

# Record of Decision

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## Glyphosate – Tolerant Event H7-1 Sugar Beet: Petition for Nonregulated Status

### Overview and APHIS Decision

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) completed and published a Final Environmental Impact Statement (FEIS) in response to a petition for a determination of nonregulated status of glyphosate-tolerant event H7-1 sugar beet (*Beta vulgaris*). APHIS prepared this FEIS to examine the potential environmental impacts of H7-1 sugar beet and potential interrelated socioeconomic impacts associated with a determination of nonregulated status of H7-1 sugar beet. APHIS examined three alternatives in the FEIS: Alternative 1, No Action Alternative; Alternative 2, Full Deregulation of H7-1 Sugar Beet; and Alternative 3, Permanently Adopt the Interim Partial Deregulation of H7-1 Sugar Beet for Root Crop and Continue Permitting of Seed Crop.

In this Record of Decision (ROD), APHIS is announcing the agency's environmental decision on the petition in light of the environmental analyses in the FEIS. In accordance with its statutory authority and following the publication of its FEIS, APHIS is choosing Alternative 2, which is the Preferred Alternative and Environmentally Preferred Alternative. APHIS' regulatory determination of nonregulated status of H7-1 sugar beet will become effective upon publication in the Federal Register of a document entitled "Determination of Nonregulated Status of Monsanto/KWS SAAT AG glyphosate-tolerant event H7-1 sugar beet."

### Background

#### *Coordinated Framework*

APHIS is one of the Federal agencies with regulatory responsibilities under the 1986 Federal Coordinated Framework for the Regulation of Biotechnology (hereafter Coordinated Framework) published by the Office of Science and Technology Policy (OSTP), Executive Office of the President. The Coordinated Framework is a policy statement which "describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products." The Coordinated Framework explains the proper allocation and coordination of oversight responsibilities under the relevant statutes and among the relevant federal agencies.

The Coordinated Framework thus addresses who shall have oversight authority in each instance, but does not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion. To that end, OSTP published a notice of Federal policy in the Federal Register in 1992 in which it set forth "the proper basis for agencies' exercise of oversight authority within the scope of discretion afforded by statute."

The notice describes:

"a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion

afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique.”

The policy statement of 1992 states further:

“In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives.”

### ***APHIS Regulation of Biotechnology***

In 1987, APHIS promulgated its biotechnology regulations (7 CFR part 340) under the authority of the Federal Plant Pest Act (FPPA) and the Plant Quarantine Act (PQA)<sup>1</sup> to address potential risks that certain genetically engineered (GE) organisms might pose as plant pests. The regulations refer to such GE organisms as “regulated articles<sup>2</sup>.”

The APHIS regulations codified at 7 CFR part 340 were amended in 1993 to provide a procedure for the release from regulation (i.e., a petition for nonregulated status) of such plants which do not present a plant pest risk and therefore should no longer be regulated. 7 CFR 340.6 describes the petition for nonregulated status process, the data requirements, and actions that the Administrator may take on the petition. It is under this procedure that, on November 19, 2003,

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<sup>1</sup> The FPPA and PQA were consolidated along with other statutory authorities into the Plant Protection Act of 2000, in which Congress found that: “it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests . . . in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests . . . ; decisions affecting imports, exports, and interstate movement of products regulated under this title shall be based on sound science . . . .”

The Plant Protection Act of 2000 defines a plant pest as:

PLANT PEST.—The term “plant pest” means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

- (A) A protozoan.
- (B) A nonhuman animal.
- (C) A parasitic plant.
- (D) A bacterium.
- (E) A fungus.
- (F) A virus or viroid.
- (G) An infectious agent or other pathogen.
- (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

7 U.S.C. §7702(14).

<sup>2</sup> A “regulated article” is defined as: “Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.” (7 CFR 340.0).

APHIS received a petition request from the Monsanto Company of St. Louis, Missouri and KWS SAAT AG of Einbeck, Germany (hereinafter referred to as Monsanto/KWS SAAT AG) seeking a determination of nonregulated status of H7-1 sugar beet.

APHIS prepared a Plant Pest Risk Assessment (PPRA) and an Environmental Assessment (EA) to assess the plant pest risk and environmental risk, respectively, posed by the use of H7-1 sugar beet if it were to have nonregulated status. A notice published in the Federal Register on March 17, 2005<sup>3</sup>, advised the public of the agency's determination decision that H7-1 sugar beet posed no plant pest risk and would no longer be considered a regulated article under APHIS regulations codified at 7 CFR part 340.

On January 23, 2008, the Center for Food Safety and a group of organic growers and several other associations filed a lawsuit in the Northern District of California that challenged the USDA determination of nonregulated status of H7-1 sugar beet<sup>4</sup>. This is the first H7-1 sugar beet lawsuit and is referred to in this document as *Sugar Beet I*.

On September 21, 2009, the U.S. District Court for the Northern District of California ruled that the APHIS EA for H7-1 sugar beet failed to consider certain environmental and interrelated economic impacts, as required by the National Environmental Policy Act (NEPA). With respect to these NEPA violations, the Court found that the EA failed to adequately analyze the impacts of the possibility of gene transmission from H7-1 sugar beet to organic and conventional sugar beet and related Swiss chard and table beets. The court ordered APHIS to prepare an Environmental Impact Statement (EIS) before making a new determination for nonregulated status of H7-1 sugar beet. Thereafter, on May 28, 2010, APHIS published in the Federal Register a Notice of Intent to prepare the EIS. On August 13, 2010, the court vacated APHIS' decision that H7-1 sugar beet varieties should have nonregulated status, i.e., be removed from APHIS's regulatory oversight, making them subject to the Plant Protection Act of 2000 and 7 CFR part 340 once again. Consistent with the court order, H7-1 sugar beet planted *before* August 13, 2010, was *not* treated as a regulated article and was not subject to the Plant Protection Act of 2000 or 7 CFR part 340 for the duration of those plantings. Thus, H7-1 sugar beet planted for root production before August 13, 2010, was allowed to remain in the ground, be harvested, transported, processed, and sold as sugar. Based on the court order, H7-1 sugar beet planted for seed production, whether planted from stecklings or direct seeded, before August 13, 2010, was allowed to be grown until harvested, transported, and stored with no restriction under 7 CFR part 340<sup>5</sup>.

On February 4, 2011, APHIS announced a new interim decision to partially deregulate H7-1 sugar beet after preparing an EA. The interim regulatory decision was made in response to a petition for partial deregulation of the H7-1 sugar beets submitted on July 29, 2010 by Monsanto/KWS SAAT AG. APHIS did not implement the partial deregulation as proposed by the petitioner but rather decided to only partially deregulate H7-1 sugar beet root crop activities

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<sup>3</sup> 70 FR 13007-13008, Docket No. 04-075-2

<sup>4</sup> *Center for Food Safety, et al. v. Vilsack, et. al., No3: 08-cv-00484*

<sup>5</sup> In the interim between the Courts August 2010 vacatur and this ROD, APHIS took action on two interim requests, and it resulted in three lawsuits challenging APHIS interim actions. These lawsuits, *Sugar Beet II (Center for Food Safety, et al. v. Vilsack et al. No.: 4:10-cv-04038)*, *Sugar Beet III (Grant, et al. v. Vilsack, et. al. No.11-cv-308)*, and *Sugar Beet IV (Center for Food Safety, et al. v. Vilsack, et. al. Nos. 11-cv—831; 11-cv-586; 11-cv-308)* are discussed in additional detail in the EIS.

subject to mandatory conditions contained in APHIS-issued compliance agreements. APHIS further announced that H7-1 sugar beet seed crop activities would not be deregulated during the interim period and that seed crop planting would only be allowed under regulatory permits with mandatory conditions issued pursuant to the agency's 7 CFR part 340 regulations. This interim decision was scheduled to expire on the issuance of a final determination decision on the petition for nonregulated status of H7-1 sugar beet (have full deregulation) or on December 31, 2012, whichever occurred first.

On October 11, 2011, APHIS released the draft EIS (DEIS) for its new determination on a petition for nonregulated status of H7-1 sugar beet for public comment. The DEIS was available for an extended 61 day comment period which closed on December 13, 2011. APHIS received 1,293 submissions that supported the use of H7-1 sugar beet and 94 submissions that did not support their use. APHIS also received 9,186 letters that were nearly identical in content and a petition from an organization with 14,592 signatures and associated comments opposed to the use of H7-1 sugar beet. APHIS received 68 submissions from commenters that attached 578 supporting documents. In addition, APHIS conducted three public meetings, at which a total of 63 people provided comments.

On June 8, 2012, EPA published a notice announcing the availability of the final EIS (FEIS) to the public. Prior to publication of this notice in the FR, APHIS distributed the FEIS and posted it on its website<sup>6</sup>.

### **Purpose and Need for Agency Action**

In the FEIS, APHIS identified a purpose and need to respond to the petition for a determination of nonregulated status in accordance with its authority under its current regulatory scheme. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as H7-1 sugar beet, and must make a determination on whether the GE organism is likely to pose a plant pest risk. If APHIS determines, based on its PPRA, that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the Plant Protection Act of 2000 and 7 CFR part 340. In summary, the agency's purpose and need is to make a decision on the petition that is consistent with the regulatory requirements in 7 CFR part 340.

### **Public Comment on the FEIS**

On June 8, 2012, APHIS published the FEIS for its determination on a petition for nonregulated status of H7-1 sugar beet. During the 30-day "wait period" required under NEPA, 40 C.F.R. § 1506.10(b)(2), APHIS accepted comments from the public on the FEIS. This 30-day period closed on July 9, 2012. APHIS received 13 total submissions. All 13 submissions did not support the deregulation of H7-1 sugar beet. Included in this total are five submissions from three organizations containing eight total supporting documents. The majority of these submissions did not raise any new, substantive issues with regard to the FEIS. These 13 submissions expressed general concerns relating to sugar beet cultivation, pesticide use, GE plants, or H7-1 sugar beet. Additionally, one commenter expressed specific concerns regarding herbicide-resistant weeds and gene flow from H7-1 sugar beet. However, with one exception

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<sup>6</sup> The FEIS can be viewed at [http://www.aphis.usda.gov/brs/aphisdocs/03\\_32301p\\_feis.pdf](http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_feis.pdf)

presented below, the concerns and issues described in these submissions, including references, were analyzed in the text and appendices of the FEIS.

APHIS received one comment, in the context of the effects on gene flow, that discussed the possibility of H7-1 sugar beet increasing sugar beet acreage if it were to be used in the synthesis of direct ethanol production. APHIS acknowledges this comment; however, this statement regarding a substantial increase in H7-1 sugar beet acreage and its use as a biofuel crop is speculative because sugar beet ethanol is not listed as an advanced biofuel by the EPA<sup>7</sup>, there are no dedicated sugar beet ethanol production plants that are operational today, and current work is limited to exploring the option of using sugar beets in ethanol production plants. Additionally, APHIS reviewed sugar beet acreage trends, which showed no clear indication that sugar beet acreage will substantially increase in the foreseeable future (Figure 5-1 of the FEIS).

### **Plant Pest Risk Assessment**

The PPRA characterizes the potential plant pest risks associated with the GE product (crop) that is the subject of the petition relative to its conventional varieties. It is based on information supplied in the petition for determination of nonregulated status together with other relevant publically available scientific data. The regulations codified at 7CFR 340.6 (c) list the information to be submitted by the petitioner for APHIS' consideration of a petition for nonregulated status.

APHIS concluded from its PPRA that H7-1 sugar beet is not likely to pose a plant pest risk. In fact, APHIS found no evidence of H7-1 sugar beet posing any plant pest risks based on the following:

- (1) H7-1 sugar beet does not exhibit plant pathogenic properties – although a plant pathogen was used in the development of H7-1 sugar beet, H7-1 sugar beets are not infected by this organism nor do they contain genetic material from pathogens used as a donor organism that can cause plant disease.
- (2) H7-1 sugar beet does not exhibit differences in susceptibility to diseases or pests compared to conventional sugar beet. Activity of the EPSPS<sup>8</sup> protein in H7-1 sugar beet did not indicate that it would cause plant disease or influence susceptibility of H7-1 sugar beet or its progeny to diseases or other pests. Therefore, pest and disease control methods are expected to be similar between it and conventional sugar beet.
- (3) Field observations, compositional data, and data on the safety of the EPSPS protein indicates that H7-1 sugar beet would not have a greater potential compared to other cultivated sugar beet varieties to damage or harm organisms beneficial to agriculture.
- (4) H7-1 sugar beet does not exhibit characteristics that would result in increased weediness or invasiveness compared to non-transgenic sugar beet. Additionally, several mechanical control options or EPA-registered herbicides are available to control volunteer sugar beet plants.
- (5) Gene introgression from H7-1 sugar beet to introduced or naturalized species of *Beta* is unlikely to increase the weediness potential of any resulting progeny any more than would

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<sup>7</sup> <http://www.epa.gov/otaq/fuels/renewablefuels/compliancehelp/rfs2-lca-pathways.htm> Last accessed July 12, 2012.

<sup>8</sup> 5-enolpyruvylshikimate-3 phosphate synthase (EPSPS) is the introduced protein conferring glyphosate tolerance in H7-1 sugar beet.

introgression from other currently cultivated sugar beet varieties. Additionally, APHIS has concluded that horizontal gene transfer is unlikely to occur with H7-1 sugar beet, and thus, poses no increased plant pest risk.

### **Final Environmental Impact Statement**

APHIS prepared an EIS to examine the potential impacts on the human environment from a determination of nonregulated status of H7-1 sugar beet. APHIS has identified and evaluated potential impacts in the FEIS associated with the decision to approve the petition request for a determination of nonregulated status. A summary of the analysis contained in the FEIS is set forth below in the section entitled "Environmental Consequences Associated with Granting Nonregulated Status."

### **Alternatives Considered in the FEIS**

#### ***Alternative 1: No Action Alternative***

Under the No Action Alternative, APHIS would deny the petition seeking a determination of nonregulated status of H7-1 sugar beet. All movements and environmental releases for H7-1 sugar beet would be subject to the regulations in 7 CFR part 340. Notifications or permits with conditions specified by APHIS would be required to move viable plant material and to plant it outdoors. However, it is anticipated that research and development activities associated with H7-1 would diminish because developers would receive no return on investment to support such activities. The No Action Alternative would return sugar beet production to the status quo from 2005, before a determination of nonregulated status of H7-1 sugar beet was made and when all environmental releases of H7-1 sugar beet were conducted under notification. It is expected that under the No Action Alternative, all H7-1 sugar beet that was planted for commercial seed and root production would be phased out of U.S. agriculture. Sugar beet growers would need to replace H7-1 sugar beet varieties with conventional sugar beet varieties, grow other crops, use the land for other purposes, or allow the land to become fallow. The environmental release of H7-1 sugar beet would no longer be expected to be field tested in anticipation of initiating a petition of nonregulated status but might be used for research purposes such as gene flow studies. The planting acreages are expected to be well under 1,000 acres per year.

#### ***Alternative 2: Full Deregulation of H7-1 Sugar Beet***

Under Alternative 2 (Preferred Alternative), if H7-1 sugar beet were determined not likely to pose a plant pest risk and received nonregulated status, H7-1 sugar beet and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. APHIS Biotechnology Regulatory Service (BRS) permits or notifications would no longer be required for introductions of sugar beet derived from the H7-1 event. Under this alternative, growers could freely move and plant H7-1 sugar beet seed and stecklings and any harvested seeds and roots without further oversight from APHIS. Following a determination of nonregulated status of H7-1 sugar beet, APHIS anticipates that adoption rates may exceed 2010 levels and approach 100 percent as more varieties are developed from the H7-1 event. APHIS expects that H7-1 sugar beet would be planted in all sugar beet root production areas, including Imperial Valley, California, and the seed production areas of the Willamette Valley and Eastern Washington. Although APHIS would no longer have any regulatory control over the planting, distribution, or other actions related to H7-1 sugar beet, APHIS expects that growers of the root crop will continue to be subject to contract restrictions imposed by Monsanto's Technology

Stewardship Agreement (MTSA) and grower cooperatives because all commercial sugar beet are produced under contracts with the grower-owned cooperatives. The MTSA restrictions require that bolting H7-1 sugar beet be rogued or topped and prohibit use of H7-1 sugar beet in wildlife feed plots. Grower cooperatives also have requirements for roguing or topping sugar beet bolters, regarding which sugar beet varieties can be planted, and restrictions on how often sugar beet can be planted in a rotation. Growers contracted to produce the seed crop are required to follow best management practices specified by either West Coast Beet Seeds or Betaseeds. These practices include isolation distances, rotation requirements, volunteer management, and product segregation from vegetable beet seed crops.

***Alternative 3: Permanently Adopt the Interim Partial Deregulation of H7-1 Sugar Beet for Root Crop and Continue Permitting of Seed Crop***

Under Alternative 3, APHIS would permanently adopt the partial deregulation measures for H7-1 sugar beet root crop issued on February 4, 2011<sup>9</sup>. If 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. The root crop could be used for commercial production, processing, and sale of sugar. Seed production activities, however, such as breeding and production of commercial seed for the production of the root crop, would continue to be regulated under permits in accordance with 7 CFR part 340. The partial deregulation conditions would not allow the planting of H7-1 sugar beet in California and Western Washington.

Alternative 3 would lead to lower H7-1 sugar beet adoption rates than Alternative 2 because the sugar beet crop would not be permitted in California; the imposition of additional regulatory requirements and burdens on growers, seed developers, and sugar beet processors; and increased costs due to compliance with mandatory conditions, reporting requirements, inspections, and audits. It is possible that some growers will elect not to grow H7-1 sugar beet due to the increased costs and time required to meet the regulatory burden.

**Major Issues Addressed in the FEIS**

The FEIS describes the alternatives considered and evaluated using identified issues. Issues considered in the FEIS were developed based upon possible impacts raised by the Court and possible impacts identified in the Notice of Intent to prepare an EIS that APHIS published in the Federal Register on May 28, 2010. APHIS sought input on issues and alternatives the Agency should consider in preparation of the EIS related to a determination of nonregulated status of H7-1 sugar beet. The following issues were fully assessed by APHIS in the FEIS.

- Biological Resources
  - Gene flow
  - Weed management
  - Animals
  - Microorganisms

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<sup>9</sup> In response to a petition for partial deregulation during the interim period for the preparation of this EIS, APHIS has partially deregulated the H7-1 sugar beet root crop until December 31, 2012. In accordance with 7 CFR part 340, the seed crop has continued to be regulated under permits for environmental release while movements could be made under either permit or notification.

- Plants
- Socioeconomic Impacts
  - Sugar production in the United States: contribution of beets to sugar market
  - Principle companies and cooperatives
  - Regional production of seeds 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

## Decision

APHIS is selecting Alternative 2, approving the petition request for a determination of nonregulated status of H7-1 sugar beet. This decision is based on APHIS' full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA; the FEIS; the public comments on the DEIS; the agency's response to comments on the DEIS; and comments on the FEIS.

APHIS is selecting Alternative 2 because:

- Alternative 2 best meets the purpose and need for agency action, while remaining in accordance with its regulatory authority under 7 CFR 340. The agency purpose and need, as stated in the FEIS, "As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms, including GE plants such as H7-1 sugar beet. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk." Also, as stated in the FEIS, "If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the GE organism is unlikely to pose a plant pest risk, the GE organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340."
- The final PPRA was issued on June 8, 2012, and APHIS concluded in the final PPRA that H7-1 sugar beet is unlikely to pose a plant pest risk. APHIS has therefore concluded that the selection of Alternative 2 in this Record of Decision is consistent with the plant pest provisions of the Plant Protection Act of 2000, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.
- APHIS reviewed the conclusions it reached on the environmental consequences of Alternative 2, and in light of those conclusions, as well as those of the final PPRA, APHIS finds that Alternative 2 best serves the purpose and need for agency action as identified in the FEIS as well as being in accord with APHIS' regulatory authority under



7 CFR 340. The environmental consequences of Alternative 2 are discussed in the next section.

## **Environmental Consequences Associated with a Determination of Nonregulated Status**

The following is a summary of the conclusions APHIS reached on the environmental consequences of Alternative 2. An inherent assumption related to this summary is the expectation that a determination of nonregulated status of H7-1 sugar beet would result in environmental conditions similar to 2009 – 2010 when it was grown with no regulatory restrictions pursuant to APHIS' 2005 determination of nonregulated status of H7-1 sugar beet.

### ***Gene Flow in Sugar Beet***

- The factors that contribute to gene flow between sugar beet and any sexually compatible relative are the same regardless of the agronomic production method. Agronomic production of sugar beet may be conventional or GE. No commercial organic sugar beet production currently occurs in the United States. Gene flow between beet plants is dependent on environmental conditions, timing of flowering, distance between plants, and successful growth of beet seed in the soil seed bank<sup>10</sup> leading to flowering of the germinated beet plants.
- There are two potential sources for gene flow of the H7-1 trait: (1) H7-1 sugar beet seed production, the majority of which occurs in the Northwest; and (2) H7-1 sugar beet root production, which currently occurs in the Northwest, Great Plains, Midwest, and the Great Lakes regions. Plants that may be pollinated by H7-1 sugar beet include wild/naturalized *Beta* species and domesticated *Beta vulgaris*.
- *Beta* species are not native to North America. Introduced and feral *Beta* populations may be found in the United States, including *B. macrocarpa* and *B. vulgaris* ssp. *maritima* in California and *B. procumbens* in Pennsylvania.
- Successful gene flow from H7-1 sugar beet to *B. macrocarpa* or *B. procumbens* is negligible, due to minimal distribution overlap and/or reproductive barriers (e.g., sexual incompatibility or flowering asynchrony).
- *B. vulgaris* ssp. *maritima* is the only naturalized species of *Beta* in the United States that is sexually compatible with H7-1 sugar beet. *B. vulgaris* ssp. *maritima* is naturalized in California and is fully compatible with H7-1 sugar beet. However, successful gene flow between H7-1 sugar beet and *B. vulgaris* ssp. *maritima* is unlikely, due to an absence of spatial overlap and the infrequent flowering of sugar beet root crops.
- Gene flow between H7-1 sugar beet and *B. vulgaris* root/vegetable crop (e.g., Swiss chard or table beet) production fields is not possible because both crops are harvested prior to flowering. Pollen gene flow can only occur into the seed crop which flowers and only affects the seed not the vegetable crop.
- Gene flow between the H7-1 sugar beet root crop and vegetable beet seed crop is not likely because the root crop and seed crops are seldom grown in proximity to root crop fields. Some plants in a H7-1 root crop field may flower, and if these flowers produce

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<sup>10</sup> Totality of plant seeds in the soil of a particular area.

pollen, the pollen would be produced months after the vegetable beet seed crop is ready to be pollinated.

- Gene flow may occur in areas where H7-1 sugar beet and *B. vulgaris* vegetable seed production overlap. In the United States, this overlap is currently limited to Western Oregon. Isolation distances customarily used to maintain varietal purity, the widespread use of the H7-1 trait on male sterile lines for hybrid sugar beet seed production, and best management practices routinely employed by the sugar beet seed producers are expected to result in non-detectable<sup>11</sup> levels of gene flow between H7-1 sugar beet and other *B. vulgaris* vegetable seed varieties.

### ***Herbicide Use***

- Herbicides are extensively used in both conventional and H7-1 sugar beet production. Thirteen herbicides are commonly used to raise conventional sugar beet, including glyphosate, which is used prior to planting. On H7-1 sugar beet, glyphosate represents about 98 percent of the herbicide applied.
- Glyphosate use in the United States would increase approximately 1 percent as a result of cultivation of H7-1 sugar beet. Non-glyphosate herbicides are expected to decrease 10 to 40 fold or their use will be discontinued, following the introduction of H7-1 sugar beet. Based on data from the 2011 growing season in the Midwest, adoption of H7-1 sugar beet will result in a 20 percent decrease of total herbicides applied on a per pound per acre basis compared to conventional sugar beet. Use of non-glyphosate herbicides may increase if glyphosate resistant weeds become more prevalent.
- Many non-glyphosate herbicides used in conventional sugar beet production present potentially greater environmental impacts than glyphosate. Cultivation of H7-1 sugar beet would result in the replacement of non-glyphosate herbicides that generally present higher environmental impacts than glyphosate, an herbicide that presents relatively lower environmental impacts.
- Glyphosate use in sugar beet represents a small proportion of total U.S. glyphosate use and, when used according to the label, is not expected to pose an acute or chronic risk to birds, reptiles, mammals, terrestrial and aquatic invertebrates, fish, amphibians, and microorganisms. Non-target plants might be at some risk from exposure to glyphosate, if they are found near H7-1 sugar beet fields. This risk, however, is not unique to glyphosate application on H7-1 sugar beet, as all non-target plants may be at some risk of direct effects from exposure to herbicides currently used in sugar beet production.

### ***Weeds in Sugar Beet***

- Cultivation of H7-1 sugar beet would encourage the use of glyphosate to maintain the improved weed control sugar beet growers previously experienced using glyphosate in the time period following APHIS's initial determination of nonregulated status on March 27, 2005<sup>12</sup>. All regions are expected to see a net decline in the selection and dispersal of some herbicide-resistant weed biotypes due to the introduction of an additional mechanism of action for weed management.

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<sup>11</sup> Non-detectable is defined as less than 1 in 10,000 seeds.

<sup>12</sup> 70 FR 13007-13008, Docket No. 04-075-2

- Alternative 2, when combined with other past, present, and reasonably foreseeable actions, could result in cumulative impacts because it could contribute to an increase in the total number of glyphosate-resistant weeds and a decrease in the weeds that are resistant to non-glyphosate herbicides. Although no glyphosate-resistant weed biotypes have been attributed to the production of H7-1 sugar beet, H7-1 sugar beet fields represent an environment where glyphosate-resistant weed biotypes may establish following dispersal from other sources. This can be a concern in sugar beet production regions such as the Midwest, Great Plains, and Great Lakes that practice crop rotations with other glyphosate-tolerant crops. Repeated use of glyphosate in rotational crops could lead to the selection of glyphosate-resistant weed biotypes in these regions. The persistence and spread of multiple herbicide resistant weeds is expected to be delayed under Alternative 2 relative to Alternative 1 because glyphosate provides another mode of action for weed control in sugar beet fields reducing the overall presence of weeds in the landscape. Weed biotypes that are not well controlled can cross with other weed biotypes that are not well controlled creating the possibility of weeds that acquire, through reproduction, multiple herbicide resistance. Under Alternative 2, weed control will be more effective than weed control under Alternative 1, so the potential for selection of multiple herbicide resistance is less under Alternative 2.
- Management regimes that incorporate only glyphosate are more likely to result in selection of glyphosate resistant weeds. Farmers are aware of the problems of glyphosate-resistant weed biotypes and are increasingly proactive in the identification and removal of new weeds. Best management practices that can help control the development of glyphosate-resistant weeds include:
  - a) identifying weeds and monitoring for escapes to determine if current practices need to be modified to achieve acceptable levels of weed control;
  - b) using proper herbicide rates and timing;
  - c) using crop rotation to facilitate use of different modes of action over time;
  - d) using agronomic management practices to supplement herbicide weed control;
  - e) alternating herbicides with different modes of action; and
  - f) tank mixing herbicides of different modes of action

#### ***Additional Potential Impacts of H7-1 Sugar Beet***

H7-1 sugar beet plants are not expected to adversely affect plants and animals, including threatened and endangered (T&E) species.

- H7-1 sugar beet is not expected to become more invasive in natural environments or have any different effect on critical habitat than conventional sugar beet. Several agronomic characteristics of H7-1 sugar beet were evaluated by APHIS, including data on plant vigor, bolting, seedling emergence, seed germination, seed dormancy, and reproductive characteristics. Based on these evaluations and observations, H7-1 sugar beet shows no meaningful differences in agronomic characteristics, performance, and phenotype when compared to conventional varieties, and the H7-1 trait does not alter weediness potential of the H7-1 variety.
- Compositional analysis of H7-1 sugar beet demonstrated that H7-1 sugar beet is compositionally equivalent to conventional sugar beet with respect to key nutrients and

components. Consequently, H7-1 sugar beet is not expected to have adverse nutritional effect on any animal that feeds upon it.

- The introduced gene product in H7-1 sugar beet is not expected to be toxic or allergenic to plants or animals. The 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from plants and from the CP4 *Agrobacterium* strain is not known to have pathogenic or toxic effects on humans, animals, or plants based on numerous laboratory and field studies with these purified proteins or plants expressing these proteins.
- Hybridization with H7-1 sugar beet is primarily limited to other sexually compatible *Beta* crops. Sugar beet is not native to the United States, resulting in few sexually compatible and free-living *Beta* species. With the exception of a naturalized population of *B. vulgaris* ssp. *maritima* in California, there is no evidence of any sexually compatible and free-living *Beta* species in the United States. Hybridization of H7-1 sugar beet with the naturalized *B. vulgaris* ssp. *maritima* populations in California is unlikely, as this population is generally found along coastal regions, away from sugar beet production areas where sugar beet is cultivated.
- APHIS concluded that the H7-1 sugar beet gene product would have no effect on federally listed T&E species or species proposed for listing, and has concluded it will have no effect on designated critical habitat or habitat proposed for designation, compared to current agricultural practices of conventional sugar beet production and therefore reached a No Effect determination. As discussed in the EIS, H7-1 sugar beet would not be sexually compatible with, or serve as a host species for, any listed species or species proposed for listing. Based on compositional analysis, consumption of H7-1 sugar beet by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Additionally, based on allergenicity and toxicity of the H7-1 sugar beet CP4 EPSPS protein, and based on the research summarized in the EIS, APHIS concludes that no substantial differences exist compared to conventional sugar beet EPSPS protein. Therefore, APHIS concludes that consumption of H7-1 sugar beet plant parts (seeds, leaves, stems, pollen, or roots) would have no effect on any listed T&E animal species or animal species proposed for listing. APHIS also considered if H7-1 sugar beet would expand the range of sugar beet production. Based on a lack of weediness in H7-1 sugar beet and the present structure of the sugar beet industry, APHIS concluded that H7-1 sugar beet would not lead to cultivation on land not previously used for agricultural production. APHIS also considered, as part of the analysis for T&E species and critical habitat, if the new phenotype imparted to H7-1 sugar beet may allow the plant to naturalize in the environment and potentially have an effect on T&E species. APHIS concluded that there was no substantial difference in the ability of H7-1 sugar beet compared to conventional sugar beet to persist as a weed. Additionally, no characteristics relating to disease or insect resistance that might affect weediness were noted that were consistent over all trial locations. H7-1 sugar beet is still susceptible to the typical insect and disease pests of sugar beet. Collectively, this information indicates that H7-1 sugar beet is unlikely to naturalize and persist in the environment. Based on these factors, APHIS has determined that H7-1 sugar beet would have no effect on listed T&E 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.

Increased glyphosate use, due to the adoption of H7-1 sugar beet, could affect non-target plants, but is not expected to adversely affect animals.

- Because of the toxicity of glyphosate to plants, glyphosate may adversely affect non-target plant species through herbicide drift, runoff of surface water containing glyphosate, or leaching of glyphosate into groundwater systems. Effects on non-target plants species through herbicide drift from sugar beet production fields may be mitigated through EPA-imposed label restrictions to apply glyphosate only when the potential for drift is minimal or by specific application technology controls. Compared to other commonly used herbicides in sugar beet production, glyphosate has a lower potential to move in runoff in solution but a higher potential to move while adsorbed to eroded soil particles. However, microorganism-mediated degradation of glyphosate in soils along with the physical properties of glyphosate that cause soil movement to surface water will reduce the amount transported to surface and ground water, and, once in surface water continued microorganism-mediated degradation and settling of transported soil will further reduce environmental exposures.
- Glyphosate is not expected to pose an unreasonable acute or chronic risk to birds, reptiles, mammals, terrestrial and aquatic invertebrates, fish, amphibians, and microorganisms when used according to the label. Compared to glyphosate tested as an acid or isopropylamine (IPA) salt, amphibians exhibited greater sensitivity to Roundup<sup>®</sup> formulations, likely due to the surfactant polyethoxylated tallowamine (POEA). POEA has been found to be more toxic to amphibians and other aquatic animals than glyphosate alone. While glyphosate formulations containing POEA are not permitted for use near aquatic habitats where amphibians may be located, at least one glyphosate formulation that contains a non-POEA surfactant is approved for use over or near surface waters. This glyphosate product (Nufarm Credit Duo Herbicide, EPA Reg. No. 71368-25) may be used on glyphosate-tolerant sugar beet. However, EPA-mandated label instructions for over the top application on glyphosate-tolerant sugar beet varieties like H7-1 sugar beet precludes use of this product over surface water. Additionally, label instructions include application when drift potential is minimal and to avoid direct application to any body of water. These use instructions in sugar beet fields, coupled with the expectation that large number of amphibians would not be present in fields where sugar beet would be planted, suggests minimal adverse impacts on amphibians.
- APHIS has no statutory authority to authorize or regulate the use of glyphosate, or any other herbicide, by sugar beet growers. Under APHIS' current part 340 regulations, APHIS only has the authority to regulate the H7-1 sugar beet plant or any GE organism as long as APHIS believes it may pose a plant pest risk. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers pesticides and prescribes the conditions for use of the pesticide on the label. Applying pesticides in a way that is inconsistent with the label is illegal. On the label, EPA includes instructions on how glyphosate herbicides should be applied. Directions include application restrictions that minimize impacts on nearby environments. EPA has determined that there are no unreasonable environmental risks if the user adheres to the labeled directions. 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 the registration review program, EPA expects to meet its responsibility under the Endangered Species Act. Glyphosate is currently undergoing the

registration review process by the EPA. EPA is scheduled to complete its registration review for glyphosate in 2015, at which time EPA will complete its national endangered species assessment of all registered uses of the herbicide.

### ***Socioeconomic Impacts***

- There is evidence that H7-1 sugar beet production has the potential to increase yields and reduce production costs related to labor, fuel, fertilizer, herbicides, and irrigation. These cost reductions are potentially offset by the technology fee for H7-1 sugar beet, potential herbicide cost increases due to weed population shifts and herbicide resistance, and an inability by domestic producers to sell H7-1 sugar beet products for animal feed to GE-sensitive livestock markets. However, existing studies indicate an increase in the overall economic returns to sugar beet root production with H7-1 adoption, although with considerable regional differences. In particular, root growers in the largest production area, the Midwest, might not benefit from H7-1 adoption as much as those of other areas such as the Northwest and Great Plains where raising conventional sugar beet has become impractical for many growers. Nationwide, the cost benefit of growing H7-1 sugar beet compared to conventional sugar beet is estimated to be greater than \$200/acre.
- Cultivation of H7-1 sugar beet is generally associated with improved flexibility, safety, convenience, and quality of life for sugar beet farmers. However, seasonal farm workers may find fewer opportunities for work in hand weeding of H7-1 sugar beet fields, compared to those of conventional sugar beet fields. It has been noted, however, that some sugar beet farmers experience difficulty in finding available seasonal workers to do hand weeding in sugar beet fields.
- The demand for organic sugar has been steadily increasing though it still remains just 1 percent of the sugar market. This demand for organic sugar is primarily met through importation of sugar derived from cane plants. There currently is a small amount of organic cane sugar production in the U.S. but no commercial organic beet sugar production. If any organic sugar beet industry were to develop, it would be sensitive to low level presence (LLP) of GE H7-1, and would require seed production to be segregated from H7-1 sugar beet. Potential development of an organic sugar beet root crop industry could occur without LLP concerns, due to the unlikelihood of gene flow from one root crop to the next as the source of gene flow, bolter formation, is generally well controlled. Because beet seed production already is established with isolation distances that minimize cross pollination between various *B. vulgaris* seed crops, it is unlikely that wide-scale adoption of H7-1 will interfere with the emergence of an organic beet sugar industry. If a seed is verified to lack LLP, then the root crop produced from that seed will also lack LLP.
- Organic *B. vulgaris* vegetable/root crop producers are unlikely to be adversely affected by wide-scale cultivation of H7-1 sugar beet because producers of both *B. vulgaris* vegetable/root crops and H7-1 sugar beet harvest their crops prior to flowering. An absence of flowering eliminates the likelihood of gene flow. Gene flow from the H7-1 sugar beet seed crop to organic *B. vulgaris* vegetable seed crops is possible. However this possibility is limited to regions where seed production of sugar beet and vegetable beet overlap. At present, this only occurs in Western Oregon. Current industry practices, including use of pinning maps to identify locations of seed fields, widespread use of the H7-1 trait on male sterile lines (85 percent of the sugar beet seed production acreage

produces pollen that lacks the H7-1 trait), large isolation distances, and industry wide best management practices to limit human error would minimize gene flow of the H7-1 trait into vegetable beet seed production fields, but would not eliminate the possibility. This possibility may adversely affect organic *B. vulgaris* vegetable seed crop producers in regions like the Willamette Valley or Rogue River Valley. The extent of this impact, however, would depend on the extent to which the market for U.S. organic *Beta* vegetable seed is sensitive to the perceived risk of presence of LLP in vegetable beet seed. It could mean that some seed producers in Western Oregon would grow other seed crops in place of vegetable beet seeds. However, so far, the production of vegetable beet seed crops in the Willamette Valley has remained consistent at 300-400 acres/year over the past seven years despite the production of H7-1 sugar beet seed crops.

- Those U.S. consumers who prefer organic and/or non-GE foods over conventional foods will continue to have access to organic sugar and vegetable beet products. U.S. organic sugar is primarily imported and derived from sugar cane and thus the supply is unaffected by H7-1 sugar beet production. Similarly the production of beet vegetables are unaffected by H7-1 production because they are harvested prior to flowering. Provided that seeds used to grow these crops lack the H7-1 trait, vegetable beet producers can continue to provide vegetable beets lacking the H7-1 trait for a GE sensitive market. Approximately 70 percent of vegetable beet seed grown in the U.S. is produced in areas outside the Willamette Valley where no H7-1 sugar beet seed is produced. In the Willamette Valley, vegetable beet seed producers who cater to a GE sensitive market would need to test their seed to ensure they meet their customer's needs. Therefore, vegetable beet seeds lacking the H7-1 trait are available from two sources: areas outside the Willamette Valley where no H7-1 sugar beet seed is produced and within the Willamette Valley where testing has been completed.

### ***Human Health and Safety***

- H7-1 sugar beet plants and products derived from H7-1 sugar beet pose no risk to human health and worker safety.
- Broad adoption of H7-1 sugar beet may lead to reductions in machinery use, resulting in proportional reductions in farm worker exposure to related machinery-related emissions, particulates, and injuries.
- Overall risk of glyphosate on human health and worker safety does not change with wide-scale adoption of H7-1 sugar beet. The general public is unlikely to be exposed to glyphosate in sugar, due to the removal of any residue during H7-1 sugar beet product processing. On the farm, glyphosate is unlikely to pose harm to farm workers, when used as directed according to the EPA-approved label. Glyphosate has lower toxicity to humans than several herbicides commonly used on conventional sugar beet. For example, clethodim is a greater skin irritant, clopyralid and desmedipham are greater eye irritants, EPTC, ethofumesate and triflusaluron-methyl are more toxic by inhalation than is glyphosate.

### ***Land Use and Physical Environment***

- The prevalence of H7-1 sugar beet may increase following a determination of nonregulated status; however, overall U.S. sugar beet land acreage is not anticipated to substantially change due to availability of H7-1 sugar beet. Despite potential regional

changes in sugar beet acreage, total U.S. sugar beet acreage will continue to be primarily influenced by the domestic sugar market, regulatory programs like USDA's sugar program, the finite processing capability of sugar processing plants, and the expectation of no new sugar processing plant openings.

- H7-1 sugar beet is not expected to have an adverse impact on soils, climate or air quality, or water and water use. This absence of adverse impacts is primarily due to the increased use of conservation and reduced tillage, decreased machinery use, decreased use of water for irrigation and spraying, and substitution of non-glyphosate herbicides with glyphosate in areas where H7-1 sugar beet may be cultivated.

### **Environmentally Preferred Alternative**

The Environmentally Preferred Alternative is the alternative that causes the least harm to the biological and physical environment, but also the alternative which best protects, preserves, and enhances historic, cultural, and natural resources. APHIS has analyzed the impacts of three alternatives analyzed in detail in the FEIS on the biological and physical environment of sugar beet seed and root crop production.

Sugar beet seed production represents a fraction (approximately 0.4 percent) of total U.S. sugar beet acreage. Its small proportion of total U.S. sugar beet acreage, combined with similar environmental impacts between the three alternatives, suggests that any contribution of seed production toward potential biological and physical impacts on the environment is likely to be minor.

The majority of U.S. sugar beet acreage is planted for root crop production. No substantial differences in agronomic attributes are observed between conventional and H7-1 sugar beet. Consequently, no potential impact to the biological or physical environment is anticipated due to H7-1 sugar beet itself under the three alternatives. However, management practices associated with the cultivation of H7-1 sugar beet as a root crop are different. Central to the management of H7-1 sugar beet is the capacity to apply glyphosate as a post-emergent herbicide to control weeds. Adoption of H7-1 sugar beet and its cultivation under Alternatives 2 and 3 will likely result in an increase in glyphosate use on sugar beet. This will most likely be accompanied by a decrease in the amount of non-glyphosate herbicide use. The magnitude of these reciprocal shifts in herbicide use is likely to be similar to 2008 – 2011, when H7-1 sugar beet was initially commercialized and adopted. This herbicide replacement trend involving glyphosate is not unique to sugar beet root crop production; this trend is also seen in U.S. GE agriculture as a whole.

Relative to other herbicides used in sugar beet root crop production, glyphosate generally poses less environmental impacts. Standard application of glyphosate in sugar beet root crop fields does not pose unreasonable risks to animals, birds, fish, or invertebrates. Increased glyphosate usage could increase the likelihood of exposure to glyphosate of nearby plants, leading to the mortality of non-target plants adjacent to sugar beet fields. Because herbicide applications are less frequent and less likely to be made by aerial applications under Alternative 2 relative to Alternative 1, impacts to non-target plants are expected to be less under Alternative 2. Additionally, increased use of glyphosate formulations containing certain types of surfactants on sugar beet may pose a potential risk to amphibians, although EPA label conditions on glyphosate formulations for use in sugar beet production containing surfactants preclude the use over open water where amphibians may be found.



The use of H7-1 sugar beet under Alternatives 2 and 3 has the potential to impact the selection of herbicide resistance in weeds due to the use of glyphosate as an herbicide, and not due to any properties of H7-1 sugar beet plants themselves. Glyphosate application in H7-1 sugar beet would permit the control of weeds with resistance to non-glyphosate herbicides such as ALS inhibitors, ACCase inhibitors, PSII inhibitors, synthetic auxins, mitosis inhibitors and fatty acid synthesis inhibitors. While increased glyphosate application in H7-1 fields may also contribute to the selection of glyphosate-resistant weeds, reliance on non-glyphosate herbicides will contribute to the selection of weeds resistant to the non-glyphosate herbicides as well. However, growers will be able to better manage the weed resistant problem by having glyphosate as an additional mechanism of action. The magnitude of this potential contribution by H7-1 sugar beet is not anticipated to be substantial, due to minimal spatial overlap of glyphosate-resistant weeds and sugar beet acreage; relatively small contribution of glyphosate use toward total U.S. glyphosate use; and the continued availability of alternative weed control methods (as described in the EIS) to manage glyphosate-resistant weeds. If glyphosate-resistant weeds were to become prevalent in sugar beet, combinations of herbicides with different mechanisms of action are expected to still provide effective control provided that the glyphosate-resistant weed does not already carry resistance to multiple herbicides. In that case, control could become difficult and expensive because of the need to use more chemicals, alternative cultivation practices, and hand labor.

APHIS has identified Alternative 2, the Preferred Alternative, as the Environmentally Preferred Alternative. Under the Preferred Alternative, near 100 percent adoption of H7-1 sugar beet by U.S. sugar beet growers is anticipated. Concurrent with the adoption of H7-1 sugar beet is an increase in glyphosate use and a decrease in non-glyphosate herbicide use. APHIS estimates that national glyphosate use may increase by about 1 percent due to 100 percent adoption of H7-1 sugar beet. Four herbicides which are used almost exclusively on sugar beet would likely be discontinued. At typical application rates, glyphosate generally poses less adverse environmental impacts than non-glyphosate herbicides. Consequently, the Environmentally Preferred Alternative results in the substantial replacement of sugar beet herbicides that pose more adverse environmental impacts with glyphosate, an herbicide that poses a relatively lower environmental impact. Under Alternative 2, adoption of conservation and reduced tillage has increased relative to Alternative 1. Conservation and reduced tillage is associated with improvements in water and air quality and reduced greenhouse gas emissions. As a result, the impacts on Biological Resources are expected to be less for Alternative 2 than for Alternative 1.

The No Action Alternative was not selected as the Environmentally Preferred Alternative. Although glyphosate use would not go up as much under the No Action Alternative compared to the Preferred Alternative, use of non-glyphosate herbicides would go up more in the No Action Alternative compared to the Preferred Alternative. Thus, the No Action Alternative would result in more use of non-glyphosate herbicides that generally pose more adverse environmental impacts than glyphosate. Additionally, Alternative 3 was not selected as the Environmentally Preferred Alternative because H7-1 sugar beet would not be permitted in California or western Washington. If H7-1 sugar beet is not cultivated in California or western Washington, then herbicide use trends in those areas would be similar to the No Action Alternative, where the use of non-glyphosate herbicides that generally pose more adverse environmental impacts than glyphosate would continue.

## **Mitigations of Impacts Associated with Alternative 2**

APHIS has identified the potential for impacts from the increased use of glyphosate associated with the adoption of H7-1 sugar beet. Impacts to plants can be mitigated by following the EPA label. EPA regulates the use of pesticides under FIFRA. Under FIFRA, EPA registers pesticides and prescribes the conditions for use of the pesticide. Applying pesticides in a way that is inconsistent with the label is illegal. On the label, EPA includes instructions on how glyphosate herbicides should be applied. Directions include application restrictions that minimize impacts on nearby environments. EPA has determined that there is no unreasonable environmental risk if the user adheres to the labeled directions. Glyphosate is currently undergoing a registration review by EPA. If EPA determines that additional restrictions beyond current restrictions on glyphosate use are required to mitigate environmental risk to non-target plant communities, then it is expected that EPA would amend glyphosate use labels accordingly.

APHIS also concluded that the use of glyphosate on H7-1 sugar beet could contribute to the selection of glyphosate-resistant weeds, though this contribution is anticipated to be minor relative to other uses in the United States. In regions where the presence of glyphosate-resistant weeds coincides with sugar beet acreage or crops used in rotation with sugar beet, adopters of H7-1 sugar beet will need to take measures to manage glyphosate-resistant weeds already present. These measures to manage already-present glyphosate-resistant weeds include:

- a) regularly field scouting to identify weeds that escaped herbicide treatment and remove weeds before flowering;
- b) monitoring changes in weed populations and restricting the spread of potentially-resistant weeds that match the field history and herbicide use patterns;
- c) planting weed-free seed;
- d) planting into weed-free fields and keeping the fields as weed free as possible;
- e) using full rates of all products and using the most effective adjuvants when tank-mixing with glyphosate;
- f) applying herbicides as recommended weed sizes;
- g) emphasizing cultural practices that suppress weeds by utilizing crop competitiveness;
- h) using mechanical and biological management practices where appropriate;
- i) preventing field to field and within field movement of weed seed or vegetative propagules;
- j) managing weed seed at harvest and post-harvest to prevent a buildup of the weed seedbank; and
- k) preventing an influx of weeds into the field by managing field borders.

Among growers there is increasing awareness of herbicide stewardship needs. Industry, academia and weed science professionals are providing more tools to help growers adopt the farming practices that will both delay the selection of herbicide resistance and help control the spread of herbicide-resistant weeds from field to field. One of these programs is Monsanto's Roundup Ready PLUS™ program which provides financial incentives for growers to use additional herbicide chemistries.

## **Compliance with Applicable Laws, Executive Orders, and Regulations**

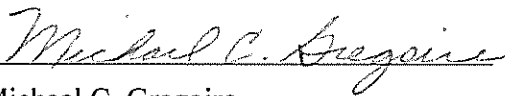
This record of decision has been prepared in accordance with: (1) the National Environmental Policy Act (NEPA), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations

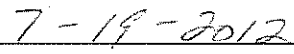
implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The decision considered the directives of Executive Order (EO) 12898 (US-NARA, 2008), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations;" EO 13045 (US-NARA, 2008), "Protection of Children from Environmental Health Risks and Safety Risks;" EO 13112 (US-NARA, 2008) "Invasive Species;" EO 13186 (US-NARA, 2008), "Responsibilities of Federal Agencies to Protect Migratory Birds;" and EO 12114 (US-NARA, 2008), "Environmental Effects Abroad of Major Federal Actions."

The decision was determined to be compliant with other Federal Statutes including, the Clean Water Act; the Clean Air Act; the National Historic Preservation Act of 1966 as amended; and the Endangered Species Act.

This decision was made under authority of the Plant Protection Act as amended (7 United States Code (U.S.C.) 7701-7772), as codified in the Code of Federal Regulations at 7 CFR part 340, and in consideration of Executive Policy (Executive Office of the President, Office of Science and Technology Policy "Exercise of Federal Oversight within Scope of Statutory Authority; Planned introductions of biotechnology products into the environment." FR Feb 27 1992.vol 57 (39):6753).

  
Michael C. Gregoire  
Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture

  
Date

