# NATIONAL ENVIRONMENTAL POLICY ACT DECISION AND FINDING OF NO SIGNIFICANT IMPACT

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

**United States Department of Agriculture**
**Animal and Plant Health Inspection Service**

United States Department of Agriculture (USDA) and the Animal and Plant Health Inspection Service (APHIS) have developed a decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA and APHIS' NEPA implementing regulations and procedures. This NEPA decision document (a Finding of No Significant Impact [FONSI]) is intended to state APHIS' NEPA decision and present the rationale for its selection.

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. 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 event H7-1 sugar beet cultivar is genetically engineered to be resistant to the herbicide glyphosate. Event 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. Event 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. Event 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.

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.

In accordance with APHIS procedures implementing the NEPA Regulations (7 CFR part 372), APHIS prepared a draft Environmental Assessment (draft EA) before making a determination on the supplemental petition. The draft EA analyzed 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. The supplemental petition by Monsanto/KWS seeks only a partial deregulation of H7-1 sugar beets (both the root and seed production activities) that would allow it to be grown in the primary sugar beet root or seed production states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming, if grown under specific mandatory conditions as proposed by the petitioners and the interstate movement and importation of event H7-1 sugar beets within and into the US.

In a notice published in the Federal Register (75 FR 67945-67946, Docket No. APHIS-2010-0047) on November 4, 2010, APHIS announced the availability of the draft EA for public review and comment as part of its decision making process to address a supplemental request for partial deregulation of sugar beets genetically engineered for tolerance to the herbicide glyphosate, or for similar administrative action to authorize the continued cultivation of the GE sugar beets subject to carefully tailored interim measures proposed by APHIS. Comments on the EA were required to be received on or before December 6, 2010.

Based on the scope of the Final 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

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

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?

APHIS' preferred action is "Partial Deregulation – Combination of Alternatives 2 and 3 (Preferred Alternative). APHIS has determined that it is appropriate to partially deregulate H7-1 sugar beets by combining Alternative 2 (for seed production activities) and a modification of Alternative 3 (for 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 for the duration of the interim action, 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, 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 return such root production activities to regulation under 7 CFR Part 340.

These mandatory conditions under the Preferred Alternative would be enforced and required 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., not subject to the procedural and substantive requirements of the Part

340 regulation for the duration of the interim action. 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 [ The 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 harvests 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.

It is important to note that APHIS' preparation of an EIS as well as an EA and this FONSI does not indicate or dictate how APHIS will decide its response to Petitioners' request for a full deregulation of event H7-1 sugar beets. APHIS will not make a decision in response to Petitioners' request for a full deregulation of H7-1 sugar beets until the EIS process is complete and a full and complete PPRA is prepared and completed. Only then will APHIS issue a Determination Decision regarding whether or not to grant a full deregulation to H7-1 sugar beets.

## Regulatory Authority

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 United States: USDA APHIS, the US Department of Health and Human Services' Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). 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.

APHIS regulates genetically engineered (GE) organisms under the Plant Protection Act of 2000. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR § 340.2) and the APHIS determines is a plant pest or has reason to believe is a plant pest. 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).

## Public Involvement

In a notice published in the Federal Register (75 FR 67945-67946, Docket No. APHIS-2010-0047) on November 4, 2010, APHIS announced the availability of a draft EA for public review and comment as part of its decision making process to address a

supplemental request for partial deregulation of sugar beets genetically engineered for tolerance to the herbicide glyphosate, or for similar administrative action to authorize the continued cultivation of the GE sugar beets subject to carefully tailored interim measures proposed by APHIS. Comments on the draft environmental assessment were required to be received on or before December 6, 2010. A total of 3,722 comments were received during the 30 day comment period, with 3,058 commenters providing support of the EA's preferred alternative; and 633 commenters expressing opposition. An additional 37,159 form letters were submitted as attachments to three of the opposing comment documents. All comments were analyzed to identify new issues, alternatives, or information. Responses to the substantive comments are included as an attachment to this Finding of No Significant Impact.

In response to APHIS' above comments and interpretations regarding the Petition for Partial Deregulation of event H7-1 sugar beets, the petitioner, Monsanto/KWS, sent APHIS a four page explanation response on November 18, 2010. In their November 18, 2010 response to APHIS Monsanto/KWS explained:

> We submit this initial comment to address an apparent misimpression by APHIS that, under a "partial deregulation" (deregulation in part with conditions), APHIS would rely for enforcement on the terms of existing agreements between Monsanto/KWS and growers or seed companies. To the contrary, we contemplate (and have previously proposed) that APHIS would have direct authority over growers of Roundup Ready® sugar beets (RRSB) under partial deregulation, as set forth below. This is consistent with the Supreme Court's 2010 opinion in *Monsanto Co. v. Geertson Seed Farms* and would allow APHIS to exercise its statutory authority to require and enforce the types of cultivation requirements discussed in its Draft Environmental Assessment (EA). We continue to believe that a partial deregulation is the best and most practical option for addressing the continued cultivation and use of Roundup Ready sugar beets, which will be critical to ensure a sufficient supply of domestic sugar.

## Major Issues Addressed in the EA

The EA describes the alternatives considered and evaluated using the identified issues. Issues considered in the 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. APHIS sought input on issues and alternatives the Agency should consider in preparation of an EIS related to granting nonregulated status for event H7-1 sugar beets. In its ruling, the Court identified certain specific issues as requiring additional analysis by APHIS.

The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

- Biological Resources
    - Gene flow
    - Weed management

    - Animals
    - Microorganisms
    - Plants
- Socioeconomic Impacts
    - Sugar production in the US: contribution of beets to sugar market
    - Principle companies and cooperatives
    - Regional production of seed and roots
    - Choice of varieties available to sugar beet growers
    - Coexistence of GE and conventional crops
    - Applicant costs
    - Availability of alternative herbicides
    - Consumer preference for non GE sugar and other non GE foods
    - Restrictions/labeling requirements by some countries on GE products
- Physical Environment
    - Land use
    - Air quality and climate change
    - Surface and ground water quality
- Human Health
    - Consumer health and safety
    - Worker safety

## Affected Environment

The areas of the proposed environmental release of event H7-1 sugar beets include agricultural lands located within 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 event H7-1 sugar beets within and into the US.

## Alternatives that were analyzed in detail

On August 13, 2010, the Court vacated APHIS's decision to grant nonregulated status to event H7-1 sugar beet varieties, making them subject to the PPA and APHIS biotechnology regulations. The Court also remanded to the agency any regulatory oversight of producers of event H7-1 sugar beets until the completion of an EIS. Under all the alternatives under consideration, consistent with the Court's Order, event H7-1 sugar beets planted *before* August 13, 2010, are *not* treated as regulated articles and are not subject to the PPA and 7 CFR Part 340 for the duration of those plantings. Thus, event 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. Event 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, event 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. 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 event 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 event 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 nonregulated status to event H7-1 sugar beets. 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 event 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 event H7-1 sugar beets. The conditions identified for each of the alternatives were developed to provide protection to the human environment and ensure that the concerns of the Court are satisfied until the EIS is completed.

Four Alternatives were examined in the EA: (1) APHIS Denies Petition Request for Partial Deregulation/No Further Actions to Authorize Cultivation of Event H7-1 Sugar Beets (No Action) [2]; (2) Event H7-1 Sugar Beet Production Regulated Under 7 CFR Part 340; (3) Partial Deregulation of Event H7-1 Sugar Beets (Seed/Root); and (4) Partial Deregulation – Combination of Alternatives 2 and 3 (Preferred Alternative).

**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 event 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 event 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 event H7-1 sugar beets. As a result, all importation, interstate movements, and environmental releases of event H7-1 sugar beets would be prohibited. Conventional (non-GE) sugar beets could 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 event 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] 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).

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

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

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

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 mean or envisioned 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.

Prior to the comment period, APHIS interpreted the supplemental petition to mean that Monsanto/KWS was 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 interpreted 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 H7-1sugar 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. Event H7-1 sugar beet seeds (including stecklings) could be harvested, processed, stored, transported and sold in commerce; and event H7-1 sugar beet roots could be harvested, stored, processed, transported and sold as sugar, so long as the Monsanto-imposed conditions were followed.

**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 preferred alternative that partially deregulates H7-1 sugar beets by combining Alternative 2 (for seed production activities) and a modification of Alternative 3 (for root production activities). Under this Preferred 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 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. 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 the 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 for the duration of the interim action, 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 for the duration of the interim action. 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.

The Preferred Alternative incorporates and adopts the key components of Alternatives 2 and 3 and represents a sensible step that was suggested by commenters. The Preferred Alternative is a logical outgrowth of Alternatives 2 and 3, and is not a substantive change in the EA that affects the analysis of environmental effects in the EA. All of the specific aspects of Alternatives 2 and 3 were fully evaluated and analyzed for any potential environmental impacts that might result from their possible implementation in the draft

EA. The environmental analyses for Alternatives 2 and 3 in the draft EA are fully and completely applicable to those same aspects now incorporated into the Preferred Alternative.

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 pursuant to written APHIS compliance agreements authorized under the PPA which would impose conditions on the movement and environmental release of the H7-1 sugar beet root crop and root production activities. These legally binding compliance agreements would formalize and impose the 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 C.F.R. Part 340 for the duration of the interim action. APHIS would employ these compliance agreements to impose and enforce the 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 (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 determined that the 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, will 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 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 harvests 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 partial deregulation, 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 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 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 for the duration of the interim action.

***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 the 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. APHIS expects that sugar beet cooperatives and processors (or other associations or entities that conduct Event H7-1 sugar beet root crop activities) will be the only entities that will enter into compliance agreements and will do so on behalf of their respective members/farmers. 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. This interim action will in place no

longer than December 31, 2012. 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 the Preferred Alternative, the following mandatory conditions and restrictions will be imposed on H7-1 sugar beets intended for root production via compliance agreements:

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 the Preferred 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 compliance agreements:

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.

## Mitigation of Environmental Impacts

While work on an EIS is in progress, APHIS will not undertake in the interim any major Federal action covered by the program which may significantly affect the quality of the human environment. Accordingly, 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 will neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS. Specifically, APHIS will mitigate any potential significant impacts through mandatory conditions and restrictions (*see* description of the Preferred Alternative above) imposed on H7-1 sugar beet producers through APHIS issued permits and compliance agreements. APHIS will ensure that these mandatory conditions and restrictions (in both the permits

and compliance agreements) are implemented by monitoring compliance and by remedying any instances of noncompliance. A description of APHIS's monitoring plans and remedial authorities appears above and in the preferred alternative section of the Final EA. In addition, through APHIS or third party inspections, as well as reports from responsible parties and audits, APHIS will monitor the compliance of the mandatory conditions and restrictions to ensure that they adequately mitigate any potential significant environmental impacts.

## Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA. The degree of impact presented in this table and in the EA takes into consideration that under all the alternatives under consideration, consistent with the Court's Order, event H7-1 sugar beets planted *before* August 13, 2010, are *not* treated as regulated articles and are not subject to the PPA and 7 CFR Part 340 for the duration of those plantings. Thus, event 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. Event H7-1 sugar beets planted for seed production before August 13, 2010, may continue until harvested, transported and stored. Therefore, the potential impacts take into consideration that the 2010 H7-1 sugar beet crop is currently being grown, transported, processed and sold as sugar.

**Table 1.**

| ***Issue*** | ***Alternative 1 (No Action) Deny the Petition Request for Partial Deregulation*** | ***Alternative 2 H7-1 Sugar Beet Production under 7 CFR 340*** | ***Alternative 3 Partial Deregulation of H7-1 Sugar Beet*** | ***Preferred Alternative Partial Deregulation – Combination of Alternative 2 and 3*** |
|---|---|---|---|---|
| **Biological Resources** | | | | |
| Gene flow | No impact | No Impact | No Impact | No Impact |
| Weed management | Minimal | No Impact | No Impact | No Impact |
| Animals | Minimal | No Impact | No Impact | No Impact |
| Microorganisms | Minimal | No Impact | No Impact | No Impact |
| Plants | No Impact | No Impact | No Impact | No Impact |
| **Socioeconomic Impacts** | | | | |
| Sugar production in the US: contribution to sugar market | High | No Impact | No Impact | No Impact |
| Principle companies and cooperatives | High | No Impact | No Impact | No Impact |
| Regional production of seed and roots | High | No Impact | No Impact | No Impact |

| | | | | |
|---|---|---|---|---|
| Choice of varieties available to sugar beet growers | High | No Impact | No Impact | No Impact |
| Coexistence of GE and conventional crops | High | No Impact | No Impact | No Impact |
| Cost of Maintaining/Producing GE-free Vegetable Beet Seed | No Impact | Minimal | Minimal | Minimal |
| Applicant costs | No impact | Minimal | Minimal | Minimal |
| Availability of alternative herbicides | Moderate | No Impact | No Impact | No Impact |
| Consumer preference for non GE sugar and other non GE foods | Moderate | No Impact | No Impact | No Impact |
| Restrictions/labeling requirements by some countries on GE products | No Impact | No Impact | No Impact | No Impact |
| **Physical Environment** | | | | |
| Land use | No Impact | No Impact | No Impact | No Impact |
| Air quality and climate change | No Impact | No Impact | No Impact | No Impact |
| Surface and ground water quality | No Impact | No Impact | No Impact | No Impact |
| **Human Health** | | | | |
| Consumer health and safety | No Impact | No Impact | No Impact | No Impact |
| Worker safety | No Impact | No Impact | No Impact | No Impact |

***Description of Impacts***:
*No Impact* - For the resource area, no environmental effects have been identified.
*Minimal* – For the resource area, environmental effects would not be detectable or would be so minor that they would be insignificant.
*Moderate* – For the resource area, environmental effects would be sufficient to alter noticeably, but not to significant level.
*High* – For the resource area, environmental effects would be clearly noticeable and would be sufficient to have significant impacts.

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 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, 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 the EA.

**Finding of No Significant Impact**

Based upon the mitigation measures comprised of the mandatory conditions and restrictions incorporated into APHIS issued permits and compliance agreements, and APHIS' authority to enforce these mitigation measures, the analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree with this conclusion and therefore find that an EIS need not be prepared for this interim action. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

*Context* – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action would be limited to agricultural lands located within 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 United States. 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. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of seeds, stecklings and roots would be used by producers for growing H7-1 sugar beets associated with this action including the use of the EPA registered herbicide glyphosate as well as other pesticides as needed.

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 the termination date of partial deregulation, which is December 31, 2012.

The environmental release (planting) of event H7-1 sugar beet under APHIS permit for seed production and under APHIS compliance agreements for root production has limited potential to affect resources outside of the release sites. Specific permit conditions and compliance agreement conditions/restrictions enforced by APHIS (*see* Mandatory Permit Conditions and Compliance Agreement Conditions/Restrictions described under the Preferred Alternative in the EA) would prevent the escape and dissemination of event H7-1 sugar beets and greatly limit the risk of any potential for inappropriately introducing or disseminating event H7-1 sugar beets into the environment. In addition, APHIS compliance agreement conditions/restrictions associated with the interstate movement and importation of event H7-1 sugar beets and 7 CFR Part 340 regulatory requirements for the importation or interstate movement of event H7-1 sugar beet under an APHIS permit or acknowledged notification would prevent inadvertent release of event H7-1sugar beets into the environment. "Performance standards for introductions under the notification procedure" (§340.3 (c)(1)) 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. APHIS 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 to prevent the escape and dissemination of the regulated article.

*Intensity* – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision*:*

1. *Impacts that may be both beneficial and adverse.* The proposed action would have no significant impact on sugar beet or *Beta* species production and processing systems. The proposed action would minimize disruptions to U.S. sugar beet production and would minimize the likelihood of impacts of concern to the Court until APHIS can complete its EIS before making a determination on whether or not to grant nonregulated status to event H7-1 sugar beets. As described in Sections A.10 and E of the EA, this action is limited to agricultural farm land 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 event H7-1 sugar beets within and into the United States. 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. The producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement

conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and greatly limit the risk of any potential for inappropriately introducing or disseminating event H7-1 sugar beets into the environment. As a result no other sugar beet or *Beta* species, including wild or weedy species, conventional or organic *Beta* species, would be impacted by this action. As described in Sections F.1 and F.2 of the EA, this action will not negatively impact consumer choice and will not result in gene flow or cross pollination to related *Beta* species, including Swiss chard and table beets; will have no economic effects on organic or conventional farmers, and those individuals that choose not to use or consume genetically engineered food products or their by-products; and will not reduce or eliminate the availability of conventional or organic *Beta* species.

2. *The degree to which the proposed action affects public health or safety.* The proposed action would have no significant impacts on human or animal health. As described in Sections F.1 and F.4 of the EA, the introduced genes are not known to cause disease in humans or non-target organisms. The FDA completed its food/feed safety evaluation and consultation process for event H7-1 in 2004 and had no further questions regarding the application (http://www.fda.gov/Food/Biotechnology/Submissions/ucm155747.htm). The producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and greatly limit the risk of any potential for inappropriately introducing or disseminating event H7-1 sugar beets into the environment. As described in Sections A.10 and E of the EA, this action will take place on agricultural farm land and therefore will reduce potential interactions with the public. 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. Glyphosate is labeled for use on H7-1 sugar beet and the producer's adherence to EPA pesticide label use restrictions will reduce any potential adverse affects from the use of glyphosate associated with the environmental release of H7-1 sugar beet.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical 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 significantly affected. 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. As described in Sections A.10 and E of the EA, this action is limited to agricultural farm land 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 event H7-1 sugar beets within and into the United States. 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. This action would not convert land use on the site to nonagricultural use and therefore would have no adverse impact on prime farm land. As described in Section E of the EA, standard agricultural practices for land preparation, planting, irrigation, and harvesting of seeds, stecklings and roots would be used by producers for growing event H7-1 sugar beet associated with this action including the use of EPA registered herbicide glyphosate. Producer's adherence to EPA label use restrictions for glyphosate will mitigate impacts to the human environment. In addition, producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and therefore 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 the environmental release site. As described in Section I of the EA, the proposed 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. The proposed action will have no potential to cause effect on historic properties and is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties. 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 nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.* The effects on the quality of the human environment are not highly controversial. Any action 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. 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 partial deregulation, which is December 31, 2012. As described in Section A.3, E and G of the EA, 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 authorized well over 100 confined field releases of glyphosate tolerant sugar beets (H7-1 and similar varieties) between 1998 and 2005. 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 field release for all types of GE regulated material. There has been no controversy or challenge regarding APHIS authorization of these plantings or movements. As described in Section A.6 of the EA, APHIS also issued four permits on September 3, 2010 to produce only non-flowering stecklings in Arizona and Oregon. Issues associated with confinement of these permitted activities have been brought forward in Court proceedings (*Ctr. for Food Safety v. Vilsack*, No. C 10-04038 JSW, 2010 WL 3835699). However, no scientific rationale has been presented to substantiate these claims. As described in Section A.2 and E.4 of the EA, event H7-1 sugar beets are genetically engineered to be glyphosate tolerant by inserting an *epsps* gene into the sugar beet genome. The EPSPS protein is ubiquitous in nature and the gene is naturally found in many plants and microbes, including corn. EPSPS protein is normally present in food and feeds derived from these plant and microbial sources. The addition of the *epsps* gene to corn, cotton and soybean plants to impart tolerance to glyphosate has not resulted in any adverse human health effects despite being grown on hundreds of millions of acres across the US over the past decade. As described in Sections A.10 and E of the EA, the proposed action is limited to agricultural farm land 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 event H7-1 sugar beets within and into the United States. 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. The producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and greatly limit the risk of any potential for inappropriately introducing or disseminating event H7-1 sugar beets into the environment. As a result no other sugar beet or *Beta* species, including wild or weedy species, conventional or organic *Beta* species, would be impacted by this action. As described in Sections F.1 and F.2 of the EA, this action will not negatively impact consumer choice and will not result in gene flow or cross pollination to related *Beta* species, including Swiss chard and

table beets; will have no economic effects on organic or conventional farmers, and those individuals that choose not to use or consume genetically engineered food products or their by-products; and will not reduce or eliminate the availability of conventional or organic *Beta* species.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.* The effects of proposed action are not highly uncertain and do not involve unique or unknown risks. The producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and greatly limit the risk of any potential for inappropriately introducing or disseminating event H7-1 sugar beets into the environment. Further, the producer's adherence to their own SOPs as well as APHIS' mandatory permit conditions and compliance agreement conditions/restrictions will prevent commingling of materials from this release with other *Beta* species. As described in Section A.3, F and G of the EA, environmental releases of event H7-1 sugar beet have been conducted under APHIS notification procedures (7 CFR 340.3) and permitting procedures (7 CFR 340.4), and in accordance with APHIS procedures for implementing the National Environmental Policy Act (NEPA) (7 CFR 372). APHIS has authorized over 200 notifications/ permits for field releasing of Beta species since 1993. Since 1993, APHIS conducted 5 environmental assessments for confined field releases of beet and reached a FONSI for all EAs. APHIS authorized well over 100 confined field releases of glyphosate tolerant sugar beets (H7-1 and similar varieties) between 1998 and 2005. During the course of those confined releases, field release data reports submitted to APHIS provided evidence that event H7-1 sugar beet and activities associated with its production did not exhibit unexpected or unintended effects. 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 for all types of GE regulated material. 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. As described in Section A.2 of the EA, these sugar beets are genetically engineered to be glyphosate tolerant by inserting a gene (from *Agrobacterium* sp. strain CP4) that codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) into the sugar beet genome. This gene, along with its regulatory sequences, was introduced into these sugar beets via an *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure that has been widely used for

over two decades for introducing various genes directly into plant genomes and has been reviewed by APHIS as part of its regulatory decision making process. As described in Section H of the EA, crops that contain the same modified EPSPS protein 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/). As described in Sections E, F and G of the EA, when used in accordance with US EPA label restrictions, the use of registered pesticides (including glyphosate) on these crops does not lead to unreasonable adverse impacts on human health or the environment. While some issues have been identified with weeds developing tolerance to the herbicide glyphosate, those have primarily been identified in locations where glyphosate has been applied on large acreages for many years (i.e., tens of millions of acres of glyphosate tolerant soybeans and cotton). On environmental releases of this size (a total acreage of approximately 3000-5000 acres for all seed production/ approximately 1 – 1.4 million acres for all root production distributed over 11 states) and where crops are rotated regularly (sugar beets are rarely grown in the same field year after year as disease problems can occur), typical agricultural management practices are effective in dealing with such issues if they were to occur. Such practices include rotation of different crops in different fields, use of herbicides with different modes of action, soil tillage, etc.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.* The proposed action would not establish a precedent for future actions with significant effects or represent a decision in principle about a future consideration. As described in Section A.3 of the EA, 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 fully deregulate event H7-1 sugar beet. APHIS will not make a determination on whether or not to grant nonregulated status to event H7-1 sugar beet until a final EIS and PPRA for full deregulation are completed. As described in Section C.4 of the EA, APHIS' permitting and notification process for the environmental release and movement of event H7-1 sugar beets associated with seed production would be carried out in accordance with 7 CFR Part 340. Similar to past regulatory requests reviewed and approved by APHIS, the decision on whether or not to issue a permit or acknowledge a notification will be based upon an independent review of the information provided by the applicant. 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 this NEPA 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 the 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. As described in Section C of the EA, APHIS would partially deregulate H7-1 sugar beets determining that H7-1 sugar beet root crop should not be subject to the procedural and substantive requirements of 7 C.F.R. Part 340 for the duration of the interim action. In addition, APHIS would impose conditions restricting movement and environmental release of the root crop via compliance agreements authorized under the PPA. 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. Actions taken by APHIS 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. 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 partial deregulation, which is December 31, 2012.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.* Considering the organism *(Beta vulgaris* ssp. *vulgaris*) and trait introduced (herbicide resistance), the limited duration of the proposed action (termination date of December 31, 2012), the manner in which environmental releases and movements must be conducted (mandatory permit conditions,7 CFR Part 340 regulatory requirements, compliance agreement conditions/restrictions), and the limited geographic region of the proposed environmental releases (existing agricultural land in 11 States), the potential effects of this proposal will not rise to a level that will significantly affect the quality of the human environment. Any action 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. 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 partial deregulation, which is December 31, 2012. The producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and greatly limit the risk of any potential for inappropriately introducing or disseminating event H7-1 sugar beets into the environment. As a result no other sugar beet or *Beta* species, including wild or weedy species, conventional or organic *Beta* species, would be impacted by this action. As described in Sections F.1 and F.2 of the EA, this action will not negatively impact consumer choice and will not result in gene flow or cross pollination to related *Beta* species, including Swiss chard and table beets; will have no economic effects on organic or conventional farmers, and those individuals that choose not to use or consume genetically engineered food products or their by-products; and will not reduce or eliminate the availability of conventional or organic *Beta* species. The only past, present, and reasonably foreseeable actions associated with the proposed action are those related to agricultural 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. As described in Section E of the EA, standard agricultural practices for land preparation, planting, irrigation, and harvesting of seeds, stecklings and roots would be used by producers for growing event H7-1 sugar beet associated with this action including the use of EPA registered herbicide glyphosate. As described in Sections E, F, G and H of the EA, when used in accordance with EPA label restrictions, the use of registered pesticides (including glyphosate) on these crops does not lead to unreasonable adverse impacts on human health or the environment. While some issues have been identified with weeds developing tolerance to the herbicide glyphosate, those have primarily been identified in locations where glyphosate has been applied on large acreages for many years (i.e., tens of millions of acres of glyphosate tolerant soybeans and cotton). On environmental releases of this size (a total acreage of approximately 3000-5000 acres for all seed production/approximately 1 – 1.4 million acres for all root production distributed over 11 states) and where crops are rotated regularly (sugar beets are rarely grown in the same field year after year as disease problems can occur), typical agricultural management practices are effective in dealing with such issues if they were to occur. Such practices include rotation of different

crops in different fields, use of herbicides with different modes of action, soil tillage, etc. Based on this information, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the release sites or the ecosystem in which it is situated. No resources will be significantly impacted due to cumulative impacts resulting from the proposed action.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.* The proposed 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. As described in Sections A.10 and E of the EA, this action is limited to agricultural farm land 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 United States. 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. As described in Section E of the EA, standard agricultural practices for land preparation, planting, irrigation, and harvesting of seeds, stecklings and roots would be used by producers for growing H7-1 sugar beet associated with this action including the use of EPA registered herbicide glyphosate. Producer's adherence to EPA label use restrictions for glyphosate will mitigate impacts to the human environment. In addition, producer's compliance with APHIS mandatory permit conditions/notification requirements and APHIS compliance agreement conditions/restrictions, and APHIS' enforcement of these permit conditions, notification requirements, and compliance agreement conditions/restrictions will prevent the escape and dissemination of event H7-1 sugar beets and therefore is not likely to affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places that may be in close proximity to the environmental release site. As described in Section I of the EA, the proposed action will have no potential to cause effect on historic properties and is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties. In general, common agricultural activities conducted under this action also 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 nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects.

9. *The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.* As described in Sections F.1 and G of the EA, expression of the genetic material from this regulated article does not result in the production of a substance known or likely to be toxic to non-target organism. As described in Section G of the EA, APHIS evaluated the potential for negative effects on federal threatened and endangered species as listed by the U.S. Fish and Wildlife Service from the proposed action and 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. In addition, 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.
10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.* The proposed action would be in compliance with all federal, state, and local laws and would be carried out in accordance with 7 CFR part 340 and the PPA. As described in Sections E.4 and G of the EA, Monsanto/KWS submitted a food and feed safety and nutritional assessment summary for event H7-1 to FDA[3] in April 2003. They completed their consultation with FDA in August 2004 when FDA had no further questions regarding their application (http://www.fda.gov/Food/Biotechnology/Submissions/ucm155747.htm). Before a product is registered as a pesticide under Federal Insecticide Fungicide and Rodenticide Act, it must be shown that when used in accordance with the label, it will not result in unreasonable adverse effects on the environment. As described in Sections E.4 of the EA, EPA is required, before establishing pesticide tolerance to reach a safety determination based on a finding of reasonable certainty of no harm under the Federal Food Drug and Cosmetics Act, as amended by the Food Quality Protection Act of 1996. The FDA enforces the tolerances set by the EPA. EPA established a tolerance for glyphosate residue found on beets, including sugar, roots, tops, and dried pulp on April 14, 1999 (64 Fed. Reg. 18360). There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

**NEPA Decision and Rationale**

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting the Preferred Alternative – Partial Deregulation – Combination of Alternatives 2 and 3.

[3] FDA, through a voluntary consultation process, consults with developers of bioengineered food crops to assist them in identifying potential food safety issues related to these products.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The Preferred Alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, the preferred alternative meets APHIS' purpose and need and is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; (2) allows APHIS to impose conditions (interim regulatory measures) to prevent any plant pest risk associated with H7-1 sugar beet seed production; (3) allows APHIS to impose conditions (interim regulatory measures) on H7-1 root production to minimize potential impacts to the human environment; (4) minimizes disruptions to U.S. sugar beet production; (5) allows APHIS to impose conditions (interim regulatory measures) to prevent any impacts of concern to the Court until APHIS can complete its NEPA analysis before making a determination on whether or not to grant nonregulated status to H7-1 sugar beets; and (6) allows APHIS to fulfill its regulatory obligations of responding to a petitioners request for a determination of the regulated status of genetically engineered organisms regulated under 7 CFR Part 340.

Therefore, it is my decision to implement the preferred alternative as described in the EA. Based on all of the analysis and reasons above, I have determined that there would be no significant impact to the quality of the human environment from the implementation of the chosen alternative and therefore, no EIS needs to be prepared.

Cindy J. Smith

Feb. 4, 2011

Cindy J. Smith
Administrator
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date

## Literature Cited

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.

USDA-APHIS. 2011. Plant Pest Risk Assessment for Sugar Beet Event H7-1 Grown for Root Production. USDA APHIS Biotechnology Regulatory Services, Riverdale, Maryland.

## Response to Comments
## Supplemental Request for Partial Deregulation of 03-323-01p

In a notice published in the Federal Register (75 FR 67945-67946, Docket No. APHIS-2010-0047) on November 4, 2010, APHIS announced the availability of a draft EA for public review and comment as part of its decision making process to address a supplemental request received from Monsanto for partial deregulation of sugar beets genetically engineered for tolerance to the herbicide glyphosate (H7-1 sugar beet), or for similar administrative action to authorize the continued cultivation of the H7-1 sugar beets subject to carefully tailored interim measures proposed by APHIS. The 30 day comment period ended on December 6, 2010 with APHIS receiving a total of 3,722 individual comments from various groups and individuals. Of this total, 3,058 respondents provided support of the EA's preferred alternative; and 633 respondents were opposed. An additional 37,159 form letters were submitted as attachments to three of the opposing comment documents.

Supporters of APHIS granting partial deregulated status or planting of H7-1 sugar beets under APHIS permits included many growers associated with sugar beet cooperatives; food or industrial companies; commodity associations; and banks and businesses in communities with sugar beet processors and equipment dealers. These individuals cited a number of benefits if H7-1sugar beets were available for commercial production including: (1) simplification of sugar beet production (2) increased yield (3) better weed management and (4) fewer herbicides being used to produce sugar beets. Various businesses noted the negative economic impacts that would be imposed on local communities if H7-1 sugar beets were not allowed to be grown commercially, including impacts on the processors, and loss of jobs. Sugar related businesses, such as candy manufacturers or those that sell processed sugar to businesses, were concerned about likely impacts to their businesses if H7-1 sugar beets were not allowed to be grown commercially. These individuals concerns were based on the potential disruption of the sugar supply from domestically sourced sugar.

Those opposed to APHIS' preferred alternative in the Draft EA included organic growers that expressed concerns about the potential for their organic chard or table beet seed crop becoming admixed with genes expressing the Roundup Ready trait. Even in the absence of measured gene introgression, these individuals were concerned with the possible economic loss that might be incurred by organic growers. Much of their concern was centered on the possibility that buyers of their organic seed would discriminate against purchasing seed from growers in areas such as Willamette Valley (OR) where both GE and non-GE *Beta* seeds were produced. Other concerns included the costs of checking genetic purity of the non-GE *Beta* crops, or possible costs of cleaning up genetic introgression of GE genes in non-GE seed stock. Others that opposed APHIS preferred alternative included individual consumers that expressed their dislike for GE products and all genetically modified plants, or those urging APHIS to complete an EIS before granting any interim approval for H7-1 sugar beets. None of these individuals provided specific disagreement with the environmental impacts analysis provided in the EA, but were primarily focused on their opposition to the presence of GE genes in vegetable

produce. Some public advocacy groups also expressed concerned that H7-1 sugar beet production would lead to weeds developing resistance to a highly useful herbicide (glyphosate), and also the potential impacts from increased glyphosate application on the environment.

## 1. Adequacy of an EA for RR Sugar Beet Rather than an EIS

**Comment:** *One commenter noted that an EIS must be prepared if substantial questions are raised as to whether a project may cause degradation of some human environmental factor. The commenter believes that deregulation of RRSB and subsequent commercialization "may affect" the environment and that an EIS is required, citing a recent Supreme Court decision noting that an interim APHIS measure to allow issuance of permits could well require its own EIS.*

**APHIS Response:** National Environmental Policy Act (NEPA) regulations allow APHIS to take at least some actions pertaining to the regulation of sugar beet during the pendency of the EIS process. However, any action that APHIS may take in APHIS Response to the request for "partial deregulation" would be an interim action, limited in scope and duration, which would neither result in significant impacts to the human environment nor prejudice any decision to be analyzed in the forthcoming EIS. (EA Section C; Alternatives Considered).

In *Monsanto v. Geertson Seed Farms*, the Court declined to "express any view" on whether the limited deregulation of Roundup Ready alfalfa would require the prior preparation of an EIS (130 S. Ct. 2743, 2758 n.5 (2010). In the same decision the Court noted, "If the agency found, on the basis of a new EA, that a limited and temporary deregulation satisfied applicable statutory and regulatory requirements, it could proceed with such a deregulation even if it had not yet finished the onerous EIS required for complete deregulation" *Id.* at 2758. In this case, APHIS has addressed all of the NEPA requirements in its EA in a complete, reasoned, and adequate manner, including a full analysis of alternatives. The permit conditions for seed production and partial deregulation of the root crop are a valid exercise of APHIS' statutory and regulatory authority.

**Comment:** *One commenter observed: APHIS claims that successful confinement during…commercial permitting will be evidence for the suitability of RRSB to once again obtain deregulated status.*

**APHIS Response:** APHIS has considered these remarks and removed them from the EA.

**Comment:** *One commenter believes APHIS shouldn't allow planting of sugar beet while they undertake an analysis. APHIS shouldn't facilitate commercialization under permits, because permit provisions were meant only for research, and this represents an end-run around actually making a decision for commercial approval.*

**APHIS Response:** APHIS regulates, among other things, the 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 under the Plant Protection Act and7 CFR part 340. There is nothing in the PPA or 7CFR part 340 that prevents issuing permits intended for commercial usage. To the contrary, a detailed description of the proposed product, its molecular biology and a detailed description of the purpose for the introduction are submitted by each applicant under 7 CFR part 340.4. Further, an applicant for a permit is required to submit 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).

**Comment:** *We reiterate our position that a full EIS is not warranted for most new biotechnology-derived products. The overwhelming consensus of scientific opinion indicates that the fact a plant has been genetically engineered does not, in itself, change the environmental impact of the plant. As a result of APHIS's regulatory review, consumers can be confident in the safety of new crops while innovative companies continue to make investments and create value for farmers and jobs.*

**APHIS Response:** Though many members of the public do not believe a full EIS is necessary, the U.S. District Court for the Northern District of California disagrees. The Court has ordered the preparation of a full EIS prior to a full deregulation of H7-1 sugar beet. APHIS is committed to fully comply with the guidelines set forth through the judicial process. In keeping with the Court's ruling, APHIS is currently preparing a thorough EIS.

**Comment:** *One commenter believes that due to the likelihood of significant environmental impact, APHIS should not approve the draft EA and permitting scheme while it prepares an EIS on the deregulation of RRSB. The commenter also believes that the draft EA is rife with indications that permitting the commercialization under the proposed scheme "may affect" the quality of the environment and hence require an EIS. Nine items are listed in support of that assertion:*

**APHIS Response:** APHIS has not concluded that allowing the commercialization of RRSB seed crop under permit and RRSB root crop under partial deregulation, under the preferred alternative, would significantly affect the quality of the environment. To the contrary, APHIS has examined the potential for any impacts to the human environment and addressed them fully in the EA. APHIS also addressed all nine assertions indicating possible environmental impacts that would make only an EIS acceptable to the court as follows (but other APHIS responses to comments provide additional details for why APHIS does not agree):

**(1) Sugar beets will occasionally bolt (produce a seed stalk that may untimely flower) in their first year of production;**

Though bolting may occur in the first year of production, 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 have an incentive to remove them. Because bolters are rare and require several weeks to develop flowers, stewardship can be nearly 100% successful in eliminating any small probability of pollen shed (EA, Section E.1; Affected Environment, Biological Resources). Under the APHIS preferred alternative, any bolters will be removed before the rare event of pollen production in root production fields.

**(2) Adventitious presence of GE seed is possible, even though seed companies follow best management practices for GE seed production, and testing must be used to ensure that undesired traits are not incorporated into stock seed and widely disseminated;**

To avoid cross-contamination, existing seed company production protocols (Loberg, 2010) "include 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." (EA, Section E.1; Affected Environment, Gene Flow from Sugar Beet to Sugar Beet).These protocols combined with APHIS' mandatory conditions for production, under compliance agreements and APHIS supervision of seed production under permits, are more than adequate to prevent adventitious mixing of glyphosate resistance into vegetable beet seed stocks. (See assertions 3 and 4 which exclude the likelihood of cross-pollination mechanisms as a source of adventitious presence.)

**(3) It is possible that in the coexistence zone, H7-1 sugar beet will occasionally pollinate conventional sugar beet, Swiss chard or table beet. USDA is aware of studies that show that beet pollination can occur over distances as great as 6 miles;**

Studies that show beet pollination over distances as great as six miles are atypical, and represent the "worst case scenario." This occurs largely in situations where there is little pollen competition and self incompatibility. The experimental observations in those studies do not consider factors which can substantially reduce the likelihood of cross-pollination, including the size of the pollen source relative to the pollen receptor. Further, commercial sugar beet operations use cytoplasmic male sterility for their hybrid production, and this system is used in about 78% of H7-1-carrying female parents that produce nearly 100% non-viable pollen. This system confines H7-1 bearing traits to female plants, preventing gene movement from H7-1 plants. Additionally, because of the decreased amount of pollen from male steriles during hybrid production, these sugar beet seed production fields would produce less pollen than open pollinated fields commonly used for Swiss chard and table beet (EA, Section F.1; Environmental Consequences,

Gene Flow from Sugar Beet to Vegetable Beet). Reduced pollen from the originating fields is outcompeted by larger relative amounts of pollen from any possible target fields.

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 (EA, Section F.1; Environmental Consequences, Gene Flow from Sugar Beet to Vegetable Beet).

**(4) Cross pollination could potentially result in adventitious (inadvertent) presence of genetic material from the sugar beet root crop in one field into a nearby vegetable crop field;**

Though cross pollination of one crop by another may result in adventitious presence, sugar beets are harvested in the vegetative stage (before they flower), so there is little potential for cross-pollination between root production fields. Furthermore, seed production has been identified as the major (relative to root crop) potential source of adventitious presence, with other sources, including planting, cultivation, cross-pollination, volunteers, harvesting and production all with no or minor potential contributions (EA, Section F.1; Environmental Consequences, Gene Flow from Sugar Beet to Sugar Beet).

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 beet root 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 (EA, Section F.1; Environmental Consequences, Gene Flow from Sugar Beet to Sugar Beet).

**(5) Sugar beet seed plants are prone to shattering during seed harvest;**

The risk of sugar beet seed shattering during harvest is reduced by the adoption of production practices that incorporate control of volunteers in seed production fields. Volunteer control is an essential component of production practices developed to maximize seed purity. For example, West Coast Beet Seed (WCBS) has detailed requirements in its protocol 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, and any remaining seed that sprout 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. Betaseed has similar requirements (Lehner, 2010) (EA; Section E.1; Affected Environment; Sugar Beet Volunteer Control).

(**(6) Unlikely to expect negligible pollen movement into conventional vegetable beet seed;**

Center for Food Safety (CFS) takes issue with an APHIS conclusion of negligible pollen movement into conventional vegetable beet lines. The frequency of incidental cross pollination in a few locations may be extremely low under most circumstances, below that allowable for organic buyers subscribing to standards of the Non-GMO Project. In the unlikely event that some admixture does appear, restoration of the GE-free seed stock can be accomplished with standard breeding techniques (EA; Section E.1; Affected Environment; Removal of unwanted traits from a breeding line).

CFS also overlooks the fact that current practice for sugar beet hybridization lines is that more than 75% of the H7-1 trait is on male sterile female lines. Also, isolation distances of at least four miles will separate any male fertile H7-1 lines from any other *Beta* species. Pollen movement (gene flow), into conventional vegetable beet lines would be negligible. (EA; Section F.1; Environmental Consequences; APHIS Conditions for Seed Production under Alternatives 1, 2, 3 or4).

**(7) Bolters from a sugar beet field may flower at the same time as bolters from a vegetable seed field;**

CFS contends that APHIS admits in its EA that bolters from a sugar beet field may flower at the same time as bolters from a vegetable seed field. This is a remote possibility. However, CFS fails to mention that both sugar beet and vegetable beet produce are harvested before flowering so gene flow is expected to be nonexistent. Also, vegetable seed crops flower at a different time of the year than sugar beet bolters. (EA; Section F.1; Environmental Consequences; APHIS Conditions for Root Production under Alternatives 1, 2, 3 or4).

Due to the mandatory permit conditions to remove bolters, it is extremely unlikely that any H7-1 root crops would produce pollen; even if they released pollen it would be too late to fertilize the seed crop. 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 ( EA; Section F.1; Environmental Consequences; APHIS Conditions for Root Production under Alternatives 1, 2, 3 or 4).

**(8) From 2003 – 2007, there were 102 incidents of non-compliance with issued permits;**

CFS purports there were 102 incidents of non-compliance with APHIS issued permits from 2003 – 2007. However, CFS's mischaracterization of the incidents and intentional omission of material facts purposefully misleads its target audience to form baseless and negative opinions of APHIS activities. (EA; Section F; Environmental Consequences).

For the period of 2003 to August 2007, APHIS-BRS acknowledged 6115 approvals. Of these, there were 5605 notifications and 510 permits. The 102 reported incidents of non-compliance stem from the entire set of 6115 approvals-not just permits. The non-compliance incident rate was nominal at less than two percent over the four year period (EA; Section F; Environmental Consequences). Further, 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. There were only five instances (0.08%) of unauthorized releases due to container failure in movement under notification. None of the five known releases under notifications had any negative environmental consequences. (EA; Section F; Environmental Consequences).

**(9) In the U.S., there are 10 weed species with glyphosate-resistant biotypes and 6% of the total population of herbicide tolerant crops contains some glyphosate-resistant weeds.**

While it is true that six percent of the total population of herbicide tolerant crops contains some glyphosate-resistant weeds, accepted methods are used to mitigate harm to sugar beet crops. 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, and available herbicide chemistries reduce the potential for herbicide resistant weed to develop even where only glyphosate resistant crops are grown. (EA; Section E.1; Affected Environment; Glyphosate Use and Potential Development of Herbicide Resistant Weeds).

It takes multiple growing seasons of herbicide use before herbicide tolerant weeds 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 an herbicide resistant weed population to develop (Kniss, 2010; Beckie, 2006; Neve, 2008; Werth et al., 2008). Fortunately, contractual agreements with sugar beet cooperatives prohibit sugar beet growers from planting sugar beets in the same field more than once every three years. (EA; Section E.1; Affected Environment; Glyphosate Use and Potential Development of Herbicide Resistant Weeds).

## 2. Adequacy of Alternatives

**Comment:** *One commenter believes that APHIS' authority to "partially deregulate" has been artificially restricted by narrow interpretation, so that only industry can "regulate" partial deregulation. APHIS' narrow interpretation of its own regulatory authority is*

*contradicted by the language in the Supreme Court (Geertson 2010) which viewed the agency as having considerable post-deregulation authority.*
**APHIS Response:** The Office of Science and Technology Policy (OSTP) published the Coordinated Framework for the Regulation of Biotechnology, which identified the USDA APHIS, the US Department of Health and Human Services-Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) as the three Federal agencies responsible to regulate biotechnology in the United States (EA, Section A.9; Purpose and Need). The Secretary of Agriculture may issue regulations to prevent the introduction of plant pests into the United States and delegated that authority to APHIS. APHIS regulates genetically engineered (GE) organisms under the Plant Pest Act contained in the Plant Protection Act of 2000, under APHIS regulations 7 CFR part 340. APHIS has the responsibility to regulate the planting of genetically engineered organisms, which includes petition determinations whether to grant deregulated status to genetically engineered articles (EA, Section A.9; Purpose and Need).

In the Supreme Court decision *Monsanto Co. v. Geertson Seed Farms* (No. 09-475; 570 F. 3d 1130) the Court discussed APHIS' authority to effect a partial deregulation under its current regulations; however, the Court did not opine to any specific partial deregulation scheme that may be utilized by APHIS. An APHIS deregulation, whether in whole or in part, requires compliance with the Plant Protection Act and NEPA. Within its regulatory authority under 7 CFR part 340, how APHIS effects a partial deregulation is left to the discretion of the Agency since APHIS has not delegated that authority to any other entity or Agency. The preferred alternative is an example of a partial deregulation scheme where APHIS would deregulate genetically engineered (GE) event H7-1 sugar beets when grown for commercial root production so long as APHIS mandated Compliance Agreements were in place.

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 H7-1 sugar beets subject to tailored interim measures proposed by APHIS (EA, Summary). The four Alternatives APHIS analyzed in the EA includes a "no action" Alternative. Alternatives 2, 3 and 4 are vastly different, but the three hinge on imposing conditions and compliance oversight to prevent transgene flow from H7-1 sugar beets to non-GE *Beta* species. Under Alternative 2, APHIS would authorize environmental release and movement using permits and notifications in accordance with 7 CFR part 340 (EA; Section C.2; Alternatives Considered). Under Alternative 3, H7-1 sugar beet is deregulated and no longer under 7 CFR part 340. Conditions proposed to the Court would be achieved through contractual agreements between Monsanto/KWS and seed companies to ensure compliance with those conditions. (EA; Section C.3; Alternatives Considered). Under the preferred alternative, implementing production conditions for root crops would be accomplished under mandatory compliance agreements between APHIS and processor/growers while seed production conditions would be accomplished under standard APHIS permitting procedures (EA; Section C.4; Alternatives Considered). The conditions imposed in Alternatives 2-4 are primarily the same. APHIS' analysis of Alternatives 3 and 4

demonstrate APHIS' acknowledgement of and willingness to use its broad regulatory authority under the PPA and 7 CFR Part 340.

Three additional alternatives were considered, but rejected from further analysis only after the APHIS evaluated each alternative on the basis of legality, environmental safety, efficacy, and practicality (EA, Section D). In an effort to be more transparent, each of the three alternatives was discussed with the specific reasons for their rejection (EA, Section D).

**Comment:** *One commenter believes that APHIS places the burden for growing non-GE Beta crops only on growers of these crops. Not only are these growers responsible for assuring their customers that their produce does not have transgenes, they must also remove such seed adventitiously present in their seed stock. When growing these crops in the Willamette Valley, non-GE growers are responsible for checking proximity of their fields to sugar beet seed production sites, apparently not the sugar beet seed growers.*

**APHIS Response:** The USDA recognizes that conditions, whether imposed via permitting, through a contractual agreement, or voluntarily, including spatial and geographic isolation distances, are intended to protect all those who choose to grow *Beta* species. Industry-developed standards for growing seed crops of *Beta* species in the Willamette Valley of Oregon were put in place many years ago and have been working well since that time. The introduction of RRSB forced the industry to changes its standards slightly but nonetheless, standards remain and growers have been using them effectively for several years. APHIS does not impose any requirements or conditions on non-GE sugar beet producers as APHIS does not regulate organisms that are not derived from genetic engineering. Under Alternative 2 the GE sugar beet producers would be responsible for ensuring that they comply with the conditions of their permit/notification (EA; Section C.2; Alternatives Considered). Those conditions for planting apply only to H7-1 sugar beet plants for both root and seed production. Compliance measures are instituted to minimize any perceived risk of genetic contamination. Under Alternative 3, compliance with confinement measures is analyzed and enforced by auditors, not non-GE sugar beet growers. (EA; Section C.3; Alternatives Considered) Under the preferred alternative, root production conditions are ensured by growers using third party inspectors hired through the agency of their processor company with oversight and inspection by APHIS, and seed production conditions are ensured by the standard APHIS permit inspection program (EA; Section C.4; Alternatives Considered).

Compliance with spatial isolation distances would have to be maintained by all parties involved in the sugar beet seed production process to ensure that compliance is achieved. Processors would be required to amend their contracts to ensure growers adopt confinement measures (EA; Section C; Alternatives Considered). Because the locations of the permitted sites are deemed CBI, APHIS provided a mechanism, a toll-free telephone hotline, that non-GE *Beta* seed producers may be able to reference and determine the approximate distance of the closest male fertile H7-1 sugar beet (EA; Section C; Alternatives Considered). The Willamette Valley Specialty Seed Association,

Oregon already requires a minimum of four mile isolation distance between hybrid and open pollinated beet fields. (EA, Section F.1; Environmental Consequences).

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."(EA, Section E.2; Affected Environment). The NOP, not APHIS, 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) (EA, Section E.2; Affected Environment). Genetic engineering, along with three other modern breeding techniques, are "excluded methods" in the regulations. However, as mentioned in the EA,"[b]ecause '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. Further, 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 (EA, Section E.2; Affected Environment).

## 3. Successful Confinement of GE Crops by APHIS

**Comment:** *Discovery phase in Sugar Beets I has uncovered conclusive evidence that contamination is not only likely but a common and continuing occurrence among producers of GE seed, and that seed company containment efforts are ineffective. Apparently small levels of exposure are able to cause large scale impacts. Starlink corn never attained more than 0.43% planting on US acreage, but was found in 9-22% of US grain samples. Despite APHIS implementing effective protocols and efforts by seed companies to minimize contamination, there will be continuing pattern of contamination of non GE Beta crops and permits will not provide sufficient containment to protect the environment.*

**APHIS Response**. The widespread appearance of Starlink corn (expressing the Cry9C protein) in commodity channels was not a result of failures by APHIS to implement compliance. APHIS completely de-regulated Starlink, but EPA issued a split approval in which the corn was permitted for only industrial and animal feed use, but not human consumption or for export. However, most commodity corn is not segregated according to such a scheme and it is believed that some growers and elevator operators failed to channel the grain as was intended. No health hazard to humans was identified and no allergies to the product were proven after widespread consumption. Even though the overall percentage of US corn acreage planted to Starlink appears small, the actual area was over 300,000 acres. The detection of Starlink in large percentages of assayed corn samples is a consequence of the high detection sensitivity in the assay for the genetic trait and the fact that samples derived from highly mixed sources. In contrast, APHIS believes that the measures detailed in the EA will be adequate to prevent contamination of organic or conventional *Beta* crops. APHIS' mandatory conditions are an expansion of management systems used by Willamette Valley seed growers and of those required by commercial sugar beet seed producers. Existing management protocols have proved

successful in protecting quality seed production among growers of interbreeding crops for several decades. Successful voluntary compliance will be made mandatory under APHIS conditions and compliance requirements, further benefitting growers of all *Beta* crops, especially those grown in general proximity such as in the Oregon seed production regions.

**Comment:** *The GAO in its 2008 report recommended that APHIS address unintended release of GED crops, and coordinate strategies for post commercialization monitoring, including evolution of resistant weeds and continuing regulatory authority to mitigate risks if and as they arise.*

**APHIS Response**. USDA responded to GAO recommendations and these were published in GAO's report on Genetically Engineered Crops (GAO, 2008). USDA maintains the authority under the Plant Protection Act to regulate a GE crop that it has granted deregulated status if it obtains new information indicating that the crop is a plant pest. A coordinated inter-agency monitoring program would be one way of obtaining information about new plant pest risks. For risks of weed resistance to glyphosate, USDA in its various units (including Agricultural Research Service and National Institute of Food and Agriculture -NIFA) recognizes the need for a broad collaboration of federal, state, academic and industry endeavors to provide responses to these and other risks to which agriculture may be exposed. USDA presently devotes substantial funds to support research, teaching and outreach programs for herbicide resistance management to agricultural researchers and growers.

**Comment:** *The record shows that unexpected gene flow will occur, despite APHIS' assurances that they know what distances will be effective, or how to prevent seed mixing. Protocols are not effective when they are not followed, and human error is often a factor in contamination events.*

**APHIS Response**. In the EA, APHIS has thoroughly analyzed the consequences of sugar beet seed production as unlikely to cause significant impact to commercial vegetable seed production. Under the conditions imposed by the preferred alternative on commercial production, measures to protect seed producers from gene flow are enforced on top of already rigorous management programs of commercial seed companies. Although APHIS deems admixture of vegetable beet seeds with Roundup Ready traits unlikely, APHIS also notes that in agricultural systems which employ a variety of production methods and crops, US and other systems make allowance for small quantities of admixture if it may occur. The policy of APHIS is to take action when "necessary to mitigate low-level presence of a regulated material in commerce to protect plant health and the environment" (APHIS' Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials). Even in the EU, in which few GE crop varieties historically have been accepted, allowance is made for admixture with approved GE traits. If "zero tolerance" were the standard for these crops, trade in agricultural products might cease. The same is true for sales of domestic US organic produce and commodities, in which small admixture is permitted under widely accepted protocols (e.g., The Non-GMO Project). APHIS has expanded on an isolation system currently in use by Willamette Valley seed growers and by commercial sugar beet seed suppliers which has proved successful in protecting quality seed production among

growers of interbreeding crops for several decades. Instead of voluntary compliance, successful in itself, APHIS will add mandatory compliance with these successful techniques.

**Comment:** *Harm resulting from contamination is likely because APHIS doesn't have resources to adequately monitor compliance with permit conditions over such a broad geographic span.*

**APHIS Response**. Under the preferred alternative, APHIS will require third party auditor/inspectors to assess compliance for the very large acreage in the various states in which sugar beet roots are produced, and APHIS will make direct inspections, as well as oversee the work of the auditors. Sugar beet root growers under the direction of the sugar processing companies which they own and to which they are responsible for crop production will be required to expend whatever resources are needed to accomplish APHIS required conditions of oversight and compliance. For seed production, which will occur under direct oversight of APHIS permit inspectors, the 3000-5000 acres involved will be well within the capacity of APHIS to oversee compliance.

**Comment:** *Never before has the agency permitted interim planting and commercial use before deregulation of any GE crop.*

**APHIS response**: In fact, APHIS has allowed commercial production of pharmaceutical and industrial products under permits, and has also allowed production of low nicotine tobacco under notification in multiple states before the trait was given non regulated status. APHIS has conducted inspections under all these situations.

**Comment:** *The USDA track record at overseeing biotech crops in field trials is abysmal, as GAO (2008), USDA Inspector General (2005) reports have disclosed. Congress ordered USDA to improve its oversight of field trials in the 2008 Farm Bill, which USDA has ignored. A proposal in the EA is made for a system of production specified for an entire industry, which is a high expectation. Given the record of USDA, the measures should not be adopted.*

**APHIS Response**: APHIS has taken into account the 28 recommendations from USDA OIG (2005) and reached management decisions with OIG on all of these except for six. Three on permit conditions and standard operating procedures were resolved and accepted by the Office of the Chief Financial Officer for actions that were to be taken on the remaining issues by the end of 2008. Another three were to be incorporated into APHIS BRS' proposed regulations, but final biotechnology regulations (7CFR 340) have not been completed at present.

GAO had two primary recommendations for action that were applicable to BRS. The one relevant to sugar beets is "USDA, EPA, and FDA should develop a coordinated strategy for risk-based monitoring of (deregulated) GE crops that are marketed, which should identify crops that warrant monitoring, such as those that produce pharmaceutical or industrial compounds, and include criteria for determining when monitoring is no longer needed." APHIS decided that in situations where APHIS partially deregulates a GE crop plant, that it is willing to consider plant pest risk-appropriate monitoring for these organisms. In Roundup Ready sugar beets, APHIS will require growers to force sprouting of seed remaining after harvest under partial deregulation, and continued

monitoring of sites planted to H7-1 sugar beets for three years. Any crops planted at the site need to be visually distinct from sugar beets during the monitoring period to avoid facilitating persistence of H7-1 sugar beets. For additional response to the comment about GAO reports and APHIS corrective measures, see previous comments.

Further, APHIS has not ignored the Farm Bill. Under the 2008 Farm Bill, APHIS was given new authority to subpoena evidence including samples of GE crops, and for increased penalties for willful violations of conditions. APHIS, in response, amended guidelines for civil penalties to take actions authorized by Congress. The Bill also encouraged design of an electronic database for permits to facilitate tracking and APHIS implemented the ePermits system to accomplish this request. The Bill directed APHIS to enhance its protocols for conducting molecular forensics. In a Memorandum of Understanding among the Agricultural Marketing Service,the Grain Inspection, Packers and Stockyards Administration and APHIS, APHIS addressed how it would secure sampling and testing of crops when necessary. Congress also asked APHIS to use the latest standards for appropriate separation distances, and APHIS has worked with AOSCA to draft these. Standards for audits of compliance were mandated, and APHIS has begun a BQMS (Quality Management) pilot program to implement this with technology developers. In addition, APHIS addressed a number of the Bill's points by revising and proposing new biotechnology regulations. The revision of 7 CFR part 340, which was published as a proposed rule, but has not been promulgated contains provisions addressing many of Congress' concerns including those it raised about the quality and completeness of records, the maintenance of identity and control in the event of an unauthorized release, corrective actions in the event of an unauthorized release, clarity in contractual agreements, and the need for a system of risk-based categories to classify each regulated article. Finally, the Farm Bill asked APHIS to impose certain requirements on permit holders including requiring them to maintain a positive chain of custody, maintain records, to conduct periodic audits, and to provide contingency and corrective action plans, APHIS addressed these concerns in the provisions of its proposed 7 CFR part 340 rule and APHIS continues to develop management plans for technology providers and require better performance in the specified areas.

**Comment:** *One commenter suggests that even with adequate protocols, preventing gene movement will not be successful. Submitted was his Federal Court Declaration (CFS v. Vilsack, Gurian-Sherman, filed 1-19-10) that cites evidence for several crops, such as corn and rice, several incidences of accidental admixtures of seeds have lead to mixtures of regulated materials in commodities.*

**APHIS Response**. As one example of a widely reported admixture, unapproved varieties of LibertyLink trait were found in commercial rice seed in 2006 and 2007. APHIS was unable to determined responsibility for the primary errors in these incidents, since the unapproved variety had been field tested many years earlier (multiyear tests ending in 2001) and many key records or seed samples were not preserved. However, it appears that the admixtures may have originated at LSU Rice Research Field Stations, where large numbers of varieties and cultivars are simultaneously grown and tested by faculty under contract to seed developers. The admixtures were likely not derived from cross-pollination events. Commercial sugar beet seed production is likely focused on key cultivars, and overseen by specialists who are in a highly competitive business where

mistakes are not tolerable. Commercial vegetable seed production in areas of Oregon where sugar beet seed is also grown are not likely to have so many separate varieties grown by individual seed producers, and consequently the chances for human error of this type are unlikely or highly reduced.

**Comment:** *Other sources of admixture of non-GE with GE crops derive from human error, (Marvier and Van Acker, 2005) and these are documented. Prevention of admixture has not been possible with current technology, "and the longer the GE crop is commercialized, the more likely, and pervasive, contamination will be." Noted for corn and soybean, admixture with deregulated genes was frequent, and a commenter cited a Union of Concerned Scientists publication (Gone to Seed) which measured .05-1% admixtures of transgenes (non regulated genes) in these commodity crops.*

**APHIS Response.** The types of admixture reported by Union of Concerned Scientists is that of APHIS-approved genes appearing in commodities in which they were not expected. These commodities are of course, not confined during production, so storage of soybean with one approved GE trait might leave residues in a consignment of corn with another trait, since no efforts are made to ensure that absolute separations are maintained. Thus, transport, storage and shipment modalities are not inspected to prevent these types of inadvertent mixtures, especially since all the GE traits are approved for marketing and use, and small amounts mixing are not relevant to commodity sales. By contrast, all possibilities for mixture of sugar beet seed and chard or table beet seed are foreclosed by the complete separation of businesses that produce them. Roundup Ready soybeans are produced under the authority of three or four large national or international seed companies, and chard and table beet seed for organic production is accomplished by small farmer operations that sell seed often to a variety of organic seed buyers. No common storage, transport or production activities occur between sugar beets and other *Beta* crops.

Reference.

GAO (2008). Genetically Engineered Crops. Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring. Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate. http://www.gao.gov/new.items/d0960.pdf

Marvier, M and Van Acker, R.C. (2005). Can crop transgenes be kept on a leash? *Front Ecol Environ* 2005; 3(2): 99–106.

## 4. Impacts of the Preferred Alternative on RR Sugar Beet Seed and Crop Growers

**Comment:** *A University plant pathologist notes that the use of glyphosate indirectly leads to decreases in the relative incidence of Fusarium yellows because six types of herbicide are no longer applied when RR sugar beets became available. Toxicity of these herbicides to sugar beet led to susceptibility to the fungus. Along with the glyphosate tolerance, resistance to Aphanomyces black root rot, Cercospora leaf spot, and cyst nematodes were also included, which were not incorporated in previous conventional seeds. Reductions of these diseases resulted in fewer pesticide applications, and greater yields than were previously possible.*

**APHIS Response:** APHIS acknowledges the comment. The potential for increased disease susceptibility in H7-1 sugar beets is covered in Sections E.1 and F.1 of the EA. The weight of evidence suggests that the disease susceptibility of H7-1 sugar beets is no different than that of conventional sugar beets. The commenter suggests that the increased resistance to *Fusarium* yellows is the result of improved plant health due to the lack of crop injury from herbicide applications. APHIS agrees with this suggestion; this topic was covered in Section E.1 of the EA. There is ample evidence that the herbicides used for weed control in sugar beet prior to the deregulation of H7-1 often resulted in crop injury.

**Comment:** *To produce sugar beet at highest yield potential, growers require the Roundup resistant H7-1 derived lines. Previous farm practices to control weeds were not effective in controlling weeds. Consequences for growers of the loss of Roundup Ready beet lines are increased weeds in the rotation crop following beets. Weed seed production will be increased in the conventional beet site, as will pesticide use and cultivation.*

**APHIS Response:** APHIS acknowledges the comment. APHIS agrees that weed control has historically been one of the primary yield constraints in sugar beet crop production, and that a reversion to conventional sugar beets will result in a significant increase in the number of herbicide applications and in the number of cultivation passes.

**Comment:** *One commenter was a grower from Snake River Growers Cooperative, who notes that because of the residual herbicides required for weed control on conventional beets, persisting toxins were present in the soil. Plant-back restrictions required different crops be planted on former sugar beet fields than those he would otherwise choose. Another commenter identified corn and dry edible beans as those impacted by "long residual impact" herbicides; not using conventional beets with the required herbicides allowed farming operations to be improved. Large financial impacts that come with planting conventional beets were also avoided.*

**APHIS Response:** APHIS acknowledges the comments. APHIS agrees that due to plant back restrictions, a reversion to production of conventional sugar beets will lead to reduced options for sugar beet rotational crops. In contrast, glyphosate is not persistent in soil and as noted in the EA, has less environmental impacts than some of the alternative herbicides needed for conventional sugar beet production.

**Comment:** *A commenter made the point that in arid environments such as the high plains of Colorado, glyphosate resistant sugar beets have been highly useful in helping to conserve water, since the crop facilitates reduced tillage and thorough weed control, and tillage and weeds both deplete available soil water.*

**APHIS Response:** APHIS acknowledges the comments and agrees with the conclusion.

**Comment:** *A crop consultant from Idaho for Amalgamated Sugar made the point that RR sugar beet growers were increasing their yields by 5 tons per acre over conventional sugar beets. Weeds harvested with the beets are far fewer, making the beets cleaner and thus easier to store in piles and to process into sugar, especially during the slicing phases of early extraction.*

**APHIS Response:** APHIS acknowledges the comments and agrees, since a variety of commenters made this report as well.

**Comment:** *RR Sugar beet has greatly reduced the use of hand labor in weed fields because the herbicide can be sprayed directly on the crop. A commenter from Wyoming said that the recruitment of adequate weeding crews was difficult and unpredictable (needed when using conventional herbicides). Application frequency of herbicides on conventional beets is higher than that for glyphosate resistant varieties, and also dependent upon temperature, weather conditions, and precise timing. Other growers repeated that contention. Failure to control weeds was always a possibility, making hand weeding highly necessary. The migrant laborers no longer come into the regions where a return to conventional sugar beets might be required. Increased numbers of herbicide treatments, cultivations, and hand labor may result in growers being unable to plant sugar beets on all the acres that they are required by their coops to produce. In other cases, growers may not plant sugar beet if no RR sugar beets are available.*

**APHIS Response:** APHIS acknowledges these comments and APHIS agrees the H7-1 technology provides obvious grower benefits, as indicated by the 95% acceptance rate of the trait.

**Comment:** *The companies claiming economic harm from the failure to plant biotech beets in 2011 - Monsanto, Syngenta, and other agro-chemical giants - have not disclosed what conventional seed stock they have to plant if they cannot plant biotech beets. Any claims of economic harm to them are speculative and a result of their own gambling, since these companies have known since 2008 that they should plan to revert to conventional beets since it was likely biotech beets would again be illegal. 2301.2 etc.*

**APHIS Response:** APHIS acknowledges the comments. Like most for-profit companies, the sugar beet seed providers produce product to meet customer demand. Since 2005, US sugar beet growers have demanded almost exclusively H7-1 sugar beet seed, so the industry has produced accordingly. With the exception of CA, there has been almost no demand for conventional seed. Contrary to the assertion in this comment, an agricultural economics professor (comment 2793.1) provided a comment that said that the sugar beet processors had shared this information with him, along with three seed companies. He also affirmed the accuracy of the EA's statements (in sections E.2 and F.2 of the EA) by USDA Farm Service Agency's head of the Sugar Program (D. Colaccico). APHIS received additional public comments from the President and CEO of the Western Sugar Cooperative that sufficient seed, especially that with regional pest and disease resistance traits, was not going to be available to growers in the next few years. APHIS also received public comments from other Western Region growers that their processor did not have sufficient quantities to supply needs of growers. Public sharing of quantitative information about product availability would likely be unwise for business and competitive reasons, and could potentially be a violation of antitrust laws. Monsanto does not market sugar beet seed; rather they are a technology provider to the beet seed industry.

**Comment:** *Farm income in Idaho of $200 million and income of $270 million from sugar processing and dried beet pulp sales will be jeopardized if farmers are not given access to the RR SB technology. Since conventional beet seed has limited availability,*

*and other necessary chemicals may not be accessible or are no longer registered for beets, the inability to produce RRSB poses a risk to the US of injury to the sugar industry, encourages increased reliance on foreign sugar sources and results in increased sugar prices to US consumers. Dan Sample, paper. Farm income from the Western Sugar Cooperative (1200 growers) was $27.5 million and the Coop's economic contribution to the four state area was more than $300 million.*

**APHIS Response:** APHIS acknowledges the comments and agrees that a ban on H7-1 sugar beets will result in significant economic harm to US sugar beet growers, especially in the western states where conventional seed supplies will be most limiting.

**Comment:** *RR sugar beets have allowed production of beets on land where the weed pressure had previously been too high to successfully control weeds. On the remainder of the sugar beet fields, five or six fewer spray passes are now required to control weeds, and production of sugar per acre has increased.*

**APHIS Response:** APHIS acknowledges the comments, and agrees that superior weed control is an important consideration for growers who wish to plant Roundup Ready sugar beets.

**Comment:** *An association of growers, Mountain States Beet Growers Association of Montana (150 growers on 20,000 acres notes that RRSB facilitated a decrease in herbicide applications to 2-3 from 4-6, and still get more effective weed control. A second Association, Idaho Sugar Beet Growers (370 growers, 140,000 acres), notes that conventional sugar beets have shorter windows and critical timing decisions necessary for multiple applications of diverse herbicides under conventional sugar beet production. Less cultivation and much less herbicide are needed for weed control under RRSB. Lower costs and environmental benefits from reduced tillage, along with increased yields have resulted from use of RRSBs.*

**APHIS Response:** APHIS acknowledges the comments and agrees that these are additional benefits of H7-1 production.

**Comment:** *A grower in Colorado noted that there would not be more than 20% of the conventional seed needed in his coop for planting the required number of sugar beet acres. In addition, there would be no additional seed for replanting in case of a freeze damaged crop, or where winds scoured away the seed.*

**APHIS Response:** APHIS acknowledges the comments and agrees that there will be sugar beet seed shortages in 2011 if planting of H7-1 is not permitted. The forecast availability of conventional sugar beet seed is discussed in sections E.2, F.2 and F.2 of the EA.

**Comment:** *A research agronomist with Western Sugar Cooperative in Nebraska notes that "many weeds had become resistant to all of the conventional sugar beet herbicides, even though the herbicides were applied multiple times at high rates." Coops also insisted on getting additional pest resistances in glyphosate tolerant varieties when these were made available. Moving away from glyphosate resistant sugar beets would be a mistake for all concerned.*

**APHIS Response:** APHIS acknowledges the comment and agrees that herbicide resistance in weeds may develop with any herbicidal protocol.

**Comment:** *The commenter rejected the contention in the EA that 100% of the chard and table beet production occurs in WA and CA, but the commenter says that 6 growers are to be found in Willamette Valley, including his own company with 200 acres of beets and chard.*

**APHIS Response:** The subject of geographic distribution of vegetable beet seed production was covered in Section E.2 and F.2 of the EA. The EA states that 7% of table beet is produced in OR and that there is minor Swiss chard production in OR. These estimates from FSA are the best data available on vegetable beet seed production. APHIS is aware that the FSA data set is incomplete and only growers who participate in FSA programs are included in the data set. APHIS has met with growers in Willamette Valley who produce vegetable beet and chard seed, but has not been able to assemble a complete directory of such growers. Additional chard seed producers in public comments have also identified themselves in southern Oregon.

**Comment:** *The National Association of Wheat Growers (NAWG) commented that they are greatly concerned that actions taken by USDA may impact the ability for other crops to have access to the benefits of biotechnology in the future. Genetically-engineered, conventional and organic crops do readily coexist under far less strict standards than those that APHIS proposes in this case. We urge APHIS to promptly grant the Monsanto/KWS SAAT AG petition for partial deregulation and set forth an orderly process for cultivation until the EIS is complete. We also urge the USDA to complete the EIS in a timely and responsible manner.*

**APHIS Response:** APHIS acknowledges the comment; however the subject of future approvals of new GE crops is outside the scope of this EA. The subject of coexistence is thoroughly addressed in sections E.2 and F.2 of the EA and the proposed interim measures presented in section C.2 are specifically designed to promote coexistence. Nevertheless, sugar beet growers may experience some indirect economic impacts if their future rotation crops, such as wheat in some areas, were not engineered with improved agronomic traits.

**Comment:** *A comment from the American Farm Bureau stated that decisions regarding Roundup Ready sugar beets should follow the precedent established by the Supreme Court on interim measures for planting Roundup Ready alfalfa. The Court's ruling confirms the importance of the continued access to safe, beneficial technology. Decisions about agriculture technology should be based on accurate data and sound science.*

**APHIS Response:** APHIS acknowledges the comment and agrees that all BRS regulatory decisions should be based on accurate data and sound science.

**Comment:** *The commenter was not in agreement that only CA and Western WA are proposed to be GMO free zones, inasmuch as the decision was made without any consultation with growers of Willamette Valley Specialty Seed Association (WVSSA) or even the OR Dept of Agriculture.*

**APHIS Response.** When it proposed conditions for segregating the various *Beta* crops, APHIS BRS intended to preserve historical patterns of production. These conditions should be especially stringent where there was a mixed pattern of multiple *Beta* crops. USDA FSA data indicates that 51% of chard seed production is in Washington State and

49% in California, while 92% of table beet seed production is in Washington State, 15% is in California, and 7% in Oregon. By contrast, sugar beet seed is grown in seven states, 74% is in Oregon (mostly Willamette Valley), 9% in Michigan, and 6% in both Washington and Nebraska, and 1% in California. No sugar beets are grown in Western Washington, and no Roundup Ready sugar beets in California. Thus, the conditions were meant to allow growers who have traditionally produced crops to continue to do so and to prevent the planting of H7-1 sugar beets in Washington and California. Since sugar beet seed production has traditionally been done in Willamette Valley, and this area has multiple table beet seed and chard seed production sites, this area will be at least one of those in the US in which coexistence rules will certainly need to be exercised. This does not exclude the possibility that there may well be additional areas in which growers of both crops need to be informed about intentions of other growers of *Beta* crops, and their proximity to the grower's own fields. Although other small plantings of H7-1 beets may be found in the general vicinity of chard seed production in Southern Oregon, these do not seem to be within less than 5-6 miles of one of the public commenter's location.

## 5. Impacts of the Preferred Alternative on non GE *Beta* Seed and Crop Growers

**Comment:** *APHIS claims that planting RR sugar beets will not have impacts on organic farmers or organic consumers because the presence of transgenic contamination does not constitute a violation of the National Organic Standards. The interpretation is arbitrary and capricious. Inputs from excluded methods such as genetic engineering are prohibited. There is no tolerance for transgenic contamination in the OFPA standard or implementing regulations. The commenter has interpreted the language of 65 FR 13534-35, "This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic food runs counter to consumer expectations, [GE foods] will not be permitted to carry the organic label," to mean that the incidental admixture of any percentage of GE crop would deprive the organic product of acceptability as actually organic.*

**APHIS Response.** APHIS recognizes that some commenters disagree with the APHIS interpretation relative to low level presence and the National Organic Program (NOP). As discussed in the EA (Section E.2. Coexistence of GE and Conventional Crops) the presence of a detectable residue of a product of excluded methods, including GE traits, alone does not necessarily constitute a violation of this regulation.'' The National Organic Program (NOP) does not set a zero tolerance for unintended low level presence of foreign DNA in an organically produced crop. 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.

More importantly, APHIS believes that the Preferred Alternative will not have significant impacts on organic farmers or consumers as a result of the required measures that are designed to minimize the likelihood of gene flow between RRSB and conventional and organic Swiss chard, table beet, and sugar beet seed. Under the Preferred Alternative in this EA, APHIS/BRS will impose mandatory conditions on seed production of RRSB to minimize potential gene flow. For example, currently, about 92% of table beet seed production occurs in western Washington where no RRSB is grown. And nearly 100% of

Swiss chard seed production occurs in California and western Washington. One of the mandatory permit conditions requires no planting of H7-1 sugar beets 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. (EA, Section C; Alternatives Considered). Those geographic restrictions on the growing of RRSB create mandatory isolation conditions far in excess of what has been scientifically determined to be adequate and allows the production of non-GE *Beta* seed crops without the possibility of gene flow from RRSB.

The Willamette Valley in Oregon is the principle identified area in the United States where there is proximity between RRSB seed crop and related *Beta* seed crops, including organic sugar beet (asserted in a Public Comment by Seeds of Change). Some chard growers in Southern Oregon have identified that they are in general proximity to H7-1 seed growers (Tipping, web blog and public comment on Draft EA), but from APHIS records, these may be more than 5-6 miles distant. A majority of H7-1 sugar beet seed are produced on male sterile female lines that produce no or very little fertile H7-1 pollen. This greatly limits the possibility of any cross pollination of non GE seed. Furthermore, APHIS mandatory condition for seed production requires 4-mile isolation between genetically engineered H7-1 sugar beets and all non-GE *Beta* seed crops. Therefore, the likelihood of gene flow from H7-1 sugar beets and non-GE sugar beet seed crops is near zero.

**Comment:** *Some commenters were concerned that table beets and Swiss chard grown as vegetables can be cross pollinated by Roundup Ready sugar beets.*

**APHIS Response:** Swiss chard is grown for its leaf and a table beet is grown for its leaf or roots. Even if sugar beet pollen lands in a field of chard or table beet plants grown for vegetable harvest, it will not alter the chard or table beets growing in the field, since only seed can potentially incorporate the trait. Thus, vegetable beet production will have no possibility of admixture deriving from pollen flow of H7-1.

**Comment:** *"The organic market place will not permit transgenic contamination. For organic consumers, organic requires products be free of any GE contamination. Organic farmers and businesses that are contaminated risk market rejections, lost business and reputation." The commenter quoted "The Geertson Court" (2007), "[E]ven APHIS is uncertain whether farmers can still label their products organic under the federal government's organic statutes."*

**APHIS Response.** Organic produce sellers such as Whole Foods Markets have a GE statement that attests to their organic standards, which are identical with those of the Non-GMO Project. The Non-GMO Project is a non-profit multi-stakeholder collaboration committed to preserving and building sources of non-GMO products and third party verification testing and labeling of non-GMO food and products. The Non-GMO Project website further clarifies the term "Non-GMO Project Verified" as follows:, "So in short, what our seal means is that a product has been produced according to rigorous best practices for GMO avoidance, including testing of risk ingredients." Since the National Organic Program (NOP) does not set a zero tolerance for unintended low level presence of foreign DNA in an organically produced crop, if the tested ingredient contains less

than 0.9 % GMO (which is in alignment with laws in the European Union), it will qualify for the "Non-GMO Project Verified" seal. (http://www.nongmoproject.org/consumers/). Some organic buyers may well require zero content of transgenic traits, but there appears to be a robust number of distributors and retailers who accept the reality that some slight levels of admixture are increasingly likely in most products grown under organic standards and which have GE products deployed in agriculture.

**Comment:** *One commenter alleges that "genetic engineering is prohibited under the Organic Foods Production Act" (1990, as amended 2005) and concludes that "any contaminated seeds that are used to grow organic crops violate the standard." Thus the presence of any GE traits would present a product that could not be marketed as organic.*

**APHIS Response.** APHIS addressed this issue in the previous APHIS responses. Federal definitions of organic products and also marketing standards of many organizations (buyers) do not demand a zero tolerance GM free product, and thus adventitious presence cannot be used to disqualify a product as organic.

**Comment:** *Past incidents of cross pollination or adventitious presence of transgenes were cited by Federal Court (CFS vs. Vilsack, Order filed 11-30-10) as evidence that effective protocols designed to minimize any environmental harm were "ineffective, either because the conditions were later determined to be insufficient or the conditions were not followed." Judge White cites these incidents, and the commenter indicates that outcrossing and contamination will occur in Willamette Valley, too. If buyers hear that the Willamette Valley will be a coexistence zone, it will be the end of vegetable seed production in OR.*

**APHIS Response.** On February 12, 2010, Dr. Neil Hoffman submitted a declaration to the United States District Court for the Northern District of California, San Francisco division, " I am aware that Frank Morton, one of the Willamette Valley (WV) organic seed producers, had his seeds tested four times in three years for the presence of the Roundup Ready GE trait (event H7-1) and each time the test was negative." There is thus no evidence of any actual harm caused by the presence of H7-1 production in proximity to vegetable beet seed production in the Willamette Valley. The evidence of previous incidents of cross pollination cited in the District Court of Northern California order did not identify any incidents that occurred in agriculture in Willamette Valley, nor in sugar beets or vegetable beets, and the conditions identified in the preferred alternative were specifically designed to limit any possible pollen movement or other admixture. Further, H7-1 sugar beet seed crops have been grown in the WV from 2005-2010 without any APHIS imposed restrictions. During that time period there is no evidence of cross-pollination with other Beta crops and no evidence of any "end of seed production in OR."

**Comment:** *A grower of organic and conventional commodities and a Certified Crop Adviser who have been involved with organic crops for 10 years both supported the partial deregulation of sugar beets because the weed control attained in RR SB fields was highly preferred over the "often weedy" conventional sugar beet fields. Weed seed arrived on the organic plots by windborne and water borne means, and organic growers have limited means to control weeds using acceptable methods. Both time and money for reduced weed control efforts are saved by neighbors of RRSB growers. Organic growers also benefit from RRSB produced adjacent to the organic fields, because they*

*provide a buffer for pollen from other surrounding crops with which they are sexually compatible on the organic farm (i.e., organic corn and alfalfa).*

**APHIS Response.** Commenters in support of the partial deregulation of Roundup Ready sugar beet stated that the use of Roundup Ready sugar beets has been shown to reduce weeds in neighboring non-GE sugar beet fields. Weed infestations are considered by a majority of growers to be the most serious problem they face in cultivation of sugar beet (Dexter and Luecke, 2003). In particular, organic farmers have limited means to control weeds using acceptable methods. Weed reduction for organic or conventional fields could result in reduced use of chemicals, and save growers the time and expense of chemical applications to control these weeds. APHIS acknowledges the comments and notes that both GE, conventional and organic producers *(non-Beta crops)* may benefit from adjacent RR SB production.

**Reference.**

Dexter, A.G., Gunsolus, J.L., and Curran, W.S. 1994. Herbicidal mode of action and sugar beet injury symptoms. Accessed on June 2, 2010 at: http://www.ag.ndsu.edu/pubs/plantsci/rowcrops/a1085w.htm#Herbicide.

## 6. Impacts on Grower Choice and Consumer Choice

**Comment:** *The commenter rejects the idea proposed in the EA that GE sugar beets are well accepted by the general public, particularly since there is no labeling of the GE source of the sugar. He believes that because there are non-GE sugar beets produced in California and organic and cane sugar use is increasing, and interest in Stevia production is increasing in CA, then this must be evidence for consumer unhappiness with GE sugar beet derived sugar.*

**APHIS Response:** APHIS acknowledges this comment. In APHIS' reading of internet descriptions of organic sugar availability, there is no lack of organic sources for the sugar. The ability of consumers to buy organic or non-GE sugar would remain unchanged by the actions proposed by APHIS, and is well analyzed in the EA (section H. Consumer Preference for Non-GE Sugar). No commercial organic sugar is produced in the US from sugar beets as far as APHIS knows. Although organic seed is produced for sugar beet, APHIS concludes that these are produced in backyard agriculture as specimen plants. Furthermore the U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds. FDA detected no distinction between sugar beet sugar from conventional or Roundup tolerant sugar beets.

**Comment:** *Consumers who desire non-GE crops will have their choices reduced because of "biological contamination." If there are reduced numbers of growers who can certify an absence of GE admixture, there will be less chard and table beets available to customers who do not want the GE products.*

**APHIS Response:** APHIS disagrees with the statement that there will be less chard or table beets available for the consumers wishing to purchase non-genetically engineered food because strict methods will be imposed to forestall GE gene flow into non GE seed crops and such occurrences will be insignificant. *Beta* seed growers have historically faced the problem of possible gene flow from one *Beta* crop to another, and have devised

means to prevent the contamination of vegetable beet seed with conventional sugar beet traits. Isolation methods are well tested (see rules developed by the Willamette Valley Specialty Seed Assoc.), and infrequent sugar beet contamination (GE or conventional) in chard or table beets for seed typically creates undesirable off-types (visible hybrids) which are currently rogued out of fields. APHIS has incorporated these and other methods into mandatory conditions to forestall movement of H7-1 GE traits into organic vegetable beet seed production sites. While WVSSA rules are voluntary, but have been successful in isolating *Beta* crop seed production, mandatory conditions should certainly increase the likelihood of effective genetic isolation between *Beta* crops.

Much of the production of Roundup tolerant seed in the Willamette Valley is conducted by the sugar beet seed companies using strategies that prevent movement of the GE trait into vegetable beet fields. "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 [non-GE] sugar beet pollen."

Although gene flow from GE sugar beet has been a concern for vegetable beet fresh market producers, it is important to clarify that gene flow is only possible if pollen from GE sugar beet fertilizes the flowers of non-GE *Beta* crops used to produce seed, that is, cross pollination. As stated in the EA no pollen is likely to be produced from H7-1 sugar beets grown for root production because there is no beet flowering in the first year of production and compliance agreements require that any rare bolters during root production be removed. In the five years that H7-1 was fully deregulated and growing on thousands of acres in root crop producing states, APHIS did not receive any reports of sugar beet root production having been a source of outcrossing to vegetable beet seed producers.

Several additional public comments addressed related issues concerning potential for loss of choice by growers or consumers to purchase non-GE vegetable products. For these comments, please see sections on "Impacts on Non-GE *Beta* Seed Growers. For example, these include possible impacts include loss of organic accreditation and markets, and increased production costs associated with monitoring for GE presence. It should be noted that the same argument, of grower choice, was made in support of continued planting of GE sugar beets.

**Comment:** *Because certain other crops have in certain situations gotten admixed with some products of GE, future presence of GE products may eliminate "the consumer's choice to eat non-genetically engineered food," and this is an undesirable consequence.*

**APHIS Response:** APHIS notes that in no cases have vegetable beet seed been identified as genetically admixed with Roundup Ready traits. In regard to consequences of admixture, see APHIS Response to previous comments in this section. In regard to high costs of detecting possible seed admixture, see Economic Consequences section, Socioeconomic Impact, and APHIS Response to comments that follow.

**Comment:** *A history of "contamination" of certain crops with GE genes will "cost farmers their right to sow the crops of their choice." This is a "cognizable harm pursuant to NEPA in [the judge's] underlying order."*

**APHIS Response**: Under the mandatory conditions stipulated in the EA for the planting of GE sugar beets, all agricultural producers will have the ability to thrive and to grow the crops of their choosing, without significant risk to the overall genetic integrity of the crop, whether they are GE, conventional or organic producers. APHIS contends prohibiting the planting of H7-1 sugar beet with the Roundup tolerant trait would also be an "undesirable consequence" having "significant effect on the human environment." Therefore under the Preferred Alternative all forms of sugar beet agriculture would be allowable, with assurance of limited risk to organic producers. For more information on mandatory conditions see EA section C.2, Alternatives Considered, Mandatory Conditions Imposed on Seed and Root Production. See also APHIS' Response to Comments, Likelihood that Proposed Methods of Confinement and Mitigation will be Successful, on the relationship of previous compliance incidents to success of confinement methods proposed for Roundup Ready sugar beet.

**Comment:** *The EA failed to factor in the prohibitive cost for non-GE farmers of detecting contamination through routine testing. The costs should have included those for sampling the plants, maintaining traceability, confirming putative positives, and possibly duplicating the results. The commenter objected to one proposed method for assessing contamination of seed sources by growing sugar beets and then treating with glyphosate because that would require that the grower would need to purchase glyphosate. Farmers must go to great lengths to ensure that their crop contains no GE-material. If the threat of admixture is too high and costs of monitoring too great, then growers will be forced to produce GE varieties.*

**APHIS Response:** The National Organic Program does not mandate testing for the presence of GE traits and neither does it promote a GMO-free policy. As stated in the EA gene flow could only potentially affect certified organic seed producers of *Beta* crops due to out-crossing. Given the containment and isolation measures proposed under the Preferred Alternative out-crossing is highly unlikely to occur. The NOP does mandate routine monitoring for the products of excluded methods, including tests for pesticide residue, which are conducted regardless of the planting of GE sugar beets. Seed testing can be done inexpensively using bulk sampling techniques and test strips to provide a measure of gene flow in the seed lot. Laboratory testing using methods of biotechnology is needed for the most sensitive analysis. The majority of seed producers (conventional, GE, and organic) routinely test seed lots for off-types, which develop as a result of any unfavorable out-crossing. This is a shared expense for all vegetable beet seed producers and is not specific to organic growers. Moreover the premium price received for organic produce should be seen in part as an offset for the added costs of organic production which might include product testing for certain growers or a subset of buyers who might require such evaluations.

**Comment:** *The growing of RRSB will compromise the ability of some growers to grow what they choose because of the costs of keeping GE out of their fields is excessively expensive.*

**APHIS Response:** APHIS imposed conditions should effectively keep GE traits out of seed production fields. If growers wished to assess whether gene flow had occurred, they could choose various types of tests, whose costs were described in the Environmental Consequences, Socioeconomic Issues section of the EA. Organic agriculture has higher input costs, and US consumers have chosen to accept the necessarily higher costs of this type of agriculture. If some growers decide that such testing is continuously needed, then such costs should be reflected in prices for the product.

**Comment:** *The court decision to prevent growing of RRSB took away farmer's choices to use a technology, even though there has been no finding of harm to the environment or to farmers who choose the strategy. The likely impact on the Panhandle region of Nebraska (90%; of Nebraska sugar beet acreage is found there) will impact production and processing industries, and University of Nebraska estimates that the benefit of this crop is $130,000,000 to the local economies through various impacts. The Alternative One would directly impact US agriculture and allow low grade sugar products to be imported into the US. Alternative Two would be cumbersome, requiring data, reporting, production of performance standards, and notifications for growers, and lengthy evaluation processes for USDA. Alternative Three would protect the environment and allow the industry to continue sugar production.*

**APHIS Response**: APHIS acknowledges the comment. Under the Preferred Alternative, planting of Roundup Ready sugar beet root crop would be conducted under compliance agreements resulting in negligible impact to the sugar production and processing industries as well as other *Beta* crop growers.

**Comment:** *The NEPA statute notes that the federal government should, in consideration of this and other policies, and in coordination with other plans and programs maintain, wherever possible, an environment which supports diversity and variety of individual choice (42 USC section 4331).*

**APHIS Response**: Recent comments by Secretary Vilsack demonstrate USDA's goal to "ensure that all forms of agriculture thrive so that food can remain abundant, affordable, and safe" and thereby promoting an individual's choice to purchase or grow food produced by either conventional, GE, or organic methods. To fulfill its commitment to NEPA, BRS has conducted an environmental assessment analyzing the potential impacts of H7-1 sugar beets on all forms of agriculture. Based on the conditions proposed in the EA for growing H7-1 sugar beets and the scope of the federal action, APHIS concluded that there is no evidence for significant environmental impact on conventional or organic agriculture.

**References:**

Non-GMO Project. 2010. Non-GMO Project Working Standard. pp. 40. http://www.nongmoproject.org/wp-content/uploads/2009/06/NGP-Standard-v6.pdf

Hawkes, B. 2004. Memo from Bill Hawkes Under Secretary for Marketing and Regulatory Programs, to Gus Douglas, NASDA. pp. 5.

Open Letter to Stakeholders from Secretary Vilsack to Urge GE and Non-GE Coexistence. U.S. Department of Agriculture, USA (USDA) Press Release No. 0674.10, December 30, 2010

## 7. Significance of an Adventitious Presence of Roundup Resistance Gene in Vegetable Crops

**Comment:** *One organic vegetable beet seed producer in Willamette Valley notes that "the greatest harm to me comes from the damage to my reputation as a safe and reliable source for seed." Financial harm is a secondary issue, and even seed that contained small adventitious amounts of seed with the Roundup resistant trait, the grower would sell commercially as conventional seed.*

**APHIS Response**. APHIS acknowledges the comment. Most growers are in business to produce profits, and organic growers are also typically so motivated. As we show in other APHIS Responses to Comments, organic products can be sold legally and commercially with specified low levels of adventitious presence of GE traits. The proposed production conditions are likely to prevent adventitious presence. From APHIS records, permits for Roundup tolerant sugar beets for seed have been grown in the Willamette Valley since 1995, and in 2003, hundreds of acres have been grown. The one vegetable seed grower who has used tests to detect presence of biotech traits in his own seed has found none, despite the potential for continuous exposure for fifteen growing seasons. Willamette Valley Specialty Seed Association rules have regulated this production, and these are nearly the same as those proposed for this production under APHIS permit conditions enumerated in the Final EA. Commercial sugar beet seed crop has been grown in WV since at least 2005 without any conditions imposed by APHIS. APHIS has never been presented with evidence of gene flow or harm to organic vegetable beets. Documentation of adventitious presence leading to rejection of seed crop purchases, or loss of sales of vegetable beet crops is also lacking. Public comments claim a loss of sales simply because buyers assumed that seed stock might have become admixed. These assertions were not substantiated by either court testimony or factual demonstration of actual genetic presence of adventitious genes in the public comments.

From the analysis in the EA and from analysis of public comments APHIS concluded that economic impacts on organic or conventional vegetable seed growers will be insignificant. APHIS must balance the needs and economic impacts of all stakeholders, too, including sugar beet seed producers, and with the H7-1 seed production grown under permit and under APHIS mandatory conditions, financial impacts on vegetable seed producers will likely be of no significance. Other, intangible concerns for presence of demonstrably safe genetic traits can neither be empirically assessed nor fairly and reasonably arbitrated.

**Comment:** *"NEPA requires that economic effects are relevant and must be examined —when they are interrelated with natural or physical environmental effects.*[72] *APHIS concludes that the commercialization will only have significant impacts on sugar beet seed companies, growers, and processors, but does not adequately examine the potential economic impacts on organic and non-GE farmers. Contamination of non-GE and organic Beta crops will in fact cause significant economic harm to organic and non-GE farmers that must be addressed under NEPA."*

**APHIS Response**. The potential impacts on vegetable beet production have been discussed in the Environmental Consequences of this EA and also in the APHIS Response to Comments (RTC) section, "Impacts on Grower Choice and Consumer

Choice," as well as in this section. Possible economic considerations for a seed producer concerned about maintaining seed purity have been added to the Environmental Consequences section on Socioeconomic Issues of the EA.

**Comment:** *" …Genetic engineering is prohibited under the Organic Foods Production Act (OFPA). The standard prohibits any inputs from excluded methods such as genetic engineering; thus any contaminated seeds that are used to grow organic crops violate the standard. There is no tolerance for transgenic contamination in OFPA standard or implementing regulations. Further during the implementation of OFPA, the Department of Agriculture indicated that the presence of GE contaminants would render a product unmarketable as organic.*

**APHIS Response**. APHIS disagrees that organic market does not permit the low level presence of a GE trait and that its presence causes irreparable harm. By law, organically certified crop cannot be knowingly grown using GE seeds. Having the adventitious presence of a GE trait in a certified organic crop does not "decertify" the crop as organic (please see the Hoffman declarations and the memo from Secretary Hawks for more discussion on USDA organic certification; also see the APHIS Response to comments (RTC) section, Impacts on Grower Choice and Consumer Choice).

**Comment:** *Further, the organic market place will not permit transgenic contamination. For organic consumers, organic requires products be free of any GE contamination. Organic farmers and businesses that are contaminated risk market rejection, lost business and reputation."*

**APHIS Response**. The non-profit organization known as the Non-GMO Project (NGP), comprised of 496 organic producers, distributors and retailers, set specific action thresholds for the presence of GE traits, indicating that low level presence would be tolerated by the organic market. As stated in their Spring 2010 standard:

"Current variances [1] for the Action Threshold [for GE presence] are as follows:

- Planting Seed and Other Propagation Materials that are listed in Appendix B: 0.25%. For all other species, below the limit of detection.
- Human Food, Products, Ingredients, Supplements, and Personal Care Products: 0.9%
- Animal Feed and Supplements: 1.5% "

[1]Variances include crops listed as having low risk of GE contamination, which includes vegetable beets (see Appendix B).

The NGP also gives a minimum separation distance of 5 miles for *seed* production between sugar beets and other *Beta vulgaris* (e.g., chard, table beets). Companies self-certify they are following the NGP Standard.

Please see the APHIS Responses to Comments (RTC) about consumer choice with regards to vegetable beet production and average costs for routine shared testing for off-types in seed lots added to the EA. Routine monitoring for the products of excluded methods are mandated by the NOP, and are conducted regardless of the planting of GE sugar beets. Given the containment and isolation

measures proposed under the Preferred Alternative out-crossing is highly unlikely to occur; and therefore, the economic impact is not significant.

## 8. Adequacy of the Analysis of Glyphosate Use and Development of Weed Resistance

**Comment:** *One commenter disagrees with APHIS's statement that there are three known mechanisms for glyphosate resistance, and indicates that there are in fact five.*

**APHIS Response**. APHIS stated (EA; Section E.1; Affected Environment) that there are three known mechanisms for glyphosate resistance, exclusion, gene amplification, and gene mutation. One of the mechanisms that the commenter states that APHIS omitted, reduced absorption/reduced translocation, is what APHIS refers to as an "exclusion mechanism." The other, referred to as ramification- or increased branching induced by the herbicide, APHIS considers to be speculative. The lone citation for ramification (Dinelli 2006) observed increased branching in glyphosate resistant horseweed compared to susceptible, but did not demonstrate that the increased branching resulted in the resistance. APHIS concludes there are three known mechanisms for glyphosate resistance.

**Comment:** *One commenter concluded that the EA has an inadequate analysis of glyphosate use and development of weed resistance. This commenter stated that "the EA rejects a relationship between use of glyphosate resistant crops and emergence of glyphosate resistant weeds."*

**APHIS Response.** APHIS stated in the EA (Section E.1; Affected Environment) the evolution of glyphosate resistant weeds is the result of selective pressures of glyphosate use, the genetic variation in the weed population, and is not specific to the adoption of glyphosate resistant crops. Also in the EA (Section E.1; Affected Environment), APHIS states that of the 19 species that have developed glyphosate resistance worldwide, 10 may have evolved resistance from use of glyphosate in glyphosate resistant crops.

**Comment:** *One commenter evaluated the accuracy of the acreage estimates for herbicide resistance weeds in the International Survey of Herbicide Resistant Weeds (ISHRW) suggesting that it may underestimate the extent of the problem, in part due to missing estimates for some species and irregular updates on the status of the infestations, and the voluntary system of reporting. It also does not report on shifts to inherently herbicide tolerant weed species. Thus, APHIS' evaluation of the extent of the problem of glyphosate resistant weeds and weed shifts was brought into question.*

**APHIS Response.** APHIS agrees that the estimates may not be 100% accurate, but they may also overestimate the total acreage infested with resistant weeds because different herbicide resistant weed biotypes may occur on the same acreage. The system could be improved by updating the status more frequently, providing incentives for reporting, and providing information at the county level. Nonetheless, in the Cumulative Impacts section of the EA, APHIS did consider

the upper estimates for acreage infested with herbicide resistant crops in sugar beet growing states.

**Comment:** *The commenter feels it is "misleading to focus on the limited number of species that have evolved resistance to glyphosate, only half of which occurred with use of glyphosate in glyphosate resistant crops." The commenter believes that the occurrence of resistance should be presented in acres infested, and numbers of populations arising in agricultural production areas.*

**APHIS Response.** APHIS believes that both statistics are informative. The former illustrates that resistance to glyphosate is a relatively rare occurrence and that it occurs from glyphosate use generally and is not limited to the farming of glyphosate resistant crops. Glyphosate is effective to control over 250 weed species for which it is registered. The total acreage infested with glyphosate resistant weeds in the US is estimated at 12.4 million (estimated to be 6% of the total acreage planted to glyphosate resistant corn, soybean and cotton) (EA; Section E.1; Affected Environment).

The commenter fails to recognize the fact that the Cumulative Impacts section of the EA (Table 16) also includes a thorough analysis of acres of crop land infested with weeds that have evolved resistance to herbicides (glyphosate as well as other herbicides) in sugar beet producing states, and relatively little acreage was found to be infested with glyphosate resistant weeds that could potentially impact sugar beets. This analysis focused on weed species that are considered major weeds of sugar beet, but these species are also weeds in a several other crops, including some that are rotated with sugar beet. From our analysis we concluded that most of the herbicide resistant biotypes are not reported as "infesting sugar beet." Upward estimates of acreage for each different herbicide resistant biotype present in sugar beet rotation crops, when added together totaled upwards of 3.5 million acres. But since the introduction of glyphosate tolerant sugar beet, few major sugar beet weeds have developed herbicide resistance, and of those, biotypes with resistance to glyphosate were reported by the ISHRW for only two species (giant ragweed and tall waterhemp); and these were reporting as infesting soybean in Minnesota, with a combined upward estimate of 600 acres (see Table 16 and Section H of the EA).

The EA also indicated that giant ragweed and tall waterhemp now occur in some sugar beet fields in Minnesota and North Dakota, along with reports of glyphosate resistant common ragweed (and lambsquarter. unconfirmed) in these two states (citing Stachler and Zollinger 2009). The estimates of acres infested with these glyphosate resistant weeds in these states have increased as updated by the ISHRW on December 24, 2010 (and these are included in the revised EA), however they are still only characterized as "infesting soybean". Although only a small fraction of soybean acres are rotated to sugar beet, APHIS notes that soybean is grown on much larger acreage than sugar beet.. In Table 18 of the EA we show that only 3.42 and 0.81 % of the estimated glyphosate resistant soybean acreage planted in Minnesota and North Dakota are rotated with sugar beets. Thus there is no indication that these glyphosate resistant weed populations arose in glyphosate resistant sugar beet or that they are currently a major problem for

sugar beets in these states. Methods used to control these glyphosate resistant weeds are described in the EA. Stachler and Zollinger both submitted comments to the EA and indicate that "In 2008 and 2009, 85 and 77% of growers planting Roundup Ready sugar beet, respectively, reported excellent weed control compared to only 34 and 22% of growers planting conventional sugarbeet, respectively, according to respondents of Annual Survey of Weed Control and Production Practices on Sugar Beet in Minnesota and Eastern North Dakota." They did not raise any concerns with our analysis of impacts and offered their support of the EA to allow the planting of Roundup Ready sugar beet for seed and commercial root production.

**Comment:** *One commenter indicated that "APHIS's treatment of herbicide-resistant sugar beet weeds, and the potential for evolution of GR and multiple herbicide-resistant biotypes, is confusing and inadequate." In particular, was noted the failure to discuss glyphosate-resistant kochia that was discovered in western Kansas and confirmed in 2010, and a more thorough analysis of herbicide resistant common ragweed. The commenter notes that "weed scientists report that glyphosate-resistant kochia has likely evolved in North and South Dakota as well (citing Anonymous (2010). The commenter notes that kochia is already resistant to ALS inhibitors in several sugar beet growing states infesting from one to three million acres, and that the "extremely large populations make it more likely that they contain individuals with the rare genetic predisposition to survive glyphosate application as well." Furthermore, the commenter cautions that mature that seed-bearing kochia plants dry out, and are snapped off at the soil surface and can disperse tens to thousands of seeds per plant over very long distances as during windstorms; thus herbicide resistant kochia could spread widely, posing problems to growers of other crops.*

**APHIS Response.** APHIS acknowledges the comment. APHIS did recognize the importance of kochia as a serious weed of sugar beets and the presence of biotypes with resistance to several different herbicide modes of action (including those resistant to ALS-inhibitor herbicides) in sugar beet growing states in several sections of the EA, including in the Cumulative Impacts section. 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". This report underscores the importance of several points. It does not change the overall conclusion in the Cumulative Effects section that glyphosate

resistant weeds have tended to develop first in other glyphosate resistant crops besides sugar beet and that these can spread to sugar beet in rotations.

Low use rates of herbicides contribute to evolution of herbicide resistant biotypes. Multiple herbicide resistant varieties could evolve through crosses of different resistant biotypes or through sequential selection, and more research and education may be needed to determine the best ways to avoid this. Removing or controlling resistant biotypes before they pollinate and set viable seed is important, particularly when resistant biotypes are present and seeds are wind dispersed. APHIS did note in Section H of the EA several herbicides in addition to glyphosate that are available to control different herbicide resistant kochia biotypes (EPTC, ethofumesate; and mitosis inhibitor herbicides trifluralin and dimethenamide-P). Control methods for glyphosate resistant weed species in sugar beet were also discussed in Section H of the EA.

The widespread occurrence of glyphosate resistant weed populations in certain glyphosate resistant crops demonstrates that additional stewardship measures, such as described in Section E.1 of the EA, should be adopted to maintain glyphosate as an effective herbicide. Other glyphosate resistant weeds that occur in sugar beet producing states are not considered major weeds of sugar beet and are not reported as infesting sugar beet (e.g. horseweed and rigid ryegrass). Even though herbicide resistant common ragweed is a common weed in corn and soybean in Michigan, APHIS did not include common ragweed in the Table 16 of herbicide-resistant sugar beet weeds because it was not included among those weeds mentioned by the ARS (2008) as preventing maximum yields in conventional sugar beets (EA; Section E.1; Affected Environment).

**Comment:** *In a related comment, it was noted that as of 12/2/10 information collated from the International Survey of Herbicide Resistant Weeds indicates that there are now "12 GR weed biotypes in the U.S. and 20 in the world, and in the U.S. they have emerged at an average pace of one per year since the first was discovered in 1998." Therefore the draft EA, published in October 2010 "is already out of date on this point" and "excludes a GR perennial ryegrass population in Argentina as well as GR annual bluegrass and GR goosegrass populations in Missouri and Mississippi, respectively, the latter two confirmed in just the past several months." The commenter notes that "the two U.S. GR biotypes not in APHIS's count are both 2010, and were posted on September 29th and December 2nd, 2010."*

**APHIS Response**. APHIS acknowledges the comment. These GR biotypes are not present in states that grow sugar beets (see Table 8 of the EA), nor are these species included among problem weeds in sugar beets that have previously prevented production of maximum yields to conventional sugar beet crops (EA; Section E.1; Affected Environment). As of 1/11/2011 there are 12 GR weed biotypes listed in the US and 21 in the world. The two new species include a GR Australian fingergrass (Chloris truncata) reported in 2010 in Australia, New South Wales on 1 site infesting 6-10 acres and GR annual bluegrass (Poa annua) that infests turf at 1 site in Missouri estimated at 6-10 acres. Neither evolved in glyphosate resistant cropping systems and neither is a weed of sugar beet. A new

biotype of GR goosegrass (Eleusine indica) arose in the US in 2010 in GR cotton. GR goosegrass has previously arisen outside the US in areas where GR crops were not grown. The GR perennial ryegrass population in Argentina was included in the count of total GR weed biotypes in the world in our draft EA.

APHIS did not include a list of all of the glyphosate resistant weed biotypes in their EA because most of these are not weeds in sugar beets so they are unlikely to have a bearing on environmental impacts for this EA. It is anticipated that additional glyphosate resistant weeds will continue to develop, particularly among weeds that have a propensity to develop herbicide resistance (for example both annual bluegrass and goosegrass have many biotypes with resistance to different herbicides) and in situations where stewardship practices to delay the development of resistant biotypes are not practiced by a majority of growers and for certain weed species. APHIS does not believe it is essential to revise the EA to incorporate updates to facts that are immaterial to the conclusions.

**Comment:** *The commenter feels that the draft EA does not consider or refute evidence that farmers will over apply Roundup, that APHIS should not presume that growers will not apply more glyphosate than contractual obligations with Monsanto require, and that growers will not honor their obligations to their cooperatives to grow sugar beets in a three to four year rotation.*

**APHIS Response**. First it should be noted that the EPA and not Monsanto determines when and how much herbicide can be applied. It is illegal to apply more herbicide than allowed. Second, national statistics for herbicide use indicate that farmers apply only a fraction of the glyphosate allowed by the EPA. As described in Section E.1 of the EA, average glyphosate use for each crop, including sugar beet, is less than 2lb/acre and EPA allows up to 6lb/acre to be applied. Contrary to what is stated by the commenter, glyphosate is not being over applied to glyphosate resistant crops. Third, sugar beet growers have two major incentives to use a three to four year rotation. They use the rotation to manage disease and are likely to face crop failure if they do not. Also, they will be fined by their cooperatives and may forfeit their shares in the cooperative if they fail to adhere to the rotation schedule. For these reasons APHIS considers it very unlikely that a sugar beet grower will avoid at least a three year crop rotation.

**Comment:** *The commenter feels that APHIS does not understand the incentives for Monsanto not to enforce contractual obligations of the Technical Use Agreement and allow glyphosate resistant weeds to develop, since Monsanto would benefit from holding the patent on the next generation of Roundup.*

**APHIS Response**. APHIS does not agree with the commenter that there are incentives for Monsanto to allow glyphosate resistant weeds to develop. APHIS has no evidence that Monsanto has condoned such resistance, or that it may do so. However, it is likely that the less effective glyphosate is at controlling weeds, the less likely it is that farmers are going to buy Monsanto seeds. The commenter thinks "Monsanto will benefit from holding the patent on the next generation of Roundup." USDA notes that 1) Monsanto no longer holds a patent on Roundup; 2) there is no guarantee that a subsequent resistant gene-herbicide combination

will be developed that is as effective as Roundup resistance and Roundup, and 3) farmers have widely adopted Roundup Ready technology and may not widely embrace a new technology they are less familiar with. Therefore Monsanto could likely benefit by preserving the effectiveness of this technology through good stewardship practices.

**Comment:** *The commenter concludes that weed shifts, i.e. the increased prevalence of new weed species that are more tolerant to glyphosate, were not discussed in the draft EA.*

**APHIS Response.** The phenomenon and the means of control are discussed in Section E.1 of the EA.

**Comment:** *The commenter raises the possibility that sugar beet growers may not avail themselves of various methods to control the development of weeds with resistance to glyphosate, "abundant evidence indicates that growers are using only a single approach to sugar beet weed control, POST application of glyphosate."*

**APHIS Response.** APHIS disagrees with this conclusion. One of the most effective means of weed resistance management is crop rotation and this practice is universally applied in raising sugar beets. APHIS also recognizes in the EA that crop rotation with non glyphosate resistant crops or at least other crops that promote the use of herbicides with a different mode of action will be necessary to avoid the delay the evolution of glyphosate resistant weeds in sugar beet (e.g. the Cumulative Impacts section of the EA).

**Comment:** *The commenter feels that APHIS understates the likelihood that growers will rotate from sugar beets to Roundup resistant crops such as soybean and corn and this rotation will enhance the development of Roundup resistant weeds.*

**APHIS Response**. APHIS disagrees that it understated the likelihood of rotation. APHIS presented the facts on Table 1in the EA. In two of the 10 states where sugar beets are grown Southern Minnesota and Michigan, some farms grow glyphosate resistant crops in all rotations. In all other states, at least one crop without glyphosate resistant varieties is used in rotation. APHIS agrees with the commenter that rotating to at least one non glyphosate resistant crop is better than only using different glyphosate resistant crops in the rotation if the grower is trying to avoid selection of glyphosate resistant weeds or shifts to more inherently glyphosate tolerant weed species.

**Comment:** *The commenter states that, "APHIS does not show how in Roundup resistant corn and soybean crops, applications of glyphosate during the growing season have increased over time. This indicates that as weed resistance increases, growers compensate with increasing glyphosate treatments, and then with additional herbicides. APHIS does not cite use of non-chemical control strategies that have value for weed control."*

**APHIS Response.** APHIS disagrees with this set of statements. The rate of herbicide application and the frequency of application are regulated by the EPA

and it is unlawful to exceed the rate and frequency of application. It is recommended [by Monsanto] that glyphosate be used at the maximum rate to reduce the evolution of glyphosate resistant weeds. Glyphosate is such an effective herbicide that it sometimes is applied at suboptimal rates to save costs and rarely needs to be used at the maximum frequency. With weed shifts to species that inherently have a higher tolerance to glyphosate, it is expected that glyphosate will be more routinely applied at the maximum rate in an attempt to control these species. In areas where weeds have evolved glyphosate resistance, farmers are likely to use tank mixes of glyphosate and additional herbicide modes of action, and tillage if necessary to control the resistant weed. There are numerous factors that determine how much herbicide needs to be used in a given year. In some years, the amount of rainfall or temperature increases the abundance of weeds throughout the growing season necessitating more frequent herbicide application. APHIS describes several non chemical strategies used for weed control including crop rotation in the EA (Section E.1; Affected Environment); tillage (Section E.1and E.3; Affected Environment), planting with narrow row width (Section E.1; Affected Environment), and use of weed free seed ( Section E.1; Affected Environment).

**Comment:** *One commenter espousing the benefits of a diversity of weed control tactics to prevent evolution of weeds resistant to glyphosate or any other herbicide, if non-chemical weed control measures are a prominent part of the mix, faults the draft EA for failing to mention a promising technique – the use of "green manure crops, such as oil radish, that suppress weeds as well as nematodes and perhaps disease agents in the follow-on main crop of sugar beets, and provide multiple other benefits as well."*

**APHIS Response**. APHIS acknowledges the comment, agrees with the commenter's statement regarding the importance of a diversity of weed control tactics to prevent weed evolution, and regrets omitting the mention of green manure crops as a possible weed suppression strategy. This has been added to the revised EA.

**Comment:** *The commenter suggests that the decreased use of hand weed control in sugar beets will be temporary based on the evolution of glyphosate resistant weeds in cotton and that now chemicals more toxic than glyphosate need to be used in cotton. The commenter also notes the "increasing expense of responding to existing resistant weeds and the potential agronomic and environmental harms may be caused by an increasing amount of applied glyphosate."*

**APHIS Response**. APHIS acknowledges that glyphosate provides tangible benefits over the current options for managing weeds in sugar beet. Namely, it reduces the use of hand weed control and reduces the use of herbicides more toxic than glyphosate. APHIS disagrees with the commenter that the possibility that these benefits may not last forever is a valid reason for not using glyphosate now. The so called "expense" of responding to resistant weeds and the "potential agronomic and environmental harms" derive largely from a loss of these benefits of glyphosate use and not some incremental harm. Not allowing the use of RRSB means that farmers will assume the expense of responding to weeds resistant to

the alternative herbicides and contribute to a greater environmental harm through continued use of herbicides that are more toxic than glyphosate. Another commenter points out that weed control is improved by rotating glyphosate resistant crops, compared to continuous cropping of glyphosate resistant cotton and soybean. Therefore cotton does not represent an analogous situation to sugar beet, since sugar beet is rarely grown continuously, but is grown in a 3-4 year rotation as noted in the EA.

**Comment:** *One commenter states that APHIS is wrong to assume that 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. He cites the case where horseweed developed in glyphosate resistant soybeans three years after the introduction of the soybeans. While he does not dispute that Kniss (2010) concurs with APHIS' statement, he feels that the other three references: Beckie 2006, Neve 2008, and Werth et al. 2008, upon close inspection do not.*

**APHIS Response**. APHIS disagrees. Regarding the evolution of resistant horseweed in glyphosate tolerant soybean, no one can say from this example that the horseweed developed resistance in three years because it is not known to what extent glyphosate use in this area prior to the introduction of the glyphosate tolerant soybean contributed to the evolution of glyphosate resistant horseweed. We do not agree that Neve (2008) contradicts the "at least five year prediction by researchers." Neve (2008) ran 14 simulations to look at glyphosate-resistant weed evolution. While it is true that in 1 of the 14 simulations, weed resistance was predicted to occur after 4 years, this scenario represents five glyphosate applications per year which is much greater than customarily used. For example sugar beet growers typically use 2-3 applications while in crops like corn and soybean 1-2 applications are made. In other words, the scenario that predicts evolution in 4 years does not represent current practice. In all the other 13 scenarios, resistance was predicted to occur after 5 years. Werth et al. (2008) concludes from simulation modeling in cotton that resistance will develop in 8 years in one case and 12 years in another. In the Beckie (2006) paper, Figure 2 shows a simulation of evolution of resistant individuals in APHIS Response to single herbicide use, two herbicides used in rotation, or two herbicides used as a mixture. In the worst case, use of a single herbicide, resistant individuals were predicted to evolve after 5 years. APHIS stands by its original statement that four researchers have concluded that even if growers completely relied on only one herbicide, it is likely to take at least five years for an herbicide resistant weed population to develop.

**Comment:** *Another commenter feels that stewardship measures to prevent development of weeds resistant to glyphosate should not be voluntary "because of the broad weed killing spectrum of glyphosate and its high facility for use on glyphosate resistant crops, growers have little incentive to engage in resistance management techniques to forestall future weed problems."*

**APHIS Response**. APHIS does not agree with this point of view. In Section E.1of the EA, APHIS cites a market survey conducted by the WSSA which

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 APHIS 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"). APHIS agrees with the commenter who stated that "growers have strong economic incentives to utilize properly their glyphosate-resistant sugar beet cropping systems, and their actions reflect this. Sugar beet growers and processors have established funds to support research and extension activities on weed resistance. Western Sugar Cooperative sponsors 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."

**Comment:** *One commenter noted that "APHIS mistakenly describes glyphosate as a "post---emergent herbicide," (draft EA p. 92), and pointed out the broad range of pre-emergence uses in both glyphosate resistant and non glyphosate resistant crops, including its broad use as a burndown herbicide to clear a field of weeds prior to planting, for instance in wheat, or for direct seeding in a no-till context.*

**APHIS Response**. APHIS acknowledges the comment and has revised the EA to include reference to its pre-emergence uses in the text corresponding to the text in the EA (Section E.1; Affected Environment). APHIS does recognize the pre-emergence uses of glyphosate elsewhere in the document, for example in the description of its uses in sugar beet production.

**Comment:** *One commenter notes that APHIS inadequately addresses the potential damage from glyphosate spray drift to the many other diverse non glyphosate resistant crops that are grown in sugar beet growing states. The commenter also quotes Congressional testimony from Steve Smith, Director of Agriculture for Red Gold, a tomato processor based in Indiana, that he and his 54 family farm growers in Indiana, Ohio, and Michigan have incurred over $1 million in losses over the past 4-5 years due to glyphosate drift damage to tomatoes:*

> *"Since the introduction of glyphosate resistant crops, the pattern of weed control in the Midwest has changed from predominantly pre-plant applications of herbicides, to almost entirely a post-plant, in-season application practice. The effects of this paradigm shift in herbicide applications has affected our company and family growers in a very negative way, due to the potential for direct drifting of spray material onto our tomato fields from applications during windy conditions. The majority of herbicide applications were historically made prior to the planting of*

*most specialty crops, so the drifting of products caused little or no harm. However, the transformation to herbicide applications during the growing season in June and July has put drift prevention at the forefront of concerns to sensitive crop producers of all kinds. Over the last four seasons, our company and growers have been involved with cropping losses exceeding a million dollars due to glyphosate drift."*

**APHIS Response:** Pesticide drift is not an issue unique to sugar beets, nor is this issue one that APHIS can regulate. However, the comment does provide a helpful note on the advantages of glyphosate use with respect to other herbicides. Mr. Smith was expressing his concern to the committee over the possible increase in dicamba use if a dicamba resistant soybean crop is authorized for wide scale planting. Mr. Smith goes on to say that dicamba is an effective herbicide on corn but is rarely used because "dicamba has proven itself to move off-target and cause injury and yield reductions to soybeans and so in a large sense, it is rarely used. Farmers respect their neighbors and know they are at risk of causing injury if they use dicamba, so it is not widely and routinely used in corn production." Mr. Smith contrasts Dicamba with glyphosate, "With glyphosate, crop injuries are the result only from direct drift while Dicamba on the other hand, is highly vulnerable to off-site movement in three forms: direct drift, volatilization, and spray tank contamination." Mr. Smith goes on to say that "Direct drift is in theory, always preventable, by either applying within label restrictions of wind or by applying when the wind direction would not result in a threat to a sensitive crop." Glyphosate is not a volatile compound that will pick up and move in the days or hours following application. Mr. Smith goes on to say that the injury caused by glyphosate is from misapplication. "He also goes on to say that "Good stewardship by neighbors and applicators has been fairly successful in preventing direct drift. In other words, spray drift is not a problem for neighboring farmers when glyphosate is applied according to the label. For conventional sugar beets, a mix of multiple herbicides (BetaMix, Betanex, UpBeet, Nortron and Stinger may be used post emergence weekly for four applications (Mauch declaration, Sugar Beet I). Glyphosate, which is used only 2-3 times, by comparison is not a volatile herbicide, and can be applied under more ideal conditions because of the flexibility when it can be applied; it is superior to the status quo with regards to pesticide drift impacts. APHIS believes that they have adequately presented the relative potential for damage to terrestrial and aquatic plants and nearby crops from herbicide drift in Sections E.3, F.1, F.2, H and Table 13 of the EA. Table 11 of the EA includes caution statements regarding herbicide drift in other herbicides used to control weeds in sugar beets.

**Comment:** *One commenter raises issues about Monsanto's Technology Use Agreement (TUG), regarding the perceived overreliance that APHIS places on it as a legally binding contractual obligation and about the appropriateness of certain recommendations for growers to avert glyphosate resistance associated with Roundup Ready crops.*

**APHIS Response**. Each of the points is elaborated more fully below:

**Comment:** *The commenter supports the TUG recommendation for mechanical tillage and/or residual herbicides as sound measures to diversify weed control practices away from a glyphosate-only approach. But the commenter was disappointed with the TUG recommendation to use "additional herbicide modes of action/residual herbicides and/or mechanical weed control in other Roundup Ready crops" rotated with RRSB, because it was viewed as supporting the notion that farmers should rotate from RRSB to another Roundup Ready crop, which will be an invitation to rely excessively on glyphosate, in some cases throughout a three to five year crop rotation. The commenter believes that prevention of glyphosate resistant weeds requires rotating away from an RR crop system to a conventional crop, where post-emergence use of glyphosate is not possible. The commenter reiterates the warning of Dr. Ian Heap: "The recently developed glyphosate-resistant crops will need to be used in rotation with conventional cultivars and in conjunction with non-chemical weed control and other herbicides if the selection of glyphosate-resistant weeds is to be avoided." The commenter indicates that "minor supplementation of glyphosate with another mode of action or tillage is simply not enough" and supports a "complete break from POST applications of glyphosate."*

**APHIS Response**. As noted in the EA, APHIS concurs that adding a non glyphosate resistant crop in the rotation will promote the use of other non-glyphosate herbicides and provide diversity of the herbicide mode of action which will reduce the selection pressure for glyphosate resistance. However, having a glyphosate resistant crop in the rotation does provide the grower with the flexibility to use glyphosate as a spot treatment without crop damage and as a post-emergent option, preferably tank-mixed with another herbicide mode of action, should the situation warrant it.

**Comment:** *The commenter also objects to another recommendation in the TUG, not cited by APHIS: "Start clean with tillage and follow-up with a burndown herbicide, such as Roundup WeatherMAX, if needed prior to planting." The commenter believes that this pre-emergent glyphosate application when added to the typical 2 or 3, and up to 4 post-emergent applications, will bring the number of glyphosate applications closer to the number that is expected to lead to evolution of glyphosate resistance within 4-5 years.*

**APHIS Response**. APHIS agrees with the comment. Use of Roundup herbicide as the sole pre-plant or pre-emergent burn down herbicide may lead to more total glyphosate applications than is necessary and drive up the glyphosate selection pressure for weeds that emerge at different times. An "if needed" clause may also encourage glyphosate use only when necessary – for example to control a flush of weeds after tillage that may be difficult to control with other herbicides.

**Comment:** *The commenter suggests that Monsanto should offer or recommend conventional varieties to farmers for the purpose of rotation with its RRSB (and other RR crop varieties). As an example, the commenter refers to an Oregon State University and BASF stewardship guide to extend the life of the ALS-inhibitor herbicide-resistant CLEARFIELD wheat which, among other measures, recommends not to plant CLEARFIELD wheat varieties continually and not to*

*apply the ALS –inhibiting herbicides more than 2 out of every 4 years, to limit the reliance on herbicides with this MOA and when applicable, use herbicides with different modes of action.*

**APHIS Response**. APHIS acknowledges the comment and agrees that growers should use multiple modes of herbicide action in rotation crop sequences.

**Comment:** *The commenter objects to the assertion in the TUG recommendation that rotating to Roundup Ready crops adds opportunities for introduction of other modes of action and the APHIS assertion the TUG is a legally binding contract: '"Indeed, H7-1 growers are required to follow Monsanto's TUG, including its recommendation for adopting growing practices aimed at reducing the development of glyphosate-resistant weed populations" (see p. 89 and 254 of the draft EA). The "required recommendations" listed on page 10 of the TUG include: scout your fields before and after herbicide application; start with a clean field, using either a burn down application or tillage; control weeds early when they are small; add other herbicides … and cultural practices … as part of your Roundup Ready cropping system where appropriate; rotate to other Roundup Ready crops to add opportunities for introduction of other modes of action; use the right herbicide at the right rate and the right time; control weed escapes and prevent weeds from setting seeds; clean equipment before moving from field to field to minimize spread of weed seed; use new commercial seed that is as free from weed seed as possible. The commenter believes that the language of the recommendations would not be enforceable.*

**APHIS Response**. APHIS acknowledges that the commenter objects to the assertion that rotating to Roundup Ready crops adds opportunities for introduction of other modes of action. This would only seem to be true if the grower were rotating from a non-Roundup Ready crop, or from a Roundup Ready crop in which the grower chose not to use glyphosate. As explained in Section E.1 of the EA, "all Roundup Ready technology users, including sugar beet growers, are contractually obligated through the Monsanto Technology Stewardship Agreement to follow the TUG." APHIS also agrees that because of the latitude given in the TUG to individual preference, specific sanction for the most preferred choices that should be taken would be difficult to enforce. Other factors described elsewhere in APHIS' responses to comments speak to the incentives that are in play for growers to follow recommendations to delay resistance.

**References.**

Anonymous (2010). "Weed Control in Beans," North Dakota State University, Crop and Pest Report: Weeds, 6/10/2010. http://www.ag.ndsu.nodak.edu/aginfo/entomology/ndsucpr/Years/2010/June/10/weeds.htm#STATUS

## 9. Mitigation to Prevent Development of Weed Resistance to Glyphosate

**Comment:** *Despite the fact that weed scientists and farmers know that specific practices will reduce development of resistance, voluntary measures to prevent*

*resistance to glyphosate identified in the EA will prove inadequate for various reasons.*

**APHIS Response.** APHIS acknowledges the comment, but believes that voluntary measures should be adequate provided that regional weed specialists continue to work with growers and consultants on the best approaches to avoid development of resistance in sugar beet, especially those that are cost effective. APHIS does not dispute the fact that glyphosate resistant weed biotypes or shifts to weed species inherently tolerant to glyphosate are likely to occur with glyphosate use in glyphosate tolerant crops

**(1) The extensive geographic area given to growing multiple Roundup tolerant crops facilitates development of resistant weeds**.

**APHIS Response**. We acknowledge that selection can still occur for these in H7-1 sugar beet production with repeated use of glyphosate particularly if other herbicide modes of action are not used in the crop or in the rotation crop, however the 1.3 million acres of sugar beet production is small in comparison to the total acreage of agricultural crop land treated with glyphosate.

**(2) 1.3 million acres of sugar beet production is appreciable enough to contribute to weed resistance to glyphosate.**

**APHIS Response**. The EA acknowledges the increased potential for glyphosate resistant weeds to develop in N. Dakota and Minnesota as well as Michigan as these states already have populations of glyphosate resistant or tolerant weeds and have a high percent of soybean and corn in their rotation which could be glyphosate resistant.

**(3) Common crop rotations include RR crops, and these will encourage resistance especially in the Red River Valley of N. Dakota and Minnesota (corn and soybeans).**

**APHIS Response**. The EA acknowledges the increased potential for glyphosate resistant weeds to develop in North Dakota and Minnesota as well as Michigan as these states already have populations of glyphosate resistant or tolerant weeds and have a high percent of soybean and corn in their rotation which could be glyphosate resistant.

**(4) Red root pigweed is one important weed of sugar beet, and is in the same genus as to two other pigweeds which already have resistance to glyphosate in soybean and cotton.**

**APHIS Response**. The EA also acknowledges the resistance of several pigweeds with glyphosate resistance and their occurrence in other crops rotated to sugar beet.

**(5) Glyphosate resistant weeds increase the likelihood that growers will use additional and more toxic herbicides; new broad spectrum replacements are not in development**.

**APHIS Response**. APHIS acknowledges that GR weeds may lead growers to use additional and more toxic herbicides. However, without glyphosate-resistant

sugar beets, they may return to using additional and more toxic herbicides as well. Additionally, growers may need to resort to use of more extensive tillage in order to control their weed problems.

**(6) Because of the broad weed killing spectrum of glyphosate and its high facility for use on glyphosate resistant crops, growers have little incentive to engage in resistance management techniques to forestall future weed problems**.

**APHIS Response**. The EA discusses the many incentives that growers of glyphosate tolerant sugar beet will have to engage in resistance management techniques to manage future weed problems.

**Comment:** *Growers have strong economic incentives to sustain their glyphosate-resistant sugar beet cropping systems, and their actions reflect this. Sugar beet growers and processors have established funds to support research and extension activities on weed resistance. Western Sugar Cooperative sponsors 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.*

**APHIS Response.** APHIS acknowledges the comment, and agrees that grower education and availability of user guides will be successful strategies to train growers how to avoid weed resistance using appropriate techniques.

**Comment:** *A Benchmark Study was conducted over a four-year period on 155 farms, across six states, with a minimum of 40 acres per farm. Results from this study demonstrated two important concepts in regard to glyphosate-resistant (GR) crops (Wilson et al. 2009). First, weed control is improved by rotating GR crops, compared to continuous cropping of GR cotton and soybean. Second, weed management is improved by adding a herbicide at planting with a different mode of action than glyphosate, or by combining glyphosate applied postemergence with another herbicide. The results from the Benchmark Study clearly relate to sugar beet. Even when sugar beet is grown in rotations that include other GR crops, the rotations usually contain non-GR crops that introduce herbicides with different modes of action. In GR crops, growers are progressing from only using glyphosate and are applying conventional preemergence herbicides at planting and mixing other herbicides with glyphosate when the herbicide is applied postemergence. This all points to the conclusion that GR sugar beets are sustainable with crop rotation and use of herbicides with different modes of action than glyphosate. These techniques also reduce the potential for weeds becoming resistant to glyphosate (Wilson et al. 2009).*

**APHIS Response**. APHIS acknowledges the comment and agrees with the conclusion.

**Comment:** *In the Draft EA, USDA's chief bulwark against this glyphosate tolerant crop enabling the development of GR weeds appears to be Monsanto's Technology Use Agreement (TUG), which APHIS cites repeatedly. In the TUG Monsanto recommends that growers use "mechanical weed control/cultivation and/or residual herbicide" with RRSB, where appropriate, and "additional herbicide modes of action/residual herbicides and/or mechanical weed control in other Roundup Ready crops" rotated with RRSB.*

**APHIS Response.** APHIS agrees with the first recommendation, that mechanical tillage and residual herbicides diversify weed control practices away from a glyphosate-only approach. APHIS does not agree with the notion that farmers should rotate from RRSB to another Roundup Ready crop, which invites excessive reliance on glyphosate, potentially throughout a three to five year crop rotation. As we have discussed at some length above, prevention of glyphosate resistant weeds requires rotating away from an RR crop system to a conventional crop, where post-emergence use of glyphosate is not possible. We repeat the warning of Dr. Ian Heap:

> "The recently developed glyphosate-resistant crops will need to be used in rotation with conventional cultivars and in conjunction with non-chemical weed control and other herbicides if the selection of glyphosate-resistant weeds is to be avoided."

While the measures Monsanto recommends to accompany the rotation from RRSB to another RR crop might help to a small degree (at least for growers who take them seriously), they will not generally be highly effective.

**Comment:** *One commenter concluded that APHIS holds the "fundamentally mistaken view that GR crop systems have little or nothing to do with GR weed evolution. We have repeatedly presented this information to APHIS in comments on various regulatory decision-making documents, and it has just as consistently been ignored."*

**APHIS Response.** APHIS has not concluded that glyphosate tolerant (GT) crop systems have little or nothing to do with GR weed evolution. APHIS has concluded that GT crop systems are not the sole cause of GR weed evolution. APHIS has repeatedly stated that GR weed evolution results from glyphosate use. To the extent that GT crop systems account for about ¾ of glyphosate use in the US, they contribute substantially to this issue. The same commenter also questions why Table 6, which documents glyphosate use in the US, includes amounts used in non Roundup Ready crops including amounts used by gardeners and homeowners. Because evolution of glyphosate resistant weeds is related to the amount of glyphosate used, it is necessary to describe all glyphosate uses in order to understand how glyphosate use on sugar beets is likely to impact the evolution of glyphosate resistant weeds. Table 6 shows that glyphosate use on RRSB represents less than 1% of the glyphosate used in the US and less than a third of that used by gardeners and homeowners. APHIS does not believe Table 6 represents "a meaningless comparison game."Table 6 documents that the wide-scale planting of RRSB will result in only a very small incremental increase in the

use of glyphosate in the US and correspondingly is likely to have only a very small incremental impact on the development of glyphosate resistant weeds.

**Comment:** *The same commenter feels that a more important question that APHIS should answer is "How much of this enormous quantity of glyphosate is being applied in APHIS Response to increasingly glyphosate resistant weeds that proper regulation on the part of APHIS and the EPA might have prevented, or at least mitigated?"*

**APHIS Response.** One recent estimate of the incremental costs of glyphosate use are $23/acre in cotton and $15/acre in soybean (http://deltafarmpress.com/soybeans/economics-pigweed-control-cotton-and-soybeans accessed Jan 13. 2011)). Another based on a study of 400 corn, soybean, and cotton producers in 17 states, growers estimated that glyphosate-resistant weeds increased their costs by $14-16/acre (Owen. Subcommittee on Domestic Policy Committee on Oversight and Government Reform U.S. House of Representatives July 28, 2010). These costs are not just from increasing glyphosate use which in many cases is ineffective in mitigating glyphosate resistant weeds but includes costs of alternative strategies which involve the use of alternative herbicides, tillage, hand weeding, and use of cover crops. Farmers use RR crops because they realize a net economic benefit. Currently that benefit is estimated to be $20/acre for corn and soybean and $50/acre for cotton (Hurley et al. 2009). If the cost of managing glyphosate resistant weeds exceeds the benefits to farmers, farmers are unlikely to adopt or continue use of the technology.

**Comment:** *One commenter mentioned that a telephone survey of 1200 farmers conducted after the 2005 planting season found that only 30% of farmers thought the GR weeds would become a serious problem, a majority of farmers thought that following the glyphosate label rate recommendation was the most effective strategy for reducing or preventing GR weeds, while very few thought that tillage and not using a GE GR crop would be effective strategies, and that information supplied by land grant studies and biotechnology companies on managing glyphosate resistance is confusing.*

**APHIS Response.** In 2005 fewer farmers were likely affected by glyphosate resistant weeds. In that same survey, only 13-19% (depending on farm size) had ever experienced a glyphosate resistant weed on their farm. Not surprisingly, farmer's attitudes are changing. The EA describes (Section E.1; Affected Environment) the higher level 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 APHIS 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). The USDA recognizes that herbicide resistant weeds pose a problem for growers. USDA's principal in-house research agency, the Agricultural Research Service (ARS) is funding nearly $4.4 million in herbicide resistant weed research in FY 2010. Some of the

research funded included developing best management practices for difficult to control weeds in herbicide resistant crops and combining effective chemical and cultural control measures into integrated systems for the management of key herbicide-resistant and invasive weeds.

**Comment:** *One commenter criticizes the recommendation of Dr. Wilson and Dr. Cole to use the full label rate of glyphosate as a means to delay the evolution of glyphosate resistant weeds. This commenter believes that using a "moderate" level of glyphosate would be preferable "to avoid both the likely adverse effects of its present, wildly excessive use, while at the same time reducing the tremendous selection pressure that is eroding its efficacy via evolution of glyphosate--resistant weeds."*

**APHIS Response.** APHIS disagrees with the commenter that it is preferable to use a moderate level of herbicide. Rather, this recommendation to use low doses of herbicide (in the case of glyphosate, below 0.75 pounds/acre/per application) will in some cases accelerate the selection of herbicide resistant weeds including those resistant to glyphosate (Neva and Powles 2005a; Neva and Powles 2005b; Busi and Powles 2009). The studies by the Powles' laboratory showed that in addition to being attributable to the inheritance of a very rare single gene, glyphosate resistance could also be attributed to a combination of resistance genes that are enriched through successive generations by treatment with sublethal doses of herbicide (Busi and Powles 2009). Busi and Powles (2009) conclude, "We believe that herbicides should be used at the recommended rate to achieve high weed mortality and therefore minimize the possibility of accumulation of minor gene traits that may endow a level of resistance over a few generations. Substantial precautions need to be taken by the industry to ensure that herbicides are used at the registered recommended rates. This should contribute to the sustainability and longevity of herbicide molecules in world agriculture. "

**Comment:** *One commenter felt that "APHIS did not consider relevant research showing changes in rhizosphere microorganisms that are specific for Roundup Ready crop systems where glyphosate is used post-emergence." In particular the commenter notes that glyphosate can inhibit some microorganisms and stimulate others, including pathogenic strains. The commenter notes that APHIS did not cite the paper by Zobiole et al. (2010b) on glyphosate treatment of soybeans.*

**APHIS Response.** APHIS discusses the literature on glyphosate effects on plant disease susceptibility and plant micronutrient levels in the EA (Sections E.1 and F.1). As discussed in the EA, APHIS does not believe there is convincing evidence that glyphosate increases plant disease susceptibility or significantly alters micronutrient availability. The recent paper (Zobiole et al., 2010b) measures changes in microorganism populations as a result of glyphosate exposure but does not produce evidence that these changes have any agronomic significance.

**References**

Anonymous (2010). "Weed Control in Beans," North Dakota State University, Crop and PestReport:Weeds,6/10/2010.

http://www.ag.ndsu.nodak.edu/aginfo/entomology/ndsucpr/Years/2010/June/10/weeds.htm#STATUS ).

Busi R, Powles SB.2009. Evolution of glyphosate resistance in a Lolium rigidum population by glyphosate selection at sublethal doses. Heredity 103: 318-325.

Frisvold, G.B., Hurley, T.M., & Mitchell, P.D. (2009). Overview: Herbicide resistant crops—Diffusion, benefits, pricing, and resistance management. AgBioForum, 12(3&4): 291-302.

Neve P, Powles SB (2005a). High survival frequencies at low herbicide use rates in populations of Lolium rigidum result in rapid evolution of herbicide resistance. Heredity 95: 485-492.

Neve P, Powles SB (2005b). Recurrent selection with reduced herbicide rates results in the rapid evolution of herbicide resistance in Lolium rigidum. Theoret Appl Genet 110: 1154-1166.

Zobiole L.H.S., R.J. Kremer, R.S. Oliveira and J. Constantin, 2010b. Glyphosate affects micro-organisms in rhizospheres of glyphosate-resistant soybeans. Journal of Applied Microbiology, on line, DOI: 10.1111/j.1365-2672.2010.04864.x.

## 10. Adequacy of the Socioeconomic Analysis

**Comment:** *One comment suggests that APHIS did not fully consider the costs to organic growers of allowing the production of GE sugar beets. The comment makes two assumptions: first that cross-pollination or comingling will occur between GE sugar beets and organically produced vegetable beets and second, that the adventitious presence of this GE material in the organic chard or table beets would then reduce the value of the organic crop.*

**APHIS Response**. APHIS evaluated the likelihood that comingling would occur between GE sugar beets and organic and convention chard in the EA (see EA; section F.1) and concluded that comingling of these crops is unlikely under the conditions proposed in alternatives 2, 3 and 4. APHIS also examined the assertion that growers of organic products would lose their market premium if detectable levels of a transgene were identified in the organic product. This analysis can be found in section F.2 of the EA.

**Comment:** *The same comment stated that APHIS did not consider the prohibitive cost to non-GE growers of testing for AP.*

**APHIS Response**. APHIS has updated the Environmental Consequences, Socioeconomic section to include information on the cost of various testing methods.

**Comment:** *In addition the previous commenter suggests that the analysis of the impacts on sugar beet growers is arbitrary and capricious because "…it relies on the testimony of Dr. Sexton for impacts on sugar beet seed companies. The court "disavowed" his testimony of a 37% decrease in sugar production and the permanent closure of 8 of 22 sugar processors in the US because he "[did not]evaluate what impact existing inventories of conventional or genetically*

*engineered sugar beet seed held by the seed producers would have on his analysis and conclusions."*

**APHIS Response**. APHIS has reviewed the information presented by Dr. Sexton as well as analyses contributed by economists in the FSA Dairy and Sweeteners Program. The data represents the best available information on the impacts to the sugar industry. The analysis can be found in section F.2 of the EA. The commenter does not provide any evidence that would controvert the information in Dr. Sexton's testimony. Therefore APHIS disagrees with the commenter's assertion.

**Comment:** *Another commenter suggested that APHIS under estimated the impacts of alternative 1 on the sugar beet seed industry. The commenter, a seed producer, estimates their loss at $50-60 million dollars under alternative 1.*

**APHIS Response.** APHIS acknowledges the comment and has updated the analysis to include this figure.

**Comment:** *Several growers commented that they have transitioned to using RRSB combined with conservation tillage. They state that they no longer have the equipment to grow conventional beets. They also state that the re-acquisition of this equipment is prohibitively expensive given the uncertainty of the future availability of RRSB.*

**APHIS Response.** APHIS acknowledges the comments. The analysis the Draft EA did not include the specific costs of reacquisition of equipment although it is factored into the analysis qualitatively in section F.2of the Draft EA. The commenters did not provide specific details of these costs so APHIS is not able to incorporate these costs into the analysis in the EA.

**Comment:** *Growers in some regions were concerned about the economic viability of the sugar beet processors of which they were owners. If growers were to face shortages of conventional replacement seed, shortages of alternative herbicides for conventional sugar beets, unlikely supply of hand laborers to control weeds, it was concluded that there would be little likelihood that growers would be able to produce sugar beets or would do so at much reduced levels. Consequently, sugar beet processors would not be able to maintain sugar program allotments for the level of sugar required, nor provide economic benefit for their grower-owners.*

**APHIS Response.** The concern expressed by the growers is consistent with the analysis in the EA, in section F.2.

**Comment:** *Several growers discuss the price per share and the number of shares that they own. They commented on the cost of paying the cooperative if they cannot produce beets.*

**APHIS Response.** The failure of growers to fulfill their pledges is heavily penalized, attempting to prevent growers from producing some other crop on acres for which they have a sugar beet allotment to produce. Such reductions in volume of beets produced penalize the remainder of the coop's shareholders, since sugar customer's needs must be met and federal sugar allotments attained.

It might be surprising if the coop's directors would not recognize that in many cases, insufficient conventional seed is available for growers to plant sugar beets, and that this deficit was a result of external causes, not of deliberate grower choice not to plant allotted sugar beet acreage.

## 11. Impacts on Businesses beyond Sugar Production and Processing

**Comment:** *Several companies and organizations that are users of beet sugar commented on the downstream impacts on their individual businesses. Generally they were concerned that alternative 1 would result in an increase in the price of sugar. These businesses expressed concern that an increase in sugar prices would result in an increase in production costs, reduce profits, and possibly cause job loss. One company that supplies food to organizations that feed people in need expressed concern that increased production costs would result in shortage of products for these organizations. One company that makes paper bags for sugar was concerned that the reduction in the domestically produced beet sugar would translate into a reduced market for this product. In addition, owners of businesses in areas where beet sugar processers are located, expressed concern that alternative 1 would negatively impact the local economy because the cooperatives are large employers in these rural areas.*

**APHIS Response.** APHIS acknowledges these comments. The economic impacts are discussed in section F.2 of the EA. APHIS does not describe the local impacts for each processing plant or cooperative because the data on which the analysis is based is confidential business information. The impact on any particular business will depend on the location of the business and its dependence on local sugar processing. In areas where processing plants close or reduce the number of seasonal workers, the impact on the local economy will be greater than those where the plants remain open or operate closer to full capacity. The impacts on the local economy will also depend on the importance of the contribution of the beet sugar processing plant to the local economy. Section F.2 of the EA discusses the impact of alternative 1 on the available sugar supply in the US.

## 12. Adequacy of Cumulative Effects Analysis

**Comment:** *Comments regarding the APHIS cumulative effects analysis in the draft EIS postulated that it was insufficient because APHIS did not adequately assess the cumulative impacts of the Preferred Alternative with relation to 1) the development of future glyphosate-tolerant sugar beet varieties with stacked traits, in particular for additional mechanisms of resistance to glyphosate or other herbicides; 2) the potential for sugar beet seed market concentrations to further exacerbate the impacts from seed market concentrations alleged to have arisen from previous deregulation decisions ; 3) the influence of glyphosate-tolerant crop systems on global climate change including tilling decisions; and 4) issuance of H7-1 permits prior to the publication of the draft EA. The commenter also discusses the issue of glyphosate-resistant weeds under a Cumulative Impacts heading, postulating that the EA needs to acknowledge that farmers have*

*a tendency to over apply glyphosate, which contributes to the emergence of glyphosate-resistant weeds.*

**APHIS Response.** Regarding the first point: Similar to the H7-1 event and given the current regulatory framework, any other biotechnology-derived sugar beet events that may be stacked with glyphosate-tolerant sugar beet event H7-1 would also be evaluated by APHIS at the time that the permit or notification is submitted, and another PPRA and EA or EIS developed prior to consideration of a request for non-regulated status. At those times, APHIS will analyze the potential impacts of the hypothetical stacking of the new event with the H7-1 event in a manner consistent 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. Such an analysis is beyond the scope of the current EA because as described in the sections on Purpose and Need, and Scope, of the EA, the permits for field release, partial deregulation or other administrative action that are the subject of this EA do not include other regulated events. Furthermore, there are no other petitions for another glyphosate-tolerant, or other herbicide tolerant, sugar beet event currently pending with APHIS, nor has APHIS been notified that such a petition is forthcoming. H7-1 releases under the preferred alternative are only proposed in the primary sugar beet root or seed production states of Arizona, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming. APHIS has searched the database for release permits or notifications for other regulated sugar beet events that that have been issued with effective dates from January of 2009 through May 28, 2012 (the latter date being the stated anticipated date of completion of the EIS for H7-1) that could potentially overlap in time and space with the proposed release of H7-1 sugar beets as described in the EA. Only two notifications were identified totaling 8 acres. These were issued after the summary judgment issued for H7-1 in September of 2009. These include sugar beets engineered for resistance to the beet necrotic yellow vein virus in Oregon (10-183-106n, issued on 07/23/2010, expires 07/23/2011) and in Minnesota and North Dakota (10-036-102n, issued on 03/12/2010, expires 05/01/2011). Neither of these notifications include the H7-1 event, and the performance standards for conduct of these field trials prevent commingling or gene flow to other sugar beets. As described in the EA, the conditions for seed production proposed for H7-1 under the preferred alternative are also designed to prevent commingling and gene flow to other sugar beets varieties. Therefore, significant cumulative impacts would not be expected to occur from stacking of H7-1 with other events as a result of past, present or reasonably foreseeable actions.

**Comment:** *A second cumulative effect, seed market concentration, was not addressed in the EA. A large part of the market for US seed is controlled by a few corporations, who have purchased the seed companies and incorporated genes for GE herbicide resistance.*

**APHIS Response**. Regarding the second point: EA Sections E.2 (Affected Environment - Socioeconomic impacts) and Sections F.2 (Environmental

Consequences – Socioeconomic impacts) provide background and details on the expected impact from the alternatives on sugar beet seed companies and cooperators, sugar beet seed availability, technology fees, and availability and price of sugar. The permitting of H7-1 event sugar beet by APHIS does not force growers, or other buyers of seed, to exclusively purchase H7-1 seed. While the H7-1 seed may have high market penetration (as evidenced by historic adoption rates), this is the result of the desired features of event H7-1 derived varieties as compared to other previously available sugar beet varieties. H7-1 has been bred into many varieties offered by sugar beet seed companies. The price and availability of sugar beet varieties will vary based on many unforeseeable factors, including litigation. Growers and other consumers will continue to make decisions based on their personal circumstances. The many variables involved make future impacts on seed beet market concentrations impossible to foresee with accuracy. APHIS acknowledges that technologies developed and owned by a private firm have the potential to lead to increased market concentration, which may, although not necessarily, favor monopolistic behavior with potential negative impacts. However, there is no indication that the deregulation of H7-1 has caused a change in the diversity of companies developing sugar beet seed, nor has it negatively impacted the availability of varieties that grower's desire. Fair competition and business practices, however, are enforced through United States anti-trust laws and institutions and are beyond the scope of this EA.

**Comment:** *APHIS has not fully analyzed the influence of glyphosate-tolerant crop systems on global climate change including tilling decisions. The commenter breaks down potential impacts of the preferred alternatives on global climate change with the following: a) the APHIS claim that glyphosate use will not increase is not supported; b) APHIS should not assume that growers of H7-1 sugar beet will adhere to herbicide application guidelines and restrictions; and c) changes in tillage practices are not necessarily correlative with the adoption of herbicide-tolerant crops.*

**APHIS Response.** APHIS disagrees that the analysis of cumulative impacts on climate change were unsupported. In the EA Section E.3 (Affected Environment – Physical Environment- Air Quality and Climate) APHIS provided information on several factors relative to agriculture production that could impact climate change and in Section F.3. (Environmental Consequences – Physical Environment- Air Quality and Climate) analyzed the impacts of the alternatives. Several citations supporting the analysis were provided. The commenter has ignored references cited in the EA Section H. Cumulative Impacts - Air Quality and Climate Change that analyzed side by side comparisons of glyphosate resistant sugar beet production compared to conventional sugar beet production with regard to factors related to climate change, in particular fuel consumption related to tillage and herbicide applications. (The EA has been revised to correct an error in the estimated amount of carbon reduction per acre in H7-1 sugar beet production compared to conventional sugar beets across four cultivation and herbicide treatment regimes, which for the H7-1 cultivars used from 1 to 3 glyphosate treatments at label-recommended rates, but the trend is still a reduction.) In the Cumulative Impacts section, APHIS notes that the positive benefits of reduced

fuel consumption in H7-1 seed production is only expected to be "cumulative in those areas where rotation crops also implement conservation tillage practices."

In the Cumulative Impacts Section of the EA, APHIS provides several references for studies of the relationship between genetically engineered crops and herbicide use that have "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)." Areas where other Roundup Ready® crops follow sugar beet in rotation were noted in Table 18 of the EA. The APHIS assumption that glyphosate use under the preferred alternative will not increase was based on the fact that in EA Section A.4 (Purpose and Need- Production History of the Event H7-1 Sugar Beet) it was mentioned that "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)." Furthermore, with respect to fuel use and carbon dioxide reduction, the number of herbicide applications would be more important than the rate, and according to the Roundup Weathermax label, maximum use rates on glyphosate tolerant sugar beets (H7-1) are for two applications prior to the 8-leaf stage and two applications after the eight leaf stage up to 30 days prior to harvest, with maximum single and combined rates specified for each (see EA Table 5 and Monsanto, 2010). Also as discussed in the EA Section on Cumulative Impacts, references are provided to support that the current glyphosate use in H7-1 sugar beets are minor compared to total US glyphosate use (~0.8%) and compared to the total US agricultural and fallow use (~1.3%). Regarding the effects of glyphosate and the assumption of adherence to label directions, EPA has analyzed these effects and designed labels accordingly. EPA also monitors label use through enforcement and other actions. No information has been obtained, nor did the commenter provide any information to indicate any significant noncompliance with glyphosate label use. Regardless of whether there is a correlation or cause/effect relationship between adoption of glyphosate tolerant crops and adoption of conservation tillage, APHIS stands by the conclusion that any cumulative impacts to global climate change resulting from the incremental impacts of the preferred alternative would be insignificant due to the crop rotation practices and crop rotation cycles for sugar beet and the relatively small total acres planted to sugar beet relative to other crops. The EA Section E.1. Affected Environment – Biological Resources) notes that sugar beet is usually grown in three to five year rotations. Table 1 of the EA shows that in 2002 approximately 1.4 million acres of sugar beet were grown compared to 48.8 million acres of rotation crops in the major sugar beet growing states.

**Comment:** *APHIS does not discuss the cumulative impacts of the previous four approved permits. Those permits (10-228-104r, 10-235-106r, 10-230-103r, 10-237-107r)*

**APHIS Response.** These permits have a theoretical total acreage of 526 acres. See the new discussion of impacts of commercial steckling production in the EA.

**Comment:** *The commenter states that the one factor contributing to the generation of glyphosate-resistant weeds is the over-application of the herbicide*

*by farmers, and that growers will not necessarily adhere to label restrictions or other legal obligations or crop rotation practices despite the potential long-term impacts. The commenter faults the draft EA for assuming that just because conditions or restrictions are in place, they will be observed and enforced. The comment addresses the larger issue of the development of glyphosate-resistant weeds.*

**APHIS Response.** APHIS believes that it is reasonable to assume that in the vast majority of cases, the label restrictions and recommendations, legal obligations, and crop and herbicide rotation practices that contribute to a reduction in potential for development of glyphosate resistant weeds in H7-1 sugar beets will be followed, and failing that, several methods are available to control glyphosate resistant weeds. This was adequately described in the EA Sections E.1. (Affected Environment-Weed management and Herbicide resistance), F.1 (Environmental Consequences – Biological Resources – Weed Management) and more specifically with respect to crop rotations, including other herbicide resistant crops, in EA Section H(Cumulative Impacts).

As shown in Table 6 of the EA the land used for production of H7-1 sugar beets constitutes less than one percent of all land in the United States under agricultural production where glyphosate is applied, meaning that the potential of H7-1 sugar beet production to contribute to glyphosate-resistant weed development is small compared to the potential contribution of the total of glyphosate resistant crops in production. While the use of glyphosate in H7-1 sugar beets may cumulatively act to increase the likelihood of glyphosate-tolerant weed formation, especially if H7-1 sugar beets are rotated with another glyphosate resistant crop as acknowledged in the EA, there is no evidence to support (nor did the commenter provide evidence) that this increase of potential would lead to significantly more glyphosate resistant weeds when combined with other cropping systems already in production.

As summarized in the Cumulative Impacts section of the EA, herbicide resistant weed biotypes are seldom first reported as occurring in sugar beets, but they do occur in several major crops grown on much larger acreage, only a small 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 have only recently been reported to occur in some sugar beet fields in Minnesota and North Dakota. Nonetheless, as noted in the EA, regional weed scientists have researched and communicated control options, and there is an increasing awareness among growers of glyphosate resistant crops to rotate or add herbicides with other modes of action and rotate crops to manage the resistance problem. APHIS stands by its conclusions.

## 13. T&E Species and the ESA

**Comment:** *APHIS received a list of TES for each state in which sugar beets would be grown, and evaluated effects on TES and critical habitat, concluding*

*that there would be no difference between impacts of conventional and RR sugar beet. On this basis, APHIS decided that there was no need to consult with FWS.APHIS failed to consult with the U.S. Fish & Wildlife Service (USFWS) and/or the National Marine Fisheries Service (NMFS) as is required under Section 7 of the ESA on the potential effects on threatened and endangered species (TES) and their critical habitats. Section 7 of the ESA requires APHIS to consult with USFWS and/or NMFS to determine whether its action 'may affect' listed species or critical habitat// under the ESA. If APHIS learns from FWS and/or NMFS that threatened or endangered species may be present, a biological assessment must be prepared to identify any TES which are likely to be affected by such action.*

**APHIS Response.** The ESA requires Federal agencies to ensure that any action that they authorize, fund, or carry out is not likely to jeopardize the continued existence of any threatened or endangered species or result in destruction or adverse modification of critical habitat. In accordance with Section 7 of the ESA, it is the responsibility of the Federal agency to assess the effects of the action and to consult with the Services if the action "may affect" listed species or critical habitat.

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) (Appendix 2 of EA). 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.

As part of this EA, APHIS analyzed the potential for effects from the preferred alternative on the listed and proposed TES, as well as designated critical habitat and habitat proposed for designation for these species (*see* Section G of EA). This analysis serves as a biological assessment under Section 7 of the ESA. After analyzing the potential for any effect, APHIS reached a determination that the proposed environmental release will have no effect on federally listed threatened or endangered species or species proposed for listing, and no effect on designated critical habitat or habitat proposed for designation. Contrary to the commenter's opinion, when an authorizing Federal agency determines that their action will have no effect, consultation with the United States Fish and Wildlife Service and/or National Marine Fisheries Service is not required.

**Comment:** *The commenter believes that APHIS should have consulted with the EPA regarding the specific impacts of glyphosate use on threatened or endangered species in conjunction with the release of H7-1 sugar beet under the current EA.*

**APHIS Response**. The ESA requires Federal agencies to ensure that any action that they authorize, fund, or carry out is not likely to jeopardize the continued

existence of any threatened or endangered species or result in destruction or adverse modification of critical habitat. As described in section A.9 of the EA, EPA has the legal responsibility to regulate glyphosate and other pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As part of the pesticide registration process under FIFRA, the EPA consults with the FWS on the potential for the use of the product to affect TES and critical habitat. The consultation sometimes results in the imposition of label restrictions to mitigate risk.

When glyphosate, or any other EPA registered pesticide, is applied to H7-1 sugar beet, applicators are required by law to follow the label use directions and restrictions including applicable restrictions to reduce potential impacts to TES and critical habitat. Pesticide applicator adherence to EPA label restrictions mitigates impacts to TES and critical habitat. EPA is the Federal agency responsible for authorizing use of glyphosate (*see* Section E.4 of the EA) and EPA has consulted with the FWS on the effects of glyphosate on TES. As a result, requirements under Section 7 of the ESA to consult on the use of glyphosate have been fulfilled. It is unnecessary for other Federal agencies to consult with EPA concerning the potential use of pesticides to be applied in accordance with EPA's required label restrictions.

## 14. Public Health Analysis

**Comment:** *"APHIS also erroneously defers to FDA's consultation on food safety on H7-1 RRSB. FDA's voluntary consultation process is insufficient. It is based on a statement of policy, not a binding regulation. GE crop developers may choose to consult with FDA, but this process is vitiated by its voluntary nature and a lack of any established testing standards; in particular, GE crop developers seldom if ever conduct animal feeding trials with GE crops for the purpose of detecting potential toxicity. The manufacturer merely sends FDA a summary of its findings. FDA makes no findings of its own. FDA did not prepare any NEPA documentation (no EA or EIS) on its policy nor provide notice and comment. In any event, APHIS cannot solely rely on another agency's evaluation of effects to the human environment under a separate statute to adequately fulfill its own NEPA obligations [ref]."*

**APHIS Response**. The "voluntary" status of the FDA consultation has been exhaustively discussed and moves to make the consultation mandatory have been taken (66 FR 4706). More information is on the FDA website at http://www.fda.gov/Food/Biotechnology/Submissions/default.htm. The FDA provides guidance to the industry as to what information they need to complete a consultation by their Biotechnology Evaluation Team (BET). In the Statement of Policy - Foods Derived from New Plant Varieties (57 FR 22984), the food safety standards applied to all foods (21 USC 348) are applied to foods derived from GE plants; "the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates. As discussed in more detail in section V.C., FDA has determined that such substances should be subject to regulation under section 409 of the act in

those cases when the objective characteristics of the substance raise questions of safety sufficient to warrant formal premarket review and approval by FDA."

The process by which the FDA's Biotechnology Evaluation Team assesses new products is described in their consultation procedures http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology).

APHIS does rely on the expertise of the FDA food safety division and its analysis of the data provided to help with its own NEPA requirements.

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), it is EPA's task to assess the toxicity (acute and chronic) of each chemical submitted for registration, including the surfactants included in different formulations. Feeding studies are routinely submitted to the EPA for the toxicity evaluation of each chemical. APHIS acknowledges that there is concern that we rely on its sister agencies to evaluate glyphosate and its residues on food and the environment under the laws that dictate each agency's actions. Each agency communicates with one another under the Coordinated Framework for the Regulation of Biotechnology Products as specified in both the 51 FR 23302 and OSTP document found in 67 FR 50578. The agencies in the Coordinated Framework try not to duplicate efforts to make better use of scarce government resources.

**Comment:** *"… APHIS defers to EPA on the toxicity of glyphosate and appears only to have reviewed the data supplied to EPA. APHIS claims that it has been twelve years since EPA's decision to increase glyphosate tolerances and no new peer-reviewed data has demonstrated a need for re-assessment of the original decision. However, APHIS does not consider the emerging data on the impacts of the Glyphosate-Tolerant Crop System. These health impacts must also be analyzed. Roundup use has been associated with increased risk of non-Hodgkin's lymphoma and hairy cell leukemia in pesticide applicators [ref], and increased risk of neurobehavioral disorders in children of Roundup applicators [ref]. Roundup/glyphosate has been shown to inhibit steroidogenesis [ref]. Both Roundup and glyphosate have been found to inhibit the aromatase enzyme involved in estrogen production, though Roundup was more potent [ref]." "APHIS overlooked peer-reviewed studies showing endocrine disrupting properties of glyphosate."*

**APHIS Response**. EPA and APHIS have not "overlooked" any peer-reviewed studies and are aware of the studies listed in the public comment (see public comment CFC Science I and II documents) and disagree with the commenter's assessment that there is an association between glyphosate and different cancers listed or its being listed as an endocrine disrupter. The selected studies by the commenters have been extensively reviewed and the agencies have weighed these against the balance of peer-reviewed studies that demonstrate the minimal human health impacts of glyphosate and glyphosate formulations when applied as directed by label restrictions set by the EPA.

APHIS will not provide an extensive review on the papers referenced as to why each study reached its conclusions although other researchers have done so (Adami and Trichopolous, 1999; Cullen 1999; Jackson et al., 1999). Williams (2000) gave an excellent summary as to what is needed to evaluate genotoxicity data using the weight-of-evidence approach.

Glyphosate as an endocrine disruptor has been refuted in APHIS EA #06-332-01p_pea on glyphosate-tolerant cotton and in the Alfalfa EIS (Appendix L 3.1.8).

**References.**

Adami H-O, Trichopolous D.,1999. Review of the study by Hardell and Erikson on Non-Hodgkin Lymphoma and Exposure to Pesticides. Cancer 1999; 85:1353-60.

Cullen M., 1999. Review of Hardell and Eriksson, A case control study of non-Hodgkin's lymphoma and exposure to pesticides, Cancer 1999; 85: 1353-60.

Jackson JR, Sorahan T, van Hemmen, J. (1999) "Rained Out." New Scientist. May 29. 162(2188): 53.

**Comment:** *"Glyphosate impacts should be considered separately from other herbicides."*

**APHIS Response.** Glyphosate as an herbicide has been discussed many times individually in APHIS EAs and most recently in the Alfalfa EIS. The EPA has also written many documents about the impacts of glyphosate alone. APHIS has extensively reviewed these documents and most recently detailed the review on glyphosate in the Alfalfa EIS.

**Comment:** *"APHIS did not evaluate differences between impacts of formulations and active ingredient."*

**APHIS Response.** EPA is responsible for determining the impacts of formulations and active ingredients of herbicides. APHIS has used the EPA's Re-registration Eligibility Decision (RED) document (EPA, 1993) along with other EPA documents to determine impacts when used at the registration rates specified by the EPA. APHIS has reviewed these documents along with other peer-reviewed articles about the environmental impact of glyphosate formulations in the Alfalfa EIS (Appendix N Impacts to Wildlife and Ecosystems).

## 15. Impacts on the Physical Environment

**Comment:** *The Draft EA referred to conservation tillage as a cure to soil erosion and air pollution as if it were brought about by the adoption of herbicide tolerant GE crops. The record of adoption of Roundup resistant soybean crops disagrees with that hypothesis, or at least does not confirm the relationship between no-till practices and adoption of HT crops.*

**APHIS Response.** The increased use of conservation tillage and the concomitant adoption of HT GE crops have both increased since 1996 (Horowitz et al 2010). Several qualitative studies done through telephone surveys of growers and farmers have supported the connection between an increase in the adoption of RR

GE crops and increased practices of conservation tillage. A joint survey conducted by several major Universities (2009) including Mississippi State University, Purdue University, Southern Illinois University, University of Nebraska, Iowa State University, and North Carolina State found that of 1200 growers in six states (approximately 200 per state) that a large percentage of growers transitioned from conventional tillage to conservation tillage including no-till and reduced tillage system after adopting Roundup Ready crops in their crop rotation (Givens et al. 2009). In addition this study found that growers achieved better success in conservation tillage systems, benefitted from the simplicity of weed management strategies, improved their time management needs, and increased crop safety practices from use of GE glyphosate resistant crops.

**Comment:** *One commenter from a public interest group contends that "glyphosate –resistant weeds are also leading to a sharp increase in tillage, especially in soybeans, meaning abandonment of soil-conserving no-till practices that…RR crop systems are credited with promoting."*

**APHIS Response**. For local weed hotspots, even technology providers for glyphosate tolerant crops suggest (see Roundup Ready Technical Use Guidelines) that tillage may be beneficial, and as noted in the section of these APHIS Responses to Comments, Analysis of Glyphosate Use and Development of Weed Resistance, tillage is a strategy that should be used to *delay development* of weed resistance. Any increases in tillage may then be an adaptive strategy for appropriate integrated pest management by some growers.

Overall however, the record may still be one of strong grower support for Roundup Ready crop usage with an accompanying increase in conservation tillage. According to a National survey done by Marra et al. (2004) in conjunction with the NSF Center for Integrated Pest Management, RR soybean adoption is still increasing even though prices of herbicides commonly used on conventional soybeans have fallen to the point that, when only monetary costs and returns are considered, conventional soybean systems are competitive with RR soybean systems. However the author goes on to state that from their research they found that many growers still preferred to use the RR soybean system in conjunction with conservation tillage. The growers cited significant value for the environment and convenience benefits of reduced tillage. In addition the survey results also suggested that growing Roundup Ready soybeans is complementary to and associated with increased rates of reduced tillage. Roundup Ready growers make 25% less tillage passes over the field than growers of traditional soybean varieties. The proportion of farmers using reduced tillage on at least 50% of their soybean acres increases with the use of Roundup Ready soybean. Although it may not be possible to conclusively demonstrate a direct relationship between tillage and Roundup Ready crops, the evidence available suggests that the tillage practices and the use of these crops are highly correlated.

**References.**

Givens et al., 2009. Survey of Tillage Practices in Glyphosate Resistant Crops. Weed Technology 23:150-155).

Horowitz, J., Ebel, R., Ueda, K. 2010. "No till farming is a growing practice /EIB-70. Economic Research Service/USDA. Pg 6.

Michele C. Marra, Nicholas E. Piggott, and Gerald A. Carlson. 2004. The Net Benefits, Including Convenience, Of Roundup Ready® Soybeans: Results from a National Survey NSF Center for IPM Technical Bulletin 2004-3. 39pp. September, 2004. Raleigh, NC.

## 16. Mitigation of Possible Environmental Hazards

Comment: *One commenter believes that the next step in the development of herbicide resistant crops will be the development of crops resistant to dicamba or 2,4-D as well as glyphosate. The commenter believes that this development will lead to the use of herbicides that are less desirable or more toxic than glyphosate alone. The commenter recommends that USDA and EPA jointly design a mandatory glyphosate-resistance management program, similar to that existing for crop-expressed Bt pesticides. The commenter believes that conservative uses of glyphosate along with mechanisms to prevent continuous exposure to weed populations are needed to preserve the usefulness of glyphosate as an effective herbicide and to prevent development of new resistance in weeds.*

APHIS Response. USDA recognizes that herbicide resistant weeds have been a problem in US agricultural production for decades, long before the deregulation and use of herbicide-tolerant crops. In addition, development of resistance is not unique to glyphosate but is faced by growers for every approved herbicide. USDA agrees with the commenter that glyphosate is a useful and effective herbicide. To halt the spread of herbicide resistant weeds, and to prevent further development of more herbicide resistant weeds, a more fundamental, scientific approach is needed to determine how herbicides result in the appearance and spread of herbicide resistant plants and how to effectively use herbicides and other control and cultural methods to minimize the risk of herbicide resistant weeds.

To address the first point, how herbicides result in the appearance and spread of resistant weeds, the USDA entered into a cooperative agreement with the Weed Science Society of America (WSSA) and is partnering with EPA to develop a comprehensive report on the understanding of the processes and extend to which herbicide resistant weeds have developed in the agroecosystems as a result of general herbicide use and with the advent of herbicide tolerant crops. This report, to be published in the next several months in the peer reviewed journal Weed Science, will serve as an informational tool for the public, farmers, federal agencies, companies and other interested entities involved in the assessment of impacts of herbicide resistant weeds on growers and the environment.

Our sister agency, EPA, who has the authority to regulate pesticides-- including herbicides-- has used this authority to mitigate the development of insect resistance to insecticides produced by genetically engineered crops. EPA

achieves this by regulating the amount of insecticide present in the environment and by imposing resistance management plans on plant incorporated protectants that make pesticidal claims. The regulation of the insecticide and use of refuges was based on scientific research on how insect resistance develops in targeted pests, and the best strategies available, in terms of deployment of insecticides, that will minimize the development of resistance in these insects.

USDA has supported scientific research into herbicide-resistant issues for many years, before the use of genetically-engineered, herbicide tolerant crops. USDA currently has committed resources in a variety of programs related to herbicide resistance and weedy invasive species, including $4.4 million dollars for Agricultural Research Service (in house) research, $4.6 million in competitive grants through the National Institute of Food and Agriculture (NIFA) and additional support through Land-Grant University funding. ARS programs include research for weed biology, and integrated management practices for herbicide resistant weeds. NIFA funds research in biology of invasive species in agroecosystems, supports extension outreach to growers, and a new web-based training system, $IPM^3$, with a module in herbicide resistance and management strategies. APHIS has partnered with the Weed Science Society of America and EPA to identify methods to manage the development of herbicide resistance to weeds, and identify what can be done to increase the use of integrated resistance management programs. A report to be published in a peer reviewed journal is anticipated in late 2011. Strong science and outreach is needed to support regulation as well as voluntary measures, and the USDA is committed to work with our partners to identify solutions, techniques and strategies that address the important issues of herbicide resistant weeds in a practical and cost effective way. A coordinated effort by all stakeholders is needed—the federal government, researchers, the agricultural community, technology and crop protection companies, public interest groups and others. APHIS scientists have been and will continue to attend scientific and stakeholder meetings on this issue.

With regard to petitions submitted to USDA for the approval of corn and soybeans that are engineered for resistance to 2, 4 D and dicamba; USDA is currently evaluating these requests and cannot speculate on future decisions that may occur on submitted petitions.

Comment: *One commenter disapproves of the writing style used to prepare the EA, citing that APHIS is represented as an onlooker, not a government agency with statutory authority to critically analyze, set conditions, make demands and disagree with the views of the registrant.*

APHIS Response. As described in the EA, the Coordinated Framework for the Regulation of Biotechnology indicates that three Federal agencies, APHIS, FDA and EPA, are responsible for regulating biotechnology in the US. 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 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). GE organisms and their products are regulated according to their intended use. Some 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.

APHIS has statutory authority to regulate genetically engineered (GE) organisms under the Plant Pest Authority contained in the Plant Protection Act of 2000. APHIS continues to fully utilize its statutory authority in making decision on data submitted in support of requests for permits and petitions. In additions, the conditions described in the 4 alternatives outlined in this EA demonstrate that APHIS has examined available options in exercising its statutory authority.