Notices

Federal Register
Vol. 64, No. 5
Friday, January 8, 1999

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 98-079-2]

Novartis Seeds and Monsanto Co.; Availability of Determination of Nonregulated Status for Sugar Beet Genetically Engineered for Glyphosate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that the Novartis Seeds and Monsanto Company's sugar beet line designated as GTSB77, which has been genetically engineered for tolerance to the herbicide glyphosate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Novartis Seeds and Monsanto Company in their petition for a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: December 23, 1998.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and all written comment received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW, Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are asked to call in advance of visiting at (202) 690-2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. James White, Biotechnology and Biological Analysis, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5940. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: Kay.Peterson@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On June 22, 1998, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 98-173-01p) from Novartis Seeds (Novartis) of Research Triangle Park, NC, and Monsanto Company (Monsanto) of St. Louis, MO, (Novartis/Monsanto) seeking a determination that a sugar beet (*Beta vulgaris* L.) line designated as GTSB77, which has been genetically engineered for tolerance to the herbicide glyphosate, does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On August 20, 1998, APHIS published a notice in the **Federal Register** (63 FR 44604-44605, Docket No. 98-079-1) announcing that the Novartis/Monsanto petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject sugar beet line and food products derived from it. In the notice, APHIS solicited written comments from the public as to whether this sugar beet line posed a plant pest risk. The comments were to have been received by APHIS on or before October 19, 1998. APHIS received one comment on the subject petition during the designated 60-day comment period. The comment was from an organization representing North American sugar beet processors, and it was in support of the petition.

Analysis

The GTSB77 sugar beet line has been genetically engineered to express an enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme derived from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), and the β- D-glucuronidase (GUS) protein from *Escherichia coli*. The CP4 EPSPS enzyme confers tolerance to the herbicide glyphosate, and the GUS protein serves as a marker in the plant transformation process. The subject sugar beet line also expresses a novel protein known as 34550, which

has no known biological activity, and was apparently created when a truncated glyphosate oxidoreductase (*gox*) gene fused to sugar beet DNA. Expression of the added genes is controlled in part by gene sequences derived from the plant pathogens figwort mosaic virus and cauliflower mosaic virus. The *Agrobacterium tumefaciens* method was used to transfer the added genes into the parental proprietary sugar beet A1012 line.

The subject sugar beet line has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of this sugar beet line conducted under APHIS permits and notifications since 1996 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of the GTSB77 sugar beet line.

Determination

Based on its analysis of the data submitted by Novartis/Monsanto, and a review of other scientific data and field tests of the subject sugar beet, APHIS has determined that sugar beet line GTSB77: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than herbicide-tolerant sugar beet developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities; and (5) will not harm threatened or endangered species or other organisms, such as bees, that are beneficial to agriculture, or have an adverse impact on the ability to control nontarget insect pests. Therefore, APHIS has concluded that the subject sugar beet line and any progeny derived from crosses with other sugar beet varieties will be as safe to grow as sugar beets that are not subject to regulation under 7 CFR part 340.

The effect of this determination is that the Novartis/Monsanto GTSB77 sugar beet line is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the subject sugar beet line or its progeny. However, importation of GTSB77 sugar beet or seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319.

National Environmental Policy Act

An environmental assessment (EA) has been prepared to examine the potential environmental impacts associated with this determination. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (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). Based on that EA, APHIS has reached a finding of no significant impact (FONSI) with regard to its determination that the Novartis/Monsanto GTSB77 sugar beet line and lines developed from it are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and the FONSI are available upon request from the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 30th day of December 1998.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–362 Filed 1–7–99; 8:45 am]

BILLING CODE 3410–34–P

Novartis Seeds and Monsanto Company Petition 98-173-01p for Determination of Nonregulated Status for Transgenic Glyphosate Tolerant Sugar Beet Line GTSB77

Environmental Assessment and Finding of No Significant Impact

December 1998

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, has prepared an environmental assessment in response to a petition (APHIS Number 98-173-01p) received from Novartis Seeds and Monsanto Company seeking a determination of non-regulated status for their genetically engineered glyphosate tolerant sugar beet designated as line GTSB77 under APHIS regulations at 7 CFR Part 340. The plants have been engineered with a gene that confers resistance to the herbicide glyphosate. Based on the analysis documented in its environmental assessment, APHIS has reached a finding of no significant impact (FONSI) on the environment from the unconfined cultivation and agricultural use of line GTSB77 and its progeny.

Sally A. McCammon

for Rebecca A. Bech
Assistant Director
Scientific Services
Plant Protection and Quarantine
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: DEC 23 1998

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 98-173-01p) from Novartis Seeds and Monsanto Company USA Company seeking a determination of non-regulated status for their transgenic glyphosate tolerant sugar beet designated as line GTSB77. Novartis Seeds and Monsanto Company seeks a determination that line GTSB77 and its progeny do not present a plant pest risk and, therefore, are no longer regulated articles under regulations at 7 CFR Part 340.

Line GTSB77 was engineered to be glyphosate tolerant by inserting into the sugar beet chromosome an enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from the common soil bacterium *Agrobacterium sp.* A scoreable marker gene, beta-glucuronidase from the common enteric bacterium *Escherichia coli*, was also introduced. This marker gene was used in the laboratory to identify the transformed plants. The genes were introduced into these sugar beets via an *Agrobacterium*-mediated transformation protocol.

This EA specifically addresses the potential for impacts to the human environment through the use in agriculture of line GTSB77. It does not address the separate issue of the potential use of the herbicide glyphosate in conjunction with these plants. The United States Environmental Protection Agency (EPA) has authority over the use in the environment of all pesticidal substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Food and Drug Administration (FDA) has authority over food and feed issues of all genetically improved plants used as food or feed.

The EAs that were prepared before granting the initial permits for field trials and subsequent trials of these transgenic sugar beets address questions pertinent to plant pest risk issues concerning the conduct of field trials under physical and reproductive confinement. However, they do not address several issues that are of relevance to the unconfined cultivation of these transgenic sugar beets. With respect to these new issues, APHIS concludes the following:

1. Glyphosate tolerant sugar beets exhibit no plant pathogenic properties. Although phytopathogenic organisms were used in their development, these plants are not infected nor can they incite disease in other plants.

2. Glyphosate tolerant sugar beets are no more likely to become weeds than similar herbicide tolerant sugar beets developed by traditional breeding techniques. Sugar beets are not a major weed pest in the U.S. and there is no reason to believe that resistance to glyphosate would enable sugar beets to become a weed.

3. Gene introgression from these sugar beets into wild or cultivated sexually-compatible plants is likely. Even in the event of gene introgression, this should not increase the weediness potential of resulting progeny or have an adverse impact on biodiversity different than similar herbicide tolerant sugar beets developed by traditional breeding techniques.

4. Except for being herbicide tolerant, these sugar beets are substantially equivalent to nontransgenic plants and, therefore, APHIS can foresee no adverse impacts on raw or processed agricultural commodities.

5. Glyphosate tolerant sugar beets exhibit no significant potential to either harm organisms beneficial to the agricultural ecosystem, to have an adverse impact on the ability to control nontarget insect pests, or to harm threatened and endangered species.

Therefore, after a review of the available evidence, APHIS believes that these glyphosate tolerant sugar beets will be just as safe as nontransgenic sugar beets that are typically grown and which are not subject to regulation under 7 CFR Part 340. This includes crosses between GTSB77 and any other sugar beet plant that is not regulated or that has been deregulated under 7 CFR Part 340. APHIS concludes that there should be no significant impact on the human environment if these glyphosate tolerant sugar beets were no longer considered regulated articles under regulations at 7 CFR Part 340.

II. INTRODUCTION

A. Development of Glyphosate tolerant Sugar Beets

The management of weeds is an expensive, labor intensive, and sometimes complicated operation. Glyphosate tolerant sugar beets will offer farmers a new option in controlling weeds. Often farmers use pre-emergent herbicides that will stop weed seeds from germinating. However, this assumes that weeds will always be a problem in all parts of the field. With GTSB77, farmers will have the option of applying herbicide after weeds have germinated and only in the areas of the field where there are weeds. Glyphosate is one of the most environmentally friendly herbicides.

These sugar beets were genetically engineered to be glyphosate tolerant by inserting into sugar beet chromosome an enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from the common soil bacterium *Agrobacterium sp.* A scoreable marker gene,

beta-glucuronidase from the common enteric bacterium *Escherichia coli*, was also introduced. This marker gene was used in the laboratory to identify the transformed plants. The genes were introduced into these sugar beets via an *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure that has been widely used for over a decade for introducing various genes of interest directly into plant genomes.

APHIS authorized the first field testing these sugar beets starting in 1996 and they have been field tested in the United States under the following APHIS authorization numbers: 96-031-01r, 96-057-03r, 96-061-01r, 96-309-01r, 96-361-02r, 97-029-02r, 97-163-03n, 97-182-08n, 97-190-02n, 98-035-01n, 98-050-02n, 98-057-01n, 98-072-11n, and 98-079-11n. They have been evaluated extensively to confirm that they exhibit the desired agronomic characteristics and do not present a plant pest risk. Although the field tests have been conducted in agricultural settings, the conditions for the tests have stipulated physical and reproductive confinement from other plants.

B. APHIS Regulatory Authority.

APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act, as amended (7 U.S.C. 150aa-150jj) and the Plant Quarantine Act, as amended (7 U.S.C. 151-164a, 166-167) regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. These sugar beets have been considered regulated articles because they contain noncoding DNA regulatory sequences derived from plant pathogens, and the vector agent used to deliver the plasmid vector is a plant pathogen.

Section 340.6 of the regulations, entitled "Petition Process for Determination of Nonregulated Status", provides that a person may petition the Agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk, and therefore should no longer be regulated. If APHIS determines that the regulated article is unlikely to present a greater plant pest risk than the unmodified organism, the Agency can grant the petition in whole or in part. As such, APHIS permits would no longer be required for field testing, importation, or interstate movement of the non-regulated article or its progeny.

C. EPA and FDA Regulatory Authority

This genetically engineered sugar beet plant is also currently subject to regulation by other agencies. The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the FDA enforces the tolerances set by the EPA.

The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992, and appears at 57 FR 22984-23005. Safety concerns for human and animal consumption of products with kanamycin resistance are also specifically addressed by the FDA in 21 CFR Parts 173 and 573. Novartis/Monsanto have successfully concluded their consultation with FDA on this sugar beet plant.

III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of these glyphosate tolerant sugar beets as regulated articles under APHIS regulations. The developer of these glyphosate tolerant sugar beets, Novartis and Monsanto, submitted a petition to USDA, APHIS requesting that APHIS make a determination that these glyphosate tolerant sugar beets shall no longer be considered regulated articles under 7 CFR Part 340.

This EA was prepared in compliance with the National Environmental Policy Act (NEPA) of 1969 as amended, (42 USC 4321 *et seq.*) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

IV. ALTERNATIVES

A. No Action.

Under the Federal "no action" alternative, APHIS would not come to a determination that these sugar beets are not regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of glyphosate tolerant sugar beets. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of glyphosate tolerant sugar beets.

B. Determination that Glyphosate tolerant Sugar Beets Are No Longer Regulated Articles.

Under this alternative, these glyphosate tolerant sugar beets would no longer be regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of glyphosate tolerant sugar beets. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969, as amended (42 USC 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 342).

V. POTENTIAL ENVIRONMENTAL IMPACTS

Potential impacts to be addressed in this EA are those that pertain to the use of line GTSB77 in the absence of confinement.

Potential Impacts Based On Increased Weediness Of Line GTSB77 Relative To Traditionally Bred Sugar beets

Almost all definitions of weediness stress as core attributes the undesirable nature of weeds from the point of view of humans; from this core, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). In further analysis of weediness, Baker (1965) listed 12 common weed attributes, almost all pertaining to sexual and asexual reproduction, which can be used as an imperfect guide to the likelihood that a plant will behave as a weed. Keeler (1989) and Tiedje *et al.* (1989) have adapted and analyzed Baker's list to develop admittedly imperfect guides to the weediness potential of transgenic plants; both authors emphasize the importance of looking at the parent plant and the nature of the specific genetic changes. The parent plant in this petition, *Beta vulgaris L. ssp. vulgaris* L., is not listed as a weed by the Weed Society of America (1992). Occasionally, sugar beets volunteer in fields the year after harvesting. These plants can be controlled by mechanical means or several other registered herbicides beside glyphosate that can be used on sugar beet volunteers (Crop Protection Chemical Reference, 1996)

Potential Impacts From Out crossing Of Line GTSB77 to Wild Relatives

Although sugar beets have escaped cultivation and their progeny have persisted in the environment for many years (especially in California), these plants are not serious weed problems (Lewellen, 1998). Some of these plants are found in the San Francisco Bay area where sugar beets are no longer cultivated. Another population of sexually compatible plants are in Imperial Valley of California. The movement of the glyphosate tolerance trait from GTSB77 to any other sexually compatible *Beta vulgaris* should not have an significant impact especially if glyphosate is not applied to these plants. APHIS cannot find any evidence that herbicides are applied routinely to these plants living

outside cultivated areas. Even if these plants become tolerant to glyphosate there are other registered herbicides that can be used to kill them.

Potential Impact On Threatened or Endangered Species or Nontarget Organisms Including Beneficial Organisms Such As Bees And Earthworms

There is no reason to believe that deleterious effects or significant impacts on nontarget organisms, including beneficial organisms, would result from the cultivation of line GTSB77. The enzyme EPSPS that confers glyphosate resistance is from the bacterium *Agrobacterium* sp. This gene is similar to the gene that is normally present in sugar beets and is not known to have any toxic property. Field observations of line GTSB77 revealed no negative effects on nontarget organisms. The lack of known toxicity for this enzyme suggests no potential for deleterious effects on beneficial organisms such as bees and earthworms. The high specificity of the enzyme for its substrates makes it unlikely that the introduced enzyme would metabolize endogenous substrates to produce compounds toxic to beneficial organisms. GTSB77 also contains a scoreable marker gene, ß-glucuronidase from the common enteric bacterium *Escherichia coli*. A truncated version of another enzyme involved in glyphosate tolerance, glyphosate oxidoreductase was also inserted into the sugar beet chromosome but expresses a nonfunctional enzyme. Both EPSPS and glyphosate oxidoreductase have received an exemption from tolerance requirement on all raw agricultural commodities (http://www.epa.gov/fedrgstr/EPA-PEST/1997/October/Day-08/p26190.htm and http://www.epa.gov/docs/fedrgstr/EPA-PEST/1996/August/Day-02/pr-840DIR/pr-840.html). APHIS has not identified any other potential mechanisms for deleterious effects on beneficial organisms. In addition, there is no reason to believe that the presence of line GTSB77 would harm any threatened or endangered species in the United States. APHIS could identify no threatened or endangered species that are associated with sugar beet plants.

Consideration Of Potential Environmental Impacts Associated With The Cultivation Of Line GTSB77 Outside the United States

Genetically engineered line GTSB77 sugar beet is no more likely to become a weed than herbicide tolerant cultivars currently in use or that can be developed by traditional breeding techniques. It is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which it may interbreed. It will not harm non-target organisms. Based on this analysis, APHIS concludes that there is no potential impact of line GTSB77 on biodiversity greater than currently available herbicide tolerant sugar beet plants.

Potential impacts on agricultural and cultivation practices.

Glyphosate, a non-selective herbicide, will provide control of most annual grass and broadleaf weeds in glyphosate resistant sugar beet. Glyphosate will control larger broadleaf weeds than currently available herbicides, thus allowing more application flexibility when environmental conditions prevent the timely application required by today's herbicides. In addition, glyphosate will provide a different herbicide mode of action in the growers' crop rotation, which is important in preventing the build up of herbicide resistant weeds. Glyphosate is applied like any other post emergent herbicide used in any other crop. Glyphosate tolerant sugar beet may alter current sugar beet cultivation practices in that it will allow for reduced herbicide use than currently is practiced in order to achieve the same crop yield.

Potential damage to raw or processed agricultural commodities.

Information provided by Novartis/Monsanto regarding the components and processing characteristics of these plants revealed no differences in any component that could have a direct or indirect plant pest effect on any raw or processed commodity. APHIS believes that the modifications for herbicide tolerance should not affect this commodity. in any significant manner.

VI. CONCLUSIONS

In accordance with the requirements of NEPA, APHIS has considered the potential for significant impact on the environment of a proposed action, i.e., reaching the determination that line GTSB77 sugar beets have no potential to present a plant pest risk and should no longer be considered a regulated article under the regulations at 7 CFR Part 340. After careful analysis of the available information, APHIS concludes that its proposed action should not have a significant impact on the environment and that the proper alternative is to approve the petition so that line GTSB77 would have a nonregulated status when grown in the United States and its territories.

1. Glyphosate tolerant sugar beets exhibit no plant pathogenic properties. Although phytopathogenic organisms were used in their development, these plants are not infected nor can they incite disease in other plants.

2. Glyphosate tolerant sugar beets are no more likely to become weeds than similar herbicide tolerant sugar beets developed by traditional breeding techniques. Sugar beets are not a major weed pest in the U.S. and there is no reason to believe that resistance to glyphosate would enable sugar beets to become a weed.

3. Gene introgression from these sugar beets into wild or cultivated sexually-compatible plants is likely. Even in the event of gene introgression, this should not increase the weediness potential of resulting progeny or have an adverse impact on biodiversity

different than similar herbicide tolerant sugar beets developed by traditional breeding techniques.

4. Except for being herbicide tolerant, these sugar beets are substantially equivalent to nontransgenic plants and, therefore, APHIS can foresee no adverse impacts on raw or processed agricultural commodities.

5. Glyphosate tolerant sugar beets exhibit no significant potential to either harm organisms beneficial to the agricultural ecosystem, to have an adverse impact on the ability to control nontarget insect pests, or to harm threatened and endangered species.

VII. REFERENCES.

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APPENDIX A

DETERMINATION OF NONREGULATED STATUS FOR TRANSGENIC GLYPHOSATE TOLERANT SUGAR BEET LINE GTSB77

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine
Scientific Services
Riverdale, Maryland

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) on reviewing the Novartis Seeds and Monsanto Company (Novartis/Monsanto) petition 98-173-01p, has concluded that the glyphosate-tolerant sugar beet designated as line GTSB77 and its progeny do not present a plant pest risk, and are, therefore, determined to be no longer regulated articles under regulations at 7 CFR part 340. The applicants are no longer required to obtain a permit or notify APHIS for the unrestricted introduction of line GTSB77 and its progeny lines into the environment within the continental United States and its territories. Exportation of such lines still will remain regulated according to Foreign Quarantine Notice regulations at 7 CFR part 319.

The Novartis/Monsanto petition was submitted to APHIS on June 22, 1998. On August 20, 1998, APHIS announced the receipt of the Novartis/Monsanto petition in the *Federal Register* (63 FR 44604-44605, Docket Number 98-079-1) seeking comments from the interested public. The public comment period ended on October 19, 1998. The Novartis/Monsanto petition sought regulatory relief for line GTSB77 and its progeny lines from the regulations at 7 CFR part 340. In the *Federal Register* notice, APHIS indicated its role in the process of reviewing the Novartis/Monsanto petition and the roles of other Federal agencies, such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in regulating glyphosate-tolerant sugar beet lines, food products derived from them, and the potential herbicide use of glyphosate on this line.

Line GTSB77 sugar beet has been engineered with a gene from *Agrobacterium sp.* that expresses 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) that encodes the glyphosate tolerance trait, ß-glucuronidase from common enteric bacterium *Escherichia coli,* and a truncated version of the glyphosate oxidoreductase (*gox*) gene from the bacterium *Ochrobactrum anthropii* that expresses a nonfunctional enzyme. These introduced genes also have accompanying DNA regulatory sequences that modulate their expression that are derived from the plant pests *A. tumefaciens*, cauliflower mosaic caulimovirus (CaMV), and figwort mosaic caulimovirus (FMV). The genes were introduced into these sugar beets via an *Agrobacterium*- mediated transformation protocol. This is a well-characterized procedure that has been widely used for over a decade for introducing various genes of interest directly into plant genomes.

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to the authority granted by the Federal Plant Pest Act (FPPA) as amended, (7 U.S.C. 150aa-jj) and the Plant Quarantine Act (PQA),as amended (7 U.S.C. 151-164a, 166-167) regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is not subjected to the regulatory oversight of 7 CFR part 340 when it is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition Process for Determination of Nonregulated Status," provides that a person may petition the Agency to evaluate the submitted data and determine that a particular regulated article does not present a plant pest risk and should no longer be regulated under 7 CFR part 340. If the Agency determines that the regulated article does not present a risk of introduction or

dissemination of a plant pest, the petition would be granted, thereby allowing for unregulated introduction of the article in question.

Line GTSB77 and its progeny have been considered "regulated articles" under 7 CFR part 340 because they contain components or DNA sequences from organisms considered to be plant pathogens, and are on the list of regulated articles (organisms). In this instance DNA sequences from well-known plant pathogens like *A. tumefaciens*, FMV, and CaMV have been used to create line GTSB77, rendering them to be regulated articles. Field tests of line GTSB77 have been conducted with APHIS approval since 1996. All field trials were performed under conditions of physical and reproductive confinement.

APHIS has determined that line GTSB77 does not present a plant pest risk and will no longer be considered a regulated article, under APHIS regulations at 7 CFR part 340. Based on an analysis of data provided to APHIS by Novartis/Monsanto, as well as other scientific data, the agency concluded that line GTSB77: (1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than other herbicide tolerant varieties developed by traditional plant breeding techniques; (3) is unlikely to increase the weediness potential of any other plant species with which it can interbreed; (4) will not cause damage to raw or processed agricultural commodities, and (5) is unlikely to harm other organisms, such as bees and earthworms, that are beneficial to agriculture, or threatened and endangered species.

The potential environmental impacts associated with this determination have been examined in accordance with regulations and guidelines implementing the National Environmental Policy Act of 1969, as amended (42 USC 4321 *et.seq.)* and pursuant implementing regulations (40 CFR 1500-1508, 7 CFR Part 1b; 7 CFR Part 372).

The body of this document consists of two parts: (1) background information which provides the regulatory framework under which APHIS has regulated the field testing, interstate movement, and importation of line GTSB77, as well as a summary of comments provided to APHIS on its proposed action and (2) analysis of the key factors relevant to APHIS decision that line GTSB77 does not present a plant pest risk.

II. BACKGROUND

A. APHIS regulatory authority.

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (FPPA), as amended (7 U.S.C. 150aa-150jj) and the Plant Quarantine Act (PQA), as amended (7 U.S.C. 151-164a, 166-167), regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. Under this regulation, a genetically engineered organism is deemed a regulated article either if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest; or if

APHIS has reason to believe that the genetically engineered organism presents a plant pest risk.

Before the introduction of a regulated article, a person is required under Section 340.0 of the regulations to either (1) notify APHIS in accordance with Section 340.3 or (2) obtain a permit in accordance with Section 340.4. Introduction under notification (Section 340.3) requires that the introduction meets specified eligibility criteria and performance standards. The eligibility criteria impose limitations on the types of genetic modifications that qualify for notification, and the performance standards impose limitations on how the introduction may be conducted. Under Section 340.4, a permit is granted for a field trial when APHIS has determined that the conduct of the field trial, under the conditions specified by the applicant or stipulated by APHIS, does not pose a plant pest risk.

An organism is not subject to the regulatory requirements of 7 CFR part 340 when it is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition Process for Determination of Nonregulated Status," provides that a person may petition the agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If the agency determines that the regulated article does not present a risk of introduction or dissemination of a plant pest, the petition will be granted, thereby allowing for unregulated introduction of the article in question. A petition may be granted in whole or in part.

B. EPA and FDA regulatory authority

Line GTSB77 is currently subject to regulations administered by the EPA or the FDA as described in the Environmental Assessment. Novartis/Monsanto has successfully completed their consultation process with FDA on food and feed safety for this transgenic sugar beet.

C. Rationale for Developing Glyphosate tolerant Sugar Beets

The management of weeds is an expensive, labor intensive, and sometimes complicated operation. Glyphosate tolerant sugar beets will offer farmers a new option in controlling weeds. Often farmers use pre-emergent herbicides that will stop weeds seeds from germinating. However, this assumes that weeds will always be a problem in all parts of the field. With GTSB77, farmers will have the option of applying herbicide after weeds have germinated and only in the areas of the field where there are weeds. Applications in this manner may reduce the amount of pre emergent herbicide used on sugar beets. Glyphosate may also control certain weeds that are not effectively control by currently registered herbicides. Glyphosate is one of the most environmentally friendly herbicides.

III. PUBLIC COMMENTS

APHIS received one favorable comment on this petition.

IV. ANALYSIS OF THE PROPERTIES OF GLYPHOSATE TOLERANT SUGAR BEETS

A. The introduced genes, their products, and the added regulatory sequences controlling their expression do not present a plant pest risk in Line GTSB77

Line GTSB77 was produced using an *Agrobacterium*-meditated transformation protocol to transform *B. vulgaris* subsp. *vulgaris* A1012. This technique is well studied (Klee and Rogers, 1989; and Zambryski, 1988). Transformed material was treated with chemicals and checked to ensure that *Agrobacterium* was not present.

The EPSPS gene codes for an enzyme that catalyzes the conversion of shikimate-3-phosphate and phosphoenolpyruvate into 5-enolpyruvlshikmate-3-phosphate, an intermediate in the production of aromatic amino acids. This enzyme is present in many plants and microorganisms. The enzyme used here is insensitive to the herbicide glyphosate unlike the EPSPS that is found in sugar beets. The original sequence from *Agrobacterium* was modified to create a synthetic gene that allows higher expression of bacterial gene sequences in plants. The EPSPS present in sugar beet line GTSB77 is functionally and structurally similar to EPSPS protein present in food and feeds derived from plant and microbial sources. Comparing the deduced amino acid sequences of EPSPS from *Agrobacterium sp.* with EPSPS from soybean, corn, petunia, *E. coli*, *Bacillus subtilis*, and *Saccharomyces cerevisiae* (Baker's Yeast) yield amino acid similarities in the range of 48.5 to 59.3% and identities in the range of 23.2 to 41.4% (Padgette et al. 1996). The amino acid homologies observed between CP4 EPSPS and EPSPSs present in plants and bacteria is comparable to the homology between the EPSPSs from, for instance, soybean and *B. subtilis* (55.6 similar, 30.1% identical). Thus, while there is some sequence diversity in EPSPSs typically found in food and feed, the sequence variation between the EPSPS in GTSB77 and EPSPSs found in currently available food or feed is of the same magnitude (Padgette et al. 1996).

Data provided by Novartis/Monsanto demonstrate that line GTSB77 contains the following sequences: (1) the 5-enolpyruvalshikimate-3-phosphate synthase gene from *A. tumefaciens* whose transcription is directed by the figwort mosaic virus promoter (Gownda *et al.*, 1989), a chloroplast transit peptide from *Arabidopsis thialiana*, and whose termination/polyadenylation sequences were derived from the ribulose biphosphate carboxylase gene from pea (Coruzzi *et al*, 1984); (2) the β-glucuronidase gene from *E. coli* whose transcription is directed by the enhanced CaMV promoter (Kay *et al.*, 1985) and the same pea terminator sequences used for the EPSPS gene; and (3) a truncated version of the glyphosate oxidoreductase gene from *O. anthropi* whose transcription is directed by the figwort mosaic promoter and chloroplast transit peptide sequences that are described above. This gene was inserted in an open reading frame of an uncharacterized plant gene resulting in the synthesis of a new protein that has a molecular weight of 35,000. Also, inserted is the right border sequence from *A. tumefaciens*.

Novartis/Monsanto presented data that the following sequences that were present in the original plasmid in *Agrobacterium* were not present in GTSB77: the *aad* gene that confers resistance to the antibiotic streptomycin, neomycin phosphotransferase that confers resistance to kanamycin/neomycin, and *oriV/ori* 322 both involved in plasmid replication in *Agrobacterium*.

Although pathogenic organisms were used in the development of line GTSB77, these sugar beet plants are not infected nor can they incite disease in other plants.

B. line GTSB77 Sugar Beet Has No Significant Potential To Become A Weed Nor Increase The Weediness Potential Of Any Other Plant With Which It Can Breed.

Sugar beets, *B. vulgaris* subsp. *vulgaris*, are a member of the family *Chenopodiaceae* which also includes the leaf beet (Swiss chard), and the red table beet (fodder beet), from which the sugar beet was derived (Hymowitz and Singh 1987; Cooke and Scott, 1993). Members of this family are dicotyledonous and usually herbaceous in nature. Sugar beets are grown world wide. Sugar beet is largely wind pollinated. It is normally a biennial and develops a large succulent root the first year and a seed stalk the second. However, certain conditions such as low temperatures after planting and longer day length can cause the sugar beet to "bolt" or produce a seed stalk during the first growing season (Bell, 1946; Jaggard *et al.*, 1983; Durrant and Jaggard, 1988).

Data provided in the petition indicate that the applicant has not observed any significant changes in the number of seeds produced, germination characteristics, final stand, over-wintering capability, or pathogen susceptibility. Thus, APHIS believes that the weediness characteristics of GTSB77 are unchanged from its parental line.

The genus *Beta*, including the wild relatives, is divided into four sections (Smith, 1987, Panella, 1996): Section Beta: *B. vulgaris* subsp. *vulgaris*, subsp. *maritima* L.,subsp. *atriplicofolia*, subsp. *macrocarpa* , subsp. *orientalis*, and subsp. *patula*: Section Corollinae: *B. lomatogona*, *B. trigyna*, *B. corolliflora*, *B. macrochiza*, *B.* foliosa, and *B. intermedia*; and Section Procumbentes: *B. patellaris*, *B. procumbens*, *B. webbiana*, and Section Nanae: *B. nana*. Sugar beet hybridizes freely with all members of the section *Beta* and the resulting progeny are fully fertile. Hybrids between sugar beet and members of the other three section do not naturally occur without human intervention. Artificial hybrids can be produced with difficulty with species in Section *Corollinae*; however, such hybrids are highly sterile and set few seeds when back crossed to sugar beet. Hybrids between sugar beet and Section *Procumbentes* members normally die at the seedling stage. No hybrids between cultivated beets and *B. nana* have been reported. Therefore, crosses between cultivated sugar beet and species from Sections other than Beta are highly improbable.

Almost all definitions of weediness stress as core attributes the undesirable nature of weeds from the point of view of humans; from this core, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980). In further analysis of weediness, Baker (1965) listed 12 common weed attributes, almost all pertaining to sexual and asexual reproduction, which can be used as an imperfect guide to the likelihood that a plant will behave as

a weed. Keeler (1989) and Tiedje *et al.* (1989) have adapted and analyzed Baker's list to develop admittedly imperfect guides to the weediness potential of transgenic plants; both authors emphasize the importance of looking at the parent plant and the nature of the specific genetic changes. According to Holm *et al.* (1979; 1991), *B. vulgaris* (subspecies not given) are classified as occasional to serious weeds in the following countries: Afghanistan, Australia, Mexico, Morocco, the United States, Iraq, Isreal, Portugal, and Egypt. Subsp. *martima* (wild sea beet) is a problem weed in coastal regions of the Mediterranean Sea and North Sea in Europe and in Asia. Subsp. *macrocarpa* and hybrids between it and commercial sugar beets are also a weed problem in production fields (Hulten and Fries, 1986)

Movement of the transgenes via pollen from line GTSB77 to other members of the Beta section is species specific. Movement of the transgenes to *B. vulgaris* subsp. *atriplicofolia*, , subsp. *orientalis*, subsp. maratima, and subsp. *patula* is not likely since these plants are not found in the Americas. Movement of the transgenes from GTSB77 potentially sexual compatible species is likely in two localities. Sugar beet plants escaped from past commercial cultivation in the San Francisco Bay area and persist to this day. However, sugar beets are no longer in commercial production in the Bay area, and thus transgene movement via pollen to these plants is highly unlikely.

The situation in the Imperial Valley of California is more complicated. There are free living sugar beets that have escaped cultivation and have persisted (Mc Farlane, 1975; Johnson and Burtch, 1958). These plants are a minor weed problem in this area. Movement of the transgenes from GTSB77 to these plants is likely. The other plant in the Imperial Valley that commercial sugar beets could potentially successfully pollinate is subsp. *macrocarpa*. There appears to be conflicting evidence on whether commercial sugar beets can pollinate subsp. *macrocarpa*. Bartsch *et al.* (1996) has suggested based on isozyme analysis that introgression of genes from commercial sugar beets has occurred. Lee Panella of the Sugar Beet Crop Germplasm Committee provided two lines of evidence that gene flow between these two plant populations is not likely. First, commercial sugar beets and subsp. *macrocarpa* flower at different times. Second, in greenhouse crosses between these plants, most F_1 hybrids are sterile and the F_2 hybrids had very disturbed growth patterns and genetic ratios. In greenhouse crosses, successful hybrids occurred only when sugar beets were the female parent.

Some scientists (Boudry *et* al., 1993; Bartsch and Pohl-Orf, 1996) have questioned whether movement of herbicide tolerance genes from commercial sugar beets to sexually compatible relatives poses an environmental risk. APHIS believes that if and when the glyphosate tolerance trait moves from GTSB77 to other sexually compatible *Beta sp.* this will not have a significant impact. If glyphosate tolerant individuals did arise through interspecific or intergeneric hybridization, the tolerance would not confer any competitive advantage to these plants unless challenged by glyphosate. This would only occur in managed ecosystems where glyphosate is applied for broad spectrum weed control, or in plant varieties developed to exhibit glyphosate tolerance and in which glyphosate is used to control weeds. As with glyphosate tolerant sugar beet volunteers, these individuals, should they arise, would be controlled using other available

chemical means. Hybrids, if they developed, could potentially result in the loss of glyphosate as a tool to control these species. However, this can be avoided by the use of sound crop management practices by not using the same herbicide every year.

Thus, APHIS concludes from the data generated in greenhouse and field trials that the glyphosate tolerant sugar beet has little potential to become a serious or successful weed or increase the weediness of any sexually compatible plants.

D. Line GTSB77 Sugar Beet Will Not Cause Damage To Raw Or Processed Agricultural Commodities.

Information provided by Novartis/Monsanto regarding the components and processing characteristics of line GTSB77 lines revealed no differences in any component that could have a direct or indirect plant pest effect on any raw or processed commodity. APHIS believes that the modifications for herbicide tolerance should not affect this commodity in any significant manner.

E. Line GTSB77 Sugar Beet Is Not Harmful To Beneficial, Threatened or Endangered Organisms.

There is no reason to believe that deleterious effects on beneficial organisms could result from the cultivation of line GTSB77. The EPSPS expressed in line GTSB77, is not known to have any toxic properties. Field observations of line GTSB77 lines revealed no negative effects on nontarget organisms, suggesting that enzyme in the tissues of the line is not toxic to beneficial organisms. Knowledge of this enzyme's mode of action, and the lack of known toxicity for this protein suggest no potential for deleterious effects on beneficial organisms, such as bees and earthworms. The high specificity of EPSPS for its substrate makes it unlikely that EPSPS would metabolize endogenous substrates to produce compounds toxic to beneficial organisms. APHIS has not identified any other potential mechanisms for deleterious effects on threatened or endangered organisms. No *Beta* sp. that is sexually compatible with GTSB77 is on the threatened and endangered list (http://www.fws.gov/r9endspp/plt1data.html). There are no threatened and endangered species associated with sugar beet plants that could affected (http://www.fws.gov/r9endspp/clams.html#Lnk1). APHIS would like to note that EPA concluded that establishment of a tolerance for this EPSPS in all plants is not necessary to protect the public health (http://www.epa.gov/docs/fedrgstr/EPA-PEST/1996/August/Day-02/pr-840DIR/pr-840.html) and that Novartis/Monsanto has successfully concluded their consultation with the FDA for line GTSB77 (http://vm.cfsan.fda.gov/~lrd/biocon.html).

The fusion protein of glyphosate oxidoreductase and the plant protein is unlikely to pose any risk. First, the amount of this protein produced is low amounts (approximately 4 nanograms per milligram of fresh plant tissue), it has no enzymatic activity, and the protein it is fused to is a normal constituent of sugar beets. APHIS would like to note that glyphosate oxidase has been granted an exemption from tolerance requirement on all raw agricultural commodities

(http://www.epa.gov/fedrgstr/EPA-PEST/1997/October/Day-08/p26190.htm). The scoreable marker protein, β-glucuronidase, is well characterized protein with no known toxicity.

F. Line GTSB77 Sugar Beet Will Not Adversely Impact Biodiversity.

As detailed in the sections above, we have concluded that line GTSB77 sugar beet is no more likely to become a weed than other herbicide tolerant sugar beet varieties developed by traditional breeding. It is unlikely to increase the weediness potential of any other cultivated plant or native wild species with which this line may interbreed. In the absence of herbicide treatment, viable offspring produced from transgenic pollen flow from line GTSB77 to weedy relatives would have no fitness enhancement over current populations of wild or weedy beets which occur naturally (Purrington and Bergelson, 1977). The glyphosate tolerance trait when present in line GTSB77 sugar beet or in any other sexually compatible species would confer no competitive advantage in unmanaged environments, and thus is not expected to have an ecological impact. Based on this analysis, APHIS concludes that the potential impact on biodiversity of line GTSB77 sugar beet is equivalent to that of currently commercialized herbicide tolerant sugar beet varieties.

G. Line GTSB77 Sugar Beet Will Not Adversely Affect Current Agricultural Practices

Glyphosate, a non-selective herbicide, will provide control of most annual grass and broadleaf weeds in glyphosate resistant sugar beet. Glyphosate will control larger broadleaf weeds than currently available herbicides, thus allowing more application flexibility when environmental conditions prevent the timely application required by today's herbicides. In addition, glyphosate will provide a different herbicide mode of action in the growers' crop rotation, which is important in preventing the build up of herbicide resistant weeds. Glyphosate is applied like any other post emergent herbicide used in any other crop. Glyphosate tolerant sugar beet may alter current sugar beet cultivation practices in that it will allow for reduced herbicide use than currently is practiced in order to achieve the same crop yield.

VI. CONCLUSION

APHIS has determined that line GTSB77 developed by Novartis/Monsanto will no longer be considered a regulated article under APHIS regulations at 7 CFR part 340. Permits or notifications under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of line GTSB77 or their progeny. Importation of line GTSB77 lines and nursery stock or seeds capable of propagation is still, however, subject to the restrictions found in the Foreign Quarantine notice regulations at 7 CFR Part 319, just as it applies to any other importation of sugar beet seed. This determination has been made based on data collected from these approved field trials, laboratory analyses and literature references presented herein which demonstrate that:

1. Glyphosate tolerant sugar beets exhibit no plant pathogenic properties. Although phytopathogenic organisms were used in their development, these plants are not infected nor can

they incite disease in other plants.

2. Glyphosate tolerant sugar beets are no more likely to become weeds than similar herbicide tolerant sugar beets developed by traditional breeding techniques. Sugar beets are not a major weed pest in the U.S. and there is no reason to believe that resistance to glyphosate would enable sugar beets to become a weed.

3. Gene introgression from these sugar beets into wild or cultivated sexually-compatible plants is likely. Even in the event of gene introgression, this should not increase the weediness potential of resulting progeny or have an adverse impact on biodiversity different than similar herbicide tolerant sugar beets developed by traditional breeding techniques.

4. Except for being herbicide tolerant, these sugar beets are substantially equivalent to nontransgenic plants and, therefore, APHIS can foresee no adverse impacts on raw or processed agricultural commodities.

5. Glyphosate tolerant sugar beets exhibit no significant potential to either harm organisms beneficial to the agricultural ecosystem, to have an adverse impact on the ability to control nontarget insect pests, or to harm threatened and endangered species.

APHIS has also concluded that there may be new varieties bred from line GTSB77. However, if such varieties are developed they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for GTSB77 during field testing or those observed for herbicide tolerant sugar beet varieties developed from traditional breeding.

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