Appendix F. APHIS Threatened and Endangered Species Analysis and Decision Tree for U.S. Fish and Wildlife Service Consultations

Threatened and Endangered Species Analysis

Congress passed the Endangered Species Act (ESA) of 1973, as amended, to prevent extinctions facing many species of fish, wildlife, and plants. The purpose of the ESA is to conserve threatened and endangered species (TES) and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS); other Federal, State, and local agencies; tribes; non-governmental organizations; and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when the USFWS and NMFS determined it to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; or
- Natural or manmade factors affecting its survival.

In accordance with the ESA, once an animal or plant is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that a Federal agency, in consultation with the USFWS or NMFS, ensures that any action the agency authorizes, funds, or carries out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of the agency's action and to consult with the USFWS or NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, the agency met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection Act (PPA) of 2000 (title IV of Public Law 106-224). This process is described in a decision tree document presented at the end of this appendix. APHIS uses this process to help fulfill its obligations and responsibilities under section 7 of the ESA for biotechnology regulatory actions.

APHIS' regulatory authority over genetically engineered (GE) organisms under the PPA is limited to those GE organisms for which it has reason to believe might be a plant pest or those

for which APHIS does not have sufficient information to determine that the GE organism is unlikely to pose a plant pest risk (title 7, part 340.1 of the Code of Federal Regulations (CFR)). APHIS does not have authority to regulate the use of any herbicide, including glyphosate. After completing a plant pest risk analysis, if APHIS determines that H7-1 sugar beet does not pose a plant pest risk, then H7-1 sugar beet would no longer be subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 and, therefore, APHIS must grant it nonregulated status. As part of its Environmental Impact Statement (EIS) analysis, APHIS is analyzing the potential effects of H7-1 sugar beets on the environment, including any potential effects to TES and critical habitat. As part of this process, APHIS thoroughly reviews GE product information and data related to the organism (generally a plant species, but may also be other GE organisms). For each transgene(s)/transgenic plant, APHIS considers the following information, data, and questions:

- A review of the biology and taxonomy of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant, including disease and pest susceptibilities, weediness potential, and agronomic and environmental impacts;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species or a host of any threatened or endangered plant or animal species; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS has evaluated the potential effects that a determination of nonregulated status of H7-1 sugar beet plants for both seed and root production may have, if any, on federally listed TES, species proposed for listing, designated critical habitat, and habitat proposed for designation. Based upon the scope of the EIS and production areas identified in section III.B.1.c(1), APHIS reviewed the list of TES (listed and proposed) for each state where sugar beet are commercially produced in the USFWS Environmental Conservation Online System (ECOS`; as accessed 4/24/2012 at http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp\,). Prior to this review, APHIS considered the potential for H7-1 sugar beets to extend the range of sugar beet production and expand agricultural production into new natural areas. H7-1 sugar beets were extensively commercialized when they had nonregulated status from 2005 to 2010. Currently, they account for approximately 95 percent of the sugar beet production in the United States. Considering that H7-1 sugar beets account for such a high percentage of the total area planted with sugar beets, it is reasonable to expect that a second decision to grant nonregulated status

would result in H7-1 sugar beets being planted in areas similar to where they were planted prior to the 2010 court order vacating the previous decision to grant nonregulated status. The genetic transformation does not impart any phenotypic characteristic that would allow for the planting of H7-1 sugar beets in areas unsuitable to sugar beet varieties currently available. In addition, as described in detail in section III.D.1.b, even when granted nonregulated status, sugar beet production requires close coordination under contractual agreements between the grower and the processor. All sugar beets are shipped to a processor to efficiently extract the sugar from the beet. All sugar beet processors in the United States are now structured as cooperatives, with the exception of Wyoming Sugar Beet Company, LLC, who is also owned primarily by sugar beet producers. The cooperatives own the processing facilities, and the sugar beet farmers are members of the cooperatives. To contain shipping costs, sugar beet production is effectively limited to areas typically within 60 miles of a processing facility, although some fields may be located up to 100 miles away (Western Sugar Cooperative,2006). Because of the high costs associated with constructing a processing facility, and the required coordination with potential growers, expansion of production into new areas is not anticipated in the foreseeable future.

Potential Effects of H7-1 Sugar Beet Plants and Plant Products on TES

To identify any potential effects of H7-1 sugar beets on threatened and endangered plant species, APHIS evaluated the potential of H7-1 sugar beets to cross with a listed species. Sugar beets are in the genus *Beta* and have the ability to cross with several species of wild beets in the same genus, but are not known to cross with any other plant species without human assistance (OECD,2001). After reviewing the list of threatened and endangered plant species in the States where sugar beets are grown, APHIS determined that H7-1 sugar beets would not be sexually compatible with any listed threatened or endangered plant species or plants proposed for listing as none of these listed plants are in the same genus or known to cross pollinate with species of the genus *Beta* (see appendix E).

To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks to threatened and endangered animals from consuming H7-1 sugar beets. As discussed in section III.F.1.a(4), there is no difference in the composition and nutritional quality of H7-1 sugar beets compared with conventional sugar beets. APHIS also examined the allergenicity and toxicity of H7-1 sugar beets' CP4 EPSPS protein and, based on the research summarized and referenced in section III.F.1.a(5), concluded that no differences exist compared to conventional sugar beets' EPSPS protein. Both types of proteins are ubiquitous in nature and normally present in food and feeds derived from these plant and microbial sources. In addition, when used to impart tolerance to glyphosate in corn, cotton, and soybean plants, the CP4 EPSPS protein has not resulted in any adverse human health effects despite being grown on hundreds of millions of acres across the United States over the past decade. Finally, the research cited and summarized in section III.F.1.a(5) also finds no difference in allergenicity between conventional and H7-1 sugar beet pollen. Therefore, based on these analyses, APHIS concluded that consumption of H7-1 sugar beet plant parts (seeds, leaves, stems, pollen, or roots) would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

APHIS considered the possibility that H7-1 sugar beets could serve as a host plant for TES. A review of the species list revealed that there are no members of the genus *Beta* that serve as a host plant for any TES.

As part of the analysis for TES and critical habitat, APHIS considered if the new phenotype imparted to H7-1 sugar beets may allow the plant to naturalize in the environment and potentially have an effect on TES. In doing so, APHIS assessed whether H7-1 sugar beets are any more likely to become a weed than the non-transgenic recipient sugar beet line or other currently cultivated sugar beets. Weediness could potentially affect TES or critical habitat if H7-1 sugar beets were to become naturalized in the environment. The assessment considers the basic biology of sugar beets and an evaluation of unique characteristics of H7-1 sugar beets. As discussed in section III.C.3.c, no *Beta* species are listed as weeds on any of the 12 weed lists from the USDA PLANTS database (USDA-NRCS,2010). Sugar beets possess few of the characteristics of plants that are notable as successful weeds. APHIS considered data on plant vigor, bolting, seedling emergence, seed germination, seed dormancy, and other characteristics that might relate to increased weediness (USDA-APHIS,2012) During field trials, no differences were observed between H7-1 lines and non-transgenic lines with respect to the plants' ability to persist or to compete as a weed (Monsanto and KWS SAAT AG,2004) No unusual characteristics were noted that would suggest increased weediness of H7-1 plants. In addition, no characteristics relating to disease or insect resistance that might affect weediness were noted that were consistent over all trial locations. H7-1 sugar beets are still susceptible to the typical insect and disease pests of sugar beets. Collectively, this information indicates that H7-1 sugar beets are unlikely to naturalize and persist in the environment.

After reviewing potential effects on the environment that could result from a determination of nonregulated status of H7-1 sugar beets, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed site-specific (or spatially explicit) exposure analysis for individually listed TES is not necessary for APHIS to reach a determination of nonregulated status for H7-1 sugar beets. APHIS considered the effect of H7-1 sugar beet production on designated critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other sugar beet varieties. Sugar beets are not considered a particularly competitive plant species, are ecologically limited due to susceptibility to plant pathogens and herbivores, and are not typically described as weeds outside of agricultural fields (Bartsch et al.,2001). Sugar beets are not considered weedy, and feral populations of sugar beets have not been identified in the United States. H7-1 sugar beets are not sexually compatible with, nor do they serve as a host species for, any listed species or species proposed for listing. Consumption of H7-1 sugar beets by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has determined that H7-1 sugar beets would have no effect on listed threatened or endangered plant or animal species or such species proposed for listing and would not affect listed threatened or endangered plant or animal species' designated critical habitat or habitat proposed for designation. Because of this no effect determination, consultation under section 7(a)(2) of the ESA or the concurrence of the USFWS or NMFS is not required.

Potential Impacts of Glyphosate Use on TES

As part of the EIS process, APHIS met with USFWS officials on June 15, 2011 to discuss whether APHIS has any obligations under the ESA to analyze the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, the USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated either with H7-1 sugar beets or other currently planted GE crops. APHIS has no statutory authority to authorize or regulate the use of glyphosate, or any other herbicide, by sugar beet growers. Under 7 CFR 340, APHIS only has the authority to regulate H7-1 sugar beets or any GE organism if the agency believes it may pose a plant pest risk. APHIS has no regulatory jurisdiction over any other risks associated with GE organisms, including risks resulting from the use of herbicides or other pesticides on those organisms. Nevertheless, APHIS is aware that there may be potential environmental impacts resulting from the use of glyphosate on H7-1 sugar beets, including potential impacts on TES and critical habitat, based on assessments provided by the EPA and in peer reviewed scientific literature. APHIS is providing the available information of potential environmental impacts resulting from glyphosate use on H7-1 sugar beet below. APHIS has provided the draft EIS to the NMFS for their review and comment. After review, the NMFS has not provided comments on the EIS.

It is important to note that the use of herbicides in the production of sugar beets is not unique to the production of H7-1 sugar beets and that H7-1 sugar beets are not dependent on the use of glyphosate for their production lifecycle. Non-glyphosate herbicides are typically used to control weeds during production of conventional sugar beet varieties, and these herbicides could presumably be used in production of H7-1 sugar beet. An analysis of herbicide use in H7-1 and conventional sugar beets and the risks associated with them is thoroughly described in section IV. In summary, because of their toxicity, many of the herbicides historically used in conventional sugar beet production potentially pose greater impacts to non-target organisms than the use of glyphosate and would also potentially pose greater impacts to TES.

Conservation tillage and no-till practices have a positive impact on wildlife (Towery and Werblow,2010). Benefits include decreased soil erosion and improved water quality in receiving waters, retention of cover, availability of waste grain on the soil surface for feed, and increased populations of invertebrates as a food source (Sharpe,2010). As described in section III.B.1.c(2), the use of glyphosate in a H7-1 sugar beet production system facilitates the use of conservation tillage practices, whereas conservation tillage is far more difficult in conventional sugar beet production. Therefore, if H7-1 sugar beets are replacing fields of conventional varieties that are not currently utilizing conservation tillage practices and where TES species are present, the production of H7-1 sugar beets could improve baseline conditions and have a beneficial impact on TES. However, any beneficial impact may have already been realized following the 2005 granting of nonregulated status of H7-1 sugar beets and their rapid adoption. In addition, it would be difficult to assess those impacts retrospectively.

EPA Endangered Species Protection Program (ESPP)

On October 7, 1988, Congress enacted Public Law 100-478 to in part address the relationship between ESA and the Environmental Protection Agency's (EPA) pesticide labeling program (section 1010) by requiring EPA to conduct a study, and report to Congress, on ways to implement its endangered species pesticide labeling program in a manner that both complies

with ESA and allows people to continue production of agricultural food and fiber. This law provided a clear sense that Congress wanted EPA to fulfill its obligation to conserve listed species, while at the same time consider the needs of agriculture and other pesticide users (70 FR 211 2005-11-02).

In 1988, EPA established the ESPP to meet its obligations under the ESA. The EPA's ESPP Web site[1] describes its assessment process for endangered species. Some of the elements of that process are summarized below. The goal of EPA's ESPP is to carry out its responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in compliance with the ESA without placing unnecessary burden on agriculture and other pesticide users consistent with Congress' intent. EPA is responsible for reviewing pesticide information and data to determine whether a pesticide product may be registered for a particular use, including those uses associated with the approval of biotechnology products. As part of that determination, the Agency assesses whether listed TES or their designated critical habitat may be affected by use of the pesticide product. All pesticide products that EPA determines "may affect" a listed species or its designated critical habitat may be subject to the ESPP. If limitations on pesticide use are necessary to protect listed species in areas where a pesticide may be used, the information is related through Endangered Species Protection Bulletins. Bulletins identify the species of concern and the pesticide active ingredient that may affect the listed species. They also provide a description of the measures necessary to protect the species, and contain a county-level map showing the geographic area(s) associated with the protection measures, depending on the susceptibility of the species. Bulletins are enforceable as part of the product label (http://www.epa.gov/oppfead1/endanger/basic-info.htm).

EPA's TES Evaluation Process

EPA evaluates the potential for effects of pesticides to listed species and their critical habitat concerns in connection with its actions under FIFRA.

EPA's review of the pesticide under FIFRA is independent of APHIS' review and regulatory decisions under 7 CFR 340. EPA does not require data or analyses conducted by APHIS to complete its reviews. EPA evaluates extensive toxicity, ecological effects data, environmental fate, and transport and behavior data, most of which are mandated under FIFRA data requirements, to assess and determine how a pesticide will move through and break down in the environment. Risks to various taxa (e.g., birds, fish, invertebrates, plants and mammals) are routinely assessed and used in EPA's determinations of whether a pesticide may be licensed for use in the United States.

EPA's core pesticide risk assessment and regulatory processes address non-target species, not just TES. EPA has developed a comprehensive risk assessment process modeled after, and consistent with, its numerous guidelines for environmental assessments (http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf). The result of an assessment, which may go through several refinements, is to determine whether the potential effects of a pesticide's registration to a listed species will result in either a "no effect" or "may affect" determination. EPA consults with the USFWS and/or NMFS on determinations that

[1] http://www.epa.gov/espp/

"may affect" a listed species or adversely modify its critical habitat (http://www.epa.gov/oppfead1/endanger). As a result of either an assessment or consultation, EPA may seek to require changes to the use conditions specified on the label of the product. When such changes are necessary only in specific geographic areas rather than nationwide to ensure protection of the listed species, EPA implements these changes through geographically specific Endangered Species Protection Bulletins. Otherwise, these changes are applied to the label for all uses of the pesticide.

Ecological Risks of Glyphosate

The ecological risks associated with use of glyphosate as an herbicide have been assessed several times since 1974 when it was first registered for use in the United States. In addition, EPA has consulted with the USFWS on the effects of glyphosate on listed species and critical habitat. Findings from relevant ecological risk assessments and the results and status of consultations are summarized below.

- In the June 1986 Registration Standard for glyphosate, EPA discussed consultations with the USFWS on hazards to crops, rangeland, silvicultural sites, and the Houston toad that may result from the use of glyphosate. Because a jeopardy opinion resulted from these consultations, the agency imposed endangered species labeling requirements in the Registration Standard to mitigate the risk to endangered species.

- In 1993, glyphosate was assessed by EPA for the Reregistration Eligibility Decision (RED) (U.S. EPA 1993) The RED concluded that direct risks to birds, mammals, invertebrates, and fish would be minimal. Under certain conditions, aquatic plants were expected to be at risk from glyphosate use. Additional data, including incident data and vegetative vigor testing, were needed on non-target terrestrial plants. The assessment stated that many endangered plants may be at risk from use of glyphosate with the registered use patterns. In addition, it was determined that the Houston toad may be at risk from use of glyphosate on alfalfa. The RED resulted in label changes to provide protection of aquatic organisms.

- In 2003, USDA's Forest Service had a risk assessment conducted for glyphosate uses in its vegetation management programs (USDA-FS,2003). For forestry uses, all commercial formulations of glyphosate contained the isopropylamine salt of glyphosate. Application rates ranged from 0.5 pounds acid equivalent per acre (lbs. ae/acre) to 7 lbs. ae/acre with the most typical at 2 lbs. ae/acre. Based on the available data, USDA concluded that the risks were minimal to mammals, birds, fish, amphibians, invertebrates, and aquatic plants. Risks to fish following application of the more toxic formulations were not considered to be high; however, the assessment did state that at an application rate of 7 lbs. ae/acre, the acute exposures slightly exceeded the acute median lethal concentration for a more tolerant freshwater fish and exceeded it by a factor of 2 for the less tolerant fish. These values were estimated from a worst-case scenario where there was a severe rainfall of about 7 inches over a 24-hour period in an area where runoff is favored. USDA did not conduct a separate assessment for amphibians. The document concluded that the amphibian data indicated that glyphosate is no more toxic to

amphibians than it is to fish. For terrestrial plants, the assessment concluded that for relatively tolerant plants, when a low-boom spray is utilized as the method of application, there is no indication that glyphosate would result in damage from spray drift at distances from the application site of 25 feet or greater. For more sensitive plants, the distance increased to approximately 100 feet. For applications requiring the use of backpack-directed spray, the distances would be less. No risks to terrestrial plants from runoff were expected.

- In 2004, EPA issued a report entitled Glyphosate Analysis of Risks to Endangered and Threatened Salmon and Steelhead. The analysis within the report included 11 evolutionary significant units (ESU)—a population that is considered distinct for purposes of conservation—in California, with one unit extending into southern Oregon. Much of the quantitative information presented and used was derived from the 1993 RED Ecological Risk Assessment. Testing was performed with formulated products, in addition to glyphosate alone, and included acute and chronic toxicity. Testing of the pure product indicated that pure glyphosate is practically non-toxic to the species examined. Glyphosate was moderately toxic to practically non-toxic in formulated products. Since this is somewhat increased over results with the pure chemical, the report concluded that it appears likely due to the added agents, generally surfactants. EPA uses a variety of chemical fate and transport data to develop "estimated environmental concentrations" (EECs) from a suite of established models. The EECs were used with toxicity for the most sensitive species from technical grade testing of the active ingredient to develop acute risk quotients (RQ). The RQ analysis indicated that glyphosate applied at 5.062 lbs. active ingredient per acre (ai/acre) does not present an acute risk to endangered and threatened salmonids from direct effects because the calculated RQ is less than the level of concern (LOC). The primary indirect effect of concern would be for the food source for listed fish. The report concluded that this rate of application does not present indirect effects from loss of food or loss of cover, as the RQ for invertebrates and plants is less than the LOC. However, the assessment determined that use of glyphosate "may affect, but is not likely to adversely affect" the species based on acute toxicity to fish for uses with application rates above 5 lbs. ai/acre. For uses with application rates below 5 lbs. ai/acre, the agency determined glyphosate would have no effect on the 11 ESU.

- In 2006, the EPA assessed glyphosate for a new use on bentgrass (U.S. EPA 2006d; U.S. EPA 2006a); and for new uses on Indian mulberry (noni), dry peas, lentils, garbanzo (U.S. EPA 2006b); as well as safflower and sunflower (U.S. EPA 2006c), with the highest proposed ground application rate of 3.73 lbs. ae/acre. For all proposed new uses, the EPA concluded that there was minimal risk of direct acute effects to terrestrial animals (birds and mammals) and aquatic animals (fish, amphibians, and invertebrates) and minimal risk to terrestrial plants (both non-target and endangered plant species), aquatic non-vascular (algae and diatoms), and vascular (duckweed) plants from off-target spray drift and runoff from ground-based applications. In addition, there were no chronic risks to animals.

- In 2008, as a part of EPA's TES effects assessment for the California red-legged frog, EPA evaluated the effect of glyphosate use at rates up to 7.95 lbs. ae/acre on fish,

amphibians, aquatic invertebrates, aquatic plants, birds, mammals, and terrestrial invertebrates (U.S. EPA 2008). This assessment determined that at the maximum application rate for in-crop applications of glyphosate to glyphosate-tolerant sugar beets (1.125 lbs. ae/acre), there would be no effects of glyphosate use on fish, amphibians, birds, and mammals. The EPA assessment was uncertain of the effects on terrestrial invertebrates, citing the potential to affect small insects at all application rates and large insects at the 7.95 lbs. ae/acre rate, which is above the maximum rate for glyphosate tolerant sugar beets.

- In 2010, EPA issued a memorandum entitled Assessment of Ecological Risk for Glyphosate, potassium salt (PC Code 103613; CAS# 70901-12-1) for Label Supplement to Add Uses on Roundup Ready Sweet Corn. Because of the potential risk from surfactants, a conservative estimation of risk to aquatic organisms was conducted on a formulation basis and a glyphosate acid equivalent basis. The names and Chemical Abstracts Service (CAS) numbers of the surfactant are proprietary and are not provided in the assessment. Instead, the surfactant polyoxyethylene alkylamine mixture (POEA, CAS # 61791-26-2) was used because it has been used in glyphosate products and is known to be considerably more toxic to aquatic organisms than technical glyphosate. The assessment was completed with the assumption that the proposed surfactants are similar to POEA. Based on the proposed labels, the maximum application rate on a glyphosate acid equivalent basis is 3.71 lbs. ae/acre glyphosate and on a formulation basis is 9.35 lbs. formulation per acre.

  The risk to fish, aquatic phase amphibians, aquatic invertebrates, aquatic plants, birds, reptiles, terrestrial phase amphibians, mammals, terrestrial invertebrates, and terrestrial plants was analyzed. The assessment concluded that there was no risk to fish, aquatic phase amphibians, aquatic invertebrates, aquatic plants, and mammals because the RQ did not exceed the LOC for any of these groups. Because of the lack of toxicity studies for reptiles and terrestrial phase amphibians, birds are used as a surrogate. None of the available acute and subacute avian studies showed mortality, so RQ were not calculated for birds. All of the terrestrial EEC values are lower than the highest dose/concentration tested (3.71 lbs. ae/acre glyphosate), but many of the EECs for 20 gram birds were greater than one-tenth of that dose. For 100 gram birds, several EECs were greater than one-tenth of the highest dose with the 1.15 lbs. ae/acre dose applied 4 times per season. Therefore, there is uncertainty associated with the effect to listed birds, reptiles, and terrestrial phase amphibians. The chronic LOC for birds (LOC = 1) was exceeded for application to short grasses at the highest dose (3.71 lbs. ae/acre glyphosate and RQ = 1.07). However, because there were no effects at the highest concentrations in the bird studies and the RQ was only slightly greater than the LOC, the risk following chronic exposure is expected to be minimal. The assessment concluded that the risk to terrestrial invertebrates is negligible based on glyphosate's classification as practically non-toxic to honeybees. Lastly, for listed terrestrial plants, the RQ is lower than the LOC at the highest application rate when applied via ground applications, but are exceeded for listed and non-listed monocots and dicots when aerially applied at the 3.71 lbs. ae/acre glyphosate rate.

EPA's pesticide registration process considers the potential for risk to non-target organisms, and label use restrictions are required when necessary to avoid unreasonable adverse effects to the environment. Through registration review, EPA is reviewing each registered pesticide every 15 years to determine whether it still meets the FIFRA standard for registration. In this way, EPA is ensuring that all registered pesticides do not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. EPA intends to meet its responsibility under the ESA in the registration review program. Glyphosate is scheduled to complete registration review in 2015, at which time EPA will complete its national endangered species assessment of all registered uses of the herbicide.

Potential Impacts of Glyphosate Use in the Production of Sugar Beets

In 2009, Stachler et al. (Stachler et al.,2009a; Stachler et al.,2009b)surveyed sugar beet growers in Minnesota, North Dakota, and Montana regarding weed control and production practices. The results showed that glyphosate is nearly always broadcast-applied to glyphosate tolerant sugar beets with a ground sprayer and aerial spraying is only used for 3 percent of applications. In Minnesota and eastern North Dakota, the most common herbicide treatment was glyphosate applied at 0.75 lb. ae/acre (Stachler et al.,2009b). The average total seasonal rate of glyphosate applied to glyphosate tolerant sugar beets was 1.85 lbs. ae/acre in 2009, compared to 1.95 lbs. ae/acre in 2008 in the same region (Stachler et al.,2009b). Similarly, in 2009, in western North Dakota and eastern Montana, the most common herbicide treatment was glyphosate applied at 1.0 lb. ae/acre (Stachler et al.,2009a). The average total seasonal rate of glyphosate application was 2.4 lbs. ae/acre (Stachler et al.,2009a).

In general, States have primary authority for compliance monitoring and enforcing the use of pesticides by the label requirements. Violators of the regulations are liable for all negative consequences of their actions (7 U.S. Code 136j (a)(2)(G)). Therefore, growers that use glyphosate are very likely to follow its label restrictions. To facilitate pesticide applicators adherence to EPA label use restrictions for glyphosate when applied to glyphosate tolerant crops, Monsanto designed a Web-based program (Pre-Serve[2]). The purpose of Pre-Serve is to "protect threatened and endangered plant species from potential impacts resulting from the agricultural use of herbicides that contain glyphosate." Pre-Serve instructs growers to observe specific precautions, including buffer zones, when spraying glyphosate herbicides on glyphosate-tolerant crops near threatened and endangered plant species that may be at risk. In addition, label requirements for Monsanto's Roundup® formulations and glyphosate formulations marketed by other manufacturers prohibit application in conditions or locations where adverse impact on federally designated threatened or endangered plants or aquatic species is likely.

In summary, glyphosate use in the production of sugar beet is nearly always broadcast-applied with a ground sprayer, the typical application rate on H7-1 sugar beets is below the maximum allowed by the label, the RQ for all effects is below the LOC for the maximum allowable rate, Monsanto instructs growers to observe specific precautions with the Pre-Serve program, and the pesticide label requires precautions to protect TES. Additionally, it is APHIS' understanding that EPA will be evaluating the effect of glyphosate application on H7-1 sugar beets and consult with the USFWS and/or NMFS if necessary. Accordingly, the available information suggests

[2] http://www.pre-serve.org/

that the glyphosate use resulting from granting nonregulated status to H7-1 sugar beets does not present an increase in potential impacts to TES.

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APHIS Threatened and Endangered Species Decision Tree for U.S. Fish and Wildlife Service Consultations

Decision Tree on Whether Section 7 Consultation with the U.S. Fish and Wildlife Service (USFWS) is Triggered for Petitions of Transgenic Plants

This decision tree document is based on the phenotypes (traits) that have been permitted for environmental releases under Animal and Plant Health Inspection Service (APHIS) oversight (for a list of approved notifications and environmental releases, visit Information Systems for Biotechnology). APHIS will re-evaluate and update this decision document as it receives new applications for environmental releases of new traits that are genetically engineered into plants.

BACKGROUND

For each transgene(s)/transgenic plant, the following information, data, and questions are addressed by APHIS, and the environmental analysis (e.g., environmental assessment [EA] or environmental impact statement [EIS]) for each petition will be publicly available. The APHIS review encompasses:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant); and
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species or a host of any threatened or endangered plant species.

The U.S. Food and Drug Administration (FDA) published a policy in 1992 on foods derived from new plant varieties, including those derived from transgenic plants (see http://www.fda.gov/food/biotechnology/default.htm). Under this policy, FDA considers its existing statutory authorities to be “fully adequate to ensure the safety of new ingredients and foods derived from new varieties of plants, regardless of the process by which such foods and ingredients are produced (U.S. FDA, 1992). Thus, genetically engineered foods must meet the same rigorous safety standards as are required of all other foods. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already consumed by humans and so may be less likely to require pre-market approval. FDA expects developers to consult with the agency on safety and regulatory

questions. A list of consultations is available at http://www.fda.gov/Food/Biotechnology/Submissions/default.htm. APHIS considers the status and conclusion of the FDA consultations in its EAs and EISs.

Below is the description of the APHIS review process to determine if consultation with USFWS is necessary. If the answer to any of the questions below is "yes," APHIS contacts USFWS to determine if consultation is required.

1. Is the transgenic plant sexually compatible with a threatened or endangered plant[3] without human intervention?
2. Are naturally occurring plant toxins (toxicants) or allelochemicals increased over the normal concentration range in parental plant species?
3. Does the transgene product or its metabolites have any significant similarities to known toxins[4])?
4. Will the new phenotype(s) imparted to the transgenic plant allow the plant to be grown or employed in new habitats (e.g., outside the agro-ecosystem)[5]?
5. Does the pest resistance[6] gene act by one of the mechanisms listed below? If the answer is "yes," then consultation with USFWS is NOT necessary.

A. The transgene acts only in one or more of the following ways:

i. As a structural barrier to either the attachment of the pest to the host, to penetration of the host by the pest, to the spread of the pest in the host plant (e.g., the production of lignin, callose, thickened cuticles);
ii. In the plant by inactivating or resisting toxins or other disease causing substances produced by the pest;
iii. By creating a deficiency in the host of a component required for growth of the pest (such as with fungi and bacteria);
iv. By initiating, enhancing, or potentiating the endogenous host hypersensitive disease resistance response found in the plant; or
v. In an indirect manner that does not result in killing or interfering with normal growth, development, or behavior of the pest;

B. A pest derived transgene is expressed in the plant to confer resistance to that pest (such as with coat protein, replicase, and pathogen virulence genes).

For the biotechnologist:

[3] APHIS will provide USFWS a draft EA that addresses the impacts, if any, of gene movement to the threatened or endangered plant.
[4] Via a comparison of the amino acid sequence of the transgene's protein with those found in the protein databases like PIR, Swiss-Port, and HIV amino acid databases.
[5] Such phenotypes might include tolerance to environmental stress such as drought, salt, frost, and aluminum or heavy metals.
[6] Pest resistance would include any toxin or allelochemical that prevents, destroys, repels, or mitigates a pest or affects any vertebrate or invertebrate animal, plant, or micro-organism.

Depending on the outcome of the decision tree, initial the appropriate decision below and incorporate its language into the EA or EIS. Retain a hard copy of this decision document in the petition's file.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS has reached a determination that the release following a determination of nonregulated status would have no effects on listed threatened or endangered species and consequently, a written concurrence or formal consultation with the U.S. Fish and Wildlife Service is not required for this EA or EIS.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of nonregulated status is not likely to adversely affect any listed threatened or endangered species and consequently obtained written concurrence from the U.S. Fish and Wildlife Service.

_____ BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation, as required under Section 7 of the Endangered Species Act, is needed. APHIS reached a determination that the release following a determination of nonregulated status is likely to adversely affect one or more listed threatened or endangered species and has initiated formal consultation with the U.S. Fish and Wildlife Service.