope of the EA.

Potential effects of H7-1sugar beets and agricultural production practices

Sugar beets are in the genus *Beta* and have the ability to cross with several species of wild beets in the same genus, but are not known to cross with any other plant species without human assistance (OECD, 2001). After reviewing the list of TES species in the states where sugar beets are grown, APHIS has determined that H7-1 sugar beet would not be sexually compatible with any listed TES plant or plant proposed for listing, or a host of any TES species because there are no listed species or species proposed for listing in the genus *Beta* or that would use *Beta* species as a host.

To identify negative effects or significant impacts on TES animal species, APHIS evaluated the risks to TES animals from consuming H7-1 sugar beet. Risk is a combination of hazard and exposure. APHIS first conducted hazard identification for H7-1 sugar beet. APHIS assessed the composition and nutritional quality of H7-1 sugar beet, and compared the composition of H7-1 sugar beet to the composition of a non-genetically engineered control sugar beet line and the natural variation found in commercial sugar beet varieties. The data presented in the petition suggests there is no difference in compositional and nutritional quality of H7-1 sugar beet compared to conventional sugar beet, apart from the presence of the enzyme EPSPS (Schneider and Strittmatter, 2003).

The enzyme EPSPS that confers glyphosate tolerance is from the bacterium *Agrobacterium* spp. strain CP4. The gene that produces this enzyme is similar to the gene that is normally present in sugar beets and is not known to have any toxic property. Field observations of H7-1 revealed no negative effects on non-target organisms (Schneider and Strittmatter, 2003). The lack of known toxicity for this enzyme suggests no potential for deleterious effects on beneficial organisms such as bees and earthworms. The high specificity of the enzyme for its substrates makes it unlikely that the introduced enzyme would metabolize endogenous substrates to produce compounds toxic to beneficial organisms.

Even though the likelihood of toxicity is low for the CP4 EPSPS protein, a number of researchers have conducted laboratory investigations with different types of arthropods exposed to genetically engineered crops containing the CP4 EPSPS protein (Goldstein, 2003; Boongird et al., 2003; Jamornman et al., 2003; Harvey et al., 2003). Representative pollinators, soil organisms, beneficial arthropods and pest species were exposed to tissues (pollen, seed, and foliage) from GE crops that contain the CP4 EPSPS protein. These studies, although varying in design, all reported a lack of toxicity observed in various species exposed to these crops (Nahas et al., 2001; Dunfield and Germida, 2003; Siciliano and Germida, 1999). In addition to a lack of toxicity demonstrated by the CP4 EPSPS protein, its potential to be a food allergen is minimal (OECD, 1999).

Since the composition of H7-1 sugar beet is similar to other commercial sugar beet plants with the exception of enhanced levels of the CP4 EPSPS protein, it is unlikely that H7-1 sugar beet poses a hazard to TES animal species. If no hazards are identified, then the risk of H7-1 sugar beet harming TES animal species is also unlikely, regardless of exposure.

The Food and Drug Administration (FDA) published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (US FDA, 1992). The FDA's policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Consistent with its 1992 policy, FDA completed the consultation for H7-1 sugar beet on August 17, 2004 - Biotechnology Notification File #90 (US FDA, 2004). FDA reached an opinion that "The notifiers conclude that glyphosate tolerant sugar beet H7-1 is not materially different in composition, safety, or other relevant parameters from sugar beet now grown, marketed, and consumed. At this time, based on the notifiers' data and information, the agency considers the notifiers' consultation on glyphosate tolerant sugar beet H7-1 to be complete." In addition, the enzyme EPSPS has received an Environmental Protection Agency tolerance exemption in all raw agricultural commodities (US EPA, 1996).

As part of the ESA analysis, APHIS considered if the new phenotype imparted to H7-1 sugar beet may allow the plant to be grown or employed in new habitats, and especially if it will be able to naturalize in the environment. In doing so, APHIS assessed whether H7-1 sugar beet is any more likely to become a weed than the nontransgenic recipient sugar beet line or other currently cultivated sugar beet. Weediness could potentially affect TES and/or critical habitat if H7-1 sugar beet were to become naturalized in the environment. The assessment considers the basic biology of sugar beet and an evaluation of unique characteristics of H7-1 sugar beet. The parent plant in this petition, *Beta vulgaris* L. ssp. *vulgaris*, is not listed as a weed by the Weed Science Society of America (1992) nor is it listed as a noxious weed species by the US Federal Government (7 CFR Part 360). Occasionally, sugar beets volunteer in fields the year after harvesting. These plants can be controlled by mechanical means or several other registered herbicides beside glyphosate that can be used on sugar beet volunteers (Crop Protection Chemical Reference, 1996). Sugar beets possess few of the characteristics of plants that are notable of successful weeds (Baker, 1965; Keeler, 1989). In trials conducted in the US under permits issued by APHIS, no differences were observed between H7-1 lines and non-transgenic lines with respect to the plants ability to persist or compete as a weed. APHIS considered data relating to plant vigor, bolting, seedling emergence, seed germination, seed dormancy and other characteristics that might relate to increased weediness. No unusual characteristics were noted that would suggest increased weediness of H7-1 plants. Additionally, no characteristics relating to disease or insect resistance that might affect weediness were noted that were consistent over all trial locations. H7-1 sugar beet is still susceptible to the typical insect and disease pests of sugar beet.

APHIS considered the potential for H7-1 sugar beet to extend the range of sugar beet production and also the potential to expand agricultural production into new natural areas. Since H7-1 sugar beet was granted nonregulated status in 2005, it has been extensively commercialized and from 2008 through 2010 accounts for 95% of the sugar beet production in the US (USDA FSA, 2010). Considering that H7-1 sugar beet and its progeny account for such a high percentage of the total area planted with sugar beets, it is reasonable to assume that the preferred alternative will result in H7-1 sugar beet being planted in areas similar to where it was planted prior to the 2009 court order vacating the deregulation decision. However, the genetic transformation does not impart any phenotypic characteristic that would allow for the planting of H7-1 sugar beet in areas unsuitable to sugar beet varieties currently available.

APHIS considered the possible effects that importing and interstate movement of H7-1 under notifications acknowledged by APHIS could potentially have on threatened or endangered species and their critical habitat. Considering the performance standards (packaging/handling requirements) and six specific requirements indentified in 7 CFR Part 340.3 for a regulated article to be imported or moved interstate under notification, APHIS-BRS considers the possibility of exposure from importing or moving a regulated article to be negligible to non-existent (APHIS-BRS ESA Memo July 14, 2010). If there were to be an unintended release resulting in exposure to a threatened or endangered species, the notification qualification criteria helps to ensure that the regulated article would have no adverse effects. In conclusion, H7-1 sugar beet exhibits no known toxicity, will not invade natural areas as a weed, and is not expected to be planted in new lands not already used for agricultural production.

After reviewing possible effects of allowing the environmental release of H7-1 sugar beet in Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming; and the interstate movement and importation of H7-1 sugar beets within and into the US, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS has considered the effect of H7-1 sugar beet production on designated critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other sugar beet varieties. Based on these factors, APHIS has determined that the environmental release of H7-1 sugar beet in Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming; and the interstate movement and importation of H7-1 sugar beets within and into the US will have no effect on listed species or species proposed for listing and would not affect designated critical habitat or habitat proposed for designation. Because of this no effect determination, consultation and/or the concurrence of the USFWS and/or the NMFS are not required.

Glyphosate Use

As the action agency for pesticide registrations, EPA has the responsibility to conduct an assessment of effects of a registration action on threatened and endangered species (TES). The EPA Endangered Species Protection Program web site, http://www.epa.gov/espp/, describes the EPA assessment process for endangered species. Some of the elements of that process, generally taken from the web site, are summarized below.

When registering a pesticide or reassessing the potential ecological risks from use of a currently registered pesticide, EPA evaluates extensive exposure and ecological effects data to determine how a pesticide will move through and break down in the environment. Risks to birds, fish, invertebrates, mammals and plants are routinely assessed and used in EPA's determinations of whether a pesticide may be licensed for use in the US.

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of nontarget species, including TES. These assessments provide EPA with information needed to develop label use restrictions for the pesticide. These label restrictions carry the weight of law and are enforced by EPA and the states (Federal Insecticide, Fungicide, and Rodenticide Act 7 USC 136j (a)(2)(G) Unlawful acts). Because TES may need specific protection, EPA has developed risk assessment procedures described in the *Overview of the Ecological Risk Assessment Process* (US EPA, 2004) to determine whether individuals of a listed species have the potential to be harmed by a pesticide, and if so, what specific protections may be appropriate. EPA's conclusion regarding the potential risks a pesticide may pose to a listed species and any designated critical habitat for the species, after conducting a thorough ecological risk assessment, results in an "effects determination" in accordance with Section 7 (a)(2) of the ESA.

As a part of EPA's TES effects assessment for the California red-legged frog (US EPA, 2008), EPA evaluated the effect of glyphosate use at rates up to 7.95 lb a.e./A on fish, amphibians, aquatic invertebrates, aquatic plants, birds, mammals, and terrestrial invertebrates. This assessment determined that at the maximum application rate for in-crop applications of glyphosate to GT sugar beets (1.125 lb a.e. /A) there would be no effects of glyphosate use on the following taxa of threatened and endangered species: fish, amphibians, birds, and mammals. The EPA assessment was uncertain of the effects on terrestrial invertebrates, citing the potential to affect small insects at all application rates and large insects at the higher application rates. EPA considered these potential effects as part of their review process and label use restrictions imposed under authority of FIFRA. To mitigate potential adverse effects to TES, EPA has imposed specific label use restrictions for glyphosate use when applied with aerial equipment including "The product should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g., when wind is blowing away from the sensitive areas)."

To facilitate pesticide applicators adherence to EPA label use restrictions for glyphosate, Monsanto has designed a web-based program (www.Pre-Serve.org), designed to ensure no effect of glyphosate applications on threatened and endangered plant species. Pre-Serve instructs growers to observe specific precautions including buffer zones when spraying glyphosate herbicides on glyphosate-tolerant crops near threatened and endangered plant species that may be at risk. In addition, label requirements for Monsanto's Roundup® formulations and glyphosate formulations marketed by other manufacturers prohibit application in conditions or locations where adverse impact on federally designated endangered/threatened plants or aquatic species is likely.

In conclusion, there are legal precautions in place (EPA label use restrictions) and "best practice" guidance to reduce the possibility of exposure and adverse impacts to TES from glyphosate application to H7-1 sugar beet; EPA has considered potential impacts to TES as part of their registration and labeling process for glyphosate; and adherence to EPA label use restrictions by the pesticide applicator will ensure that the use of glyphosate will not adversely affect TES or critical habitat. Based on these factors and the legal requirements for pesticide applicators to follow EPA label use restrictions, APHIS has determined that the use of EPA registered glyphosate for H7-1 sugar beet production will not adversely impact listed species or species proposed for listing and would not adversely impact designated critical habitat or habitat proposed for designation.

H. Cumulative Impacts

Cumulative impacts, as defined by CEQ (40 CFR 1508.7), are impacts to the environment that result from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts may result from individually minor, but collectively significant, actions taking place over time.

This section discusses the cumulative impacts that are associated with the preferred alternative, when combined with other recent past, present, and reasonably foreseeable future actions within the affected environment. APHIS has published a Notice of Intent in the *Federal Register* announcing its intent to prepare an EIS in association with the petitioner's request to deregulate H7-1 sugar beets. However, APHIS' decision to produce an EIS and this interim EA by no means is an indication of when or if APHIS will or will not decide to deregulate H7-1 sugar beet. APHIS will not make a determination on whether or not to grant nonregulated status to H7-1 sugar beet until a final EIS and PPRA are completed. Therefore the potential impacts of fully deregulating H7-1 sugar beets will not be included in this cumulative impacts analysis.

Cumulative impacts occur when the effects of an action are added to the effects of other actions occurring in a specific geographic area and timeframe. The cumulative impact analysis follows CEQ's guidance: Considering Cumulative Effects under the National Environmental Policy Act (CEQ, 1997). The steps associated with the analysis include:

- Specify the class of actions for which effects are to be analyzed.
- Designate the appropriate time and space domain in which the relevant actions occur.
- Identify and characterize the set of receptors to be assessed.
- Determine the magnitude of effects on the receptors and whether those effects are accumulating.

Class of Actions to be Analyzed

This analysis addresses large, regional and national-scale trends and issues that have impacts that may accumulate with those of the proposed conditions.

a. Geographic and Temporal Boundaries for the Analysis

As described in the Affected Environment, over the past 10 years, the number of acres planted annually in sugar beets in the US has ranged from 1.1 to 1.4 million (USDA NASS 2010c). H7-1 sugar beets are produced in five major regions in the US (see Figure 5). Commercial production of sugar beet seeds takes place primarily in the Willamette Valley of Oregon (see Figure 5), with some minor production in Madras, Medford, and Grants Pass, Oregon (Greg Loberg, personal communication to Bill Doley, Sept. 2, 2010) and in south-central Washington in the Columbia River Basin, and small acreage production of stecklings occurs in Oregon, Arizona, and Washington (personal comm., Bill Doley). Therefore, the spatial domain for past, present, and reasonably foreseeable future actions considers these areas for issues associated with growing H7-1 sugar beets and the nation, and in some cases international areas, for issues associated with consumption of sugar beet food and feed products and for socioeconomic impacts. This analysis focuses more on geographic interaction of projects than timing of interactions because the actual timeframes for many of the reasonably foreseeable future actions are not definitively known. APHIS considers reasonably foreseeable actions as those future actions for which there is a reasonable expectation that the action could occur, such as the preferred alternative under analysis, a project that has already started, or a future action that has obligated funding. Thus harvesting of H7-1 sugar beet roots, stecklings and seeds that were planted prior to the decision on the lawsuit and planting of stecklings under permits that APHIS has issued, are actions that either have occurred, will occur or are reasonably certain to occur. It also includes other actions such as crop rotations and associated weed and land management practices that overlap in space and time with areas that are likely to grow H7-1 derived sugar beet varieties.

APHIS has identified activities relevant to the cumulative impacts analysis from reviews of information available from government agencies, such as environmental impact statements, land-use and natural resource management plans, and from private organizations. Not all actions identified in this analysis would have cumulative impacts on all resource areas.

Resources Analyzed

Issues evaluated in this cumulative impacts analysis are associated with the resource areas discussed in the Affected Environment and Environmental Consequences sections. Specific topics analyzed include: cumulative impacts related to any possibility of development of herbicide resistant weeds, and cumulative impacts related to changes in tillage and herbicide usage, including potential increased glyphosate usage with the cultivation of glyphosate tolerant crops.

a. Magnitude of Effects on Resources

The potential extent of the impacts of the preferred alternative combined with other actions, and the duration of those impacts are considered in determining the magnitude of cumulative effects that impact each resource area. When possible, the assessment of the effects on a resource is based on quantitative analysis, however, many effects are difficult to quantify. In these cases, a qualitative assessment of cumulative impacts is made. Incomplete or unavailable information is documented in accordance with 40 CFR § 1502.22 .

As suggested by the CEQ (1997) handbook, *Considering Cumulative Effects under the National Environmental Policy Act*, this EIS considered the following basic types of cumulative effects that might occur due to the preferred alternative:

- *Additive*—loss of a resource from more than one incident.
- *Countervailing*—adverse effects are compensated by beneficial effects.
- *Synergistic*—total effect is greater than the sum of effects when considered independently.

In the following analysis, cumulative impacts should be considered additive unless designated as otherwise. In the case of most resources that may experience cumulative impacts, the preferred alternative is only responsible for a contribution of an incremental portion the total impact on the resource. The past, present, and reasonably foreseeable connected actions typically contribute to the majority of impacts experienced by the resource, and would continue to have impacts on the resource even if the no action alternative were implemented.

Analysis of Cumulative Impacts by Resource Area

a. Biological Resources

Beta Crops. As discussed in the Environmental Consequences section, no or negligible effects are expected from the cultivation of H7-1 sugar beet derived varieties under the preferred alternative with respect to all conventional or organic *Beta* crops based on the following conclusions: (1) In most cases no gene flow from H7-1 lines to other *Beta* crops is expected and if it does occur is not expected to exceed detectable levels of 1 seed in 10,000. Inconsequential admixture will have little impact on grower sales of organic products to many buyers (neither

Federal regulations nor major commercial standards prohibit such sales). Hence no or negligible impacts from gene flow from H7-1 sugar beet root or seed crops to conventional Beta seed or root crops would be expected; (2) The availability of vegetable beet seeds with no detectable H7-1 trait, together with the fact that gene flow cannot occur during vegetable production means that there will be no negative impacts to organic vegetable beet production; (3) The permit conditions will prevent seed mixing (permit condition 4), which makes current seed and steckling production and handling practices mandatory (described in the Affected Environment section), is expected to eliminate any admixture of H7-1 in conventional sugar beet and vegetable crop seeds. Hence no impacts are expected resulting from mechanical mixing of harvested beets of H7-1 and conventional sugar beet and vegetable crop seeds; (4) There is currently no commercial organic sugar beet production in the US, and the preferred alternative is not expected to result in impacts to organic growers who may choose to grow sugar beets in the future. Therefore the preferred alternative would have no cumulative impact on conventional or organic sugar beet root crops.

Herbicide Resistant Weeds and Glyphosate. Glyphosate offers many benefits to the grower as a weed control product. Glyphosate controls a broad spectrum of grass and broadleaf weed species present in sugar beet root production fields and sugar beet seed and steckling production fields, has flexible use timings, and when used in glyphosate-tolerant crops, has a very high level of crop safety (see petition 03-323-01p, Tables VII-4 and VII-5, pages 90 and 92, respectively). As the adoption of glyphosate-resistant crops has grown, the use of glyphosate has increased over the past several years. Crops that contain the same modified EPSPS protein as H7-1 sugar beet have been granted non-regulated status and have included corn, soybean, cotton and rapeseed (http://www.aphis.usda.gov/brs/not_reg.html). In 2004, significant acreages of corn (10.3 million acres or 11% of the total), upland cotton (4.1 million acres or 30% of the total) and soybean (62.6 million acres or 85% of the total) grown in the U.S. were planted with herbicide tolerant varieties (http://usda.mannlib.cornell.edu/). With the increased use of glyphosate, there is also the potential for increased selection pressure for the development of glyphosate-resistant weeds.

Shifts to more inherently herbicide tolerant weed species and evolution of herbicide resistant biotypes of species that are normally susceptible to a given herbicide under normal use rates are not unique to glyphosate resistant crop systems (Heap, 2010). These shifts are influenced by the intensity of the selection pressure by the herbicide mode of action, the mechanisms of resistance, and diversity in the cropping system including herbicide mode of action and other weed control and cultivation practices. The Affected Environment section provides information about the major sugar beet weeds and occurrence of resistance to those herbicide groups used in sugar beet production (Table 7). In this cumulative impacts section, APHIS considered the likelihood that herbicide tolerant or resistant weeds would develop in sugar beet seed and root production systems and produce cumulative impacts in rotational or nearby cropping systems.

Sugar Beet Seed Production. Herbicides with several different modes of action are available for control of the major weeds in sugar beets in the Pacific Northwest (Oregon, Washington, and Idaho) (Morishita, 2009). The weed control program for sugar beet seed and steckling production is essentially the same as for sugar beet root crops with some exceptions, i.e. glyphosate is not generally used post-emergent in seed production except for sometimes the glyphosate resistant parent is sprayed if the other non-resistant parent is not present (Greg Loberg, personal communication to Bill Doley, Sept. 2, 2010; Kockelmann and Meyer, 2006). Major sugar beet weeds that have developed resistance to herbicide modes of action that are used in sugar beets and that occur in Oregon and/or Washington include:

- Wild oat (*Avena fatua*) with resistance to ACCase inhibitors and/or mitosis inhibitors infesting wheat;
- Kochia (*Kochia scoparia*) and spiny sowthistle (Sonchus asper) with resistance to ALS inhibitors, infesting wheat and/or cereals;
- Redroot pigweed (*Amaranthus retroflexus*) and Powell amaranth (*Amaranthus powellis*) with resistance to photosynthesis II (PSII) inhibitors infesting mint (Heap, 2010).

No major sugar beet weeds with resistance to glyphosate have been confirmed by the International Survey of Herbicide Resistant Weeds in Oregon or Washington (Heap 2010). The International Survey of Herbicide Resistant Weeds (Heap, 2010) also does not identify any herbicide resistant weeds in Arizona.

The Willamette Valley is used for seed production for many different kinds of seeds. In addition to seeds, many vegetables are also commercially grown in the valley. It is a major area for production of “most temperate vegetables, herbs and vegetable seeds” (Mansour, 1999). Rotation crops for seed and steckling production are highly variable, but often include a grass or a grain (e.g. wheat) (Greg Loberg, personal communication to Bill Doley, Sept. 2, 2010). Preceding crops feature those that are harvested early enough to allow plowing and field preparation before sugar beet seed planting or before transplanting of stecklings (typically cereals, wheat or vegetable crops). As noted in the Biological Resources Section of the Affected Environment, a minimum of five years of rotation with non *Beta* crops are required for seed production fields, however there are no rotation restrictions or requirements for steckling nurseries because no seed is produced and there is less concern with root diseases. Field herbicide history is also a factor taken into consideration.

Because a glyphosate-based herbicide program is currently being used with H7-1 sugar beet seed and steckling production, glyphosate use for H7-1 is not expected to increase beyond current levels, as market penetration is already at 95%. Since no major sugar beet weeds with resistance to glyphosate occur in Oregon, Washington or Arizona, it is anticipated that they are unlikely to be selected under the preferred alternative due to several factors: 1) glyphosate use would not be expected to increase beyond its current use as a pre-emergent or pre-transplant application in fields where conventional non-glyphosate resistant sugar beet seed or stecklings are being grown or as a post-emergent application in a limited number of fields which contain ONLY glyphosate tolerant parents or stecklings; 2) herbicides with other modes of action can be used after emergence or transplanting and later before canopy closure; and 3) other typical cultural practices can reduce weed populations or reduce the likelihood that mature seed will be set, e.g. mechanical tillage, roguing and swathing of the sugar beet seed. Major weeds of sugar beet may continue to be selected for resistance to other herbicides commonly used in sugar beets in these seed production areas (Morishita, 2009). Selection could also continue for those weeds that have already developed herbicide resistance. The major weeds of sugar beet which have already developed resistance to herbicides that are also commonly used in sugar beet are reported as infesting crops other than sugar beet (i.e. wheat, cereals, and/or mint as indicated above) (Heap 2010). Therefore it is unlikely that past weed control practices in sugar beet have significantly contributed to the development of herbicide resistance in these weed biotypes, and is therefore unlikely to occur as a result of actions occurring under the preferred alternative . At least three alternative herbicides with other modes of action to which these weeds have not developed resistance can provide at least fair control of these major weed species in sugar beet (Morishita 2009). Examples for each resistant weed and the herbicides effective at controlling it include:

- Wild oat: Fatty acid and lipid biosynthesis inhibitor herbicides EPTC, cycloate, and ethofumesate.
- Kochia: EPTC, ethofumesate; and mitosis inhibitor herbicides trifluralin and dimethenamide-P,
- Sowthistle: EPTC, ethofumesate, clopyralid, and dimethenamide-P
- Pigweeds: [redroot pigweed (*Amaranthus retroflexus*) and Powell amaranth]: EPTC, cycloate, and ethofumesate, trifluralin and dimethenamide-P, and triflusulfuron.

The limited use of glyphosate as a post-emergent herbicide to control weeds only around glyphosate tolerant plants in seed production or steckling fields would continue to allow for an additional post-emergent weed control option for herbicide resistant wild oats, kochia, and pigweeds (Table 4). Glyphosate can provide fair to excellent control of these weeds as well as eight other major weeds in sugar beets.

In summary, significant cumulative impacts with respect to increased resistance to herbicides are not anticipated for sugar beet seed and steckling production areas given the relatively low acreage planted to sugar beet seed and stecklings; the rotation cycle for sugar beet seed production; the diversity of rotation crop options and weed control options; the lack of sugar beet weeds with resistance to glyphosate in sugar beet seed and steckling production areas; and the ability of glyphosate to provide an extra post-emergent control option for sugar beet weeds that have already developed resistance to some other herbicides used in sugar beets.

In addition, sugar beet itself is not considered a significant weed, and furthermore, the permit conditions proposed for the control of volunteers of H7-1 in seed production fields should prevent it from becoming a weed problem in rotation crops.

Sugar Beet Root Production. APHIS examined herbicides available for the control of major sugar beet weeds in states in the five regions where sugar beet root production occurs, the occurrence of weed biotypes resistant to those herbicides, the availability of alternative options to control those weeds, and the impact that resistant weeds would have on regional agriculture and rotation crops, including those that are resistant to glyphosate.

Table 3 in the Biological Resources section of the Affected Environment in this EA shows herbicide applications to sugar beet acres in the US in 2000, prior to the commercial cultivation of glyphosate resistant H7-1, in terms of the herbicide, its trade name, the WSSA mode of action group for the herbicide, the percentage of acres treated, applications per year, the rate per application and the total applied per year. Thirteen different herbicides, including glyphosate, are included representing 8 different WSSA modes of action groups. From this data, the most commonly used herbicide in terms of either percentage of acres treated (> 45 %) or number of applications/year (>2.0) are listed below along with their mode of action:

- Desmedipham (94%, 2.8 application/yr) – Grp. 5 - photosynthesis inhibitor
- Triflusulfuronmethyl (83%, 2.7 applic./yr) – Grp. 2- ALS inhibitor,
- Phenmedipham (80%, 2.6 applic./yr) – Grp. 5 – photosynthesis inhibitor
- Clopyralid (74%, 2.8 applic./yr) – Grp. 4 – synthetic auxin
- Clethodim (46%, 2.5 applic./yr) – Grp. 1- ACCase inhibitor.

Table 7 in the Biological Resources section of the Affected Environment shows the major sugar beet weeds with resistance to herbicide groups used in sugar beets as obtained from the International Survey of Herbicide Resistant Weeds (Heap, 2010), organized by states in which sugar beets are grown commercially. Biotypes of seventeen weeds with confirmed resistance to one or more herbicides are noted. Weed biotypes with resistance to ALS inhibitor herbicides, PSII inhibitor herbicides and ACCase inhibitor herbicides are the most prevalent in terms of the number of weed biotypes and states with reported resistance. This trend follows the trend in herbicide resistant weed biotypes worldwide as herbicides in these classes have the highest number of resistant weed biotypes (Figure 3).

With the exception of the synthetic auxin herbicides, the trend in resistant weed biotypes by mode of action also follows the overall herbicide use pattern for sugar beets, the vast majority of which is for root production. However, this does not necessarily mean that cultivation of conventional or glyphosate-resistant sugar beets has led to the development of these resistant biotypes in these states. Many of these major weeds in sugar beet that have developed herbicide resistance are also considered weeds in other crops which are planted to much larger acreages . Resistance may have developed in these other crop situations or the resistant weeds may have been transported to these situations from contaminated seed, field equipment or by other means from other areas. Because sugar beet yield and/or quality are usually higher when sugar beets follow barley or wheat in the crop rotation compared to corn, potatoes, soybean, edible dry beans, or summer fallow (Cattanach et al., 1991), resistant weeds in these crops may be more likely to impact sugar beets. Based on information in the International Survey of Herbicide Resistant Weeds (Heap, 2010) for situations in which the resistant weeds are reported to infest, very few of the resistant weed biotypes are specifically reported as infesting sugar beet (or general cropland which could possibly include sugar beet), however several occur in crops that are grown in rotation with sugar beet (See Tables 16 and 17). Table 4 summarizes the effectiveness of herbicides on major weeds in sugar beets as provided by three sources. The Table 16 also includes an analysis of information from Table 4 as to whether glyphosate and/or an alternative herbicide with a mode of action different from the reported resistance is rated as providing fair to excellent control of the resistant weed species in either a pre-plant incorporated, pre-emergent, or post-emergent application.

Table 16. Major sugar beet weeds with resistance to herbicide groups

Weed Common Name	Herbicide Mode of Action	States Reported & Year Reported or Confirmed	Crops infested, estimated number of sites and acres. (+ indicates that either the # sites or acres is increasing)	Effective control option with glyphosate and/or alternative non-resistant herbicide.
Barnyardgrass	ACCase Inhibitor & Fatty acid synthesis inhibitor	CA 2000	Rice-11-50 sites, 101-500 A+	Glyphosate/Post-E
Kochia	PSII inhibitor	CO 1982, WY, MT 1984, ND 1998	CO-Corn, 501-1000 sites, 1001-10,000 A+; WY-Corn, 11-50 sites, 1001-10,000 A stable; MT-railways, 6-10 sites, 501-1000 A+, ND-Corn,1 site, 11-50 A.	Glyphosate/Pre-E, Post-E
	ALS inhibitor	ND 1987, WA, MT, CO, ID 1989, OR 1993, MN	ND-Cropland & wheat, 501-1000 sites, 1-2 million A+; WA-Cereals & wheat,	Glyphosate/Pre-E, Post-E,

Weed Common Name	Herbicide Mode of Action	States Reported & Year Reported or Confirmed	Crops infested, estimated number of sites and acres. (+ indicates that either the # sites or acres is increasing)	Effective control option with glyphosate and/or alternative non-resistant herbicide.
		1994, WY 1996, MI 2005	501-1000 sites, 1001-10,000 A+; MT-Cropland & wheat, 1001-10,000 sites, 0.10-1.0 million A+; CO-Roadsides & wheat, 501-1000 sites, 10,001-100,000 A+; ID- Roadsides & wheat, 501-1000 sites, 10,001-100,000 A+; OR-Wheat, 51-100 sites, 1001-10,000 A+; MN-Cropland & wheat, 11-50 sites, 1001-10,000 A +; WY-Wheat, 2-5 sites, 501-1000 A+; MI-Sugar beet, 2-5 sites, 101-500 A+	
	Synthetic auxin	ND, MT 1995, ID 1997	ND-Wheat, 6-10 sites, 101-500 A+; MT-Cropland & wheat, 101-500 sites, 1001-10,000 A+; ID-Roadsides, 1 site, 1-5 A+.	Glyphosate/Pre-E, Post-E,
Wild oat	ACCase inhibitor	MT 1990 & 2002; OR 1990; WA, MN, ND 1991; ID 1992; CO 1997	MT-Cropland, sugar beet and wheat. 51-100 sites, 1001-10,000 A+ OR-Wheat, 101-500 sites, 1001-10,000 A+; WA- Wheat, 51-100 sites, 10,000 A+; MN- Sugar beet & wheat. 51-100 sites, 1001-10,000 A+.; ND-Cereals & wheat. 101-500 sites, 1001-10,000A+ ID - Cereals & wheat. 11-50 sites, 1001-10,000A+ CO- Barley & wheat. 6-10 sites, 101-500 A+	Glyphosate/PPI, Pre-E, Post-E
	Fatty acid synthesis inhibitor	MT 1990, ID 1993	MT-Barley. 501-1000 sites, 10,001-100,000A+; ID-Cereals. 51-100 sites, 10,001-100,000A+	Glyphosate/Post-E
	ALS inhibitor	MT &	MT-Cereals,. 2-5	Glyphosate/PPI, Pre-E,

Weed Common Name	Herbicide Mode of Action	States Reported & Year Reported or Confirmed	Crops infested, estimated number of sites and acres. (+ indicates that either the # sites or acres is increasing)	Effective control option with glyphosate and/or alternative non-resistant herbicide.
		ND1996,	sites, 11-50 A+; ND-Wheat. 2-5 sites, 501-1000 A+.	Post-E
	Mitosis inhibitor	OR 1990	Cropland. 1 site, 11-50 A stable.	Glyphosate/PPI, Pre-E, Post-E
Lambsquarter	PSII inhibitor	MI 1975 MN 1982	MI -Corn, nurseries, soybean. 100,000 A. MN – Corn. 101-500 sites, 501-1000 A. stable.	Glyphosate/PPI, Pre-E, Post-E
	ALS inhibitor	MI 2001	Soybean. 2-5 sites, 101-500 A+.	Glyphosate/PPI, Pre-E, Post-E
Redroot pigweed	PSII inhibitor	CO 1982, MN 1991 OR 1994 ID 2005,	CO - Corn, 501-1000 sites, 10,000 A +; MN – Corn, 1 site, 11-50 A stabilized; OR-Mint, 6-10 sites, 101-500 A+. ID- Potato, 2-5 sites, 501-1000 A.	Glyphosate/PPI, Pre-E, Post-E
	PSII inhibitor (incl. Ureas and Amides)	MI 2001	Asparagus. 6-10 sites, 51-100 A+	Glyphosate/PPI, Pre-E, Post-E
	ALS inhibitor	ND 1999	Soybean. 1 site. 1-5 A. stable.	Glyphosate/PPI, Pre-E, Post-E
Tall water hemp	ALS inhibitor	MI 2000;	Soybean. 6-10 sites, 101-500 A.	Glyphosate/PPI, Pre-E, Post-E
	Glycine	MN 2007	Soybean. 2-5 sites, 51-100 A +.	PPI, Pre-E, Post-E
	PSII inhibitor	NE 1996	Corn – NA	Glyphosate/PPI, Pre-E, Post-E
Powell Amaranth	PSII inhibitor	WA 1992;	Mint – NA	Glyphosate/PPI, Pre-E, Post-E
	PSII inhibitor, Urea and amides	MI 2001	Asparagus & nurseries. 11-50 sites, 101-500 A +.	Glyphosate/PPI, Pre-E, Post-E
Smooth pigweed	ALS inhibitor	MI 2002	Soybean. 2-5 sites, 101-500 A.	Glyphosate/PPI, Pre-E, Post-E
Velvetleaf	PSII inhibitor	MI 2004	Corn, nurseries, soybean. 2-5 sites, 101-500 A +.	Not rated
	PSII inhibitor	MN 1991	Corn. 1 site, 11-50 A. Stabilized	Not rated but not a weed in SB rotation crops in MN.
Eastern Black nightshade	PSII inhibitor	MI 2004	Blueberry. 2-5 sites, 101-500 A.	Glyphosate/PPI,Pre-E, Post-E
	ALS inhibitor	ND 1999	Soybean. 2-5 sites, 501-1000 A +	Glyphosate/PPI,Pre-E, Post-E
Giant Foxtail	ALS inhibitor	MN 1996; MI 2006	Corn & soybean. MN -1 site, 11-50 A. + MI -1 site, 101-500 A.	Glyphosate/PPI, Pre-E, Post-E
Robust White Foxtail	ALS inhibitor	MN 1996	Corn & soybean. 1 site, 11-50 A, +.	Glyphosate/PPI, Pre-E, Post-E

Weed Common Name	Herbicide Mode of Action	States Reported & Year Reported or Confirmed	Crops infested, estimated number of sites and acres. (+ indicates that either the # sites or acres is increasing)	Effective control option with glyphosate and/or alternative non-resistant herbicide.
	ACCase inhibitor	MN 1999	Soybean. 6-10 sites, 11-50 A, stabilized.	Glyphosate/PPI, Pre-E, Post-E
Purple Robust Foxtail	ACCase inhibitor	MN 1999	Soybean. 1 site, 11-50 A, stabilized.	Glyphosate/PPI, Pre-E, Post-E
Yellow Foxtail	ALS inhibitor	MN 1997	Soybean. 1 site,1-5 A, increasing.	Glyphosate/PPI, Pre-E, Post-E
Green Foxtail	Mitosis inhibitor	ND 1989	Sunflower and wheat. 501-1000 sites, 1001-10,000 A, increasing.	Glyphosate/PPI, Pre-E, Post-E
Giant Ragweed	Glycine	MN 2006	Soybeans. 2-5 sites, 101-500 A, increasing.	/Post-E
Common Cocklebur	ALS Inhibitor	MN 1994	Soybeans. 2-5 sites, 11-50 A, increasing.	Glyphosate/Marginal Pre-E; Post-E
Spiny Sowthistle	ALS Inhibitor	WA 2000.	Lentils and wheat. 6-10 sites and acres.	/Pre-E; Post-E

Table 17: Sugar beet weed biotypes with confirmed herbicide resistance that are reported as infesting sugar beet or as general "cropland" (e.g. specific crop unspecified)*

Weed	Herbicide Resistance	State & Year	Crops infested
Kochia	ALS-inhibitor resistant	ND 1987, MT 1989, MN 1994	Cropland & wheat
		MI 2005	Sugar beet
	Synthetic auxin	MT 1985	Cropland & wheat
Wild Oat	ACCase inhibitor	MT 1990 & 2002	Cropland, sugar beet, wheat
		MN 1991	Sugar beet & wheat
	Mitosis inhibitor	OR 1990	Cropland

***Summarized from preceding Table 16**

Based on data in the International Survey of Herbicide Resistant Weeds (Heap, 2010), since 2005, the year that H7-1 sugar beet was first commercially grown, there have been five confirmed cases of sugar beet weeds with herbicide resistance in sugar beet root production states. These include weeds with resistance to at least 3 modes of action:

- PSII inhibitors (redroot pigweed infesting potato in Idaho in 2005),
- ALS-inhibitors (kochia in Michigan infesting sugar beet in 2005 and giant foxtail in Michigan infesting corn and soybean in 2006), and
- Glyphosate (glycine mode of action), (Giant ragweed (*Ambrosia trifida*) and tall waterhemp (*Amaranthus tuburculatus*) infesting soybean in 2006 and 2007, respectively, both in Minnesota.

This is also consistent with world-wide trends in resistant weed biotypes since 2005, as there has been a relative leveling off of new weed biotypes with resistance to most herbicides, concurrent with an increase in the rate of new weed biotypes with resistance to glyphosate (Figure 3). In total 10 weed species in the US have been confirmed with resistance to glyphosate. Minnesota is the only sugar beet production state with confirmed cases of glyphosate resistant weeds that are major sugar beet weeds based on analysis of data collected by the International Survey of Herbicide Resistant Weeds (ISHRW) (Heap, 2010). However, although the ISHRW does not specifically report that these glyphosate resistant weeds occur in sugar beet, recent information indicates that they do occur in sugar beet fields near Hutchinson, MN and near Buxton, ND. In addition, in their recent weed control guide for sugar beet weed management, weed extension specialists Stachler and Zollinger (2009) indicate that glyphosate resistant giant ragweed, common ragweed and lambsquarter (unconfirmed) occur in Minnesota, and the latter two resistant species also occur in North Dakota. Since the draft EA was published in October 2010, the status for some of the glyphosate resistant weeds in Minnesota and North Dakota was updated by the ISHRW on December 24, 2010, but they are still characterized as infesting soybean:

- Tall waterhemp in MN increased to upwards of 1000 sites and 100,000 acres.
- Giant ragweed in MN infests upwards of 1000 sites and 100,000 acres.
- Common ragweed in ND infests upwards of 50 sites, 1,000 acres and in MN infests up to 100 sites and 10,000 acres.

In summary, these data support the following conclusions:

- Herbicide resistant biotypes of weeds that are considered major weeds in sugar beet, are seldom reported as "infesting sugar beets", but resistant sugar beet weed biotypes do occur in several major crops grown on much larger acreage, a portion of which are rotated with sugar beet in several sugar beet producing states.
- Since the introduction of glyphosate resistant sugar beet, few major sugar beet weeds have developed herbicide resistance, but glyphosate resistance has developed in at least two weed biotypes in soybeans in Minnesota, and these now occur in some sugar beet fields in Minnesota and North Dakota.

Table 1 in the Affected Environment section includes a summary of rotational crops that follow US sugar beet production and an estimation of the rotational crops as glyphosate-resistant (Roundup Ready) crops.

The major crops that follow sugar beet in rotation (from Table 1) and are confirmed to be infested with herbicide resistant biotypes of weeds that are also considered major weeds in sugar beet production states, and the maximum acreage estimated to be infested based on data from the International Survey of Herbicide Resistant Weeds (Heap, 2010), are listed below (Note: Sugar beet and other crops in parentheses were included in the original acreage estimate in the ISHRW but are not considered a major rotation crop for sugar beet).

ND – corn = 50 A, soybean = 1005 A, cropland, cereals & wheat = 2,021,500 A

MT – cereals = 50 A, barley = 100,000A, cropland & wheat & (sugar beet) = 1,020,000 A

ID – cereals & wheat = 210,000 A

MN – (corn) & soybean = 855 A, cropland & (sugar beet) & wheat = 20,000 A

MI – corn & soybean = 101,000 A, soybean = 1500 A

CO - corn = 20,000 A, barley & wheat = 500 A

WY - corn = 10,000 A

NE – corn (no acreage estimate available)

Thus the upper combined estimate of infested acres approaches 3.5 million. The lower estimate is roughly one-third this amount based on information in the ISHRW (Heap, 2010). By comparison, 1.4 million acres of sugar beet were planted in 2002 in these states (see EA Table 18).

Of the variety of crops that are included in rotations with sugar beet (see Table 18), those that include Roundup Ready crops are summarized in the Table 18 below. Minnesota has the highest acreage planted to sugar beet (table 18, column 2) and also the highest estimated acreage of Roundup Ready® rotational crop (soybean) planted in rotation with sugar beets (322,000 acres, which represents an estimated 64% of the total sugar beet crop planted in Minnesota) (Table 18, column 5). Rotational crops following sugar beets for which Roundup Ready® varieties are available were estimated to be mostly corn (ranging from 3-70%) and soybean (ranging from 25-70%). Lower estimates were given for alfalfa (5% in Idaho) and for sugar beets (10% in Wyoming). Nonetheless, the estimated acreage of Roundup Ready crop that is grown in rotation with sugar beet is estimated to be no more than 3.5% of the total acreage planted in that rotation crop (e.g. corn, soybean, alfalfa, or sugar beet) in those states (Table 18, last column).

Table 18. Rotational crops following US sugar beet production and an estimation of rotational crops as Roundup Ready® crops.

State	Total Sugar Beet Acres	Major Crops that Follow sugar beet in Rotation that have Roundup Ready® Varieties	Percent of Rotational Crop of Total Sugar Beet	Acreage of Roundup Ready® Rotational Crop Option and Percent of Total Sugar Beet Acres	Estimated Percent of Roundup Ready® Crops as Major Rotations
Minnesota	505,000	Soybean	70%	322,000 – 64%	3.42%
Colorado	44,000	Corn	70%	16,000 – 36%	1.10%
Idaho	212,000	Corn	3%	3,000 – 1.4%	0.40%
		Alfalfa	5%	6,000 – 2.8%	
Michigan	180,000	Soybean	25%	41,000 – 23%	2.23%
		Corn	65%	61,000 – 34%	
Montana	58,000	Corn	25%	7,000 – 12%	0.14%
North Dakota	265,000	Soybean	40%	96,000 – 36%	0.81%
		Corn	15%	21,000 – 7.9%	
Nebraska	57,000	Corn	50%	15,000 – 26%	0.15%
Wyoming	40,000	Corn	25%	5,000 – 12%	2.89%
		Sugar beets	10%	2,000 – 5.0%	

See Legend for Table 1 above.
Acreage planted of the specific crop is based on 2002 planting data (USDA-NASS. 2003).
Rotated crops and acreage following sugar beet production are based on communications from individual local experts. i.e., university agronomists, USDA-ARS and Monsanto field personnel.
Percent of Rotational Crop of Total Sugar Beet Column obtained by dividing Rotational Crop Acres Following Sugar beet by Total Sugar Beet Acres, Column 2, and multiplying by 100. (See Legend for Table 1 above).
Column 5, Acreage of Roundup Ready® Rotational Crop Option was derived from Table 1. In addition, Percentage of Total Sugar beet Acreage was derived by dividing the estimated RR rotational crop option acreage(table 18, column 5) by the sugar beet acreage planted for each state in Table 18, column 2.
Estimated Percentage of Roundup Ready ® Crops as Major Rotations obtained from Table 15 (last column), obtained by dividing the Acreage of Roundup Ready® Rotational Crop Option Total by the Total Acreage of Rotation Crop in the State Total (Column D Total of Table 15) and multiplying by 100.

The Affected Environment section describes the management practices that can be used to retard the development of herbicide resistance in general and for sugar beet in particular, including those available to conventional sugar beet growers and those who grow glyphosate resistant H7-1. Additive adverse cumulative impacts would be those that result from the inability of weed control methods to delay the development of herbicide resistant weed biotypes and/or control those that are already present in sugar beet such that the resistant weed populations affect rotation crops or other crops in the area to a level that is beyond what currently exists.

Because a glyphosate-based herbicide program is currently being used with H7-1 sugar beet, under the preferred alternative, glyphosate use for H7-1 is not expected to increase beyond current levels, as market penetration is already at 95%; therefore the current trend in selection of glyphosate resistant weeds in glyphosate resistant sugar beet is likely to continue. Thus far, as demonstrated above, the current trend has been that glyphosate resistant weeds that have developed in other crops, e.g. soybeans, are beginning to appear in sugar beet fields. Current levels of glyphosate use in H7-1 sugar beets are a minor (approximately 0.8%) amount of total US glyphosate use (Table 6). In 2009, glyphosate use on sugar beet (1.8075 million lbs of acid equivalence) was roughly 1.3% of the total agricultural and fallow use of glyphosate in the US based on AgroTrak data (Gregory Watson and Keith Reding, Monsanto, personal communication, September 29 -30, 2010). Additionally, growers still would have the currently available weed control tools (e.g., non-glyphosate herbicides and cultural practices described in the Biological Environment Section of the Environmental Consequences Section) needed on a small scale to manage any glyphosate-resistant weeds, whether they are present in sugar beet or other crop production fields.

The Monsanto Technical Use Guide (Monsanto, 2010) makes general recommendations on management practices for weed resistance management for Roundup Ready® sugar beets, but it does not specifically make recommendations for Roundup Ready® sugar beets on how to control the major sugar beet weeds such as tall waterhemp and giant ragweed in Minnesota that have developed glyphosate resistance (alone and in combination with resistance to ALS-inhibitor herbicides and/or other herbicides). Stachler and Zollinger (2009) also report that giant ragweed with multiple resistances to glyphosate and ALS-inhibitor herbicides exist in Minnesota. Glyphosate resistant common ragweed has also been reported in North Dakota in 2008, and these biotypes continue to increase in both North Dakota (Stachler et al., 2009) and southern Minnesota (Stachler and Zollinger, 2009). Most of the APHIS analysis relied on confirmed reports of resistance. The recent internet report from NDSU from June 2010 indicates that there are also “reports from South Dakota and now in North Dakota of kochia escaping normal applications of glyphosate.” APHIS agrees that, if confirmed in these states, glyphosate resistant kochia could indeed be difficult to control in rotations with glyphosate resistant sugar beets and their rapid means of seed spread could lead to rapid expansion of the resistant populations with adverse consequences for nearby crops, particularly if biotypes are also resistant to all ALS inhibitors. The ISHRW Quik Stats last updated Feb 16, 2010 indicates that a biotype of kochia was reported as glyphosate resistant in 2007 and infests cotton, corn, and soybean in Kansas on up to 150 acres, but it was not reported in sugar beet growing states. In the NDSU report, Zollinger notes that of the glyphosate resistant kochia populations in Kansas, “areas that practiced low use rates were the first to exhibit lack of control of kochia”.

Monsanto believes it is better to refer questions on what products to use to manage glyphosate resistant weeds in sugar beets to the local extension expert because recommendations are region-dependent (Keith Reding, Monsanto, personal communication September 30, 2010). North Dakota State University research conducted in 2009 by Fisher, Stachler, and Luecke has shown that clopyralid (Stinger, a synthetic auxin mode of action herbicide) mixed with glyphosate can provide effective post-emergent control of glyphosate resistant giant ragweed less than 6 inches tall. At two Minnesota locations, one NW of Hutchinson and the other SW of Hutchinson, 2-3 applications of the herbicide clopyralid (Stinger, a synthetic auxin mode of action herbicide) mixed with glyphosate provided excellent control of 1-3 inch glyphosate-resistant giant ragweed while preserving yield and extractable sucrose in glyphosate-resistant sugar beet. Similar results were obtained in North Dakota. Clopyralid without glyphosate was also tested. Increasing rates of clopyralid and frequency of applications were shown to improve common ragweed control, but increased sugar beet injury (Stachler et al., 2009). These preliminary results indicate that clopyralid used alone may be an effective option for control of glyphosate resistant ragweed that is 7.6 cm or smaller, although maximum control and yields were obtained when clopyralid was mixed with glyphosate. Sugar beet weed biotypes with confirmed resistance to synthetic auxin mode of action herbicides do not occur in Minnesota, however in North Dakota, kochia biotypes with this resistance were confirmed in 1995. Table 4 indicates that clopyralid is also rated as providing at least fair control of the following sugar beet weeds: nightshade, cocklebur, sowthistle, and Canada thistle. Ratings for lambsquarter ranged from poor to fair. However, it should also be noted that label recommendations for Clopyralid indicate that up to 18-month rotation restrictions apply to many crops due to risk of injury; and a field bioassay is recommended (Table 11). Clopyralid (Stinger) may have a herbicidally active residual in the soil. Wheat, barley, oats, grasses, corn, and sugar beets have good tolerance and can be planted any time after application. Other crops such as lentils, peas, safflower, potatoes, alfalfa, sunflowers, edible beans or soybean, can usually be planted 12 months after treatment, but extreme weather conditions can sometime cause the herbicide to persist longer (Cattanach et al., 1991). In addition to soybean, wheat and barley are already common rotation crops for sugar beet in Minnesota and North Dakota, and for N. Dakota, corn is also (see Table 1 above).

Specific recommendations for managing glyphosate-resistant weeds in glyphosate-resistant soybean are provided in the Monsanto TUG, and these do include recommendations for waterhemp (*Amaranthus* species) and giant ragweed.

For glyphosate resistant *Amaranthus* species the recommendations are:

> *"Preplant:*
> *Apply a tank-mix of 22 oz I/A Roundup WeatherMAX with a pre emergence residual herbicide such as alochlor (lNTRRO®), flumioxaxin (Valor®) or another residual herbicide for preemergence control of Amaranthus species. 2,4-D may be added to the tank-mix to help control emerged Amaranthus species and other broad leaf weeds preplant only. Follow label instructions regarding application timing relative to soybean planting.*
>
> *In-crop:*
> ***It is strongly encouraged that a preemergence residual product be used to control Amaranthus species prior to emergence.***
> *If there is emerged Amaranthus in-crop, apply a tank-mixture of 22 oz/A Roundup WeatherMAX with a postemergence product with activity on Amaranthus such as lactofen (Cobra®), fomesafen (Flexstar®) or cloransulam (FirstRate). Applications should be made on emerged Amaranthus that does not exceed 3" in height. Read and follow all product label instructions.*
> *It is likely that visual soybean injury will occur with these tank-mixtures."*

The only differences in the recommendations for Giant ragweed are for the preemergence control recommendations which recommend the use of a "preemergence residual herbicide such as cloransulam (FirstRate) or cloransulam + flumioxazin (Ganster®) or another residual herbicide for preemergence control of *Ambrosia* species."

The TUG does not provide specific recommendations for biotypes of species with multiple herbicide resistance. Nonetheless, the herbicides specifically recommended for these two species are not of the class of herbicides (ALS-inhibitors and PI) for which multiple herbicide resistant biotypes have been reported with glyphosate, with the exception of cloransulam which is an ALS-inhibitor herbicide. With respect to the herbicide mode of action, lactofen, fomesafen and flumioxazin are all protoporthyrinogen oxidase inhibitors. If recommended herbicides are not effective, hand weeding may be the best option for control before resistant populations become too large to manage cost-effectively with this method. Stachler and Zollinger (2009) also provide recommendations for managing herbicide resistant weeds in sugar beet in Minnesota and North Dakota based on the mode of action of the resistant herbicide.

As discussed in the Affected Environment – Biological Resources section, glyphosate use in GR sugar beet has proven to be an effective tool against weeds resistant to non-glyphosate herbicides, such as ALS-inhibitors and ACCase-inhibitors. The most widespread herbicide resistant weeds likely to impact sugar beet root production include kochia resistant to ALS-inhibitors and wild oat with resistance to ACCase inhibitors. This is based on the estimated large acreage of cropland infested with these resistant biotypes that includes sugar beets and/or its rotation crops as analyzed above. Of the herbicides commonly used in sugar beets, kochia is not controlled well with the typical preplant incorporated herbicide (Ro-Neet). In addition, these two species have biotypes that are resistant to many of the other herbicide modes of action used in sugar beets. Therefore the potential exists for multiple-herbicide resistant biotypes to emerge over time through crossing, and multiple herbicide resistant biotypes of both of these species have already been reported in North Dakota and/or Minnesota (Stachler and Zollinger, 2009; Stachler et al., 2009). However, because glyphosate generally has greater control ratings than other post-emergent herbicide options available to control ALS-inhibitor resistant kochia and ACCase inhibitor resistant wild oat biotypes (see Table 4), the preferred alternative will continue to allow growers of glyphosate resistant H7-1 derived varieties the option to control these resistant weed biotypes with post-emergent applications of glyphosate if they are present in sugar beet fields, and this in turn may reduce populations of these resistant biotypes in crops grown in rotation. These two biotypes are mostly a problem in wheat and cereals and one or both are known to infest these major rotation crops of sugar beet in ND, MT, ID, MN, and CO. Thus the post-emergent glyphosate control option in H7-1 sugar beet afforded by the preferred alternative has a small countervailing positive impact against the adverse effects of these existing herbicide resistant weeds.

Also, as indicated in the Environmental Consequences – Biological Environment Section, impacts, if any, with respect to the development of glyphosate-resistant weeds in sugar beet crops in the timeframe considered in this EA are expected to be very small, and that trend is expected to continue. First, sugar beets are a relatively small crop. H7-1 sugar beets account for less than one percent of the glyphosate-resistant crops grown in the US, and in those major sugar beet production states where glyphosate resistant crops (corn and soybean) are major rotation crops for sugar beet, H7-1 represents approximately 7% of the estimated total acreage planted to those glyphosate resistant rotation crops based on 2002 planting data from Table 1. This suggests that the likelihood for the development of new glyphosate-resistant weed populations in H7-1 when compared to other herbicide resistant crops in general or those that are grown in rotation with sugar beet (particularly corn and soybean) is smaller (Management practices in Roundup Ready alfalfa probably also result in a low chance of leading to glyphosate resistant weeds due to the small amount of glyphosate use in alfalfa.) This is borne out by analysis of the incidence of sugar beet weeds that have developed resistance to herbicides since the time that glyphosate resistant sugar beets were first grown commercially and the incidence of glyphosate resistant weeds in crops grown in rotation with sugar beet. The previous statement can also be justified on the following basis: 1) weed escapes in sugar beets are likely to be removed by hand hoeing prior to harvest which would reduce the chances for a glyphosate resistant weed to set seed; 2) sugar beets are rotated with crops where herbicides with other modes of action can be used for weed management across the rotation; and 3) it is as common for sugar beets to be rotated with small grains as it is to be rotated with Roundup Ready corn or soybeans. As discussed in the Environmental Consequences Section, the nature of glyphosate itself and the growing practices for sugar beets makes it less likely that new glyphosate-resistant weed populations will develop in sugar beets as a result of the use of glyphosate in sugar beets. Additionally, there is a high level of awareness about the potential for glyphosate resistant weeds and many readily available resources to assist growers with management strategies. Indeed, H7-1 growers are required to follow Monsanto's TUG, including its recommendations for adopting growing practices aimed at reducing the development of glyphosate-resistant weed populations. Finally, because herbicide resistance is a heritable trait, it takes multiple growing seasons for herbicide tolerant weeds to emerge and become the predominant biotype in a specific area (Cole, 2010). Researchers have concluded that even if growers completely relied on only one herbicide, it is likely to take at least five years for a herbicide-resistant weed population to develop (Kniss, 2010; Beckie 2006; Neve, 2008; Werth, 2008). This is a reason why crop monitoring and follow up by University and industry weed scientist in cases of suspected resistance are important parts of all herbicide resistance stewardship programs. New research regarding the control of glyphosate resistant tall waterhemp and ragweed confirmed in sugar beet fields in parts of Minnesota and North Dakota indicate that an alternative post-emergent herbicide can provide control but the outcome is enhanced when combined with glyphosate. Thus the continued ability to use H7-1 along with post-emergent application of glyphosate will provide countervailing benefits to manage the adverse impacts of glyphosate resistant weeds as well as other herbicide resistant weeds in sugar beet, thereby reducing populations in subsequent crop rotations with other crops. Of all of the sugar beet growing states, Minnesota and North Dakota are estimated to have the largest acreages of soybean as a rotational crop following sugar beet, and 70 and 40% of the sugar beet acreage, respectively, is estimated to be rotated with soybean in these states (see Tables 1 and 18 above). To further reduce the possibility of glyphosate resistant weeds in subsequent crops and/or damage from some of the residual herbicides that may be needed to control them, growers can use alternative herbicides and/or alternative herbicide resistant crop systems, e.g. Liberty Link® soybeans, additional tillage or weeding, or alternative rotation crops (Gunsolus, 2008). The incremental impact with respect to herbicide resistant weeds in sugar beet root production areas with continued cultivation of H7-1 under the preferred alternative is not expected to result in significant cumulative adverse impacts when combined with the impacts from herbicide resistant weeds already present and any continued cultivation of other glyphosate resistant crops presently being grown in sugar beet production areas.

Other Biological Resources

Cumulative Impacts of Potential Increased Glyphosate Usage with the Cultivation of Glyphosate Tolerant Crops

Studies of the relationship between genetically engineered crops and herbicide use has shown that an increase in glyphosate tolerant crops can result in a decrease in mechanical tillage (Brimner et al., 2005; Fernandez-Cornejo, 2006; Gianessi and Reigner, 2006; Kleter et al., 2007; Sankula, 2006; Johnson et al., 2007). The potential cumulative impact from this reduction in mechanical tillage is discussed in the following sections along with differences in toxicological profiles of glyphosate compared to other herbicides used in sugar beet production to arrive at potential cumulative impacts on other biological resources, and is also taken into consideration for the later sections on physical resources and human health and worker safety.

According to the USDA ERS (2009a), US farmers have adopted genetically engineered crops widely since their introduction in 1996. Soybeans and cotton genetically engineered with herbicide-tolerant traits have been the most widely and rapidly adopted GE crops in the US, followed by insect-resistant cotton and corn. Figure 6 shows the percentage of acres of genetically engineered crops in the US between 1996 and 2009.

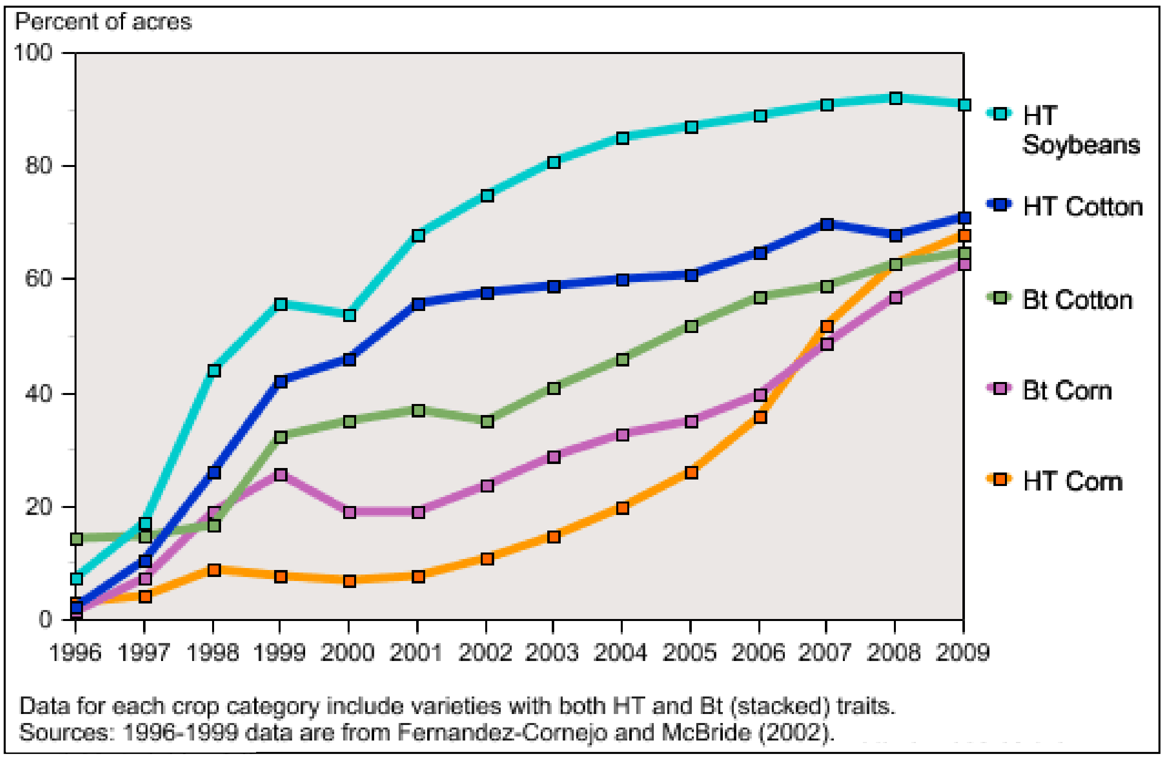

Figure 6. Growth in Adoption of Genetically Engineered Crops in US
Source: Graph from USDA ERS, 2009

Herbicide-tolerant crops, which are engineered to survive application of specific herbicides that previously would have damaged the crop, provide farmers with a broader variety of options for effective weed control. Based on USDA survey data, herbicide tolerant soybeans went from 17% of US soybean acreage in 1997, to 68% in 2001 and 91% in 2009. Plantings of herbicide tolerant cotton expanded from approximately 10% of US acreage in 1997 to 56% in 2001 and

71% in 2009. The adoption of herbicide tolerant corn, was slower in previous years, but has reached 68% of US corn acreage in 2009 (USDA ERS, 2009a).

Any cumulative impacts from continued glyphosate use as a result of the preferred alternative will be additive to the benefits already afforded by adoption of glyphosate resistant H7-1 derived varieties of sugar beet and other glyphosate resistant crops in those areas where sugar beet production overlaps that with other glyphosate tolerant crop production. Of the glyphosate resistant crops currently grown, cotton is not a major rotation crop for sugar beet. Furthermore, cotton is not grown in major sugar beet production states, with the exception of Arizona and California, were limited numbers of acres of sugar beet steckling production and small amount of sugar beet production occur, respectively (Furthermore, Alternatives 2, 3 and the Preferred Alternative would prevent the planting of H7-1 sugar beets in all of California for both root or seed production). However, corn and soybean can precede sugar beet in the rotation, and soybean, corn, and to a lesser extent alfalfa are considered major crops following sugar beets in rotation. The percent of total sugar beet estimated to be rotated with Roundup Ready® soybean, corn, and alfalfa for major sugar beet root production states based on 2002 sugar beet production acres is shown in Table 18 above.

Corn growers use the largest volume of herbicides. Approximately 96% of the 62.2 million acres used for growing corn in the 10 major corn-producing States were treated with more than 164 million pounds of herbicides in 1997 (USDA ERS, 2009a). Soybean production in the US also uses a large amount of herbicides. Approximately 97% of the 66.2 million soybean acres in the 19 major soybean producing States were treated with more than 78 million pounds of herbicides in 1997 (USDA ERS, 2009a). Cotton production relies heavily on herbicides to control weeds, often requiring applications of two or more herbicides at planting and postemergence herbicides later in the season (Culpepper and York, 1998). Close to 28 million pounds of herbicides were applied to 97% of the 13 million acres devoted to upland cotton production in the 12 major cotton-producing States in 1997 (USDA ERS, 2009a).

Pesticide use on corn and soybeans has declined since the introduction of GE corn and soybeans in 1996. Several studies have analyzed the agronomic, environmental, and economic effects of adopting GE crops, including actual pesticide use changes associated with growing GE crops (McBride and Brooks, 2000; Fernandez-Cornejo et al., 1999; Fernandez-Cornejo et al., 2002;

Giannessi and Carpenter, 1999; Culpepper and York, 1998; Marra et al., 1998; Falck-Zepeda and Traxler, 1998; Fernandez-Cornejo and Klotz-Ingram, 1998; Gibson et al., 1997; ReJesus et al., 1997; Stark, 1997). Many of these studies have concluded that herbicide use is reduced with herbicide-tolerant varieties (USDA ERS, 2009a). In contrast, Benbrook et al 2009, report "that GE crops have been responsible for an increase of 383 million pounds of herbicide use in the US over the first 13 years of commercial use of GE crops (1996-2008)."

Studies conducted by the USDA however, also show an overall reduction in pesticide use related to the increased adoption of GE crops. Based on the adoption of GE crops between 1997 and 1998 (except for herbicide-tolerant corn, which is modeled for 1996-97), the decline in pesticide use was estimated to be 19.1 million acre-treatments, 6.2% of total treatments (USDA ERS, 2009a). Most of the decline in pesticide acre treatments was from less herbicide used on soybeans, accounting for more than 80% of the reduction (16 million acre-treatments) (USDA ERS, 2009a). Sugar beet is estimated to be rotated to soybean more than 35% of the time, more than any other major rotation crops (Table 1), and 91% of the US soybean crop is estimated to be glyphosate tolerant. The adoption of herbicide-tolerant crops such as H7-1 sugar beets, glyphosate-tolerant soybeans and glyphosate-tolerant corn will result in the substitution of glyphosate for some of the previously used herbicides. As discussed in the Environmental Consequences section (and see Table 1), only in southern Minnesota and Michigan are farmers likely to include glyphosate resistant crops in a large majority of the rotations. Even so, as described earlier in the Affected Environment Biological Resources section, the glyphosate used on H7-1 derived sugar-beet varieties accounts for less than 1% of the US total. The glyphosate tolerant crops allow farmers to limit and simplify herbicide treatments based around use of glyphosate, while a conventional weed control program can involve multiple applications of several herbicides. In addition, and more importantly, herbicide-tolerant crops often allow farmers to use more benign herbicides (USDA ERS, 2009a) unless resistance develops.

There are known benefits associated with the use of glyphosate herbicides compared to herbicides currently used by sugar beet producers. Glyphosate has documented favorable characteristics with regard to risk to human health, non-target species, and the environment (Malik et al., 1989; Geisy et al., 2000; Williams et al., 2000).

For non-target terrestrial species, available ecological assessments in EPA RED (US EPA, 1993) documents or registration review summary documents provide the support that the use of glyphosate represents reductions in chronic risk to birds compared to trifluralin and sethoxydim, in acute risk to small mammals in comparison to EPTC, in chronic risk to mammals from quizalofop-p-ethyl, in acute risk to endangered birds and mammals from pyrazon, and in chronic risk to mammals and potentially birds from cycloate. For all other sugar beet herbicide products, as well as glyphosate, no significant risks to birds or other non-target terrestrial species were indicated in the available information.

For non-target aquatic species, Tables 12, 13, and 14 provide summaries of the estimated exposure and hazard information for the traditional herbicides used in conventional sugar beet production, and present quantitative comparisons of the derived Risk Quotients. Exposure, defined as the EEC, was calculated for all products using the standard assumptions (assuming aerial application) of 5% drift of spray applied to a one-acre field onto water and 5% runoff from 10 treated acres into a one-acre pond six feet in depth. Herbicide treatments were based on the maximum single application rate taken from product labels. Hazard information (LC50 or EC50) for each active ingredient was taken from the EPA OPP Pesticide Ecotoxicity Database (if available) or other EPA source documents and summarized in Tables 12, 13, and 14 as the upper and lower values from the range of values reported. Hazard information for the end-use formulated products is generally not readily available, thus this analysis is a comparison based solely on the active ingredients. Any label warnings and other available hazard and/or risk descriptions for non-target aquatic species are also included. The Risk Quotient is determined for each active ingredient by dividing the EEC by the hazard (LC50 or EC50) value.

Plants potentially at risk from the use of glyphosate are potentially at risk from the use of any herbicide to which they are sensitive. Like many broad-spectrum herbicides, plants are highly sensitive to glyphosate. Monsanto has developed a program named Pre-Serve to address aerial spraying in areas where threatened or endangered plants may be located. Following label use instructions and use limitations described in Pre-Serve would address any such risk of exposure. Federal law requires pesticides to be used in accordance with the label. Because glyphosate binds strongly to soil particles, conservation tillage and no tillage practices provide additional assurance that the impacts to aquatic plants are negligible.

The labels for products containing desmedipham, phenmedipham, sethoxydim, clethodim, pyrazon, quizalofop-p-ethyl, and trifluralin include warnings of toxicity or adverse effects to fish, and/or aquatic invertebrates and/or aquatic plants. Risk Quotients that exceed the Trigger Value of 0.5 for aquatic animals and 1.0 for aquatic plants are highlighted in bold text in Tables 10, 11, and 12 as exceeding a Level of Concern, based on EPA Ecological Effects Rejection Analysis and Deterministic Risk Characterization Approach. Current sugar beet herbicide products containing trifluralin and pyrazon are shown to exceed these Levels of Concern. As supported by the EPA designation of reduced risk for application of glyphosate to H7-1 sugar beet, glyphosate is a more environmentally preferred herbicide compared to other herbicides currently used in sugar beet production since glyphosate is generally less toxic and has favorable degradation properties. No significant impacts on microorganisms from changes in herbicide use patterns for roots, seeds or steckling production were identified in the previous Environmental Consequences sections.

The preferred alternative would allow for the continued use and application of glyphosate-based herbicide formulations as post-emergent applications in H7-1 derived sugar beet varieties, in addition to pre-emergent applications. This could result in continued glyphosate exposure to animal and plant species within and adjacent to those fields through drift as discussed previously, and a decrease in exposure to other herbicides from runoff and/or drift (USDA APHIS, 2009).

Based on the data available on glyphosate usage, chemical fate, and toxicity, glyphosate is not expected to pose an acute or chronic risk to the following categories of wildlife: (US EPA, 1993)

- birds
- mammals
- terrestrial or aquatic invertebrates
- fish
- microorganisms

Glyphosate is practically nontoxic to slightly toxic to birds, freshwater fish, marine and estuarine species, aquatic invertebrates and mammals and practically nontoxic to honey bees (which are used to assess effects on nontarget insects in general); (EPA 1993). Glyphosate is not expected to accumulate in fish or other animal tissues. Glyphosate products containing surfactants with toxicity to aquatic organisms are required to carry restrictions regarding application near water (US EPA, 1993). Under the preferred alternative, impacts on animals especially could continue to be reduced by the continued use of glyphosate on sugar beet root production because of reduced exposure to other more toxic herbicides from runoff and/or drift (USDA APHIS, 2009). When used according to Pre-serve methods, glyphosate drift to non-target plants should not pose a hazard. Positive impacts, relative to those used in conventional sugar beet production, are expected to produce greater cumulative impacts when combined with benefits expected from herbicide use in rotation crops and surrounding crops in those areas where glyphosate resistant cropping systems are more prevalent and are included in rotation with glyphosate resistant sugar beet. These areas include sugar beet root production areas in Minnesota, North Dakota, Nebraska, Michigan, and Colorado (see Tables 1 and 18 above). In addition, the risk to nearby nontarget crop plants through accidental drift will be reduced if the nearby crop is also glyphosate resistant. If growers adopt low- or no-till farming practices, which is common with users of this technology, negative impacts associated with water/fertilizer/pesticide run off from fields would also continue to be reduced. Nonetheless, given the diversity in crop rotation options and the crop rotation cycle for sugar beet production in most states and the relatively small acreage of sugar-beet production and associated glyphosate use compared to other glyphosate-resistant crops and overall glyphosate use, the cumulative impacts are not expected to be significant.

Socioeconomic Environment

Sugar Beet Production in the US and Its Contribution to the Sugar Market

As summarized in the Environmental Consequences Section on Socioeconomic Impacts, the preferred alternative would permit H7-1 seed to be planted for root and seed production for the 2012 root crop under appropriate regulatory authorization. This would allow breeding programs and variety trials to continue to inform future planting decisions and fulfill grower contracts for planting. This will result in less disruption to the sugar industry compared to the no action alternative and allow for long term stability of the US sugar market. This will result in the maintenance of the supply of improved and approved sugar beet varieties to breeders and growers; maintenance of sugar beet yields and income to growers, contractors and sugar beet processors; continued availability of sugar from sugar beets to consumers and food processors;

and price stability to consumers.   There would be no or negligible impact on sugar companies and cooperatives. No cumulative impact is expected.

Non-GE Sugar Beet Seed Availability and Impacts on Consumers Choosing Non-GE Sugar

As summarized in Environmental Consequences Section on Socioeconomic Impacts, conventional sugar beet seed is in short supply. However, there has been little demand for conventional (non-GE) sugar beet varieties, and due to the adoption of varieties with the H7-1 trait, nearly all new official entries for trials for approved varieties have the H7-1 trait. Seed production decisions are based on the forecasted demand in future years, and H7-1 varieties are what the large majority of sugar beet farmers have been choosing to purchase. Under the preferred alternative, seed providers would continue to initiate seed production of H7-1 varieties, and would only initiate seed production of conventional varieties where there is a clear market demand. This alternative would therefore continue the trend toward lower reserves and availability of conventional seed in future years; however this is not expected to result in a significant impact unless there is later an increase in the demand for these conventional seeds. Since none of the US sugar beet processing facilities process organic sugar beets, there is unlikely to be an increase in demand of conventional sugar beet seeds. Furthermore, no impact is expected on the ability of consumers and industrial food producers to continue to use other sources of sweeteners that are not derived from GE organisms (such as cane sugar, honey, maple syrup, and stevia) if they have preferences that do not include products of biotechnology.

Vegetable Beet Seed and Root Production

As summarized in Environmental Consequences Section on Socioeconomic Impacts, the preferred alternative is expected to have no or negligible impacts to vegetable beet seed production and vegetable beet root production, regardless of whether the vegetable beet or seed is intended to be certified as organic through the National Organic Program. Any impacts that could arise through: (1) gene flow from H7-1 sugar beet seed fields, volunteers, or bolters to vegetable beet seed fields or bolters; or (2) mixing of H7-1 sugar beet seed or beets with vegetable beet seed or beets are expected to be reduced to no or negligible impacts through the permit conditions proposed by APHIS. Furthermore, if breeder seed did have a low level presence of H7-1, steps can be taken to clean up the seed (see Environmental Consequences section). From the above analysis, it can be concluded that there should be no significant cumulative impacts on co-existence of growers who choose to grow conventional or organic crops and those who choose to grow H7-1 derived sugar beet varieties.

Physical Resources

Land Use

As discussed in Environmental Consequences Section on Physical Resources, sugar beet acreage has fluctuated little for the past 50 years, was not impacted by the introduction of H7-1, and is not expected to be impacted by continued use of H7-1 as proposed under the preferred alternative. Therefore, as discussed in the Environmental Consequences Section, the preferred alternative is not expected to impact land use, and therefore there will be no cumulative impacts on land use.

Air Quality and Climate

As discussed in the Environmental Consequences Section on Physical Resources, the preferred alternative is expected to continue to have small positive impacts on air quality and climate, primarily resulting from reduced tillage. Emissions related to global warming, ozone depletion, summer smog and carcinogenicity, among others, were found to be lower in glyphosate-tolerant crop systems than conventional systems (Bennett et al., 2004). In a study of conventional compared to Roundup tolerant sugar beets in Idaho, the Roundup® tolerant sugar beets required fewer cultivations, fewer herbicide applications, and on average 1.7 fold less fuel to make these passes through the crop, and consequently, it was estimated that among the four cultivation and herbicide treatment regimes, fuel reductions ranging from 0.6-2.5 gallons/acre resulted in 5.8 to 24.1 fewer pounds of carbon released per acre (as CO_2) in H7-1 production than in conventional sugar beet production (Hirnyck and Morishita, 2007). This impact will be less for H7-1 seed production due to the limited use of glyphosate as a post-emergent herbicide in hybrid seed production fields compared to H7-1 sugar beet root production and also in terms of lower acreage planted to seed and stecklings. The positive impact is only expected to provide incremental impacts that will be cumulative in those areas where rotation crops also implement conservation tillage practices. One such situation would be in those areas where other Roundup

Ready® crops follow sugar beet in rotation (see Table 18 above). Because of the crop rotation practices and crop rotation cycles for sugar beet, and the relatively small number of acres planted to sugar beet relative to other crops, none of the cumulative impacts are expected to be significant.

Water Quality and Availability

As discussed in the Environmental Consequences Section on Physical Resources, the advent of glyphosate tolerant crops and the use of post-emergent herbicides that could be applied over a crop during the growing season have facilitated the use of conservation tillage farming practices, since weeds could be controlled after crop growth without tilling the soil (USDA ERS, 2009a). The use of glyphosate tolerant crops (particularly soybeans) has intensified that trend since it often allows a more effective and less costly weed control regime than using other post-emergent herbicides (USDA ERS, 2009a; Carpenter and Gianessi, 1999).

The impact of conservation tillage (including no-till, ridge-till, and mulch-till) in controlling soil erosion and soil degradation is well documented (Edwards, 1995; Sandretto, 1997). By leaving substantial amounts of plant matter over the soil surface, conservation tillage 1) reduces soil erosion by wind; 2) reduces soil erosion by water; 3) increases water infiltration and moisture retention; 4) reduces surface sediment and water runoff; and 5) reduces chemical runoff (USDA ERS, 2009a). However, conservation tillage systems and glyphosate based weed management can also affect weed population dynamics and results have been mixed. In a detailed review, Moyer et al. (1994) provided a list of weeds that are reportedly favored by conservation or conventional tillage systems.

Glyphosate may potentially be found in surface water runoff when erosion conditions lead to the loss of surface particles. However, as discussed in the Environmental Consequences Section on Physical Resources, the preferred alternative is expected to lead to an increase in conservation tillage and no tillage systems, which would result in less mechanical disturbance of the soil during sugar beet cultivation and thereby decrease the loss of surface soil. Because of this, and the fact that glyphosate binds strongly to soil particles, no-tillage and conservation tillage are expected to further reduce the likelihood of any impact from surface water runoff (Wiebe and

Gollehon, 2006). Therefore, no cumulative adverse impacts to surface water or groundwater are anticipated.

In addition, as discussed in Environmental Consequences section on Physical Resources, glyphosate has a lower risk potential with respect to surface and ground water contamination compared to many of the other alternative herbicides used in sugar beet (Hirnyck and Morishita 2007), and it has reduced risk potential to aquatic organisms and humans (see Tables 10-14 above and the Human Health section below).

Since the cumulative impacts on water quality are related to both tillage and relative toxicity (particularly with respect to humans and aquatic organisms) of herbicides likely to be used in conventional sugar beets compared to glyphosate resistant sugar beets, the cumulative impact summary for biological organisms and human health are also applicable. Because of the crop rotation practices and crop rotation cycles for sugar beet, and the relatively small number of acres planted to sugar beet relative to other crops, none of the cumulative impacts are expected to be significant.

Human Health and Safety

A tolerance increase was required to support approval for the use of glyphosate in the H7-1 sugar beet-cropping system compared to the limited pre-emergent use of glyphosate in conventional sugar beet production. However, the potential health effects of pesticide residues that may be present in food, regardless of whether they result from uses in conventional or glyphosate tolerant crops, are carefully considered by EPA before establishing maximum residue limits or tolerances. Regardless of whether Alternative 1, 2, 3 or the Preferred Alternative is chosen for sugar beet root production, it will not change the tolerance level set by EPA for glyphosate in sugar beet or other crops, but Alternative 1 is expected to result in a return to glyphosate use levels in conventional sugar beets similar to those before 2005 when H7-1 was originally deregulated.

Before establishing a tolerance in an agricultural commodity, EPA must find that the potential resulting residues covered by the proposed tolerance will be “safe”. Section 408(b)(2)(A)(ii) of the FFDCA [21 USC 346a(b)(2)(A)(i)] defines “safe” as a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. As part of this determination, the total maximum theoretical level of residue present in all food commodities with approved uses for the pesticide must not exceed the EPA established Reference Dose (RfD), or chronic Population Adjusted Dose (cPAD). Following a comprehensive review of the results of toxicological studies conducted on the pesticide, the RfD is set by applying appropriate uncertainty factors to the most appropriate No-Observed-Adverse-Effect-Level (NOAEL).

In 1999, EPA conducted a dietary exposure risk assessment and concluded that the incremental dietary exposure associated with the use of glyphosate on glyphosate tolerant sugar beet did not pose a concern to human health (64 FR 18360, 1999).

In a recent risk assessment supporting establishment of certain new food crop tolerances for glyphosate, EPA estimated that chronic (daily dietary) exposure to glyphosate from all food and water sources would use only 2% of the glyphosate RfD (1.75 mg/kg/day) for the general US population and 7% of the RfD for the highest potentially exposed subgroup population (71 FR 76180, 2006).

The cumulative impacts to pesticide applicators from use of glyphosate on sugar beets were considered. Biomonitoring of pesticide applicators conducted by independent investigators has shown that bodily adsorption of glyphosate as the result of routine, labeled applications of registered glyphosate-based agricultural herbicides to crops, including to glyphosate tolerant sugar beet, was thousands of times less than the allowable daily intake level established for glyphosate (Acquavella et al., 2004). Given similarity to current use pattern, herbicide label rates, and the percentage of cultivated acres for sugar beets, the continued use of H7-1 sugar beet as under the preferred alternative will not significantly increase the exposure risk to pesticide applicators. Furthermore, EPA, the European Commission, the WHO, and independent scientists have concluded that glyphosate is not mutagenic or carcinogenic, not a teratogen nor a reproductive toxicant, and that there is no evidence of neurotoxicity associated with glyphosate (US EPA, 1993; EC, 2002; WHO, 2005; Williams et al., 2000).

Bystander exposure to glyphosate as a result of pesticide application to H7-1 sugar beet would be negligible, since such applications would occur in an agricultural setting in relatively rural sugar beet fields, not in an urban setting.

Presented below is a brief, comparative analysis of the hazard/risk characteristics of glyphosate, the active ingredient in Roundup WeatherMAX® herbicide (EPA Registration No. 524-537), to the most commonly used herbicides applied in conventional sugar beet production, based on total pounds of active ingredient applied (USDA NASS, 2001c). A detailed assessment of the potential chronic human health risks compared to traditional products will not be presented in this comparison; it is sufficient to state that the chronic RfD values for each active ingredient is lower (less safe) than that of glyphosate. Acute RfDs where available in their respective RED (cycloate, EPTC, ethofumesate, sethoxydim and trifluralin) reflect greater acute toxicity than glyphosate. The assessment is based on information obtained from various sources, including product-specific labeling (for comparing all acute toxicities), EPA Reregistration Eligibility Documents, EPA RED Fact Sheets (for all comparator active ingredients), product-specific *Federal Register* publications (Clethodim Human Health Risk Assessment for Proposed Use on Field Corn, EPA-HQ-OPP-2008-0658-0004; Clopyralid Tox, *Federal Register* Vol. 62, No. 48 p. 11362), the EPA Ecotoxicology One-Liner database (now called the EPA OPP Pesticide Ecotoxicity Database), the USDA Pesticide Properties database11, and other public sources of product-specific toxicological and environmental profile information. The assessment shows that in the majority of cases, weed control with glyphosate formulated and sold as Roundup WeatherMAX herbicide in the H7-1 sugar beet system offers the benefit of less risk from potential exposure for applicators and handlers of concentrated product and a reduced potential to impact non-target species and water quality.

Table 11 provides a comparison of product-specific labeling for herbicides commonly used for weed control in sugar beet production, including required precautionary statements associated with acute exposure hazards and environmental risk concerns. Although most alternative products carry the same signal word as Roundup WeatherMAX herbicide (CAUTION), the associated precautionary statements of each of the alternative herbicide products are indicative of toxicity findings that represent a greater acute exposure risk than Roundup WeatherMAX.

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Nearly every sugar beet herbicide product evaluated has more restrictive requirements for the use of Personal Protective Equipment (PPE) than those required for Roundup WeatherMAX herbicide, indicating a greater need to reduce the risk of acute exposure, and, in some cases, the risk of longer-term or chronic exposure, for applicators and handlers of these other products.

The comparative analyses provided in this section are summarized in Table 19 and show those areas for which glyphosate (designated with a checkmark ✓), using Roundup WeatherMAX herbicide in the comparison, offers the benefit of potential risk reduction compared to the most commonly used sugar beet herbicides in sugar beet production. In this cumulative comparison, glyphosate offers potential benefits over all the traditional sugar beet herbicides in at least one and up to six risk assessment categories. These comparisons demonstrate the benefits to not only applicators and mixers, but also to non-target organisms from the use of glyphosate in the H7-1 sugar beet system.

Table 19. Potential Reduction in Risk from Use of Glyphosate Compared to Traditional Herbicides Used in US Sugar Beet Production

Active Ingredients[1]	Human Health Risk		Non-Target Species Risks					Groundwater Contamination	Total Number of Areas for Potential Risk Reduction
	Acute	Chronic	Mammals	Fish	Aquatic Invertebrates	Aquatic Plants	Avian		
Clethodim	✓	✓						✓	3
Clopyralid	✓							✓	2
Cycloate	✓		✓				✓	✓	4
Desmedipham	✓	✓						✓	3
EPTC	✓	✓	✓					✓	4
Ethofumesate	✓			✓				✓	3
Phenmedipham	✓								1
Pyrazon	✓		✓			✓	✓	✓	5
Quizalofop-p-ethyl	✓		✓					✓	3
Sethoxydim	✓	✓					✓		3
Trifluralin	✓	✓		✓	✓	✓	✓		6
Triflusulfuron	✓								1

[1] Traditional herbicides are compared to glyphosate, using the label from Roundup WeatherMAX herbicide.

✓ Indicates there is a potential for reduction in risk category by using Roundup agricultural herbicides.

Summary of Potential Cumulative Impacts to Biological Organisms from Increased Use of Glyphosate

When considering the impact that the use of glyphosate in the H7-1 sugar beet system could have on the human environment in conjunction with the use of glyphosate in other glyphosate tolerant crops already being cultivated in the same affected environments, the facts suggest that this use will have little or no additive effect. Alternatively, this has the potential to reduce risks to the affected environment from the use of other, more harmful, herbicides. This is supported by the assessment of the environmental and worker safety hazards associated with glyphosate when compared to other available herbicides used for weed control in sugar beet production. Based on such an assessment, EPA granted reduced risk status for this use of glyphosate, and expedited the review of supporting residue data. Therefore, there is no reasonably anticipated adverse cumulative impact on human health or the environment from the use of glyphosate associated specifically with the continued cultivation of H7-1 sugar beets as proposed with or without conditions proposed under Alternative 2, 3 or the Preferred Alternative.

I. Compliance with Statutes, Executive Orders and Regulations

Executive Order (EO) 12898 (US NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

EO 13045 (US NARA, 2010), "Protection of Children from Environmental Health Risks and Safety Risks," acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) required each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Each alternative was analyzed with respect to EO 12898 and 13045. Based on the information submitted by the applicant and assessed by APHIS, H7-1 is not significantly different than conventional sugar beet production and has successfully completed the FDA voluntary consultation for food and feed use. Therefore, H7-1 is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children. Based on historical experience with sugar beet production and the data submitted by the applicant and assessed by APHIS, H7-1 should eliminate the use of a variety of conventional herbicides, which in some cases may increase worker safety by replacement of these with glyphosate which has increased safety compared to some of these additional herbicides formerly used in sugar beet production.

EO 13112 (US NARA, 2010), "Invasive Species", states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause. Both non-GE and the present GE sugar beet variety that had been previously been granted nonregulated status was widely grown in the U.S. Based on historical experience with sugar beet and the data submitted by the applicant and assessed by APHIS, H7-1 sugar beet plants are very similar in fitness characteristics to other sugar beet varieties currently grown and are not expected to become weedy or invasive (USDA APHIS, 2010).

EO 13186 (US-NARA 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds", states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within 2 years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations. Data submitted by the applicant has shown no difference in compositional and nutritional quality of H7-1 compared to conventional sugar beet, apart from the presence of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase protein (EPSPS). The migratory birds that occasionally forage or injure sugar beets are unlikely to be affected by the H7-1 plants, since the variety was grown for four years before it was re-regulated, and no adverse affects on birds are known to APHIS. Based on APHIS' assessment of H7-1 it is unlikely that granting permits for this sugar beet variety will have a negative effect on migratory bird populations.

Impacts on Unique Characteristics of Geographic Areas. There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by the proposed action alternative. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance, do not cause any physical destruction or damage to property, do not cause any alterations of property, wildlife habitat, or landscapes, and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to allowing permits for growing H7-1 sugar beet. The product will be deployed on a similar number of acres of agricultural farm land used recently for sugar beet production of this same variety while in non regulated status. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to H7-1 sugar beet including the use of EPA registered herbicides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. If APHIS allows permits for H7-1 sugar beet, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to sugar beet production sites.

International Implications. EO 12114 (US NARA, 2010), "Environmental Effects Abroad of Major Federal Actions", requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken. APHIS has given this due consideration and does not expect a significant environmental impact outside the U.S. should APHIS regulate H7-1 sugar beets under the stated Permit Conditions. APHIS' considered a no "action" alternative, and the environmental and socioeconomic consequences for non-US growers of the product may be substantial, because greater exports of sugar may be made to make up for decreased US sugar production from sugar beets.

Monsanto KWS sugar beet has been extensively planted in the US and Canada, and beets from both countries may be processed for sugar products in the US. APHIS is unaware of any US grown beets that are sold abroad as unprocessed beets, but only non-reproductive parts, such as pulp, molasses and sugar. Canadian growers may purchase seed and grow H7-1 sugar beets unrestricted by the decision of US Federal Court to cease production of the crop until APHIS completes an environmental assessment and takes action to regulate the crop without environmental consequences to identified crops, organisms or habitats. Under the No Action Alternative (Alternative 1) no mechanism would be established for movement of the Canadian H7-1 beets into the US and purchase or receiving by a processor. Certain Canadian growers sell to US processors on a yearly basis (Ontario growers; Michigan Sugar Co.) and under this Alternative would not likely grow this crop. Under pteferred alternative, the movement of Canadian sugar beets into the US would be allowed. All conditions applicable to US production would apply to the movement and processing of these imported beets. Under these conditions, production of sugar deriving from Ontario beets would be possible in US processing plants, and no impacts other than requirements for regulatory notification and use of certain containment conditions would be imposed on Canadian growers.

It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new sugar beet cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR Part 340. Any international trade of H7-1 sugar beet subsequent to a determination of nonregulated status for the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the *International Plant Protection Convention* (IPPC 2010).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC 2010); the protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

Compliance with Clean Water Act and Clean Air Act. H7-1 will not lead to the increased production of sugar beet in U.S. agriculture. There is no expected change in water use due to the production of H7-1 compared to current sugar beet seed or root production regimes, nor is it expected that air quality will change because of production of H7-1.

National Historic Preservation Act (NHPA) of 1966 as amended. The NHPA of 1966, and its implementing regulations (36 CFR 800), requires federal agencies to: 1) determine whether activities they propose constitute "undertakings" that has the potential to cause effects on historic properties and, 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e. State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate. This action will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe’s request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties.

This action would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to granting permits to H7-1 seed and root production. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. This action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. There is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices such as the use of tractors and other mechanical equipment are in close proximity to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible qualities of a site and can be ended at any time to restore those qualities of such sites to their original condition with no further adverse effects.

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K. References

Acquavella, J.F., Alexander, B.H., Mandel, J.S., Gustin, C., Baker, B., Chapman, P., and Bleeke, M. 2004. Glyphosate biomonitoring for farmer-applicators and their families: Results from the farm family exposure study. Environmental Health Perspectives 112:321-326.

Ali, M.B, 2004. Characteristics and production costs of U.S sugarbeet. Sugar beet farms. USDA statistical bulletin no. 974-8.

American Crystal Sugar Company, 2009. Annual Report. Accessed on May 30, 2010 at: http://www.crystalsugar.com/coopprofile/annual.aspx.

American Crystal Sugar Company, 2010. Producing Sugarbeet Seed. Accessed Dec. 28, 2010. http://www.crystalsugar.com/agronomy/bs.new/producingseed.aspx

Anderson, M., and Magleby, R. 1997. Agricultural resources and environmental indicators, 1996-1997. Agriculture Handbook No. AH712. USDA ERS. 356 p.

Anderson, J., Wachenheim, C., and Lesch, W. 2006. Perceptions of genetically modified and organic foods and processes. AgBioForum 9:180–194.

Anfinrud, M. 2010. Declaration of Mark Anfinrud in support of defendant intervenors' opposition. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Ashton, F., and Crafts, A. 1981. Mode of Action of Herbicides, 2nd ed. John Wiley & Sons. New York, NY. p. 525.

Aylor, D.E. 2003. Rate of dehydration of corn (Zea mays L.) pollen in the air. Journal of Experimental Botany 54:2307-23-2312.

Baerson, S.R., Rodriguez, D.J., Tran, M., Feng, Y., Biest, N.A., and Dill, G.M. 2002. Glyphosate-resistant goosegrass. Identification of a mutation in the target enzyme 5-enolpyruvylshikimate-3-phosphate synthase. Plant Physiology 129:1265–1275.

Baker, J.B., Southard, R.J., and Mitchell, J.P. 2005. Agricultural dust production in standard and conservation tillage systems in the San Joaquin Valley. Journal of Environmental Quality 34:1260-1269.

Baker, H. G. 1965. Characteristics and modes of origin of weeds. *In*: The Genetics of Colonizing Species. Baker, H. G. and Stebbins, G. L. (eds.). Academic Press. New York and London. pp. 147-172.

Baker, J.L., and Johnson, H.P. 1979. The effect of tillage systems on pesticides in runoff from small watersheds. Transactions of the American Society of Agricultural Engineers 0001-2351/79/2203-0554. pp. 554-559.

Baker, J.L., Laflen, J.M., and Hartwig, R.O. 1982. Effects of corn residue and herbicide placement on herbicide runoff losses. Transactions of the American Society of Agricultural Engineers 0001-2351/82/2502-0340. pp. 340-343.

Bandeen, J.D., Stephenson, G.R., and Cowett., E.R. 1982. Discovery and distribution of herbicide-resistant weeds in North America. *In:* Herbicide Resistance in Plants. LeBaron H.M. and Gressel J. (eds.) J.Wiley. New York. pp. 9-30.

Bartsch, D., Cuguen, J., Biancardi, E., and Sweet, J. 2003. Environmental implications of gene flow from sugar beet to wild beet – current status and future research needs. Environmental Biosafety Research 2:105-115.

Bartsch, D., and Ellstrand N.C. 1999. Genetic evidence for the origin of California wild beets. Theoretical and Applied Genetics. 99:1120-1130.

Baucum, L.E., and Rice, R.W. 2009. An overview of Florida sugarcane. University of Florida IFAS Extension Publication: SS-AGR-232. http://edis.ifas.ufl.edu/sc032

Beckie, H.J. 2006. Herbicide-Resistant Weeds: Management Tactics and Practices. Weed Technology. 20:793–814.

Bell, G.D.H. 1946. Induced bolting and anthesis in sugar beet and the effect of selection of physiological types. The Journal of Agricultural Science 36:167-184.

Benbrook, C. 2009. Impacts of genetically engineered crops on pesticide usage in the United States: The first thirteen years. The Organic Center. Accessed Sept. 16, 2010 at: http://www.organic-center.org/reportfiles/13Years20091126_ExSumFrontMatter.pdf

Bennett, R., Phipps, R., Strange, A., and Grey, P. 2004. Environmental and human health impacts of growing genetically modified herbicide-tolerant sugar beet: a life-cycle assessment. Plant Biotechnology Journal 2:273-278.

Berg, D. 2010. Declaration of David Berg. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Berglund, D.R., Riveland, N., and Bergman, J. 2007. Safflower production. North Dakota State University Agriculture and University Extension. Accessed June 6, 2009 at: http://www.ag.ndsu.edu/pubs/plantsci/crops/a870w.htm

Berglund, L., Brunstedt, J., Nielsen, K.K., Chen, Z., Mikkelsen, J.D., and Marcker, KA. 1995. A proline-rich chitinase from *Beta vulgaris*. Plant Molecular Biology 27: 211-216.

Bertolini, P., Wolf, M.M., Shikama, I., and Berger, A. 2003. Attitudes towards food and biotechnology in the U.S., Japan and Italy. International Consortium on Agricultural Biotechnology Research (ICABR), 7th ICABR International Conference on Public Goods and Public Policy for Agricultural Biotechnology. Ravello, Italy.

Boland, M. 2003. Arthur Capper Cooperative Center Case Study Series 03-02. Accessed on May 30, 2010 at: www.agmrc.org/.../wyomingsugarcompany_5253A0C0B243F.pdf

Bonnette, R. 2004. Glyphosate-tolerant sugar beet H7-1. Biotechnology consultation note to the file, BNF No. 00090. . FDA. Washington, DC, FDA. August 7. Accessed on June 26, 2010 at: http://www.fda.gov/Food/Biotechnology/Submissions/ucm155775.htm

Boongird, S., Seawannasri, T. Ananachaiyong, T., and Rattithumkul, S. 2003. Effect of Roundup Ready corn NK603 on foraging behavior and colony development of *Apis mellifera* L. under greenhouse conditions. Proceeding of the Sixth National Plant Protection Conference, November 24-27. pp. 26-27

Borggaard, O.K., and Gimsing, A.L. 2008. Fate of glyphosate in soil and the possibility of leaching to ground and surface waters: A review. Pest Management Science 64:441-456.

Bosemark, N.O. 2006. Genetics and breeding. *In:* Sugar Beet. Draycott, A.P. (ed.). Blackwell Publishing. Oxford UK. pp. 50-88.

Bott, S., Tesfamariam, T., Candan, H., Cakmak, I., Römheld, V., and Neumann, G. 2008. Glyphosate-induced impairment of plant growth and micronutrient status in glyphosate-resistant soybean (*Glycine max* L.). Plant and Soil 312:185-194.

Brimner, T.A., Gallivan, G.J., and Stephenson, G.R. 2005. Influence of herbicide-resistant canola on the environmental impact of weed management. Pest Management Science 61:47-52.

Brookes and Barfoot, 2003. Co-existence of GM and non GM crops: case study of maize grown in Spain. PG Economics, UK.

Brookes and Barfoot, 2004a. Co-existence of GM and non GM arable crops: case study of the UK. PG Economics, UK. November 2003.

Brookes and Barfoot, 2004b. Co-existence of GM and non GM arable crops: the non-GM and organic context in the EU. PG Economics, UK. May 2004,

Brookes, G., and Barfoot, P. 2008. Global impact of biotech crops: socio-economic and environmental effects, 1996-2006. AgBioForum 11:21-38.

Burgener, P.A., Feuz, D.M., and Wilson, R.G. 2000. Economics of transgenic sugarbeet production. Western Agricultural Economics Association Annual Meeting. Vancouver, Canada. June 29-July1. Western Agricultural Economics Association. 12 p.

California Beet Growers Association. 1998. The sugar beet industry in California. Accessed on May 30, 2010 at: http://sugarbeet.ucdavis.edu/sugar_industry.html.

California Beet Growers Association. 1999. Crop profile for sugar beets in California. Accessed on May 30, 2010 at: http://www.ipmcenters.org/cropprofiles/ListCropProfiles.cfm?typeorg=crop&USDARegion=National%20Site.

Campbell, C.A., and Janzen, H.H. 1995. Effect of tillage on soil organic matter. Farming for a better environment. pp. 9-11.

Carlsen, S.C.K., Spliid, N.H., and Swensmark, B. 2006. Drift of 10 herbicides after tractor spray application. 1. Secondary drift (evaporation). Chemosphere 64:787–794.

Cattanach, A.W., Dexter, A.G., and Oplinger, E.S. 1991. Sugarbeets. Alternative Field Crop Manual. Accessed on June 28, 2010 at: http://www.hort.purdue.edu/newcrop/afcm/sugarbeet.html

CCC. 2005. Petition of Cargill, Inc. before the Secretary of Agriculture. SMA Docket No. 03-0002. Petitioner Decision. Commodity Credit Corporation.

Cerdeira, A.L., and Duke, S.O. 2006. The current status and environmental impacts of glyphosate–resistant crops: A review. Journal of Environmental Quality. 35:1633-1658.

CEQ. 1981. Forty most asked questions concerning CEQ's National Environmental Policy Act Regulations. Council for Environmental Quality. (40 CFR 1500-1508) *Federal Register* 46(55):18026-18038.

CEQ. 1997. Considering cumulative effects under the National Environmental Policy Act. Council for Environmental Quality.

CFIA. 2005. Decision document DD2005-54 Determination of the safety of Monsanto Canada Inc. and KWS SAAT AG's Roundup Ready® Sugar Beet (*Beta vulgaris ssp. vulgaris* L.) Event H7-1. Canadian Food Inspection Agency. Issued September 2005. Accessed on June 16, 2010 at: http://www.inspection.gc.ca/english/plaveg/bio/dd/dd0554e.shtml#a1.

Chamberlain, A.C. 1967. Cross-pollination between fields of sugar beet. Quarterly Journal of the Royal Meteorological Society 93:509-515.

Chern, W.S., and Rickertsen, K. 2002. Consumer acceptance of GMO: survey results from Japan, Norway, Taiwan, and the United States. Working Paper: AEDE-WP-0026-02, Department of Agricultural, Environmental and Development Economics, The Ohio State University.

Colacicco, D. 2010. Second declaration of Daniel Colacicco. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Cole, R. 2010. Declaration of Richard Cole, Ph.D. in support of intervenors' opposition to PL. permanent injunction case no. 08-484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Colorado Department of Agriculture. undated. Noxious weed management program. Online. Accessed on June 1, 2010 at: http://www.colorado.gov/cs/Satellite/Agriculture-Main/CDAG/1178305828928.

Consortium of California Herbaria. 2008. Jepson on-line interchange. Accessed on June 14, 2010 at: http://ucjeps.berkeley.edu/cgi-bin/get_consort.pl.

Cooter, E.J., and Hutzell, W.T. 2002. A regional atmospheric fate and transport model for Atrazine. 1. Development and implementation. Environmental Science & Technology 36: 4091-4098.

Crop Protection Chemical Reference. 1996. 12th ed. Chemical and Pharmaceutical Press. New York. NY.

Culpepper, A.S., and York, A.C. 1998. Weed management in glyphosate-tolerant cotton. The Journal of Cotton Science. 4:174-185.

Darmency, H., Vigouroux, Y., Gestat De Garambe, T., Richard-Molard, M., and Muchembled, C. 2007. Transgene escape in sugar beet production fields: data from six years farm scale monitoring. Environmental Biosafety Research 6:197-206.

Darmency, H., Klein, E.K., De Garanbé, T.G., Gouyon, P.H., Richard-Molard, M., and Muchembled, C. 2009. Pollen dispersal in sugar beet production fields. Theoretical and Applied Genetics 118:1083-1092.

Dean, A.H. 2006. Artificially sweetened: an analysis of the United States sugar program. Senior Honors Thesis. University of Pennsylvania. College Undergraduate Research Electronic Journal. http://repository.upenn.edu/cgi/viewcontent.cgi?article=1028&context=curej

Desplanque, B., Hautekeete, N., and Van Dijk, H. 2002. Transgenic weed beets: possible, probable, avoidable? Journal of Applied Ecology 39:561-571.

Dewar, A., and Cooke, D. 2006. Pests. *In:* Sugar Beet. Draycott, A.P. (ed.). Blackwell Publishing. Oxford UK. pp. 316-358.

Dexter, A.G. 2004. History of sugarbeet (*Beta vulgaris*) herbicide rate reduction in North Dakota and Minnesota. Weed Technology 8:334-337.

Dexter, A.G., Gunsolus, J.L., and Curran, W.S. 1994. Herbicidal mode of action and sugar beet injury symptons. Accessed on June 2, 2010 at: http://www.ag.ndsu.edu/pubs/plantsci/rowcrops/a1085w.htm#Herbicide.

Dexter A.G., and Luecke, J.L. 2003. Survey of weed control and production practices on sugar beet in eastern North Dakota and Minnesota - 2002. 2002 Sugar beet Research and Extension Reports, North Dakota State University Extension. 33:35-64.

Dexter, A.G. and Zollinger, R.K. 2003. Weed control guide for sugar beet. 2002 Sugar beet Research and Extension Reports, North Dakota State University Extension. 33:3-34.

Dhar, T., and Foltz, J. 2005. Milk by any other name…consumer benefits from labeled milk. The American Journal of Agricultural Economics 87:214–228.

Dillen, K., Demont, M., and Tollens, E. 2009. Global welfare effects of GM sugar beet under changing EU sugar policies. AgBioForum 12:119-129.

Dimitri, C., and Oberholtzer, L. 2005. Market-led versus government-facilitated growth development of the U.S. and EU organic agricultural sectors. WRS-05-05. United States Department of Agriculture, Economic Research Service. Washington, D.C.

Duke, S.O. and Cerdeira, A.L. 2007. Risks and benefits of glyphosate-resistant crops. Accessed on Sept. 15, 2010 at: http://www.isb.vt.edu/articles/jan0702.htm

Dumas, C.R. 2008. Weed scientists tells do's, don'ts of Roundup Ready sugar beets. Farm and Ranch Guide. Accessed on July 25, 2010 at: http://www.farmandranchguide.com/articles/2008/03/27/ag_news/production_news/product12.txt

Dunfield, K.E., and Germida, J.J. 2003. Seasonal changes in the rhizosphere microbial communities associated with field-grown genetically modified canola (*Brassica napus*). Applied and Environmental Microbiology 69:7310-7318.

Durgan, B.D. 1998. Identification of the noxious weeds of Minnesota. University of Minnesota Extension. Accessed on June 1, 2010 at: www.mda.state.mn.us/news/publications

Durrant, M.J., and Jaggard, K.W. 1988. Sugar beet seed advancement to increase establishment and decrease bolting. The Journal of Agricultural Science 110:367-374.

du Toit, L.J. 2007. Crop profile for table beet seed in Washington. Washington State University, 20 pp.

EC. 2001. European Commission's Scientific Committee on Plants. Opinion concerning the adventitious presence of GM seeds in conventional seeds. Opinion adopted by the Committee on 7 March 2001.

EC. 2002. European Commission's Scientific Committee on Plants. Report for the Active Substance Glyphosate, Directive 6511/VI/99.

Edwards, W.M. 1995. Effects of tillage and residue management on water for crops. Crop Residue Management to Reduce Erosion and Improve Soil Quality: Appalachia and Northeast Region. Blevins R.L., and Moldenhauer, W.C., (eds.). U.S. Dept. of Agriculture, Agricultural Research Service, Conservation Research Report No. 41, 1995.

EFSA. 2006. European Food Safety Authority. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA-GMO-UK-2004-08) for the placing on the market of products produced from glyphosate-tolerant genetically modified sugar beet H7-1, for food and feed uses, under Regulation 9EC) No1829/2003 from KWS SAAT and Monsanto, The EFSA Journal 431:1-18.

Ellstrand, N.C. 2003. Dangerous liaisons? When cultivated plants mate with their wild relatives. *In:* Syntheses in Ecology and Evolution. Scheiner, S.M. (ed.). The Johns Hopkins University Press. Baltimore, MD. pp. 137–204.

Ellstrand, N.C. 2006. When crop transgenes wander in California, should we worry? California Agriculture. 60:116-118.

Fagan, J. 2010. Declaration of John Fagan in support of plaintiffs' motion for permanent reflief. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Falck-Zepeda, J.B., and Traxler, G. 1998. Rent creation and distribution from transgenic cotton in the U.S. Department of Agricultural Economics and Rural Sociology, Auburn University, AL. Prepared for the symposium entitled: Intellectual Property Rights and Agricultural Research Impacts. NC-208 and CIMMYT, El Batan, Mexico, Mar. 5-7.

Fawcett, R.S. 1995. Agricultural tillage systems: Impacts on nutrient and pesticide runoff and leaching. *In:* Farming for a Better Environment. A White Paper. Soil and Water Conservation Society. Ankeny, IA. pp. 67.

Fénart, S., Austerlitz, F., Cuguen, J., and Arnaud, J.F. 2007. Long distance pollen-mediated gene flow at a landscape level: the weed beet as a case study. Molecular Ecology 16:3801-3813.

Fernandez-Cornejo, J. 2006. Agricultural resources and environmental indicators (AREI), Chapter 3.3: Biotechnology and agriculture. USDA Economic Research Service. http://www.ers.usda.gov/publications/arei/eib16/Chapter3/3.3/.

Fernandez-Cornejo, J., and Caswell, M. 2006. The first decade of genetically engineered crops in the United States. Economic Information Bulletin 11 (EIB-11). USDA Economic Research Service. www.ers.usda.gov/publications/eib11/

Fernandez-Cornejo, J., and Klotz-Ingram, C. 1998. Economic, environmental, and policy impacts of using genetically engineered crops for pest management. Selected paper presented at the 1998 Northeastern Agricultural and Resource Economics Association meetings. Ithaca, NY, June 22-23.

Fernandez-Cornejo, J., Klotz-Ingram, C., and Jans, S. 1999. Farm-level effects of adopting genetically engineered crops in the U.S.A. Proceedings of NE-165 Conference, Transitions in Agbiotech: Economics of Strategy and Policy. Lesser, W.H. (ed). Washington, DC, June 24-25.

Fernandez-Cornejo, J., Klotz-Ingram, C., and Jans, S. 2002. Farm-level effects of adopting herbicide-tolerant soybeans in the U.S.A. Journal of Agricultural and Applied Economics. 31:149-163.

Fernandez-Cornejo, J., and McBride, W.D. 2002. Adoption of bioengineered crops. Agricultural Economic Report No. 810. Washington, DC: USDA ERS.

Friesen LF, Nelson AG, and Van Acker RC. 2003. Evidence of contamination of pedigreed canola (*Brassica napus*) seedlots in western Canada with genetically engineered herbicide resistance traits. Agronomy Journal 95:1342-47.

FSANZ. 2005. First review report, application A525: Food derived from herbicide-tolerant sugar beet line H7-1. Food Standards Australia and New Zealand. 6 p.

Futuyma, D.J. 1998. Evolutionary Biology. 3rd ed. Sinauer Associates. Sunderland, MA. 763 p.

Gaines, T.A., Zhangb, W., Wangc, D., Bukuna, B., Chisholma, S.T., Shanerd, D.L., Nissena, S.J., Patzoldte, W.L., Tranele, P.J., Culpepperf, A.S., Greyf, T.L., Websterg, T.M., Vencillh, W.K., Sammonsc, R.D., Jiangb, J., Prestoni, C., Leacha, J.E., and Westraa, P. 2010. Gene amplification confers glyphosate resistance in *Amaranthus palmeri*. Proceedings of the National Academy of Science. 107:1029-1034.

Ganiere, P., Chern, W., and Hahn, D. 2006. A continuum of consumer attitudes toward genetically modified foods in the United States. Journal of Agricultural and Resource Economics 31:129-149.

Gealy, D.R., Bradford, K.J., Hall, L., Hellmich, R., Raybould, A., Wolt, J., and Zilberman, D. 2007. Implications of gene flow in the scale-up and commercial use of biotechnology-derived crops: Economic and policy consideration. Council for Agricultural Science and Technology Issue Paper 37. CAST. Ames, IA. 24 p.

Gianessi, L.P., and Carpenter, J.E. 1999. Agricultural biotechnology: insect control benefits. National Center for Food and Agricultural Policy. Washington, DC, July 1999. Accessed September 15, 2010 at: http://www.bio.org

Gianessi, L., and Reigner, N. 2006. Pesticide use in U.S. crop production: 2002 - With comparison to 1992 & 1997: Fungicides and herbicides. Crop Life Foundation, Crop Protection Institute. Washington, D.C. 40 p. Accessed September 15, 2010 at: http://www.croplifefoundation.org/Documents/PUD/NPUD%202002/Fung%20&%20Herb%202002%20Data%20Report.pdf.

Gibson VI, J.W., Laughlin, D., Lutrell, R.G., Parker, D., Reed, J., and Harris, A. 1997. Comparison of costs and returns associated with *Heliothis* resistant *Bt* cotton to non-resistant varieties. Proceedings of the Beltwide Cotton Conferences. Vol. 1. Dugger, P., and Richter, D. (eds.) Memphis, TN: National Cotton Council of America, 1997.

Giesy, J.P., Dobson, S., and Solomon, K.R. 2000. Ecotoxicological risk assessment for Roundup herbicide. Reviews of Environmental Contamination & Toxicology 167:35-120.

Gliddon, C. 1994. The impact of hybrids between genetically modified crop plants and their related species: biological models and theoretical perspectives. Molecular Ecology 3:41-44.

GMO Safety, 2010. Glossary. Accessed on June 27, 2010 at: http://www.gmo-safety.eu/glossary.html

GM Crop Database. 2008. Center for Environmental Risk Assessment. Last modified 2008. Accessed on Oct. 1, 2010. http://cera-gmc.org/index.php?evidcode=H7-1&hstIDXCode=&gType=&AbbrCode=&atCode=&stCode=&coIDCode=&action=gm_crop_database&mode=Submit

Goldstein, S.M. 2003. Life history observations of three generations of *Folsomia candida* (Willem) (Colembola: Isotomidae) fed yeast and Roundup Ready soybeans and corn. Masters thesis. Michigan State University. p.83.

Gordon, B. 2007. Manganese nutrition of glyphosate resistant and conventional soybeans. Better Crops 91:12-14.

Grant, D. 2010. Declaration of Duane Grant in support of intervenor's opposition to motion for permanent injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Gregory, M.M., Shea, K.L, and Bakko, E.B. 2005. Comparing agroecosystems. Effects of cropping and tillage patterns on soil, water, energy use and productivity. Renewable Agriculture and Food Systems. 20:81-90.

Gressel, J. 2005. Introduction- the challenges of ferality. *In:* Crop Ferality and Volunteerism. Gressel, J. (ed.). CRC Press, Taylor and Francis Group. Boca Raton, FL. pp. 1-7.

Gunsolus, J.L. 2002. University of Minnesota. Herbicide resistant weeds. WW-06077. Reviewed 2008. Accessed on June 1, 2010 at: http://mn4h.net/distribution/cropsystems/DC6077.html#Figure 1.

Hallman, W.K., and Aquino, H. 2003. Public perceptions of genetically modified food. An international comparison. International Consortium on Agricultural Biotechnology Research (ICABR), 7th ICABR International Conference on Public Goods and Public Policy for Agricultural Biotechnology. Ravello, Italy.

Hallman, W., and Hebden, W. 2005. American opinions of GM food: awareness, knowledge, and implications for education. Choices 20:239–242.

Harland J.L., Jones, C.K., and Hufford, C. 2006. Co-products. *In:* Sugar Beet. Draycott A.P. (ed.). Blackwell Publishing. Oxford UK. pp. 443-463.

Harper, J. L. 1957. Ecological aspects of weed control. Outlook on Agriculture 1:197-205.

Harrison, L., Bailey, M., Naylor, M., Ream, J., Hammond, B., Nida, D., Burnette, B., Nickson, T., Mitsky, T., Taylor, M., Fuchs R., and Padgette, V. 1996. The expressed protein in glyphosate-tolerant soybean, 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium sp.* strain CP4, is rapidly digested *in vitro* and is not toxic to acutely gavaged mice. American Institute of Nutrition. 126:728-740.

Hartzler, B.G. 2010. Glyphosate-manganese interactions in Roundup Ready soybean. Iowa State University Weed Science. Accessed Sept 16, 2010 at: www.weeds.iastate.edu/mgmt/2010/glymn.pdf

Harveson, R.M. 2007. Aphanomyces root rot of sugar beet. Univ. Nebr. Ext. Publ. G1407.

Harvey, L.H., Martin, T.J., and Seifers, D. 2003. Effect of Roundup Ready wheat on greenbug, Russian wheat aphid, and wheat curl mite. Journal of Agriculture and Urban Entomology 20:203-206.

Heap, 2010. The International survey of herbicide resistant weeds. Online. Accessed on June 27, 2010 at: www.weedscience.com.

Hecker, R.J., Stanwood, P.C., and Soulis, C.A. 1986. Storage of sugarbeet pollen. Euphytica 35:777-783.

Herro, A. 2008. Adjustments to agriculture may help mitigate global warming. Blog. Worldwatch Institute. January 18, 2008.

Hirnyck, R., Downey, L., O'Neal Coates, S. 2005. Pest management strategy for Western U.S. sugar beet production. Summary of a workshop held December 15-16, 2004. Boise, ID.

Hirnyck, R.E. and Morishita, D. 2007. Environmental assessment of Roundup Ready sugar beet: A case study of four Idaho sugar beet fields, 2006. Report submitted to the Beet Sugar Development Foundation, August 7, 2007. p.18. http://www.sugarindustrybiotechcouncil.org/wp-content/uploads/2007/09/environmental-assessment-of-roundup-ready-sugar-beet-a-case-study-of-four-idaho-sugar-beet-fields-2006.pdf

Hoeft, R.G., Nafziger, E.D., Gonzini, L.C., Warren, J.J., Adee, E.A., Paul, L.E., and Dunk, R.E. 2000a. Strip till, N placement, and starter fertilizer effects on corn growth and yield. Illinois Fertilizer Conf Proceedings. Jan 24-26, 2000.

Hoeft, R.G., Nafziger, E.D., Johnson, R.R., and Aldrich, S.R. 2000b. Modern corn and soybean production. MCSP Publ. Champaign, IL.

Hofer, M. 2010. Declaration of Michael Hofer in support of intervenor's opposition to motion for permanent injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Hoffman, N. 2010a. Declaration of Neil Hoffman. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. February 12, 2010.

Hoffman, N. 2010b. Third declaration of Neil Hoffman. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. June 15, 2010.

Hovland, B.J. 2010. Declaration of Bruce J. Hovland in support of intervenors' opposition to PL. preliminary injunction motion. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW.

Jackson, S.T., and Lyford, M.E. 1999. Pollen dispersal models in Quaternary plant ecology: assumptions, parameters, and prescriptions. Botanical Review 65:39-75.

Jaggard, K.W., Wickens, R., Webb, J.D., and Scott, R.K. 1983. Effects of sowing date on plant establishment and bolting and the influence of these factors on yields of sugar beet. The Journal of Agricultural Science 101:147-161.

Jamornman, S., Sopa, S., Kumsri, S., Anantachaiyong, T., and Rattithumkul, S. 2003. Roundup Ready corn NK603 effect on Thai greenlacewing, *Mallada basalis* (Walker) under laboratory conditions. Proc. Sixth National Plant Protection Conference Nov. 24-27. pp. 29-30.

Jasieniuk, M., Ahmad, R., Sherwood, A.M., Firestone, J.L., Perez-Jones, A., Lanini, W.T., Mallory-Smith, C., and Stednick, Z. 2008. Glyphosate resistant Italian ryegrass (*Lolium multiflorum*) in California: Distribution, response to glyphosate, and molecular evidence for an altered target enzyme. Weed Science 56:496-502.

Jimenez, M., Horra, A., Pruzzo L., and Palma, M. 2002. Palma, Soil quality: a new index based on microbiological and biochemical parameters, Biology & Fertility of Soils 35: 302–306.

Johnson, R.T. and Burtch, L.M. 1959. The problem of wild annual sugar beets in California. Journal of American Society of Sugar Beet Technology 10:311-317.

Johnson, S.R., Strom, S., and Grillo, K. 2007. Quantification of the impacts on U.S. agriculture of biotechnology derived crops planted in 2006. National Center for Food and Agricultural Policy. Washington, DC.

Kaffka, S. 1998. University of California, Davis. The effects of the El Nino on the sugar beet industry. Accessed June 7, 2010 at: http://sugarbeet.ucdavis.edu/notes/June98.html

Kaffka S., and Hills, F.J. 1994. University of California, Davis. Encyclopedia of agriculture science. Vol. 4. Academic Press, Inc. Accessed on May 30, 2010 at: http://sugarbeet.ucdavis.edu/sbchap.html.

Keeler, K. 1989. Can genetically engineered crops become weeds? Bio/Technology 7:1134-1139.

Khan, M. 2010. Introduction of glyphosate-tolerant sugar beet in the United States. Outlooks on Pest Management 21:38-41

Kiely, T., Donaldson, D., and Grube, A. 2004. Pesticide industry sales and usage: 2000 and 2001 market estimates. U.S. Environmental Protection Agency, Office of Prevention, Pesticides, and Toxic Substances (7503C) EPA-733-R-04-001. Washington, D.C., USA.

Kleter, G.A., Bhula, R., Bodnaruk, K., Carazo, E., Felsot, A.S., Harris, C.A., Katayama, A., Kuiper, H.A., Racke, K.D., Rubin, B., Shevah, Y., Stephenson, G.R., Tanaka, K., Unsworth, J., Wauchope, R.D., and Wong, S. 2007. Altered pesticide use on transgenic crops and the associated general impact from an environmental perspective. Pest Management Science 63:1107-1115.

Klocke, N.L., Watts, D.G., Schneekloth, J.P., Davison, D.R., Todd R.W., and Parkhurst, A.M. 1999. Nitrate leaching in irrigated corn and soybean in a semi-arid climate. Transactions of the ASAE. American Society of Agricultural Engineers 42:1621-1630.

Kniss, A.R. 2010. Declaration of Andrew R. Kniss Ph.D. in support of intervenors' opposition to PL. permanent injunction case no. 08-484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Kniss, R.A., Wilson, R.G., Martin, A.R., Burgener, P.A., and Feuz, D.M. 2004. Economic evaluation of glyphosate-resistant and conventional sugar beet. Weed Technology 18:388-396.

Kockelmann, A., and Meyer, U. 2006. Seed production and quality. *In:* Sugar beet. Draycott, A.P. (ed.) Blackwell, Oxford, UK. pp. 89–113.

Larson, R.L., Hill, A.L., Fenwick, A., Kniss, A.R., Hanson, L.E., and Miller, S.D. 2006. Influence of glyphosate on Rhizoctonia and Fusarium root rot in sugar beet. Pest Management Science 62:1182-1192.

Larue, B., West, G., Gendron, C., and Lambert, R. 2004. Consumer response to functional foods produced by conventional, organic, or genetic manipulation. Agribusiness 20:155-166.

Lehner, C. 2010. Declaration of Casper Lehner in opposition to plantiffs' motion for preliminary injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. March 5, 2010.

Lewellen, R.T., Liu, H., Wintermatel, W.M., and Sears, J.L. 2003. Inheritance of beet necrotic yellow vein virus (BNYVV) systemic infection in crosses between sugar beet and *Beta macrocarpa*. Proceedings of the 1st joint IIRB-ASSBT Congress, San Antonio.

Lilleboe, D. 2008. Idaho beet growers catch strip-till fever. The Sugarbeet Growers Magazine. Accessed on July 22, 2010 at: http://www.sugarpub.com/event/article/id/52/

Lilleboe, D. 2009. Nonstop farming. The Sugarbeet Growers Magazine. Accessed on July 22, 2010 at: http://www.sugarpub.com.

Lilleboe, D. 2010. Nebraska growers pleased with benefits of strip till. The Sugarbeet Growers Magazine. Accessed on July 22, 2010 at: http://www.sugarpub.com

Loberg, G. 2010. Declaration of Greg Loberg in support of intervenors' opposition to PL. permanent injunction case no. 08-0000484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Luoto, S., Lambert, W., Blomqvist, A., Emanuelsson, C. 2008. The identification of allergen proteins in sugar beet (*Beta vulgaris*) pollen causing occupational allergy in greenhouses. Clinical and Molecular Allergy 6:7-10.

Lusk, J., Roosen, J., and Fox, J. 2003. Demand for beef from cattle administered growth hormones or fed genetically modified corn: a comparison of consumers in France, Germany, the United Kingdom, and the United States. American Journal of Agricultural Economics 85:16-29.

Lusk, J., Jamal, M., Kurlander, L., Roucan, M., and Taulman, L. 2004. A Meta analysis of genetically modified food valuation studies. Journal of Agricultural and Resource Economics 30:28-44.

Lusk, J.L., and Rozan, A. 2005. Consumer acceptance of biotechnology and the role of second generation technologies in the USA and Europe. Trends in Biotechnology 23:386-387.

Madden, N.M., Southard, R. J., and Mitchell, J. P. 2008. Conservation tillage reduces PM10 emissions in dairy forage rotations. Atmospheric Environment 42:3795–3808.

Malik, J., Barry, G., and Kishore, G. 1989. The herbicide glyphosate. BioFactors. 2:17-25.

Mallory-Smith, C.A., and Zapiola, M.L. 2008. Gene flow from glyphosate-resistant crops. Pest Management Science 64:428-440.

Mallory-Smith, C. 2010. Declaration of Carol Mallory-Smith. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. January 19, 2010.

Manning, S.H. 2010. Declaration of Susan Henley Manning, Ph.D. in support of intervenors' opposition to PL. preliminary injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Mansfeld, R. 1986. Verzeichnis landwirtschaftlicher und gärtnerischer Kulturpflanzen (ohne Zierpflanzen), Vol. 1, 2nd ed., Springer Verlag, Berlin, Heidelberg, New York.

Mansour, B. 1999. Willamette Valley vegetable crops. Accessed on July 23, 2010 at: http://www.hort.purdue.edu/newcrop/cropmap/oregon/crop/wv-veg.html.

Marks, L.A., Kalaitzandonakes, N., and Vickner, S.S. 2004. Consumer purchasing behavior toward GM foods in Europe. *In:* Consumer Acceptance of Biotech Foods. Evenson, R. and Santaniello, V. (eds.). CABI Publisher. Wallingford, UK. p. 23-39.

Marra, M., Carlson, G., and Hubbell, B. 1998. Economic impacts of the first crop biotechnologies. http://www.ag-econ.ncsu.edu

Massey, R. 2002. Identify preserved crops. File A4-53. Accessed on June 30, 2010 at: http://www.extension.iastate.edu/agdm/crops/html/a4-53.html

Mauch, R. 2010. Declaration of Russell Mauch in support of intervenors' opposition to motion for permanent injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

May, M. 2001. Crop protection in sugar beet. Pesticide outlook. Royal Society of Chemistry. pp.188-191.

McBride, W.D., and Brooks, N. 2000. Survey evidence on producer use and costs of genetically modified seed. Agribusiness 16:6-20.

McDonald, S.K., Hofsteen, L., and Downey, L. 2003. Colorado State University. Crop profile for sugar beets in Colorado. Accessed on May 30, 2010 at: http://www.ipmcenters.org/cropprofiles/ListCropProfiles.cfm?typeorg=crop&USDARegion=National%20Site.

McFarlane, J.S. 1975. Naturally occurring hybrids between sugar beet and *Beta macrocarpa* in the Imperial Valley of California. Journal of the American Society of Sugar Beet Technology 18:245-251.

Meier, B. 2010. Declaration of Bryan Meier in support of intervenors' opposition to PL. permanent injunction case no. 08-0000484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Mesbah, A., Miller, S.D., Fornstrom, K.J., and Legg, D.E. 1994. Sugar beet – weed interactions. University of Wyoming Agricultural Experiment Station. B-998. Accessed on June 1, 2010 at: http://www.ces.uwyo.edu/PUBS/Wy998.pdf

Messéan, A., Squire, G., Perry, J., Angevin, F., Gomez, M., Townsend, P., Sausse, C., Breckling, B., Langrell, S., Dzeroski, S., and Sweet, J. 2009. Sustainable introduction of GM crops into European agriculture: a summary report of the FP6 SIGMEA research project. Agronomie 16:37-51.

Michigan Sugar Company. 2009. 2009 growers' guide for producing quality sugar beets. Accessed on May 31 at: http://www.michigansugar.com/agriculture/guide.php.

Michigan Sugar Company. 2010a. Producing sugar. Accessed on May 30, 2010 at: http://www.michigansugar.com/about/education/production.php.

Michigan Sugar Company. 2010b. About Michigan Sugar Company. Accessed on May 30, 2010 at: http://www.michigansugar.com/about/index.php.

Mikkelson, M., and Petrof, R.1999. Montana State University. Crop Profile for Sugar Beets in Montana. Accessed on May 30, 2010 at: http://www.ipmcenters.org/cropprofiles/ListCropProfiles.cfm?typeorg=crop&USDARegion=National%20Site

Milford, G.F.J. 2006. Plant structure and crop physiology. *In:* Sugar Beet. Draycott, A.P. (ed.). Blackwell Publishing. Oxford UK. pp. 30-49.

Miller, T. 2009. Vegetable Seed Crops. *In:* 2010 PNW Weed Management Handbook. Peachy, E. (ed). Extension Services of Oregon State University, Washington State University, and the University of Idaho pp. 340-389. Accessed on June 1, 2010 at: http://uspest.org/weeds.

Miller, J.S. and Miller, T.D. 2008. The value of cultivation with Roundup Ready sugar beets. Presented at the University of Idaho Snake River Sugar beet Conference on January 11, 2008. Accessed on July 22, 2010 at: millerresearch.com/reports/Value%20of%20cultivation.pdf

Minn-Dak Farmers Cooperative. undated. History. Accessed on May 30, 2010 at: http://www.mdf.coop/Web%202007/About%20MD/History.html.

Monsanto. 2007. Honcho® herbicide MSDS version 2.0. Monsanto Company. St. Louis, Missouri. 63167 USA. 9 p. Accessed at: http://www.monsanto.com/products/Documents/MSDS-Labels/honcho_msds.pdf

Monsanto. 2010. Technology Use Guide.

Monsanto KWS. 2007. Roundup Ready® Sugar Beet H7-1, Herbicide tolerance: Key facts. Monsanto-KWS SAAT AG. 4 p.

Morishita, D.W. 2009. Sugar beets. *In*: 2010 PNW Weed Management Handbook. Peachy, E. (ed). Extension Services of Oregon State University, Washington State University, and the University of Idaho pp. 262-266. Accessed on June 1, 2010 at: http://uspest.org/pnw/weeds

Morton, F. 2010a. Declaration of Frank Morton in support of plaintiffs' motion for permanent relief. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. June 4, 2010.

Morton, F. 2010b. Declaration of Frank Morton in support of plaintiffs' motion for temporary restraining order and preliminary injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. September 16, 2010.

Moyer, J.R., Roman, E.S., Lindwall, C.W., and Blackshaw, R.E. 1994. Weed management in conservation tillage systems for wheat production in North and South America. Crop Protection 13:243–259.

Murdock, S.W. 2010. Declaration of Shea W. Murdock, Ph.D. in support of intervenors' opposition to PL. permanent injunction case no. 08-484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484-JSW. May 7, 2010.

Nahas, E. 2001. Environmental monitoring of the post-commercialization of the Roundup Ready soybean in Brazil, Report 2. Microbiological Parameters. pp 1-29.

Navazio, J., Colley, M., and Zyskowski, J. 2010. Principles and practices of organic beet seed production in the Pacific Northwest. Organic Seed Alliance.19 p.

Nelson, N. 2009. Manganese response of conventional and glyphosate-resistant soybean in Kansas. Insights: International Plant Nutrition Institute, Southern and Central Great Plains Reg. July: 3.

Neogen Corporation, 2001. Agri-Screen CP-4 (Round Up Ready) StripTest. Neogen Corporation, Lansing, MI. http://www.jsunitech.com/product/fkit/pdf/agri-cp4.pdf

Neve, P. 2008. Simulation modeling to understand the evolution and management of glyphosate resistance in weeds. Pest Management Science 64:392–401

Nielsen, K., Nielsen, J., Madrid, S.M., and Mikkelsen, J.D. 1996. New antifungal proteins from sugar beet (*Beta vulgaris* L.) showing homology to non-specific lipid transfer proteins. Plant Molecular Biology 31: 539-552.

Nielsen, K., Nielsen, J., Madrid, S.M., and Mikkelsen, J.D. 1997. Characterization of a new antifungal chitin-binding peptide from sugar beet leaves. Plant Physiology 113: 83-91.

Non-GMO Project. 2010. Non-GMO project working standard, v6, dated June 7. Accessed on July 23, 2010 at: http://www.nongmoproject.org/common/non-gmo-project-standard/ngp-standard-v6-2nd-comment-period-2/.

Noussair, C., Robin, S., and Ruffieux, B. 2004. Do consumers really refuse to buy genetically modified food? The Economic Journal 114:102-120.

NRC. 2010. Environmental impacts of genetically engineered crops at the farm level. *In*: The Impact of Genetically Engineered Crops on Farm Sustainability in the United States. National Research Council of the National Academies. National academies press. Washington, DC. pp. 59-134.

Odero, D.C., Mesbah, A.O., and Miller, S.D. 2008. Economics of weed management systems in sugar beet. Journal of Sugar Beet Research. 45:49-63.

OECD. 1999. Organization for Economic Cooperation and Development. Consensus document on general information concerning the genes and their enzymes that confer tolerance to glyphosate herbicide. OECD Environmental Health and Safety Publications. Paris. ENV/JM/MONO (99)9. Accessed Sept. 6, 2010 at: http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=ENV/JM/MONO(99)9&doclanguage=en.

OECD. 2001. Organization for Economic Cooperation and Development. Consensus Document on the biology of *Beta vulgaris* L. (Sugar Beet). OECD Environmental Health and Safety Publications. Paris. ENV/JM/MONO(2001)11. Accessed Sept 15, 2010 at: http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2001)11&doclanguage=en

Organic Trade Association. 2006. Executive summary: Organic trade association's 2006 manufacturer survey.

Organic Trade Association. 2007. Executive summary: Organic trade association's 2007 manufacturer survey, conducted by Packaged Facts.

Organic Trade Association. 2008. Mini fact sheet: organic industry overview.

OSCS. 1993. Certification Standards – Sugar beet (*Beta vulgaris*). Oregon Seed Certification Service. Revised Feb.10. Accessed on Sept 15, 2010at: http://seedcert.oregonstate.edu/sites/default/files/standards/sugar-beets-standards.pdf

Overstreet, L., Cattanach, N., and Franzen, D. 2009. Strip tillage in sugar beet rotations- year 3. 2009 Sugarbeet Research an dExtension Reports. Vol. 39. Sugarbeet Res. and Ed. Bd. of MN and ND. Accessed on July 22, 2010 at: http://www.sugarpub.com

Padgette, S.R., Kolacz, K.H., Delannay, X., Re, D.B., Lavallee, B.J., Tinius, C.N., Rhodes, Y.I., Otero, W.K., Barry, G.F., Eichholtz, D.A., Peschke, V.M., Nida, D.L., Taylor, N.B., and Kishore, G.M. 1995. Development, identification, and characterization of a glyphosate-tolerant soybean line. Crop Science 35:1451–1461.

Panella, L. 2003. Letter to Dr. J.R. Stander, Betaseed, Inc., September 25. Appendix 2: Petition for Determination of Nonregulated Status for Roundup Ready ® Sugar Beet Event H7-1.

Panella, L. 2010. Declaration of Leonard Panella in support of the intervenors' opposition to motion for permanent injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW.

Pierson, P.E. 2010. Declaration of Paulette E. Pierson, Ph.D. in support of intervenors' opposition to PL. permanent injunction case no. 08-00484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Prather, T.S., DiTomaso, J.M. and Holt, J.S. (2000). Herbicide resistance: Definition and management strategies. University of California. Publication 8012.

Putnam, D. 2005. Market sensitivity and methods to ensure tolerance of biotech and non-biotech alfalfa production systems. Proceedings, 35th California Alfalfa & Forage Symposium. UC Cooperative Extension, Agronomy Research and Extension Center. Plant Sciences Department, University of California, Davis. Visalia, CA. 12-14 December, 2005.

Randall, G.W., and Mulla, D.J. 2001. Nitrate nitrogen in surface waters as influenced by climatic conditions and agricultural practices. Journal of Environmental Quality. 30:337-344.

Rigby D., Young, T., and Burton, M. 2004. Consumer willingness to pay to reduce GMOs in food and increase the robustness of GM labeling. Report to Department of the Environment, Food and Rural Affairs. University of Manchester.

ReJesus, R.M., Greene, J.K., Hamming, M.D., and Curtis, C.E. 1997. Economic analysis of insect management strategies for transgenic Bt cotton production in South Carolina. Proceedings of the Beltwide Cotton Conferences, Cotton Economics and Marketing Conference 1:247-251.

Rognli, O.A., Nilsson, N., and Nurminiemi, M. 2000. Effects of distance and pollen competition on gene flow in the wind-pollinated grass *Festuca pratensis* Huds. Heredity 85:550-560.

Ronald, P.C., and Fouche, B. 2006. Genetic engineering and organic production systems. Division of Agriculture and Natural Resources Communication Services. Agricultural Biotechnology in California series. Publication 8188. pp.1-5.

Roseboro, K. 2009. GM sugar beets found in soil mix sold to gardeners: Contamination incident highlights challenges of containing GM beets. The Organic and Non-GMO Report July - August 2009. Accessed at: http://www.organicconsumers.org/articles/article_18708.cfm

Rosolem, C.A., Gabriel, G.J.M., Lisboa, I.P., and Zoca, S.M. 2009. Manganese uptake and distribution in soybeans as affected by glyphosate. Proceedings of the International Plant Nutrition Colloquium XVI. http://www.escholarship.org/uc/item/3f53794z?query=Mn soybean

Ross, M.A., and Childs, D.J. undated. Herbicide mode of action summary. WS-23-W. Purdue University Cooperative Extension Service. Reviewed April 1996. Accessed on June 2, 2010 at: http://www.ces.purdue.edu/extmedia/ws/ws-23-w.html

Sandretto, C. 1997. Crop residue management. Agricultural Resources and Environmental Indicators. AH-712. USDA ERS. pp. 155-174.

Sandretto, C., and Payne, J. 2006. Soil management and conservation. *In:* Agricultural resources and environmental indicators, 2006 edition. Wiebe, K., and Gollehon, N. (eds.). (Economic Information Bulletin No. EIB-16). Washington, DC: USDA ERS.

Sankula, S. 2006. Quantification of the impacts on U.S. agriculture of biotechnology-derived crops planted in 2005. Technical Report, National Center for Food and Agricultural Policy. http://www.researchtriangle.org/uploads/Reports/2005biotechimpacts-finalversion.pdf

Schneider, F. 1942. Züchtung der Beta-Rüben. *In*: Handbuch der Pflanzenzüchtung, vol. 4, Verlag Paul Parey, Berlin, Hamburg, Germany.

Schneider, R.W., and Strittmatter, G. 2003 Petition for determination of nonregulated status for Roundup Ready ® sugar beet H7-1. http://www.aphis.usda.gov/brs/aphisdocs/03_32301p.pdf

Schrader, W.L., and Mayberry, K.S. 2003. Beet and Swiss chard production in California. University of California Publishing. 8096. 8 p. Accessed on Sept. 15, 2010 at: http://ucanr.org/freepubs/docs/8096.pdf

Schumacher, S., Boland, M., and Brester, G. 2010. MRC agricultural marketing resource center. Revised Sept. 2010 by Diane Huntrods, AgMRC, Iowa State University. http://www.agmrc.org/commodities__products/grains__oilseeds/sugarbeet_profile.cfm

Sexton, R.J. 2010. Declaration of Richard J. Sexton, Ph.D. in support of the intervenors' opposition to motion for permanent injunction. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010

Sharpley, A.N., 1985. The selective erosion of plant nutrients in runoff. Soil Science of America Journal. 49:1527-1534.

Shipitalo, M.J., Malone, R.W., Owens, L.B. 2008. Impact of glyphosate-tolerant soybean and glufosinate-tolerant corn production on herbicide losses in surface runoff. Journal of Environmental Quality. 37:401-408.

Siciliano, S.D., and Germida, J.J. 1999. Taxonomic diversity of bacteria associated with the roots of field-grown transgenic *Brassica napus* cv. Quest, compared to the nontransgenic *B. napus* cv. Excel and *B. rapa* cv. Parkland. FEMS Microbiology Ecolology 29:263-272.

Smith, C.J. 2010a. Declaration of Cindy J. Smith. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. February 12, 2010.

Snake River Sugar Company. 2009. FAQs. Accessed on May 30, 2010 at: http://www.amalgamatedsugar.com/.

Southern Minnesota Beet Sugar Cooperative. 2010. By-products marketing. Accessed on July 25, 2010 at: http://www.smbsc.com/Products/ByProductsMarketing.aspx

Sprague, C. 2007. Research may help sugar beet growers reap sweeter future. Michigan Agricultural Experiment Station. Accessed on July 23, 2010 at: http://www.maes.msu.edu/news/news_December2007.htm#sugar

Spreckels Sugar. 2009. Growing sugar beets in California. Accessed on May 30, 2010 at: http://www.spreckelssugar.com/about.php

Stachler, J.M., Luecke, J.L., and Fisher, J.M. 2009. Management of glyphosate-resistant common ragweed. Abstact 178, North Central Weed Science Society Proceedings 64:178. Available online at http://www.ncwss.org/proceed/2010/Abstracts/178.pdf.

Stachler, J., and Zollinger, R.K. 2009. Weed control guide for sugar beet. Sugarbeet Research and Education Board of MN and ND. Accessed on June 1, 2010 at: http://www.sbreb.org/research/weed/weed09/weed09.htm.

Stander, J.R. 2010. Declaration of John R. (J.R.) Stander, Ph.D. in support of intervenors' OPP. To PL. permanent injunction case no. 08-0000484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Stankiewicz Gabel, R.L. 2010. Declaration of Rebecca L. Stankiewicz Gabel. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. February 12, 2010.

Stark Jr., C.R. 1997. Economics of transgenic cotton: Some indications based on Georgia producers. Proceedings of the Beltwide Cotton Conference. Cotton Economics and Marketing Conference. 1:251-254.

Stearns, T. 2010. Declaration of Tom Stearns in support of plaintiffs' motion for summary judfement. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. June 2, 2010.

Steinman, H. 2008. Allergens within food of plant origin: f227 sugar beet seeds. Retrieved August, 2010, from http://www.allergenicplants.com/dia_templates/ImmunoCAP/Allergen____28361.aspx

Stewart, C.N. 2008. Gene flow and the risk of transgene spread. Accessed on June 16, 2010 at: agribiotech.info/.../StewartGeneFlow%20Mar%20B%20-%2003.pdf

Thomson, J., and Dininni, L. 2005. What the print media tell us about agricultural biotechnology: will we remember? Choices 20:247–252.

Thomas, J.A., Hein, G., and Kamble, S.G. 2000. Crop profile for sugar beets in Nebraska. Accessed on May 30, 2010 at: http://www.ipmcenters.org/cropprofiles/ListCropProfiles.cfm?typeorg=crop&USDARegion=National%20Site.

Tranel, P.J. 2003. University of Illinois. Weeds and weed control strategies. *In:* Plants, genes and crop biotechnology. Chrispeels, M.J., and Sadava, D.E. (eds.) 2nd Edition. Jones and Bartlett publishers. pp. 446-471.

Traveller, D.J., and Gallian, J.T. 2000. Crop profile for sugar beets in Idaho. Accessed on May 30, 2010 at: http://www.ipmcenters.org/cropprofiles/ListCropProfiles.cfm?typeorg=crop&USDARegion=National%20Site.

UC IPM. 2010. Identification: Weed photo gallery, all categories. University of California integrated pest management. Accessed on June 2 at: http://www.ipm.ucdavis.edu/PMG/weeds_multi.html#BROAD.

University of Arizona. 2001. Crop profile for Swiss chard in Arizona. 28 pp.

USDA 1999. U.S. Department of Agriculture. Crop profile for sugar beets in Michigan. Accessed on May 30 at: http://www.ipmcenters.org/cropprofiles/ListCropProfiles.cfm?typeorg=crop&USDARegion=National%20Site.

USDA. 2008. What issues should USDA consider regarding coexistence among diverse agricultural systems in a dynamic, evolving, and complex marketplace? United States Department of Agriculture Advisory Committee on Biotechnology and 21st Century Agriculture. Accessed on June 30, 2010 at: http://www.usda.gov/documents/Coex_final.doc

USDA. 2010a. Plant profile: Beta L. United States Department of Agriculture. Accessed on June 14, 2010 at: http://plants.usda.gov/java/profile?symbol=BETA

USDA. 2010b. Invasive and noxious weeds. United States Department of Agriculture. Accessed on June 14, 2010 at: http://plants.usda.gov/java/invasiveOne?startChar=B

USDA. 2010c. 2008 organic survey. United States Department of Agriculture. Accessed on July 5, 2010 at: http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Organics/

USDA APHIS. 2005. USDA/APHIS Environmental Assessment and Finding of No Significant Impact. Includes determination of non-regulated status for glyphosate tolerant sugar beet H7-1 (OECD unique identifier KM-000H71-4) as Appendix D. United States Department of Agriculture, Animal and Plant Health Inspection Service. Determination signed by Cindy Smith, Deputy Administrator, Biotechnology Regulatory Services, APHIS, March 4, 2005. Accessed on June 28, 2010 at: http://www.aphis.usda.gov/biotechnology/not_reg.html

USDA APHIS. 2009. Draft environmental impact statement, glyphosate-tolerant alfalfa events J101 and J163: Request for nonregulated status. United States Department of Agriculture, Animal and Plant Health Inspection Service. November 2009.

USDA APHIS. 2010. Questions and answers: environmental impact statement on GE sugar beets. APHIS BRS Factsheet. Accessed on Oct. 1, 2010. http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/faq_sugarbeets_2010.pdf

USDA-APHIS. 2011. Plant Pest Risk Assessment for Sugar Beet Event H7-1 Grown for Root Production. USDA APHIS Biotechnology Regulatory Services, Riverdale, Maryland.

USDA ARS. 2008. NP304 crop protection and quarantine action plan 2008-2013, Appendix I. United States Department of Agriculture, Agriculture Research Service. Accessed on June 1, 2010 at: www.ars.usda.gov

USDA ARS. 2010. National genetic resources program germplasm resources information network - (GRIN) [Online Database]. United States Department of Agriculture, Agriculture Research Service. National Germplasm Resources Laboratory, Beltsville, Maryland. Accessed on June 14, 2010 at: http://www.ars-grin.gov/cgi-bin/npgs/acc/display.pl?1441384

USDA ERS. 2009a. Adoption of genetically engineered crops in the U.S. United States Department of Agriculture, Economic Research Service. updated on July 1, 2009. Accessed on June 22, 2010 at: http://www.ers.usda.gov/data/biotechcrops/

USDA ERS. 2009b. Sugars and sweeteners: briefing room. United States Department of Agriculture, Economic Research Service. Accessed on May 30, 2010 at: http://www.ers.usda.gov/Briefing/Sugar/Background.htm.

USDA ERS, 2010a. Sugars and sweeteners: yearbook tables. United States Department of Agriculture, Economic Research Service. Accessed on July 6, 2010 at: http://www.ers.usda.gov/Briefing/Sugar/data.htm#yearbook

USDA ERS, 2010b. U.S. beetpulp exports, by major destination, calendar year. United States Department of Agriculture, Economic Research Service. http://www.ers.usda.gov/Briefing/Sugar/data.htm

USDA FAS, 2004. Situation and outlook in selected countries. United States Department of Agriculture, Foreign Agriculture Service. http://www.fas.usda.gov/htp/sugar/2001/May/Sit_out.htm

USDA FAS, 2007. World sugar situation. United States Department of Agriculture, Foreign Agriculture Service. http://www.fas.usda.gov/htp2/sugar/1997/97-06/jun97sug.htm

USDA FAS. 2010. Sugar: world production, supply and distribution. United States Department of Agriculture, Foreign Agriculture Service. May 2010. Accessed on June 23, 2010 at: http://www.fas.usda.gov/htp/sugar/2010/sugarMay2010.pdf

USDA FS. 2003. Glyphosate – Human health and ecological risk assessment final report. Thomas, D., and Durkin, P. (eds.). United States Department of Agriculture, Forest Service. USDA FS BPA WO-01-3187-0150. Washington, DC.

USDA NASS. 2003. Prospective plantings: 2003 summary. United States Department of Agriculture, National Agricultural Statistics Service, Agricultural Statistics Board. Washington, DC. CR Pr 2-4 (3-03), March.

USDA NASS. 2007. Agricultural statistics 2006, Chapter II – Statistics of cotton, tobacco, sugar crops, and honey. United States Department of Agriculture, National Agriculture Statistics Service. Washington, D.C.

USDA NASS. 2008. United State Department of Agriculture, National Agricultural Statistics Service. Available at: http://www.nass.usda.gov/QuickStats/PullData_US.jsp

USDA NASS. 2009. Acerage. United Stated Department of Agriculture, National agricultural Statistics Service. Accesssed June 26, 2010 at: http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000

USDA NASS. 2010a. U.S. crop acreage down slightly in 2009, but corn and soybean acres up. U.S. Department of Agriculture, National Agricultural Statistics Service. Accessed on June 14, 2010 at: http://www.nass.usda.gov/Newsroom/2009/06_30_2009.asp.

USDA NASS. 2010b. Quick stats. United States Department of Agriculture, National Agricultural Statistics Service. Accessed on June 29, 2010 at: http://quickstats.nass.usda.gov/#42911035-7FB5-37FA-AAC1-47F474ABB0A2.

USDA NASS. 2010c. Crop production. Historical track records. United States Department of Agriculture, National Agricultural Statistics Service. April 2010. p. 7 http://usda.mannlib.cornell.edu/usda/current/htrcp/htrcp-04-12-2010.pdf.

USDC. 2008. United States District Court for the Northern District of California San Francisco Division. Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al. Defendants. No. C 08-00484 JSWUS District Court 2008

US EPA. 1993. Reregistration eligibility decision (RED) glyphosate. United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. EPA 738-R-93-014.

US EPA. 1996. Plant pesticide inert ingredient CP4 enolpyruvylshikimate-3-D and the genetic material necessary for its production in all plants. United States Environmental Protection Agency. US EPA *Federal Register* Vol. 61 No. 150. http://www.epa.gov/fedrgstr/EPA-PEST/1996/August/Day-02/pr-840.html

US EPA. 2004. Overview of the ecological risk assessment process in the office of pesticide programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. http://epa.gov/espp/consultation/ecorisk-overview.pdf

US EPA. 2008a. Agricultural management practices for water quality protection. United States Environmental Protection Agency. Website, accessed on May 19, 2010 at: http://www.epa.gov/watertrain/agmodule/.

US EPA. 2008b. Risks of glyphosate use to federally threatened California red-legged frog (*Rana aurora draytonii*). United States Environmental Protection Agency. Pesticide Effects Determination
http://www.epa.gov/espp/litstatus/effects/redleg-frog/glyphosate/determination.pdf

US FDA. 1992. Guidance to industry for foods derived from new plant varieties. United States Food and Drug Administration. US FDA *Federal Register* Volume 57. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm

US FDA. 2004. Completed consultations on bioengineered foods. United States Food and Drug Administration. BNF No. 90. Accessed at: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=bioListing&id=20

US NARA. 2010. Executive orders. U.S. National Archives and Records Administration. Accessed October, 18, 2010 at: http://www.archives.gov/federal-register/executive-orders/

US Pharmacopeia. 1990. The Official Compendia of Standards.

Vencill, W.K., Nichols, R.N., Webster, T.M., Sotores, J. Mallory-Smith, C. Burgos, N. and Johnson, W.G. (2011). The influences of herbicide resistant crops on the evolution of herbicide resistant weeds. Sections I-VI. Weed Sci. (in press or in review)

Virchow, D.R., and Hygnstrom, S.E. 1991. Movements of deer mice and house mice in a sugarbeet field in western Nebraska. Tenth Great Plains Wildlife Damage Control Workshop Proceedings. Lincoln, NE, University of Nebraska. April 15-18th. pp. 107-111.

Vogel, J.R., Majewski, M.S., and Capel, P.D. 2008. Pesticides in rain in four agricultural watersheds in the United States. Journal of Environmental Quality 37:1101-1115.

Wakelin, A. M. and C. Preston. 2006. A target-site mutation is present in a glyphosate-resistant *Lolium rigidum* population. Weed Resistance 46:432-440.

Walz, E. 2004. Final results of the fourth national organic farmers' survey: sustaining organic farms in a changing organic marketplace. Organic Farming Research Foundation. www.ofrf.org/publications/survey/index.html/.

Werth, J.A., Preston, C., Taylor, I.N., and Charles, G.W. 2008. Managing the risk of glyphosate resistance in Australian glyphosate resistant cotton production systems. Pest Management Science 64:417–421.

West, T.O., and Post, W.M. 2002. Soil organic carbon sequestration rates by tillage and crop rotation: a global analysis. Soil Science Society of American Journal 66:930-1046.

Westgate, M. 2010. Declaration of Mark Westgate Ph.D. in support of intervenors' opposition to motion for permanent injunction case no. 080484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

Western Sugar Cooperative. 2006. Sugar beet process. Accessed on May 30, 2010 at: http://www.westernsugar.com/ProductionAndProcessing.aspx.

WHO. 2005. World Health Organization. Glyphosate and AMPA in drinking-water, background document for development of WHO guidelines for drinking-water quality, 3rd ed. 2004. (updated 2005).

Wiebe, K. and Gollehon, N. 2006. Agricultural reources and environmental indicators, 2006 edition. Economic Information Bulletin 16 (EIB-16). United States Department of Agriculture, Economic Research Service.

Willer, H., and Geier, B. 2005. More than 26 million certified organic hectares worldwide. Press release issued by the International Federation of Organic Agriculture Movements, FiBL, SOL, NurnbergMesse.

Willer, H., Yussefi-Menzler, M., and Sorensen, N. 2008. The world of organic agriculture: statistics and emerging trends 2008. Bonn, Germany: International Federation of Organic Agriculture Movements.

Willerton, N. 2008. US Organic Food and Organic Sugar Market. Organic Trade Association. Power Point presentation.
http://www.usda.gov/oce/forum/2008_Speeches/PDFPPT/Willerton.pdf

Williams, G.M., Kroes, R., and Munro, I. 2000. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate for humans. Regulatory Toxicology and Pharmacology. 31:117-165.

Wilson, Jr., R.G. 2009. Roundup Ready crops: how have they changed things? Agricultural Research Division of IANR: Press Releases from Panhandle Research and Extension Center. Accessed on July 22, 2010 at: http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1020&context=panpressrel

Wilson, R.G. 2010. Declaration of Robert G. Wilson, Ph.D. in support of intervenors' opposition to PL. permanent injunction case no. 08-484. United States District Court for the Northern District of California, San Francisco Division, regarding Center for Food Safety, et al., Plaintiffs, v. Thomas J. Vilsack, et al., Defendants. Case No. 3:08-cv-00484 JSW. May 7, 2010.

WSSA. 1994. Herbicide Handbook, Ahrens, W.H. (ed.). 7th ed. Weed Science Society of America. Champaign, Illinois. ISBN# 0-911733-18-3.

WSSA. 1998. Resistance and tolerance definitions. Weed Science Society of America. Accessed on July 20, 2010 at: http://www.wssa.net/Weeds/Resistance/definitions.htm

WSSA. 2010a. Composite list of weeds as compiled by the standardized plant names subcommittee. Weed Science Society of America. Accessed on June 16, 2010 at: http://wssa.net/Weeds/ID/WeedNames/namesearch.php.

WSSA. 2010b. WSSA supports NRC findings on weed control. Weed Science Society of America. Accessed on June 16, 2010 at: http://www.wssa.net/

Young, B.G. 2006. Changes in herbicide use patterns and production practices resulting from glyphosate- resistant crops. Weed Technology 20:301-307.

Zhou, X., Helmers, M., Al-Kaisi, M., and Hanna, M. 2009. Cost effectiveness and cost-benefit analysis of conservation management practices for sediment reduction in an Iowa agricultural watershed. Journal of Soil and Water Conservation 64:314-323.

Zobiole, L.H.S., de Oliveira Jr., R.S., Huber, D.M., Constantin, J., de Castro, C., Oliveira, F.A., and Oliveira, Jr., A. D. 2010. Glyphosate reduces shoot concentration of mineral nutrients in glyphosate-resistant soybeans. Plant and Soil 328:57-69.

L. Appendices

1. Seed Processing

Seed Production by WCBS. With the exception of Betaseed, WCBS produces the commercial sugar beet seed for the other three US beet seed providers. Management of these fields and planting locations is controlled with a tracking and tracing system distinguishing seed lots from the moment of initial delivery to WCBS of basic seed designated for seed production through subsequent planting and harvest. Management further continues until the delivery of pre-cleaned seed to the member companies that requested the seed. Some member companies further incorporate various computerized and digital tracking systems designed to manage real-time seed batch movement and quality testing. Many of these companies have sealed packaging and specified color coding designations to further identify seed batches/lots (Meier, 2010).

WCBS contracts to individual growers for seed production. WCBS prohibits production of a vegetable beet seed crop by any WCBS grower in a year in which that grower is producing sugar beet seed, whether genetically engineered (GE) or conventional. WCBS also prohibits the sharing of planting, cultivation and harvesting equipment for vegetable beet seed, whether they are producing GE or conventional sugar beet seed (Loberg, 2010). In addition, WCBS requires its growers, by contract, to adhere to minimum isolation distance within a three mile radius of any GE field.

WCBS maintains control of all material, whether GE or conventional, from point of origin to return of the seed to the member seed company. This includes control of the disposal of any excess GE stecklings that are not used for seed production. When those stecklings are not used for seed production and remain in the nursery field, they are uprooted and mixed into the soil during tillage for soil preparation for the next crop. Destruction occurs with this tillage and is followed by chemical control in the subsequent crop. Stecklings that are removed from the nursery, but are not used, are destroyed or securely disposed. The prevailing method is returning unused stecklings to the nursery field of origin and subsequent destruction through standard agricultural practices (physical destruction with tillage and chemical destruction in the subsequent crop) (Loberg, 2010).

WCBS pre-cleans the seed prior to shipment to the seed provider, and this pre-cleaning takes place in a dedicated WCBS facility. This process removes sticks, chaff, weeds and the like that may be contained in the seed when initially harvested. Because WCBS does not handle vegetable beet seed, its seed pre-cleaning operations present no opportunity for mechanical mixing of sugar beet seed, whether conventional or GE, with red beet or Swiss chard seed. In years when WCBS produces both GE and conventional sugar beet seed, physical separation requirements and cleaning protocols protect against inadvertent mixing.

In 2009-2010, nearly 100% of the sugar beet seed crop in the Willamette Valley was glyphosate tolerant, and 78.6% was produced with the glyphosate-tolerance trait (H7-1) on the CMS (male sterile) female parental line. Since the CMS parental lines produce only negligible amounts of pollen, the risk of H7-1 pollen reaching other seed production fields is negligible or zero. (Preliminary Injunction Hearing, March 5, 2010). In 2009, only two growers produced conventional seed for WCBS. All of this conventional seed was pre-cleaned at the end of the season, after completion of the pre-cleaning of the H7-1 seed and after complete cleaning of the equipment.

After pre-cleaning, WCBS ships each seed lot to the member companies in sealed containers with color-coded labeling and shipping documents, which are checked upon arrival at the respective seed processing facilities. Syngenta, for example, marks each container with a computer-generated and tracked batch number (Meier, 2010). SESVanderHave labels its H7-1 seed with an orange triangle (Anfinrud, 2010).

Seed Production by Betaseed. Like WCBS, Betaseed contracts commercial seed production to individual growers. Betaseed has adopted SOPs that require all materials to be adequately identified and tracked through a computerized, bar-coded system from basic seed production to commercial seed production to final processing and shipping. All Betaseed personnel involved in seed production are trained in the SOPs and required to sign an acknowledgement that they have read, understood, and will comply with the SOPs (Lehner, 2010).

Betaseed supervises its commercial seed growers' practices for conformance with Betaseed's stewardship requirements. Betaseed's grower contracts provide for such supervision, as well as

Betaseed's right to enter the grower's fields and take remedial action if the grower does not comply with Betaseed's instructions. Betaseed pins all of its commercial seed fields in compliance with the WVSSA's pinning rules to ensure that isolation distance guidelines are followed. In addition, Betaseed requires its growers, by contract, to adhere to an isolation distances of four miles from other crops that may cross-pollinate with sugar beets. Betaseed also requires growers to clean their equipment before and after harvesting a sugar beet variety, and to monitor for and eliminate volunteer sugar beets. According to the SOPs, Betaseed personnel are present for the beginning of every harvest by a commercial grower. Betaseed provides bar-coded tote boxes into which the harvested seed is placed for transport to Betaseed's processing facility (Lehner, 2010).

2. T&E State List

Arizona

Animals – 39 listings

Status	Species/Listing Name
E	Ambersnail, Kanab (*Oxyloma haydeni kanabensis*)
E	Bat, lesser long-nosed (*Leptonycteris curasoae yerbabuenae*)
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)
E	Bobwhite, masked (quail) (*Colinus virginianus ridgwayi*)
T	Catfish, Yaqui (*Ictalurus pricei*)
E	Chub, bonytail entire (*Gila elegans*)
E	Chub, Gila (*Gila intermedia*)
E	Chub, humpback entire (*Gila cypha*)
T	Chub, Sonora (*Gila ditaenia*)
E	Chub, Virgin River (*Gila seminuda (=robusta)*)
E	Chub, Yaqui (*Gila purpurea*)
E	Condor, California U.S.A. only (*Gymnogyps californianus*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Falcon, northern aplomado (*Falco femoralis septentrionalis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
E	Flycatcher, southwestern willow (*Empidonax traillii extimus*)
T	Frog, Chiricahua leopard (*Rana chiricahuensis*)
E	Jaguar (*Panthera onca*)
E	Jaguarundi, Sinaloan (*Herpailurus (=Felis) yagouaroundi tolteca*)
T	Minnow, loach (*Tiaroga cobitis*)

Status	Species/Listing Name
E	Ocelot (*Leopardus (=Felis) pardalis*)
T	Owl, Mexican spotted (*Strix occidentalis lucida*)
E	Pronghorn, Sonoran (*Antilocapra americana sonoriensis*)
E	Pupfish, desert (*Cyprinodon macularius*)
E	Rail, Yuma clapper U.S.A. only (*Rallus longirostris yumanensis*)
T	Rattlesnake, New Mexican ridge-nosed (*Crotalus willardi obscurus*)
E	Salamander, Sonora tiger (*Ambystoma tigrinum stebbinsi*)
T	Shiner, beautiful (*Cyprinella formosa*)
T	Spikedace (*Meda fulgida*)
T	Spinedace, Little Colorado (*Lepidomeda vittata*)
E	Squirrel, Mount Graham red (*Tamiasciurus hudsonicus grahamensis*)
E	Sucker, razorback entire (*Xyrauchen texanus*)
E	Topminnow, Gila (incl. Yaqui) U.S.A. only (*Poeciliopsis occidentalis*)
T	Tortoise, desert U.S.A., except in Sonoran Desert (*Gopherus agassizii*)
T	Trout, Apache (*Oncorhynchus apache*)
T	Trout, Gila (*Oncorhynchus gilae*)
E	Vole, Hualapai Mexican (*Microtus mexicanus hualpaiensis*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
E	Woundfin except Gila R. drainage, AZ, NM (*Plagopterus argentissimus*)

Plants – 17 listings

Status	Species/Listing Name
E	Blue-star, Kearney's (*Amsonia kearneyana*)
E	Cactus, Arizona hedgehog (*Echinocereus triglochidiatus var. arizonicus*)
E	Cactus, Brady pincushion (*Pediocactus bradyi*)
T	Cactus, Cochise pincushion (*Coryphantha robbinsorum*)
E	Cactus, Nichol's Turk's head (*Echinocactus horizonthalonius var. nicholii*)
E	Cactus, Peebles Navajo (*Pediocactus peeblesianus var. peeblesianus*)
E	Cactus, Pima pineapple (*Coryphantha scheeri var. robustispina*)
T	Cactus, Siler pincushion (*Pediocactus (=Echinocactus,=Utahia) sileri*)
E	Cliff-rose, Arizona (*Purshia (=Cowania) subintegra*)
T	Cycladenia, Jones (*Cycladenia jonesii (=humilis)*)
T	Groundsel, San Francisco Peaks (*Senecio franciscanus*)
E	Ladies'-tresses, Canelo Hills (*Spiranthes delitescens*)
E	Milk-vetch, Holmgren (*Astragalus holmgreniorum*)
E	Milk-vetch, Sentry (*Astragalus cremnophylax var. cremnophylax*)
T	Milkweed, Welsh's (*Asclepias welshii*)
T	Sedge, Navajo (*Carex specuicola*)
E	Water-umbel, Huachuca (*Lilaeopsis schaffneriana var. recurva*)

Colorado

Animals – 18 listings

Status	Species/Listing Name
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)
E	Butterfly, Uncompahgre fritillary (*Boloria acrocnema*)
E	Chub, bonytail entire (*Gila elegans*)
E	Chub, humpback entire (*Gila cypha*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
E	Flycatcher, southwestern willow (*Empidonax traillii extimus*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
T	Mouse, Preble's meadow jumping U.S.A., north-central CO (*Zapus hudsonius preblei*)
T	Owl, Mexican spotted (*Strix occidentalis lucida*)
E	Pikeminnow (=squawfish), Colorado except Salt and Verde R. drainages, AZ (*Ptychocheilus lucius*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
T	Skipper, Pawnee montane (*Hesperia leonardus montana*)
E	Sucker, razorback entire (*Xyrauchen texanus*)
E	Tern, least interior pop. (*Sterna antillarum*)
T	trout, Greenback Cutthroat (*Oncorhynchus clarki stomias*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 13 listings

Status	Species/Listing Name
E	Beardtongue, Penland (*Penstemon penlandii*)
T	Bladderpod, Dudley Bluffs (*Lesquerella congesta*)
T	Butterfly plant, Colorado (*Gaura neomexicana var. coloradensis*)
T	Cactus, Colorado hookless (*Sclerocactus glaucus*)
E	Cactus, Knowlton's (*Pediocactus knowltonii*)
T	Cactus, Mesa Verde (*Sclerocactus mesae-verdae*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)
E	Milk-vetch, Mancos (*Astragalus humillimus*)
E	Milk-vetch, Osterhout (*Astragalus osterhoutii*)
T	Mustard, Penland alpine fen (*Eutrema penlandii*)
E	Phacelia, North Park (*Phacelia formosula*)

Status	Species/Listing Name
T	Twinpod, Dudley Bluffs (*Physaria obcordata*)
E	wild buckwheat, clay-loving (*Eriogonum pelinophilum*)

Proposed Species

Plants – 3 proposed listings

Status	Species/Listing Name
PT	Beardtongue, Parachute (*Penstemon debilis*)
PT	Phacelia, DeBeque (*Phacelia submutica*)
PE	Skyrocket, Pagosa (*Ipomopsis polyantha*)

Idaho

Animals – 17 listings

Status	Species/Listing Name
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)
E	Caribou, woodland Selkirk Mountain population (*Rangifer tarandus caribou*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Limpet, Banbury Springs (*Lanx sp.*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
E	Rabbit, pygmy Columbia Basin DPS (*Brachylagus idahoensis*)
T	Salmon, chinook fall Snake R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook spring/summer Snake R. (*Oncorhynchus (=Salmo) tshawytscha*)
E	Salmon, sockeye U.S.A. (Snake River, ID stock wherever found.) (*Oncorhynchus (=Salmo) nerka*)
T	Snail, Bliss Rapids (*Taylorconcha serpenticola*)
E	Snail, Snake River physa (*Physa natricina*)
E	Springsnail, Bruneau Hot (*Pyrgulopsis bruneauensis*)
T	Squirrel, northern Idaho ground (*Spermophilus brunneus brunneus*)
T	Steelhead Snake R. Basin (*Oncorhynchus (=Salmo) mykiss*)
E	Sturgeon, white U.S.A. (ID, MT), Canada (B.C.), Kootenai R. system (*Acipenser transmontanus*)
T	Trout, bull U.S.A., conterminous, lower 48 states (*Salvelinus confluentus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 5 listings

Status	Species/Listing Name
T	Catchfly, Spalding's (*Silene spaldingii*)
T	Four-o'clock, MacFarlane's (*Mirabilis macfarlanei*)
T	Howellia, water (*Howellia aquatilis*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)
T	Peppergrass, Slickspot (*Lepidium papilliferum*)

Michigan

Animals – 16 listings

Status	Species/Listing Name
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Beetle, Hungerford's crawling water (*Brychius hungerfordi*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Butterfly, Mitchell's satyr (*Neonympha mitchellii mitchellii*)
E	Catspaw, white (pearlymussel) (*Epioblasma obliquata perobliqua*)
E	Clubshell Entire Range; Except where listed as Experimental Populations (*Pleurobema clava*)
E	Curlew, Eskimo (*Numenius borealis*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
E	Puma (=cougar), eastern (*Puma (=Felis) concolor couguar*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
T	Snake, copperbelly water Indiana north of 40 degrees north latitude, Michigan, Ohio (*Nerodia erythrogaster neglecta*)
E	Warbler (=wood), Kirtland's (*Dendroica kirtlandii*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
T	Wolf, gray MN (*Canis lupus*)

Plants – 9 listings

Status	Species/Listing Name
E	Chaffseed, American (*Schwalbea americana*)
T	Daisy, lakeside (*Hymenoxys herbacea*)
T	Fern, American hart's-tongue (*Asplenium scolopendrium var. americanum*)
T	Goldenrod, Houghton's (*Solidago houghtonii*)
T	Iris, dwarf lake (*Iris lacustris*)
E	Monkey-flower, Michigan (*Mimulus glabratus var. michiganensis*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)

Status	Species/Listing Name
T	Pogonia, small whorled (*Isotria medeoloides*)
T	Thistle, Pitcher's (*Cirsium pitcheri*)

Minnesota

Animals – 12 listings

Status	Species/Listing Name
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (*Lycaeides melissa samuelis*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
E	Mussel, scaleshell (*Leptodea leptodon*)
E	Plover, piping Great Lakes watershed (*Charadrius melodus*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)
T	Wolf, gray MN (*Canis lupus*)

Plants – 4 listings

Status	Species/Listing Name
T	Bush-clover, prairie (*Lespedeza leptostachya*)
E	Lily, Minnesota dwarf trout (*Erythronium propullans*)
T	Orchid, western prairie fringed (*Platanthera praeclara*)
T	Roseroot, Leedy's (*Sedum integrifolium ssp. leedyi*)

Montana

Animals – 11 listings

Status	Species/Listing Name
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)

Status	Species/Listing Name
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Sturgeon, white U.S.A. (ID, MT), Canada (B.C.), Kootenai R. system (*Acipenser transmontanus*)
E	Tern, least interior pop. (*Sterna antillarum*)
T	Trout, bull U.S.A., conterminous, lower 48 states (*Salvelinus confluentus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 3 listings

Status	Species/Listing Name
T	Catchfly, Spalding's (*Silene spaldingii*)
T	Howellia, water (*Howellia aquatilis*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)

Nebraska

Animals – 11 listings

Status	Species/Listing Name
E	Beetle, American burying (*Nicrophorus americanus*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Higgins eye (pearlymussel) (*Lampsilis higginsii*)
E	Mapleleaf, winged Entire; except where listed as experimental populations (*Quadrula fragosa*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Shiner, Topeka (*Notropis topeka (=tristis)*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Tiger beetle, Salt Creek (*Cicindela nevadica lincolniana*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 5 listings

Status	Species/Listing Name
T	Butterfly plant, Colorado (*Gaura neomexicana var. coloradensis*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)
T	Orchid, eastern prairie fringed (*Platanthera leucophaea*)

Status	Species/Listing Name
T	Orchid, western prairie fringed (*Platanthera praeclara*)
E	Penstemon, blowout (*Penstemon haydenii*)

North Dakota

Animals – 8 listings

Status	Species/Listing Name
E	Beetle, American burying (*Nicrophorus americanus*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 1 listing

Status	Species/Listing Name
T	Orchid, western prairie fringed (*Platanthera praeclara*)

Oregon

Animals – 42 listings

Status	Species/Listing Name
E	Albatross, short-tailed (*Phoebastria (=Diomedea) albatrus*)
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)
E	Butterfly, Fender's blue (*Icaricia icarioides fenderi*)
T	Butterfly, Oregon silverspot (*Speyeria zerene hippolyta*)
E	Chub, Borax Lake (*Gila boraxobius*)
T	Chub, Hutton tui Hutton (*Gila bicolor ssp.*)
T	Chub, Oregon (*Oregonichthys crameri*)
E	Condor, California U.S.A. only (*Gymnogyps californianus*)
E	Curlew, Eskimo (*Numenius borealis*)
T	Dace, Foskett speckled Foskett (*Rhinichthys osculus ssp.*)

[Status](#)	Species/Listing Name
E	Deer, Columbian white-tailed Columbia River DPS (*Odocoileus virginianus leucurus*)
T	Fairy shrimp, vernal pool (*Branchinecta lynchi*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
T	Murrelet, marbled CA, OR, WA (*Brachyramphus marmoratus*)
T	Otter, southern sea except where EXPN (*Enhydra lutris nereis*)
T	Owl, northern spotted (*Strix occidentalis caurina*)
T	Plover, western snowy Pacific coastal pop. (*Charadrius alexandrinus nivosus*)
E	Rabbit, pygmy Columbia Basin DPS (*Brachylagus idahoensis*)
T	Salmon, chinook fall Snake R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook lower Columbia R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook spring/summer Snake R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook upper Willamette R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chum Columbia R. (*Oncorhynchus (=Salmo) keta*)
T	Salmon, coho Lower Columbia River (*Oncorhynchus (=Salmo) kisutch*)
T	Salmon, coho OR, CA pop. (*Oncorhynchus (=Salmo) kisutch*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea turtle, loggerhead (*Caretta caretta*)
T	Sea-lion, Steller eastern pop. (*Eumetopias jubatus*)
E	Sea-lion, Steller western pop. (*Eumetopias jubatus*)
T	Steelhead Snake R. Basin (*Oncorhynchus (=Salmo) mykiss*)
T	Steelhead middle Columbia R. (*Oncorhynchus (=Salmo) mykiss*)
T	Steelhead upper Willamette R. (*Oncorhynchus (=Salmo) mykiss*)
E	Sucker, Lost River (*Deltistes luxatus*)
E	Sucker, Modoc (*Catostomus microps*)
E	Sucker, shortnose (*Chasmistes brevirostris*)
T	Sucker, Warner (*Catostomus warnerensis*)
T	Trout, bull U.S.A., conterminous, lower 48 states (*Salvelinus confluentus*)
T	Trout, Lahontan cutthroat (*Oncorhynchus clarki henshawi*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, killer Southern Resident DPS (*Orcinus orca*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 15 listings

Status	Species/Listing Name
T	Catchfly, Spalding's (*Silene spaldingii*)
T	Checker-mallow, Nelson's (*Sidalcea nelsoniana*)
E	Daisy, Willamette (*Erigeron decumbens var. decumbens*)
E	Desert-parsley, Bradshaw's (*Lomatium bradshawii*)
T	Four-o'clock, MacFarlane's (*Mirabilis macfarlanei*)

Status	Species/Listing Name
E	Fritillary, Gentner's (*Fritillaria gentneri*)
T	Howellia, water (*Howellia aquatilis*)
E	Lily, Western (*Lilium occidentale*)
E	Lomatium, Cook's (*Lomatium cookii*)
T	Lupine, Kincaid's (*Lupinus sulphureus (=oreganus) ssp. kincaidii (=var. kincaidii)*)
E	Meadowfoam, large-flowered woolly (*Limnanthes floccosa ssp. grandiflora*)
E	Milk-vetch, Applegate's (*Astragalus applegatei*)
E	popcornflower, rough (*Plagiobothrys hirtus*)
T	Thelypody, Howell's spectacular (*Thelypodium howellii spectabilis*)
E	Wire-lettuce, Malheur (*Stephanomeria malheurensis*)

Proposed Species

Status	Species/Listing Name
PT	Salmon, coho Oregon coast (*Oncorhynchus (=Salmo) kisutch*)

Washington

Animals – 34 listings

Status	Species/Listing Name
E	Albatross, short-tailed (*Phoebastria (=Diomedea) albatrus*)
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)
T	Butterfly, Oregon silverspot (*Speyeria zerene hippolyta*)
E	Caribou, woodland Selkirk Mountain population (*Rangifer tarandus caribou*)
E	Curlew, Eskimo (*Numenius borealis*)
E	Deer, Columbian white-tailed Columbia River DPS (*Odocoileus virginianus leucurus*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
T	Murrelet, marbled CA, OR, WA (*Brachyramphus marmoratus*)
T	Otter, southern sea except where EXPN (*Enhydra lutris nereis*)
T	Owl, northern spotted (*Strix occidentalis caurina*)
T	Plover, western snowy Pacific coastal pop. (*Charadrius alexandrinus nivosus*)
E	Rabbit, pygmy Columbia Basin DPS (*Brachylagus idahoensis*)
T	Salmon, chinook Puget Sound (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook fall Snake R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook lower Columbia R. (*Oncorhynchus (=Salmo) tshawytscha*)

Status	Species/Listing Name
E	Salmon, chinook spring upper Columbia R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chinook spring/summer Snake R. (*Oncorhynchus (=Salmo) tshawytscha*)
T	Salmon, chum Columbia R. (*Oncorhynchus (=Salmo) keta*)
T	Salmon, chum summer-run Hood Canal (*Oncorhynchus (=Salmo) keta*)
T	Salmon, coho Lower Columbia River (*Oncorhynchus (=Salmo) kisutch*)
T	Salmon, sockeye U.S.A. (Ozette Lake, WA) (*Oncorhynchus (=Salmo) nerka*)
T	Sea turtle, green except where endangered (*Chelonia mydas*)
E	Sea turtle, leatherback (*Dermochelys coriacea*)
T	Sea-lion, Steller eastern pop. (*Eumetopias jubatus*)
E	Sea-lion, Steller western pop. (*Eumetopias jubatus*)
T	Steelhead Puget Sound DPS (*Oncorhynchus (=Salmo) mykiss*)
T	Steelhead Snake R. Basin (*Oncorhynchus (=Salmo) mykiss*)
T	Steelhead lower Columbia R. (*Oncorhynchus (=Salmo) mykiss*)
T	Steelhead middle Columbia R. (*Oncorhynchus (=Salmo) mykiss*)
T	Steelhead upper Columbia R. Basin (*Oncorhynchus (=Salmo) mykiss*)
T	Trout, bull U.S.A., conterminous, lower 48 states (*Salvelinus confluentus*)
E	Whale, humpback (*Megaptera novaeangliae*)
E	Whale, killer Southern Resident DPS (*Orcinus orca*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 9 listings

Status	Species/Listing Name
T	Catchfly, Spalding's (*Silene spaldingii*)
T	Checker-mallow, Nelson's (*Sidalcea nelsoniana*)
E	Checkermallow, Wenatchee Mountains (*Sidalcea oregana var. calva*)
E	Desert-parsley, Bradshaw's (*Lomatium bradshawii*)
T	Howellia, water (*Howellia aquatilis*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)
T	Lupine, Kincaid's (*Lupinus sulphureus (=oreganus) ssp. kincaidii (=var. kincaidii)*)
T	Paintbrush, golden (*Castilleja levisecta*)
E	Stickseed, showy (*Hackelia venusta*)

Wyoming

Animals – 15 listings

Status	Species/Listing Name
T	Bear, grizzly lower 48 States, except where listed as an experimental population or delisted (*Ursus arctos horribilis*)

Status	Species/Listing Name
E	Chub, bonytail entire (*Gila elegans*)
E	Chub, humpback entire (*Gila cypha*)
E	Crane, whooping except where EXPN (*Grus americana*)
E	Dace, Kendall Warm Springs (*Rhinichthys osculus thermalis*)
E	Ferret, black-footed entire population, except where EXPN (*Mustela nigripes*)
T	Lynx, Canada (Contiguous U.S. DPS) (*Lynx canadensis*)
T	Mouse, Preble's meadow jumping U.S.A., north-central CO (*Zapus hudsonius preblei*)
E	Pikeminnow (=squawfish), Colorado except Salt and Verde R. drainages, AZ (*Ptychocheilus lucius*)
T	Plover, piping except Great Lakes watershed (*Charadrius melodus*)
E	Sturgeon, pallid (*Scaphirhynchus albus*)
E	Sucker, razorback entire (*Xyrauchen texanus*)
E	Tern, least interior pop. (*Sterna antillarum*)
E	Toad, Wyoming (*Bufo baxteri (=hemiophrys)*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico. (*Canis lupus*)

Plants – 5 listings

Status	Species/Listing Name
T	Butterfly plant, Colorado (*Gaura neomexicana var. coloradensis*)
T	Ladies'-tresses, Ute (*Spiranthes diluvialis*)
T	Orchid, western prairie fringed (*Platanthera praeclara*)
E	Penstemon, blowout (*Penstemon haydenii*)
T	Yellowhead, desert (*Yermo xanthocephalus*)

3. Willamette Valley Specialty Seed Association-Pinning Rules

Version 04, 7/07

WVSSA Specialty Seed Production Pinning Rules

To facilitate communication and protect the specialty seed industry in the Willamette Valley of Oregon, isolation mapping procedures have been drafted and agreed upon by the Willamette Valley Specialty Seed Association (WVSSA). The procedures and isolation distances as established by the "Isolation Guidelines" have been set up to ensure quality seed production of all vegetable and other specialty seed in the designated areas from potential cross pollination. The isolation control area of interest referred to as the Willamette Valley includes the counties of; Multnomah, Washington, Clackamas, Yamhill, Polk, Marion, Benton, Linn, and Lane.

Maps The association has two separate maps for the purpose of pinning and maintaining appropriate isolation distances. The maps are divided by the North and South valley isolation areas. They are established at two different locations as follows:

Two Locations

Map1 - North Valley Pinning

OSU Extension Service Marion County Phone: 503-588-5301 At: 3180 Center NE, Salem, Oregon 97301 Room 1361

Map 2 - South Valley Pinning

OSU Extension Service Linn County Phone: 541-967-3871 At: 104 4th Ave SW, Albany, Oregon 97321 Room 102

The non-Beta types are to be pinned in respect to their valley area. The North map is for pinning isolations: Including and North of Township 9 South. The South map is for pinning isolations: Including and South of Township 9 South. Fields located within Township 9 S. must be pinned on both North and South maps.

The Beta types are to be pinned in respect to their valley area. The North map is for pinning isolations: Including and North of Township 11 South. The South map is for pinning isolations: Including and South of Township 12 South.

Pinning Procedures Only WVSSA members are allowed to use the maps. Members using the maps must follow the WVSSA rules. Fields must be currently identified for the designated crop year by use of the two maps at each location.

The map cannot be pinned until an established agreement has been made with the grower for planting the crop. The map cannot be pinned on a speculative basis in order to reserve isolation. Upon cancellation of an intended production prior to planting the pin must be removed within 5 days. Upon abandonment of an established production, the pin must be marked failed. Record the failure by use of pinning cards. Failure to mark and/or pull pins may result in a penalty under the WVSSA of $50.00 if in violation and payment is required to remain a member in good standing.

To identify production fields for crop isolation on the map, pins and flags are used to mark the location. On the maps, different color flags are used to separate the major crop types.

1 Must have approved pinning rights and abide by the Isolation Guidelines of the WVSSA.
2 Observe the dates covered under the priority pinning.
3 Check for acceptable isolation distance on the maps.
4 Contact any companies involved if isolation guidelines are in question.
Use the proper colored flag to pin the field. Write on each flag**:** Party name, Crop type, Hybrid or O.P., Legal location.

5 Fill out pinning card at time of pinning.
6 Hand the card to an Extension personal for posting. At Marion Co., they date stamp card and place in a lock box. At Linn Co, they post in log book and secure card in order received.

Pins are to be placed as close to the center of the field to be planted as possible. This will be done to facilitate proper isolation distances to other fields. The crop isolation is only valid after posting it with the extension office. The isolation is not valid if that isolation is pinned incorrectly.

Pinning Priority The WVSSA allows the grower to hold the right to the isolation in his perspective farming area for the following year, to produce the same crop within a one-mile radius to the prior year's isolation. The grower maintains the right to elect the contracting company. The isolation right, known as a prior year's priority can only be held for the specific grower until the dates specified below.

A prior year's priority is only valid until the following dates:
For non-Beta species: Annuals - March 1st Biennials - August 1st
For Beta species: Transplants - February 1st Direct seeded - August 1st
After these dates, all isolations are available on a first come basis.

Pinning Rights The contracting company or responsible seed representative, who is a member of the WVSSA, may do the pinning. The intent is for the contracting company or responsible seed representative to do the pinning. The representative appointed by a company may also do the pinning if the company is a member of the WVSSA. Oregon State University is considered here as a non-due paying member that has pinning privileges.

The contracting company or responsible seed representative with a grower agreement acts as the grower's appointed representative in establishing the isolation. Individual growers are to allow their contracting company or responsible seed representative who is a member of the WVSSA, to establish the isolation. Growers are allowed to be members of the WVSSA and would be considered as a responsible seed representative and as a member would be allowed to pin isolations for their farms under their own agreements. The contracting company or responsible seed representative agrees to abide by the pinning and isolation guidelines of the WVSSA.

New pinning parties need to contact an officer of the WVSSA for eligibility approval a membership is required prior to pinning. The responsible party may be required to have membership approval by the association. The association may elect to appoint a representative to meet with the new parties at the appropriate isolation map to clarify pinning practices.

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Membership and Pinning Fees The member or responsible party for the seed is subject to fees as established by the WVSSA. Fees are inclusive of the WVSSA annual membership dues of $150.00 per year, or a Homestead membership fee of $5.00 per year. The pinning fees are; $10.00 per OP crop, $25.00 per Hybrid crop, and $25.00 Multi-crop fee. Annual dues are assessed at the beginning of each year in January, and the pinning fees for the prior year's pinning are assessed after clearing of the maps in June of each year. If dues and pinning fees are not received, pinning rights may be revoked. A multi-crop fee may apply when producing multiple crop species of an OP in one location, and one acre or less. Only one per member is allowed and is intended for research farms, and small commercial farms used for seed production. The multi-crop fee is a "fee", not a "pin". Crop pins must be used to pin different species, and "multi-crop" must be designated on each card turned in. A Homestead membership fee and no pinning fees may apply for a Homestead non-voting member when producing in one location non commercial Open Pollinated seed crops. Intended for the seed saver this member is not eligible for the pinning priority and is required to follow WVSSA rules and to be accompanied by a designated appointee when pinning the map. Crop pins must be used to pin different species, and Homestead must be designated on each card turned in.

Exceptions Agreements There are two exception agreements, the Isolation Distance Encroachment, and the One Year Isolation Deferral. The Encroachment exception applies to an established crop isolation where one company agrees to allow another company to produce a like crop under less than the set isolation distance. The deferral applies to an established crop isolation where one grower and company agrees to allow another grower and company to produce a like crop for one year, and the established grower retains the isolation priority. The parties involved prior to planting a specific crop must agree upon any exception to the established isolation for the specific crop year. The exception agreement needs to be in writing annually and to include the right to the isolation the following year. There are exception agreement forms available for this use. All parties must agree and all other WVSSA isolation rules must be followed.

Securing Isolations At both maps a system of cards will be used to secure the posting of the isolation. A representative from two different company members of the WVSSA, in addition to an Extension Agent, is required to be present to review the cards. The non current crop year cards will be separated by two members of the WVSSA annually when the prior crop year's map is cleared in June of each year. The non current crop year pinning cards for will be archived up to three years at the Extension office. The purpose of securing the cards is: 1.To use as the archive and formal record of posting of pins. 2. To review established pinning priority rights. 3. To be used for pinning dispute resolutions. Any discrepancies over pinning locations will be solved through the cards. The cards will be used for accuracy of pinning and in case of arbitration.

Arbitration Should all precautions fail in preventing potential cross-pollination problems between seed companies or responsible seed representative, and or growers, the WVSSA suggests the following system or arbitration: Fields not pinned will be considered at fault in event of arbitration. If the parties agree to arbitration by the three-person committee, they agree to abide by the committee's recommendation. The two contesting seed companies or responsible seed representative, in consultation with their growers, each chooses an outside field representative from the WVSSA. The arbitrators, A and B, are suggested to a neutral facilitator who notifies them of their role. They do not know whom they represent and together choose a third committeeman. Arbitrators A, B and C agree to hear the facts of each seed company. Maximum would be two representatives on each side of the issue. After both parties present the facts, only the arbitration committee, A, B and C, remain in the room to discuss the facts fully. They agree to a solution before leaving the room and the chairman will deliver the recommendation immediately to both parties.

4. APHIS Threatened and Endangered Species Decision Tree for FWS Consultations

DECISION TREE ON WHETHER SECTION 7 CONSULTATION WITH FWS IS TRIGGERED FOR PETITIONS OF TRANSGENIC PLANTS

This decision tree document is based on the phenotypes (traits) that have been permitted for environmental releases under APHIS oversight (for a list of approved notifications and environmental releases, visit Information Systems for Biotechnology.) APHIS will re-evaluate and update this decision document as it receives new applications for environmental releases of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant the following information, data, and questions will be addressed by APHIS, and the EAs on each petition will be publicly available. APHIS review will encompass:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant),
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

FDA published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (http://vm.cfsan.fda.gov/~lrd/fr92529b.html and http://vm.cfsan.fda.gov/~lrd/consulpr.html). The FDA's policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already consumed by human and thus do not require pre-market approval. Consistent with its 1992 policy, FDA expects developers to consult with the agency on safety and regulatory questions. A list of consultations is available at http://vm.cfsan.fda.gov/~lrd/biocon.htmlhttp://vm.cfsan.fda.gov/~lrd/biocon.html. APHIS considers the status and conclusion of the FDA consultations in its EAs.

Below is a description of our review process to whether a consultation with U.S. Fish and Wildlife Service is necessary.

If the answer to any of the questions 1-4 below is yes, APHIS will contact FWS to determine if a consultation is required:

1) Is the transgenic plant sexually compatible with a TE plant[12] without human intervention?

2) Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?

3) Does the transgene product or its metabolites have any significant similarities to known toxins[13])?

4) Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside agro-ecosystem)[14]?
5) Does the pest resistance[15] gene act by one of the mechanisms listed below? If the answer is **YES** then a consultation with U.S. Fish and Wildlife Service is **NOT** necessary.

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[12] APHIS will provide FWS a draft EA that will address the impacts, if any, of gene movement to the TES plant.

[13] Via a comparison of the amino acid sequence of the transgene's protein with those found in the protein databases like PIR, Swiss-Prot and HIV amino acid data bases.

[14] Such phenotypes might include tolerance to environmental stresses such as drought, salt, frost, aluminum or heavy metals.

[15] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels or mitigates a pest or effects any vertebrate or invertebrate animal, plant, or microorganism.

A. The transgene acts only in one or more of the following ways:

   i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
   ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
   iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
   iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant;
   v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

For the biotechnologist:

Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA. Retain a hard copy of this decision document in the petition's file.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of non-regulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the Fish and Wildlife Service is not required for this EA.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the Fish and Wildlife Service.

________ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of non-regulated status is likely to affect adversely one or more listed threatened or endangered species and has initiated a formal consultation with the Fish and Wildlife Service.

5. APHIS BRS Regulations

Title 7: Agriculture

PART 340—INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

Section Contents

§ 340.0 Restrictions on the introduction of regulated articles.
§ 340.1 Definitions.
§ 340.2 Groups of organisms which are or contain plant pests and exemptions.
§ 340.3 Notification for the introduction of certain regulated articles.[5]
§ 340.4 Permits for the introduction of a regulated article.[6]
§ 340.5 Petition to amend the list of organisms.[10]
§ 340.6 Petition for determination of nonregulated status.[11]
§ 340.7 Marking and identity.
§ 340.8 Container requirements for the movement of regulated articles.
§ 340.9 Cost and charges.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Source: 52 FR 22908, June 16, 1987, unless otherwise noted.

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless the Administrator is:

(1) Notified of the introduction in accordance with §340.3, or such introduction is authorized by permit in accordance with §340.4, or such introduction is conditionally exempt from permit requirements under §340.2(b); and

(2) Such introduction is in conformity with all other applicable restrictions in this part.[1]

[1] Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests. The introduction into the United States of such articles also may be subject to other regulations promulgated under the Plant Protection Act (7 U.S.C. 7701–7772) and found in 7 CFR parts 319, 330, and 360. For example, under regulations promulgated in “Subpart-Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products” (7 CFR 319.37–3), a permit is required for the importation of certain classes of nursery stock whether such stock is genetically engineered or not. Accordingly, individuals should refer to those regulations before importing any nursery stock.

(b) Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests.[2]

[2] An inspector may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of plants, plant pests, or other articles in accordance with sections 411, 412, 421, and 434 of the Plant Protection Act (7 U.S.C. 7711, 7712, 7731, and 7754).

[52 FR 22908, June 16, 1987, as amended at 58 FR 17056, Mar. 31, 1993; 62 FR 23956, May 2, 1997; 66 FR 21058, Apr. 27, 2001]

§ 340.1 Definitions. [Deleted]

§ 340.2 Groups of organisms which are or contain plant pests and exemptions. [Partially Deleted]

(a) *Groups of organisms which are or contain plant pests.* The organisms that are or contain plant pests are included in the taxa or group of organisms contained in the following list. Within any taxonomic series included on the list, the lowest unit of classification actually listed is the taxon or group which may contain organisms which are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain plant pests, and are regulated *if they meet the definition of plant pest in §340.1* [4]

[4] Any organism belonging to any taxa contained within any listed genera or taxa is only considered to be a plant pest if the organism "can directly or indirectly injure, or cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." Thus a particular unlisted species within a listed genus would be deemed a plant pest for purposes of §340.2, if the scientific literature refers to the organism as a cause of direct or indirect injury, disease, or damage to any plants, plant parts or products of plants. (If there is any question concerning the plant pest status of an organism belonging to any listed genera or taxa, the person proposing to introduce the organism in question should consult with APHIS to determine if the organism is subject to regulation.)

Note: Any genetically engineered organism composed of DNA or RNA sequences, organelles, plasmids, parts, copies, and/or analogs, of or from any of the groups of organisms listed below shall be deemed a regulated article if it also meets the definition of plant pest in §340.1.

Unclassified organisms and/or organisms whose classification is unknown.

(b) *Exemptions.* (1) A limited permit for interstate movement shall not be required for genetic material from any plant pest contained in *Escherichia coli* genotype K–12 (strain K–12 and its derivatives), sterile strains of *Saccharomyces cerevisiae,* or asporogenic strains of *Bacillus subtilis,* provided that all the following conditions are met:

(i) The microorganisms are shipped in a container that meets the requirements of §340.8(b)(3);

(ii) The cloned genetic material is maintained on a nonconjugation proficient plasmid and the host does not contain other conjugation proficient plasmids or generalized transducing phages;

(iii) The cloned material does not include the complete infectious genome of a known plant pest;

(iv) The cloned genes are not carried on an expression vector if the cloned genes code for:

(A) A toxin to plants or plant products, or a toxin to organisms beneficial to plants; or

(B) Other factors directly involved in eliciting plant disease (*i.e.* , cell wall degrading enzymes); or

(C) Substances acting as, or inhibitory to, plant growth regulators.

(2) A limited permit for interstate movement is not required for genetic material from any plant pest contained in the genome of the plant *Arabiodopsis thaliana,* provided that all of the following conditions are met:

(i) The plants or plant materials are shipped in a container that meets the requirements of §340.8(b) (1), (2), and (3);

(ii) The cloned genetic material is stably integrated into the plant genome;

(iii) The cloned material does not include the complete infectious genome of a known plant pest.

[52 FR 22908, June 16, 1987, as amended at 53 FR 12913, Apr. 20, 1988; 55 FR 53276, Dec. 28, 1990; 58 FR 17056, Mar. 31, 1993]

§ 340.3 Notification for the introduction of certain regulated articles.[5]

[5] APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

(a) *General.* Certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements of this section. Any other introduction of regulated articles require a permit under §340.4, with the exception of introductions that are conditionally exempt from permit requirements under §340.2(b) of this part.

(b) *Regulated articles eligible for introduction under the notification procedure.* Regulated articles which meet all of the following six requirements and the performance standards set forth in paragraph (c) of this section are eligible for introduction under the notification procedure.

(1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Plant Protection Act (7 U.S.C. 7712), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.

(2) The introduced genetic material is “stably integrated” in the plant genome, as defined in §340.1.

(3) The function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease.

(4) The introduced genetic material does not:

(i) Cause the production of an infectious entity, or

(ii) Encode substances that are known or likely to be toxic to nontarget organisms known or likely to feed or live on the plant species, or

(iii) Encode products intended for pharmaceutical or industrial use.

(5) To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:

(i) Noncoding regulatory sequences of known function, or

(ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

(6) The plant has not been modified to contain the following genetic material from animal or human pathogens:

(i) Any nucleic acid sequence derived from an animal or human virus, or

(ii) Coding sequences whose products are known or likely causal agents of disease in animals or humans.

(c) *Performance standards for introductions under the notification procedure.* The following performance standards must be met for any introductions under the notification procedure.

(1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.

(2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release.

(3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.

(4) There must be no viable vector agent associated with the regulated article.

(5) The field trial must be conducted such that:

(i) The regulated article will not persist in the environment, and

(ii) No offspring can be produced that could persist in the environment.

(6) Upon termination of the field test:

(i) No viable material shall remain which is likely to volunteer in subsequent seasons, or

(ii) Volunteers shall be managed to prevent persistence in the environment.

(d) *Procedural requirements for notifying APHIS.* The following procedures shall be followed for any introductions under the notification procedure:

(1) Notification should be directed to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737–1237.

(2) The notification shall include the following:

(i) Name, title, address, telephone number, and signature of the responsible person;

(ii) Information necessary to identify the regulated article(s), including:

(A) The scientific, common, or trade names, and phenotype of regulated article,

(B) The designations for the genetic loci, the encoded proteins or functions, and donor organisms for all genes from which introduced genetic material was derived, and

(C) The method by which the recipient was transformed;

(iii) The names and locations of the origination and destination facilities for movement or the field site location for the environmental release; and the size of the introduction,

(iv) The date and, in the case of environmental release, the expected duration of the introduction (release); and

(v) A statement that certifies that introduction of the regulated article will be in accordance with the provisions of this section.

(3) Notification must be submitted to APHIS:

(i) At least 10 days prior to the day of introduction, if the introduction is interstate movement.

(ii) At least 30 days prior to the day of introduction, if the introduction is an importation.

(iii) At least 30 days prior to the day of introduction, if the introduction is an environmental release.

(4) Field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(5) The Administrator, shall be notified of any unusual occurrence within the time periods and in the manner specified in §340.4(f)(10).

(6) Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance with the provisions of paragraphs (b) and (c) of this section.

(e) *Administrative action in response to notification.* (1) APHIS will provide copies of all notifications to appropriate State regulatory official(s) for review within 5 business days of receipt. Comments to APHIS from appropriate State regulatory officials in response to notifications for interstate movement of regulated articles will not be required by APHIS prior to acknowledgment, although States may provide their reviews to APHIS at their discretion.

(2) The Administrator, will provide acknowledgement within 10 days of receipt that the interstate movement is appropriate under notification.

(3) The Administrator, will provide acknowledgement within 30 days of receipt that the importation is appropriate under notification.

(4) APHIS will provide acknowledgment within 30 days of receipt that the environmental release is appropriate under notification. Such acknowledgment will apply to field testing for 1 year from the date of introduction, and may be renewed annually by submission of an additional notification to APHIS.

(5) A person denied permission for introduction of a regulated article under notification may apply for a permit for introduction of that regulated article without prejudice.

[58 FR 17056, Mar. 31, 1993, as amended at 59 FR 67610, Dec. 30, 1994; 62 FR 23956, May 2, 1997; 66 FR 21058, Apr. 27, 2001; 68 FR 46436, Aug. 6, 2003]

§ 340.4 Permits for the introduction of a regulated article.[6]

[6] See footnote 5 in §340.3.

(a) *Application for permit.* Two copies of a written application for a permit to introduce a regulated article, which may be obtained from APHIS, shall be submitted by the responsible person to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River

Road, Unit 147, Riverdale, Maryland 20737–1237. If there are portions of the application deemed to contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked “CBI Copy”. In addition, those portions of the application which are deemed “CBI” shall be so designated. The second copy shall have all such CBI deleted and shall be marked on each page of the application where CBI was deleted, “CBI Deleted”. If an application does not contain CBI then the first page of both copies shall be marked “No CBI”.

(b) *Permit for release into the environment.* An application for the release into the environment of a regulated article shall be submitted at least 120 days in advance of the proposed release into the environment. An initial review shall be completed by APHIS within 30 days of the receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 120 day review period commenced.[7] If the application is not complete, the responsible individual will be advised what additional information must be submitted. APHIS shall commence the 120 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State where the release is planned, a copy of the initial review and a copy of the application marked, “CBI Deleted”, or “No CBI” for State notification and review. The application shall include the following information:[8]

[7] The 120 day review period would be extended if preparation of an environmental impact statement in addition to an environmental assessment was necessary.

[8] Application forms are available without charge from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737–1237, or from local offices which are listed in telephone directories. A person should specify in requesting the application that the permit is for the introduction of a regulated article subject to regulation under part 340.

(1) Name, title, address, telephone number, signature of the responsible person and type of permit requested (for importation, interstate movement, or release into the environment);

(2) All scientific, common, and trade names, and all designations necessary to identify the: Donor organism(s); recipient organism(s); vector or vector agent(s); constituent of each regulated article which is a product; and, regulated article;

(3) Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article;

(4) A description of the means of movement (e.g., mail, common carrier, baggage, or handcarried (and by whom));

(5) A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics);

(6) A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article;

(7) Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced;

(8) A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design;

(9) The quantity of the regulated article to be introduced and proposed schedule and number of introductions;

(10) A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: Donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article;

(11) A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location; pilot project location; production, propagation, and manufacture location; proposed sale and distribution location);

(12) A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;

(13) A detailed description of any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement; and

(14) A detailed description of the proposed method of final disposition of the regulated article.

(c) *Limited permits for interstate movement or importation of a regulated article.* An application for the interstate movement or importation of a regulated article shall be submitted at least 60 days in advance of the first proposed interstate movement and at least 60 days prior to each importation. An initial review shall be completed by APHIS within 15 days of the receipt of the application. If the application is complete, the responsible person shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible person will be advised what additional information must be submitted. APHIS shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State of destination of the regulated article a copy of the initial review and the application marked, “CBI Deleted”, or “No CBI” for State notification and review.

(1) *Limited permit for interstate movement.* The responsible person may apply for a single limited permit for the interstate movement of multiple regulated articles in lieu of submitting an application for each individual interstate movement. Each limited permit issued shall be numbered and shall be valid for one year from the date of issuance. If a permit is sought for multiple interstate movements between contained facilities the responsible individual shall specify in the permit application all the regulated articles to be moved interstate; the origins and destinations of all proposed shipments; a detailed description of all the contained facilities where regulated articles will be utilized at destination; and a description of the containers that will be used to transport the regulated articles. A limited permit for interstate movement of a regulated article shall only be valid for the movement of those regulated articles moving between those locations specified in the application. If a person seeks to move regulated articles other than those specified in the application, or to a location other than those listed in the application, a supplemental application shall be submitted to APHIS. No person shall move a regulated article interstate unless the number of the limited permit appears on the outside of the shipping container. The responsible person shipping a regulated article interstate shall keep records for one year demonstrating that the regulated article arrived at its intended destination. The responsible person seeking a limited permit for interstate movement shall submit on an application form obtained from APHIS, the data required by paragraphs (b) (1), (2), (4), (6), (7), (9), and (11) through (14) of this section.

(2) *Limited permit for importation.* The responsible person seeking a permit for the importation of a regulated article shall submit an application for a permit prior to the importation of *each* shipment of regulated articles. The responsible person importing a regulated article shall keep records for one year demonstrating that the regulated article arrived at its intended destination. The responsible person seeking a limited permit for importation shall submit on an application form obtained from APHIS data required by paragraphs (b) (1), (2), (4), (6), (7), (9), and (11) through (14) of this section.[9]

[9] Renewals may receive shorter review. In the case of a renewal for a limited permit for importation that has been issued less than one year earlier, APHIS will notify the responsible person within 15 days that either: (1) The renewal permit is approved or (2) that a 60 day review period is necessary because the conditions of the original permit have changed.

(d) *Premises inspection.* An inspector may inspect the site or facility where regulated articles are proposed, pursuant to a permit, to be released into the environment or contained after their interstate movement or importation. Failure to allow the inspection of a premises prior to the issuance of a permit or limited permit shall be grounds for the denial of the permit.

(e) *Administrative action on applications.* After receipt and review by APHIS of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by APHIS, a permit shall be granted or denied. If a permit is denied, the applicant shall be promptly informed of the reasons why the permit was denied and given the opportunity to appeal the denial in accordance with the provisions of paragraph (g) of this section. If a permit is granted, the permit will specify the applicable conditions for introduction of the regulated article under this part.

(f) *Permit conditions.* A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article;

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only through any USDA plant inspection station listed in §319.37–14 of this chapter;

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with §340.5 of this part.

(g) *Withdrawal or denial of a permit.* Any permit which has been issued may be withdrawn by an inspector or the Administrator if he/she determines that the holder thereof has not complied with one or more of the conditions listed on the permit. APHIS will confirm the reasons for the withdrawal of the permit in writing within ten (10) days. Any person whose permit has been withdrawn or any person who has been denied a permit may appeal the decision in writing to the Administrator within ten (10) days after receiving the written notification of the withdrawal or denial. The appeal shall state all of the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn or denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

(h) *Courtesy permit* —(1) *Issuance.* The Administrator may issue a courtesy permit for the introduction of organisms modified through genetic engineering which are not subject to regulation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part.

(2) *Application.* A person seeking a courtesy permit shall submit on an application form obtained from APHIS data required by paragraphs (b) (1), (2), and (5) of this section and shall indicate such data is being submitted as a request for a courtesy permit. A person should also include a statement explaining why he or she believes the organism or product does not come within the definition of a regulated article. The application shall be submitted at least 60 days prior to the time the courtesy permit is sought.

(3) *Administrative action.* APHIS shall complete an initial review within 15 days of the date of receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible individual will be advised what additional information must be submitted, and shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. Within 60 days from the date of receipt of a complete application, APHIS will either issue a courtesy permit or advise the responsible individual that a permit is required under paragraph (b) or (c) of this section.

(Approved by the Office of Management and Budget under control number 0579–0216)

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17058, Mar. 31, 1993; 59 FR 67610, Dec. 30, 1994; 62 FR 23956, 23957, May 2, 1997; 68 FR 46436, Aug. 6, 2003; 72 FR 43523, Aug. 6, 2007]

§ 340.5 Petition to amend the list of organisms.[10] [Deleted]

§ 340.6 Petition for determination of nonregulated status.[11]

[11] See footnote 5 in §340.3.

(a) *General.* Any person may submit to the Administrator, a petition to seek a determination that an article should not be regulated under this part. A petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator, and without affecting resubmission at any time until the Administrator, rules on the petition. A petition for determination of nonregulated status shall be submitted in accordance with the procedure and format specified in this section.

(b) *Submission procedures and format.* A person shall submit two copies of a petition to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Coordination and Technical Assistance, 4700 River Road, Unit 146, Riverdale, Maryland 20737–1237. The petition shall be dated and structured as follows:

Petition for Determination of Nonregulated Status

The undersigned submits this petition under 7 CFR 340.6 to request that the Administrator, make a determination that the article should not be regulated under 7 CFR part 340.

(Signature) ________________________________ ____________________

A. Statement of Grounds

A person must present a full statement explaining the factual grounds why the organism should not be regulated under 7 CFR part 340. The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination. The petition shall include all information set forth in paragraph (c) of 7 CFR 340.6. If there are portions of the petition deemed to contain trade secret or confidential business information (CBI), each page of the petition containing such information should be marked “CBI Copy”. In addition, those portions of the petition which are deemed “CBI” shall be so designated. The second copy shall have all such CBI deleted and shall have marked on each page where the CBI was deleted: “CBI Deleted.” If a petition does not contain CBI, the first page of both copies shall be marked: “No CBI.”

A person shall also include information known to the petitioner which would be unfavorable to a petition. If a person is not aware of any unfavorable information, the petition should state, “Unfavorable information: NONE.”

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner which are unfavorable to the petition.

(Signature) ________________________________ ____________________
(Name of Petitioner)____________________
(Mailing Address)____________________
(Telephone Number)____________________

(c) *Required data and information.* The petition shall include the following information:

(1) Description of the biology of the nonmodified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable.

(2) Relevant experimental data and publications.

(3) A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

(4) A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

(5) Field test reports for all trials conducted under permit or notification procedures, involving the regulated article, that were submitted prior to submission of a petition for determination of nonregulated status or prior to submission of a request for extension of a determination of nonregulated status under paragraph (e) of this part. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(d) *Administrative action on a petition.* (1) A petition for determination of nonregulated status under this part which meets the requirements of paragraphs (b) and (c) of this section will be filed by the Administrator, stamped with the date of filing, and assigned a petition number. The petition number shall identify the file established for all submissions relating to the petition. APHIS will promptly notify the petitioner in writing of the filing and the assigned petition number. If a petition does not meet the requirements specified in this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a completed petition, APHIS shall publish a notice in the Federal Register. This notice shall specify that comments will be accepted from the public on the filed petition during a 60 day period commencing with the date of the notice. During the comment period, any interested person may submit to the Administrator, written comments, regarding the filed petition, which shall become part of the petition file.

(3) The Administrator shall, based upon available information, furnish a response to each petitioner within 180 days of receipt of a completed petition. The response will either:

(i) Approve the petition in whole or in part; or

(ii) deny the petition.

The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public petition file in the offices of APHIS and notice of availability published in theFederal Register.

(e) *Extensions to determinations of nonregulated status.* (1) The Administrator may determine that a regulated article does not pose a potential for plant pest risk, and should therefore not be regulated under this part, based on the similarity of that organism to an antecedent organism.

(2) A person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question.

(3) APHIS will announce in theFederal Registerall preliminary decisions to extend determinations of nonregulated status 30 days before the decisions become final and effective. If additional information becomes available that APHIS believes justifies changing its decision, it will issue a revised decision.

(4) If a request to APHIS to extend a determination of nonregulated status under this part is denied, APHIS will inform the submitter of that request of the reasons for denial. The submitter may submit a modified request or a separate petition for determination of nonregulated status without prejudice.

(f) *Denial of a petition; appeal.* (1) The Administrator's written notification of denial of a petition shall briefly set forth the reason for such denial. The written notification shall be sent by certified mail. Any person whose petition has been denied may appeal the determination in writing to the Administrator within 10 days from receipt of the written notification of denial.

(2) The appeal shall state all of the facts and reasons upon which the person relies, including any new information, to show that the petition was wrongfully denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. An informal hearing may be held by the Administrator if there is a dispute of a material fact. Rules of Practice concerning such a hearing will be adopted by the Administrator.

[58 FR 17057, Mar. 31, 1993, as amended at 59 FR 67611, Dec. 30, 1994; 62 FR 23957, May 2, 1997]

§ 340.7 Marking and identity.

(a) Any regulated article to be imported other than by mail, shall, at the time of importation into the United States, plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated or cultured;

(3) Name and address of shipper, owner, or person shipping or forwarding the organism;

(4) Name, address, and telephone number of consignee;

(5) Identifying shipper's mark and number; and

(6) Number of written permit authorizing the importation.

(b) Any regulated article imported by mail, shall be plainly and correctly addressed and mailed to APHIS through any USDA plant inspection station listed in §319.37–14 of this chapter and shall be accompanied by a separate sheet of paper within the package plainly and correctly bearing the name, address, and telephone number of the intended recipient, and shall plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated, or cured;

(3) Name and address of shipper, owner, or person shipping or forwarding the regulated article; and

(4) Number of permit authorizing the importation;

(c) Any regulated article imported into the United States by mail or otherwise shall, at the time of importation or offer for importation into the United States, be accompanied by an invoice or packing list indicating the contents of the shipment.

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17059, Mar. 31, 1993; 62 FR 23958, May 2, 1997; 72 FR 43523, Aug. 6, 2007]

§ 340.8 Container requirements for the movement of regulated articles.

(a) *General requirements.* A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section, unless a variance has been granted in accordance with the provisions of paragraph (c) of this section.[12]

[12] The requirements of this section are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed by the Department of Transportation in Title 49 CFR or any other agency of the Federal government.

(b) *Container requirements* —(1) *Plants and plant parts.* All plants or plant parts, except seeds, cells, and subcellular elements, shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leak-proof, outer shipping container constructed of corrugated fiberboard, corrogated cardboard, wood, or other material of equivalent strength.

(2) *Seeds.* All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) *Live microorganisms and/or etiologic agents, cells, or subcellular elements.* All regulated articles which are live (non-inactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:

(i) *Volume not exceeding 50 ml.* Regulated articles not exceeding 50 ml shall be placed in a securely closed, watertight container (primary container, test tube, vial, etc.) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) *Volume greater than 50 ml.* Regulated articles which exceed a volume of 50 ml. shall comply with requirements specified in paragraph (b)(3)(i) of this section. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml. of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml. may be placed in a single, secondary container. The maximum amount of micro-organisms or etiologic agents, cells, or subcellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(iii) *Dry ice.* If dry ice is used as a refrigerant, it shall be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbing material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(4) *Insects, mites, and related organisms.* Insects, mites, and other small arthropods shall be packed for shipment as specified in this paragraph or in paragraph (b)(3) of this section. Insects (any life stage) shall be placed in an escape-proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be placed within the secondary shipping container; and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) *Other macroscopic organisms.* Other macroscopic organisms not covered in paragraphs (b) (1), (2), and (4) of this section which do not require continuous access to atmospheric oxygen shall be packaged as specified in paragraph (b)(3) or (b)(4) of this section. All macroscopic organisms which are not plants and which require continuous access to atmospheric oxygen shall be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material, surrounded by escape-proof mesh or netting of a strength and mesh

size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape of organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container constructed of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers.

(c) *Request for a variance from container requirements.* A responsible person who believes the container requirements normally applicable to the movement of the person's regulated article(s) are inappropriate due to unique circumstances (such as the nature, volume, or life stage of the regulated article) may submit in an application for a permit, a request for a variance from the container requirements. The request for a variance under this section shall consist of a short statement describing why the normally applicable container requirements are inappropriate for the regulated article which the person proposes to move and what container requirements the person would use in lieu of the normally prescribed container requirements. USDA shall advise the responsible person in writing at the time a permit is granted on the person's request for a variance.

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993; 62 FR 23956, May 2, 1997]

§ 340.9   Cost and charges. [Deleted]