Notices

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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. 96–019–2]

AgrEvo USA Company; Availability of Determination of Nonregulated Status for Soybeans Genetically Engineered for Glufosinate Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that certain soybean lines developed by AgrEvo USA Company that have been genetically engineered for glufosinate herbicide tolerance are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by AgrEvo USA Company in its petition for a determination of nonregulated status, an analysis of other scientific data, and our review of comments received from the public in response to a previous notice announcing our receipt of the AgrEvo USA Company's petition. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: July 31, 1996.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and all written comments received regarding the petition 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.

FOR FURTHER INFORMATION CONTACT: Dr. Sivramiah Shantharam, Biotechnology Permits, BBEP, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1237; (301) 734–7612. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734–7612; E-mail: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On March 8, 1996, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 96–068–01p) from AgrEvo USA Company (AgrEvo) of Wilmington, DE, seeking a determination that Glufosinate Resistant Soybean (GRS) Transformation Events W62, W98, A2704–12, A2704–21, and A5547–35 that have been genetically engineered for resistance, or tolerance, to the herbicide glufosinate, do not present a plant pest risk and, therefore, are not regulated articles under APHIS' regulations in 7 CFR part 340.

On April 29, 1996, APHIS published a notice in the Federal Register (61 FR 18718–18719, Docket No. 96–019–1) announcing that the AgrEvo 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 soybean lines and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether these soybean lines posed a plant pest risk. The comments were to have been received by APHIS on or before June 28, 1996.

During the designated 60-day comment period, APHIS received eight comments on the subject petition from universities, cooperative extension service research centers, and a seed company. All of the comments were favorable to the petition.

Analysis

GRS Transformation Events W62 and W98 have been genetically engineered to contain the *bar* gene derived from *Streptomyces hygroscopicus* and the *gus* marker gene derived from *Escherichia coli*. The *bar* gene encodes the enzyme phosphinothricin-N-acetyltransferase (PAT), which confers tolerance to glufosinate. Expression of the added genes is controlled in part by gene sequences from the plant pathogens *Agrobacterium tumefaciens*, alfalfa mosaic virus, and cauliflower mosaic virus (CaMV). GRS Transformation Events A2704–12, A2704–21, and A5547–35 contain a synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes*, which encodes the PAT enzyme and confers tolerance to glufosinate. Expression of the synthetic *pat* gene is controlled by a 35S promoter and terminator derived from CaMV. The particle acceleration method was used to transfer the added genes into the GRS parental soybean cultivars.

The subject GRS Transformation Events have been considered regulated articles under APHIS' regulations in 7 CFR part 340 because they contain gene sequences derived from plant pathogens. However, evaluation of field data reports from field tests of these lines conducted under APHIS permits or notifications indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of the soybean lines.

Determination

Based on its analysis of the data submitted by AgrEvo and a review of other scientific data, comments received, and field tests of the subject soybean lines, APHIS has determined that GRS Transformation Events W62, W98, A2704–12, A2704–21, and A5547–35: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weeds than soybean lines developed by traditional breeding techniques; (3) are unlikely to increase the weediness potential for any other cultivated or wild species with which they 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. Therefore, APHIS has concluded that the subject soybean lines and any progeny derived from hybrid crosses with other nontransformed soybean varieties will be as safe to grow as soybeans in traditional breeding programs that are not subject to regulation under 7 CFR part 340.

The effect of this determination is that AgrEvo's GRS Transformation Events W62, W98, A2704–12, A2704–21, and

A5547–35 are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the field testing, importation, or interstate movement of the subject soybean lines or their progeny. However, importation of the subject soybean lines 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)(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 AgrEvo's GRS Transformation Events W62, W98, A2704–12, A2704–21, and A5547–35 and lines developed from them 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 13th day of August 1996.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–20921 Filed 8–15–96; 8:45 am]

BILLING CODE 3410–34–P

AgrEvo USA Company Petition 96-068-01p for Determination of Nonregulated Status for Transgenic Glufosinate Resistant Soybean (GRS) Lines W62, W98, A2704-12, A2704-21, and A5547-35

Environmental Assessment and Finding of No Significant Impact

July 1996

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 96-068-01p) received from AgrEvo USA Company (AgrEvo) seeking a determination of non-regulated status for their genetically engineered glufosinate resistant soybean (GRS) lines W62, W98, A2704-12, A2704-21, and A5547-35 under APHIS regulations at 7 CFR Part 340. The plants have been engineered with a gene that confers resistance to the phosphinothricin herbicide, glufosinate. 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 GRS lines and their progeny.

Arnold S. Foudin - for John H. Payne

John H. Payne, Ph.D.
Acting Director
Biotechnology, Biologics,
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Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: JUL 31 1996

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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 96-068-01p) from AgrEvo USA Company (AgrEvo) seeking a determination of non-regulated status for their transgenic glufosinate resistant soybean (GRS) lines W62, W98, A2704-12, A2704-21, and A5547-35. AgrEvo seeks a determination that GRS lines do not present a plant pest risk and, therefore, are no longer regulated articles under regulations at 7 CFR Part 340. GRS lines W62 and W98 have been genetically engineered to express the *bar* gene originally isolated from *Streptomyces hygroscopicus* that confers tolerance to the application of the phosphinothricin class of herbicides by coding for a phosphinothricin-N-acetyltrasferase (PAT) enzyme which catalyzes the conversion of the active ingredient Glufosinate-Ammonium to the inactive form L-phosphinothricin. In addition, GRS lines W62 and W98 also express a selectable marker gene, *gus*, coding for ß-glucuronidase. GRS lines A2704-12, A2704-21, and A5547-35 express the *pat* gene which is a synthetic version of the PAT coding gene originally isolated from *S. viridochromogenes*. The *gus* gene expressed only in W62 and W98 lines was originally isolated from *Escherichia coli*.

AgrEvo submitted its petition after numerous field tests of GRS lines at 197 sites throughout the continental United States under 8 permits and 26 notifications. Field trial reports from these tests demonstrate that the transformed lines had no deleterious effects on plants, did not exhibit weedy characteristics, and had no effect on nontarget organisms or the general environment.

An Environmental Assessment (EA) was prepared prior to granting field test permits involving the GRS lines. The EA for the previous introductions of GRS lines addressed plant pest risk issues relative to the conduct of field trials under physical and reproductive confinement. This EA specifically addresses the potential impacts of the

GRS lines to the human environment through the unrestricted use in agriculture. The U.S. Environmental Protection Agency (EPA) has the authority over the potential uses of the herbicide glufosinate (Basta®, Ignite®, Rely®, Liberty®, Harvest®, and Finale®) in conjunction with GRS lines through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

APHIS has considered the information provided by AgrEvo in its petition as well as other scientific data, information, and comments received from the public relating to potential plant pest risk and related environmental impacts of the GRS lines. A thorough evaluation of the potential for significant impact to the human environment through the unconfined, agricultural use of GRS lines resulted in a Finding of No Significant Impact (FONSI) by APHIS. This conclusion is based upon (1) the nature of the genetic modification; (2) the fact that soybean has no weedy relatives with which it can interbreed in the United States and its territories; and (3) the fact that this modification will not increase the weediness potential of the soybeans or negatively affect any nontarget organisms, including beneficials. In conjunction with the FONSI, APHIS has made the determination that GRS lines and their progeny have no potential to pose a plant pest risk and are, therefore, determined to be no longer regulated articles according to 7 CFR 340.

II. INTRODUCTION

This EA examines potential environmental impacts from the unrestricted introduction of GRS lines. GRS lines have been field tested under permits since 1990 and notifications since 1993. The genetic material introduced into these lines has been discussed in detail in the EA prepared for field tests under APHIS permits, 90-274-05r, 91-051-03r, 91-203-01r, 92-043-02r, 92-043-03, 93-090-01r, 93-047-02r, and 93-047-03r. AgrEvo based its petition, in part, on the data gathered from these trials. Field trial reports from these tests demonstrate no deleterious effects on plants, nontarget organisms, or the

environment as a result of these field releases. All field trials were performed under conditions of physical and reproductive confinement. Further discussions of the biology of soybean, as well as of the genetic components of GRS lines, are found in the determination document (Appendix A). Because this information is included in Appendix A, it will not be described in detail in the body of this document.

Prior to issuing a permit for a field release, APHIS analyzes the potential impacts associated with the proposed introduction and prepares an environmental assessment that documents the environment analysis in accordance with regulations and guidelines implementing the National Environmental Policy Act (NEPA) of 1969 (42 USC 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372). APHIS also evaluates cumulative impact to the human environment from its determination of nonregulated status.

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. The transgenic soybean plants described in the AgrEvo petition have been considered regulated articles because they contain certain noncoding regulatory sequences (DNA) derived from known plant pathogens listed in 7 CFR Part 340.

III. PURPOSE AND NEED

The purpose of this EA is to ascertain whether the approval of a petition submitted to USDA/APHIS for the determination of nonregulated status of GRS lines (that would allow their unconfined introduction into the environment) will present any plant pest risk or have any significant impact on the environment.

A petition was submitted to APHIS pursuant to regulations codified in 7 CFR Part 340 entitled "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests." The regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. 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 to seek a determination 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 would be approved for the unregulated introduction (importation, inter-state movement, and release into the environment) of the articles or their progeny in question without any permit from USDA, APHIS. Normal agronomic practices with these lines, e.g., cultivation, propagation, movement, and cross-breeding could then be conducted without further APHIS approval.

Effects associated with the potential uses of the herbicide glufosinate in conjunction with GRS lines are outside the scope of the regulatory authority of APHIS. APHIS determination does not constitute authorization to use glufosinate on GRS lines. The EPA has authority over the use in the environment of pesticidal substances, including herbicides, under FIFRA; specifically, EPA has jurisdiction over registration of glufosinate for use on GRS soybeans. EPA considers both human health and safety as well as nontarget effects of the herbicide and its breakdown products in making a decision on registration of a herbicide.

that glufosinate resistant biotypes of soybean weeds are unlikely to appear under field conditions should there be an excessive use of the herbicide.

No other variation seen in GRS lines is indicative of increased weediness. AgrEvo data from greenhouse studies, included as part of the administrative record for the petition, show no significant differences between the mean germination rate percentage for GRS lines and the parental variety. In addition, AgrEvo field data reports showed no volunteers from seed, regrowth from stubble, or increase in seed dormancy.

Potential Impacts From Outcrossing Of GRS Lines To Wild Relatives

There are no relatives of cultivated soybean in the continental United States. However, some members of the wild perennial species of subgenus *Glycine* may be found in United States territories in the Pacific (Hermann, 1962; Hymowitz and Singh, 1987; Newell and Hymowitz, 1978). The subgenus *Glycine* consists of wild perennial species. Soybeans are almost exclusively self-pollinating plants. Inter-subgeneric hybrids between *G. max* and *Glycine* species have been obtained only through *in vitro* seed culture (reviewed by Hymowitz et al., 1992, and Hymowitz and Singh, 1987). Hybrids from such crosses have generally been sterile, and further progeny have only been obtained with extreme difficulty. The formation of hybrids between GRS lines and *Glycine* species in nature is, therefore, highly unlikely.

Crosses between the annuals *G. max* and *G. soja* in the subgenus *Soja* can be made easily. The latter species is found in China, Korea, Japan, Taiwan, and the former USSR. However, even if both species are found growing together in any United States territory, flower development in cultivated soybeans leads to a high percentage of self-fertilization (Carlson and Lersten, 1987; McGregor, 1976), and no competitive advantage would be conferred on any hybrid progeny in the absence of sustained glufosinate use (selection pressure).

Even if wild *Glycine* populations were near sites of commercial soybean production, it is highly unlikely that pollen from GRS lines would fertilize the wild relatives because soybeans are: (1) not wind-pollinated; and (2) almost completely self-pollinated. Certified Seed Regulations (7 CFR 201.76) recognize this low probability of cross-pollination in the safeguards set up for Foundation, Registered, and Certified seed. For Foundation Seed, the most stringent category in the Certified Seed Regulations, soybeans are permitted to be grown close to the nearest contaminating source (i.e. other soybean cultivars), as long as the distance is adequate to prevent mechanical mixing. Even if cross-pollination occurred, there would be no significant impacts because any potential effect of the trait would not alter the weediness potential of the wild soybean in the absence of sustained glufosinate use.

Potential Impact On 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 GRS lines. The enzyme that confers glufosinate resistance in GRS soybean lines is normally not present in soybeans and is not known to have any toxic property. Field observations of GRS lines revealed no negative effects on nontarget organisms, suggesting that the relatively higher levels of the enzyme in the tissues of GRS lines are not toxic to 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. 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 GRS lines would have an effect on any threatened or endangered species in the United States.

IV. ALTERNATIVES

In the course of preparing the environmental assessment for the AgrEvo petition, APHIS considered the following three alternatives: (1) deny the petition, so that GRS lines would continue to be regulated under 7 CFR Part 340; (2) approve the petition, with geographical limitations; and/or (3) approve the petition so that GRS lines would no longer be regulated when grown in the United States and its territories. Based on the biology of soybean, the nature of the genetic change, data and information presented by AgrEvo, scientific literature, and information and comment provided by the public, APHIS could find no basis for denying the petition (Alternative 1) or for imposing geographical limitations on the use of GRS lines (Alternative 2).

V. POTENTIAL ENVIRONMENTAL IMPACTS

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

Potential Impacts Based On Increased Weediness Of GRS Lines Relative To Traditionally Bred Soybeans

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, *Glycine max*, does not show any especially weedy characteristics. The genus *Glycine* also seems to be essentially devoid of such characteristics and show no particular weedy (aggressive colonization) tendencies (Hermann, 1962; Lackey, 1981; personal communication, Lackey; Skvortzov, 1927). The standard texts and lists of weeds give no indication that the cultivated soybean, *G. max*, is regarded as a weed anywhere (Holm et al., 1979; Muenscher, 1980; Reed, 1970; Weed Science Society of America, 1989). Only the nearest wild relative of cultivated soybean, *G. soja*, is listed as a common weed in Japan by Holm et al. (1979). However, texts on weeds found in Japan place it neither among the harmful weeds on cultivated lands (Kasahara, 1982), nor among the weeds of pastures and meadows (Nemoto, 1982). In addition, *G. gracilis*, known from Northeast China and described as a weedy form (Lackey, 1981) somewhat intermediate between *G. max* and *G. soja* (Skvortzov, 1927), is not listed in any texts or lists of weeds.

The introduced glufosinate resistance trait is unlikely to cause or increase weediness of GRS soybeans. Glufosinate resistance phenotype of GRS lines of soybean does not warrant that these lines require application of the herbicide for their growth. Glufosinate would be applied on GRS lines cultivating fields for the purpose of controlling the weeds that are sensitive to the application of the herbicide. To increase weediness of the soybean plant there would have to be selection pressure on GRS lines (Tiedje et al., 1989; Office of Technology Assessment, 1988) in association with the use of the herbicide glufosinate. Because the application of glufosinate herbicide will not kill the GRS lines and *G. max* is not itself a weed, there is no likelihood of converting the transgenic soybeans into weeds. Even if such glufosinate tolerant weedy plants did exist, glufosinate treatment would not be the control method of choice; alternative methods of control are readily available including roging and other current chemical control methods for weeds in soybean fields. It is important to note that efforts by the petitioner to generate glufosinate resistant soybean cell lines in tissue culture using unusually high doses of the herbicide were never successful, suggesting

Consideration Of Potential Environmental Impacts Associated With The Cultivation Of GRS Lines Outside The United States

In accordance with Executive Order 12114, January 4, 1979, entitled "Environmental effects abroad of major federal actions," APHIS has also considered potential environmental impacts associated with the cultivation of GRS lines outside the United States and its territories.

Our analysis of the biology of soybean leads to the conclusion that the cultivation of GRS lines anywhere in the world will not have an adverse impact on the environment. The GRS lines show no significant differences from its parent line, in all avenues investigated, except for its production of a phosphinothricin-N-acetyltransferase (PAT), and ß-glucuronidase (GUS) enzymes.

Several factors contribute to the conclusion that there should be no environmental impacts in foreign countries from the cultivation of this soybean line or its progeny.

Any international trade in GRS lines of soybeans subject to this determination would be fully subject to national and regional phytosanitary standards promulgated under the International Plant Protection Convention (IPPC) of the Food Agricultural Organization. IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (98 countries as of December 1992). The treaty, administered by a Secretariat housed with the Food and Agriculture Organization in Rome, came into effect on April 3, 1952, and establishes standards to facilitate the safe movement of plant materials across international boundaries. Plant biotechnology products are fully subject to national legislation and regulations or regional standards and guidelines

promulgated under the IPPC. The IPPC also has led to the creation of Regional Plant Protection Organizations (RPPOs) to facilitate regional harmonization of phytosanitary standards.

Issues that may relate to commercialization of agricultural commodities produced through biotechnology are being addressed in international fora. APHIS has played a leading role in working toward harmonization of biosafety and biotechnology guidelines and regulations included within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States. NAPPO's Biotechnology Panel advises NAPPO on biotechnology issues as they relate to plant protection.

APHIS participates regularly in biotechnology policy discussions at fora sponsored by the European Union and the Organization for Economic Cooperation and Development. In addition, APHIS periodically holds discussions on biotechnology regulatory issues with other countries. APHIS also assists in the development of biotechnology guidelines and regulations and has interacted with governments around the world in this matter, including those in regions where soybean originated or is cultivated in significant quantities. APHIS has participated in numerous conferences intended to enhance international cooperation on safety in biotechnology and has sponsored several workshops on safeguards for planned introductions of transgenic crops (crucifers, maize, wheat, potatoes, rice, tomatoes, and sorghum), most of which have included consideration of international biosafety issues.

In addition to the assurance provided by the analysis leading APHIS to a finding of no significant impact for the introduction of this soybean variety, it should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally apply equally to those covered by this determination.

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 GRS lines 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 GRS lines would have a nonregulated status when grown in the United States and its territories. APHIS has identified no factors that would suggest any impact to the environment of the United States and its territories. While isolated environments, such as are found in Hawaii, Puerto Rico, or in territories or possessions of the United States, have fragile ecologies that have frequently been damaged through human intervention, APHIS has determined that in these environments GRS lines will have impacts no different from traditional soybean varieties that are not subject to petition requirements under 7 CFR Part 340 before they enter agriculture. This conclusion is based on factors discussed herein or in the determination included as appendix A, as well as the following factors:

1. Neither the glufosinate resistance gene nor its product, the associated marker gene, or the regulatory sequences confer on GRS lines or their progeny any plant pest characteristic. Either a *pat* or a *bar* gene that confers tolerance to the herbicide glufosinate has been inserted into a soybean chromosome in GRS soybean lines. In nature, chromosomal genetic material from plants can only be transferred to another sexually compatible flowering plant by cross-pollination. There are no other sexually compatible species of soybeans in nature in the United States and its territories.

2. The gene that confers tolerance to the herbicide, glufosinate, will not provide GRS lines or their progeny with any measurable selective advantage over nontransformed

soybean plants in their ability to disseminate or to become established in the environment. There is no reason to believe that GRS lines exhibit any increased weediness relative to that of traditional varieties or the unmodified parental lines.

3. There is no reason to believe that the use of GRS lines or their progeny in agriculture will have a significant impact on any beneficial organisms in the environment or on any threatened or endangered species.

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VIII. PREPARERS AND REVIEWERS

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DETERMINATION OF NONREGULATED STATUS FOR TRANSGENIC GLUFOSINATE RESISTANT SOYBEAN (GRS) LINES W62, W98, A2704-12, A2704-21, AND A5547-35

Petitioner: AgrEvo USA Company, Wilmington, Delaware
Petition Number: 96-068-01p

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology, Biologics, and Environmental Protection
Riverdale, Maryland

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I. SUMMARY

Based on a review of AgrEvo USA Company's petition 96-068-01p, the Animal and Plant Health Inspection Service (APHIS) has determined that the glufosinate resistant soybean (GRS) lines W62, W98, A2704-12, A2704-21, and A5547-35 do not present any plant pest risk and are, therefore, determined to be no longer regulated articles under its regulations at 7 CFR Part 340. As such, the applicant is no longer required to obtain a permit or notify APHIS for the unrestricted introduction of GRS lines into the environment within the continental United States and its territories. Importation of GRS lines still will remain regulated according to Foreign Quarantine Notice regulations at 7 CFR 319. Variety registration and/or seed certification of GRS lines of soybean may involve future actions by the U. S. Plant Variety Protection Office and State Seed Certification officials.

The AgrEvo petition was submitted to APHIS on March 8, 1996. On April 29, 1996, APHIS announced the receipt of the AgrEvo petition in the Federal Register 61 FR 18718-18719, Docket Number 96-019-1 seeking comments from the interested public. The public comment period ended on June 28, 1996. The AgrEvo petition sought regulatory relief for its GRS lines from the regulations at 7 CFR 340. In the Federal Register notice, APHIS indicated its role in the process of reviewing the AgrEvo petition and the roles of other Federal agencies, such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in regulating GRS lines, and food products derived from them, and the potential herbicide use of glufosinate on the GRS lines.

GRS lines W62 and W98 of soybean have been described by AgrEvo as parental soybean lines A5403 and A3322 containing gene for conferring tolerance to the herbicide glufosinate and progeny derived from crosses involving GRS lines by expressing the *bar* and *pat* genes. The *pat* gene is a synthetic version of *bar* gene originally isolated from *Streptomyces viridochromogenes*, a soil microbe. Both the genes code for the same enzyme and have similar substrate specificities. The *bar* gene coding for the same phenotype only in GRS lines W62 and W98 originally was isolated from another soil microbe, *S. hygroscopicus*. In addition, GRS lines W62, and W98 carry a marker gene *gus* from *Escherichia coli*, coding for beta-glucuronidase. The marker gene is necessary for selecting or distinguishing the transformed plant cells from a population of cells used in the transformation experiment.

The vector system was introduced by particle acceleration, also referred to as the biolistic, microprojectile bombardment or particle gun method of transformation (reviewed by Sanford, 1990). In this method plant tissues are bombarded with particles that are coated with DNA, with the result that particles are able to penetrate the cell wall and the cell membrane and deliver the DNA to the interior of the cell. (Particles are typically tungsten or gold with a diameter of 0.2 to 4.0 microns.) DNA introduced in this way has been shown generally to be incorporated into the nucleus (Christou et al.1988; Hain et al. 1985).

The GRS lines were developed by genetically transforming soybean lines W62 and W98 with *bar* (synthetic version of a similar gene originally isolated from *Streptomyces viridochromogenes*) gene coding for phosphinothricin acetyl transferase (PAT) enzyme, and lines A2704-21, and A5547 with the *pat* gene, and other regulatory DNA elements necessary for the expression of *pat* and *bar* gene like the 35S promoter from cauliflower mosaic virus (CaMV), an alfalfa mosaic virus (AMV) leader sequence, a nontranslated 3' region of the RuBP carboxylase SSU gene from soybean, and the nopaline synthase 3' terminator from *Agrobacterium tumefaciens*. All these genetic elements or sequences of DNA were introduced into the genome of the parental lines of soybean with the help of a chimeric vector molecule based on a well known plasmid vector known as pUC19 (Viera and Messing, 1987) and the Ti-plasmid of *A. tumefaciens* (Fraley et al. 1983; Zambryski, 1988). None of the regulatory DNA sequences are known to code for a discernible product, but they are essential for controlled gene expression.

Glufosinate-ammonium (GA) is in the phosphinothricin (glufosinate) class of herbicides. It is a non-systemic, non-selective herbicide that provides effective post-emergence control of many broadleaf and grassy weeds. GA, the active ingredient of glufosinate controls weeds through the inhibition of glutamine-synthase (GS), which leads to the accumulation of phytotoxic levels of ammonia in the plants. The enzyme phosphinothricin acetyl transferase (PAT) catalyzes the conversion of GA to L-phosphintothricin (PPT), the active ingredient in GA, to its inactive form, thereby conferring tolerance to the herbicide.

APHIS regulations at 7 CFR 340, which were promulgated pursuant to the authority granted by the Federal Plant Pest Act (FPPA), (7 U.S.C. 150aa-jj) as amended, and the Plant Quarantine Act (PQA), (7 U.S.C. 151-164a, 166-167) as amended, 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 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 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. AgrEvo submitted a petiton with data from their 195 field tests conducted under physical and reproductive containment under 8 APHIS permits and 26 notifications which provided evidence that GRS lines of soybeans in question did not present the risk plant pest introduction into the environment.

GRS lines have been considered "regulated articles" under 7 CFR 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*, AMV, and CaMV have been used to create the GRS lines, rendering them to be regulated articles. Field tests of GRS Lines have been conducted with APHIS approval since 1990. AgrEvo submitted its petition after the completion of field tests of

GRS lines under 8 APHIS permits and 26 notifications. These authorized field tests took place at approximately 197 sites throughout the continental United States. All field trials were performed under conditions of physical and reproductive confinement.

APHIS has determined that GRS lines do not present a plant pest risk and will no longer be considered regulated articles, under APHIS regulations at 7 CFR Part 340. The Agency decision is based on an analysis of data provided to APHIS by AgrEvo as well as other scientific data and comments received from the public relating to the potential plant pest risk of GRS lines. AgrEvo provided both general and specific information and data from field testing of GRS lines. From our review, we have determined that GRS lines: (1) exhibit no plant pathogenic properties; (2) are no more likely to become a weed than their non-engineered parental varieties; (3) are unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the can interbreed; (4) will not cause damage to raw or processed agricultural commodities, and (5) are unlikely to harm other organisms, such as bees and earthworms, that are beneficial to agriculture.

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 (42 USC 4321 *et.seq.*; 40 CFR 1500-1508, 7 CFR Part 1b; 7 CFR Part 372. An Environmental Assessment (EA) was prepared and a Finding of no Significant Impact (FONSI) was reached by APHIS for the determination that GRS lines are no longer regulated aricles under its regulations at 7 CFR Part 340. The EA and FONSI are available from APHIS upon written request.

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 GRS lines, 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 GRS lines do not present a plant pest risk.

II. BACKGROUND

USDA Regulatory Authority. APHIS regulations, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (FPPA), (7 U.S.C. 150aa-150jj) as amended, and the Plant Quarantine Act (PQA), (7 U.S.C.) 151-164a, 166-167) as amended, regulate the introduction (importation, interstate movement or release into the environment) of certain genetically engineered organisms and products. 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 section 340.2 of the regulations and is also a plant pest, if it is unclassified, or if APHIS has reason to believe that the genetically engineered organism presents a plant pest risk.

Prior to the introduction of a regulated article, a person is required under § 340.1 of the regulations to either (1) notify APHIS in accordance with § 340.3 or (2) obtain a permit in accordance with § 340.4. Introduction under notification (§ 340.3) requires that the introduction meet 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 § 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.

The FPPA gives USDA authority to regulate plant pests and other articles to prevent direct or indirect injury, disease, or damage to plants, plant products, and crops. The PQA provides an additional level of protection by enabling USDA to regulate the importation and movement of nursery stock and other plants which may harbor injurious pests or diseases and requires that they be grown under certain conditions after importation. For certain genetically engineered organisms, field testing may be required to verify that they exhibit the expected biological properties and to demonstrate that although they were developed by using components from plant pests, they do not possess plant pest characteristics.

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.

GRS lines have been considered "regulated articles" for field testing under Part 340.0 of the regulations because certain noncoding regulatory sequences were derived from the plant pathogens, *A. tumefaciens*, AMV, and CaMV.

APHIS believes it is prudent to provide assurance prior to commercialization that organisms, such as GRS lines, that are developed in part from plant pest sequences, do not present any potential plant pest risk. Such assurance may aid the entry of new plant varieties into commerce or into breeding and development programs. The decision by APHIS that GRS lines are no longer regulated articles is based in part on evidence provided by AgrEvo concerning the biological properties of GRS lines and their similarity to other varieties of soybean grown using standard agricultural practices for commercial sale or private use. GRS lines have been field tested under 8 permits (90-274-05r, 91-051-03r, 91-203-01r, 92-043-02r, 92-043-03r, 93-090-01r, 93-047-02r, and 93-047-03r) and 26 notifications (93-120-31n, 93-120-35n, 93-127-02n, 93-270-03n, 94-080-03n, 94-090-02n, 94-131-01n, 95-122-03n, 95-034-02n, 95-069-01n through to 95-069-

12n, 95-079-02n, 95-115-04n, 95-135-04, and 95-142-02n). Field test reports from these tests show no deleterious effects on plants, nontarget organisms, or the environment as a result of these releases.

The fact that APHIS regulates genetically engineered organisms having plant pest components does not carry with it the presumption that the presence of part of a plant pest makes a whole plant pest or that plants or genes are pathogenic. The regulations, instead, are based on the premise that when plants are developed using biological vectors from pathogenic sources, transforming material from pathogenic sources, or pathogens as vector agents, that they should be evaluated to assure that there is not a plant pest risk. For each field test, APHIS performs a review that allows a verification of the biology and procedures used assesses the degree of uncertainty and familiarity and allows the identification of any predictable hazards. The overall aim of APHIS regulations in the Code of Federal Regulations at 7 CFR Part 340 is to allow for the safe testing of genetically engineered organisms under an appropriate level of oversight and to enable any issues of potential or hypothetical risks to be addressed early enough in the development of the new organisms for the safe utilization of the technology in agriculture.

A certification that a genetically engineered organism does not present a plant pest risk means that there is reasonable certainty that the organisms cannot directly or indirectly cause disease, injury, or damage either when grown in the field, or when stored, sold, or processed. This approach is considerably broader than a narrow definition of plant pest risk arising from microbial or animal pathogens, including insect pests. Other traits, such as increased weediness, and harmful effects on beneficial organisms, such as earthworms and bees, clearly come under what is meant by direct or indirect plant pest risk. In APHIS regulations at 7 CFR Part 340, a "plant pest" is defined as: "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses, or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants." Lack of plant pest risk may be concluded when there is evidence that the plant under consideration: (1) exhibits no plant pathogenic properties; (2) is no more likely to become a weed than its non-engineered parental varieties; (3) is unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organism can interbreed; (4) does not cause damage to processed agricultural commodities; and (5) is unlikely to harm other organisms, such as bees, that are beneficial to agriculture. Evidence presented by AgrEvo bears on all of these topics. In addition, because the AgrEvo petition seeks a determination regarding GRS lines, it should be established that there is a reasonable certainty that any new soybean varieties bred with GRS lines will exhibit plant pest properties not substantially different from any observed for soybeans in traditional breeding programs or as seen in the development of GRS lines.

Oversight by Other Federal Agencies. The EPA regulates the use of pesticide chemicals, including herbicides, in the environment. Under the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), EPA has the authority to regulate the testing, sale, distribution, use, storage, and disposal of pesticides. Before a pesticide may be sold, distributed, or used in the United States, it must be registered under FIFRA Section 3. For a pesticide that is already registered, the use of the pesticide on a new crop plant (i.e., use on a crop for which the pesticide is not already registered) requires EPA approval of an amendment to the registration. In determining whether to approve the new use of the pesticide, EPA considers the possiblity of adverse effects to human health and the environment. Under the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 201 *et.seq.*), EPA also has responsibility for establishing tolerances for pesticide residues on food or feed. However, any new use of the herbicide on soybean would require the approval by EPA of an amendment to the registration under FIFRA and a tolerance review under FFDCA.

The FFDCA provides FDA with authority to ensure the safety and wholesomeness of all food(s), other than meat and poultry. The FDA policy statement concerning the regulation of foods derived from new plant varieties, including genetically engineered plants, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Regulatory oversight for the safety of any food or feed products derived from GTS line 40-3-2 is under the jurisdiction of the FDA.

III. PUBLIC COMMENTS

APHIS received 8 public comments on the AgrEvo petition from universities, cooperative extension service research centers, and a seed company. All the comments supported the approval of the petition.

IV. PROPERTIES OF GRS LINES

Brief discussions of the biology of soybean and soybean cultivation practices follow in the next section to help in the subsequent analysis.

Biology and Cultivation of Soybean: Soybean (*Glycine max*) is primarily grown for edible vegetable oil and the high protein food supplement for livestock. Other fractions and derivatives of the seed have substantial economic importance in a wide range of industrial, food, pharmaceutical, and agricultural products (Smith and Huyser, 1987). Soybean is the third largest crop grown in the United States and is grown in 29 states. The principal soybean producing States are Illinois, Iowa, Missouri, Minnesota, Indiana, and Ohio (Jewell, 1988). The United States, Brazil, China, and Argentina account for over 90 percent of world soybean production (Jewell, 1988).

The cultivated soybean plant is a branced, frost-sensitive (Johnson, 1987) annual that grows between one meter above ground and two meters below ground level. In the United States it is grown as a monoculture of row crops for sale to off-farm processors. Generally each field is planted as pure lines, although blends of two or more lines are sometimes planted (Johnson, 1987). Clean tillage has been the traditional method of field preparation, but recently no tillage

and reduced tillage systems have become more common. Irrigation is not usually practiced (VanDoren and Reicosky, 1987). A complex and sophisticated system of cultivars, agricultural implements, agricultural chemicals, and processing techniques have been developed for the crop.

The genus *Glycine* is divided into two subgenera, *Glycine* and *Soja*. The first consists of twelve wild perennial species (Hymowitz et al., 1992) that are primarily distributed in Australia, South Pacific Islands, Philippines, and Taiwan (Newell and Ymowitz, 1978). The subgenus *Soja* consists of three annual species from Asia, G.*max*, *G.soja*, and *G.gracilis*. The first species is the cultivated soybean, the second species is the wild form of the soybean, and the third species is referred to as the "weedy" form of the soybean (Lackey, 1981).

Cultivated soybean is essentially self-pollinated (Carlton and Lersten, 1987; McGrefor, 1976). The anthers mature in the bud and shed their pollen directly onto the stigma of the same flower, thus ensuring a high degree of self-pollination. Cross-pollination is generally very low and various studies have shown it to be from 0.03 to 3.62% (McGregor, 1976, Woodworth, 1992). Caviness (1970) showed that honey bees are responsible for the occasional cross-pollination and that thrips are ineffective pollinators. Soybean plants are virtually pure breeding homozygous lines, although manual cross-pollination is practiced routinely in breeding programs (Fehr, 1987). Certified Seed Regulations (7CFR Part 201.67-201.78) recognize the unlikelihood of cross-pollination in the standards they set for the production of Foundation, Registered, and Certified seed. For Foundation seed, the most stringent category in the Certified See Regulations, soybeans are permitted to be grown zero distance from the nearest contaminating source (i.e., other soybean cultivars), as long as the distance is adequate to prevent mechanical mixing.

Cultivated soybean is sexually compatible only with members of the genus *Glycine*, only imperfectly, through human intervention. Soybean does not cross with any extra-generic relatives (Hymowitz and Sinbgh, 1987). Cultivated soybean is the only member of the genus *Glycine* that grows both in the United States and its territories and is sexually compatible with cultivated soybean, with the exception of specialized research collections maintained under scientific care and scrutiny.

Soybean plants are annuals and do not survive vegetatively in the cultivated fields of the United States from one growing season to the next (Hymowitz and Singh, 1987). Survival from one season to the next is by seed; however, volunteers are seldom seen when cultivated soybean is grown in the United States. Since soybeans do not retain high germination rates and vigor for long periods, fresh, properly grown and handled seed is required for commercial varieties each growing season (TeKrony et al, 1987).

Plant Pest Risk Assessment and the Determination:

APHIS has analyzed not only public comments and basic information on the biology of soybean but also data presented by AgrEvo and scientific data on other topics relevant to a discussion of

plant pest risk. Based on the data, APHIS has arrived at a series of conclusions regarding the properties of GRS lines.

1. Neither the introduced genes, their products, nor the added regulatory sequences controlling their expression presents a plant pest risk in the GRS lines.

2. The introduction of the vector DNA does not present a plant pest risk in GRS lines.

3. The vector system used to transfer the glufosinate resistance gene into the soybean nuclear genome, pWRG2114 also known as pCMC2114, is a derivative of a high copy *Escherichia coli* plasmid pUC19 and does not contain any sequences from the natural Tumor-Inducing (Ti) plasmid system used by the plant pathogenic bacterium *A. tumefaciens* for plant infection and gene transfer.

4. The vector system was introduced by particle acceleration, also referred to as the biolistic, microprojectile bombardment, or particle gun method of transformation. In this method plant tissues are bombarded with particles that are coated with DNA, with the result that particles are able to penetrate the cell wall and the cell membrane and deliver the DNA to the interior of the cell. (Particles are typically tungsten or gold with a diameter of 0.2 to 4.0 microns.) DNA introduced in this way has been shown generally to be incorporated into the nucleus.

5. AgrEvo has presented evidence in its petition that the GRS lines that carry the glufosinate tolerance genes are transmitted through mitosis and meiosis in a Mendelian fashion, i.e., to a fashion consistent with integration of the added material into nuclear-chromosomal DNA. As integrated pieces of plant chromosomes, introduced foreign DNA is subject to the same rules governing chromosomal reaarangements and gene stability as other plants.

6. AgrEvo has analyzed the physical structure of the integrated genetic material in GRS lines. (See Figures V.1 through V.7 in Volume of the petition.) This analysis revealed that the vector DNA sequences of DNA was not present in the plant's genome. Polymerase chain reaction (PCR) and Southern analyses indicate that the soybean genome contains a single copy of the insert DNA. The introduced coding regions do not confer a plant pest risk.

7. The soybean plants have been transformed with the glufosinate resistance gene and a selectable marker gene, none of which code for pathogenic properties. The glufosinate resistance gene pressed in GRS lines is a single insert of DNA chimera comprised of a 35S promoter derived from cauliflower mosaic virus, an alfalfa mosaic virus leader sequence, a nonstranslated 3' region of the RuBP carboxylase SSU gene from *Glycine max* and the nopaline synthase 3' terminator from *A. tumefaciens*. The GRS lines W62 and W98 have been inserted with the *bar* gene *S. hygrosopicus*, a soil microbe, and the *pat* gene in GRS lines A2704-12, A2704-21, and A5547-35 is a synthetic version of the same gene originally isolated from another species of soil microbe, *S. viridochromogenes*. In addition only GRS lines W62 and W98 of soybean carry expressible selectable marker gene *gus*, coding for an enzyme B-glucuronidase isolated from

Escherichia coli. The basic skeleton of the transformation vector used as a widely used laboratory plasmid known as pUC19. The promoter, leader, and the terminator sequences are all pieces of DNA sequence that are necessary for the expression of the introduced herbicide resistance and selectable marker genes in soybean plants, but they themselves do not code for any gene product.

8. Glufosinate-ammonium (GA) is in the phosphinothricin class (Glufosinate) of herbicides. It is a non-systemic, nonselective herbicide that currently provides effective post-emergence control of many broadleaf and grassy weeds. Glufosinate-ammonium controls weeds through the inhibition of glutamine-synthetase (GS), which leads to the accumulation of phytotoxic levels of ammonia in the plant. The *PAT* enzyme catalyzes the conversion of L-phosphinothricin (PPT), the active ingredient in GA, to an inactive form, thereby conferring resistance to the herbicide.

9. The introduced regulatory sequences do not confer a plant pest risk. Both of the regulatory sequences fused to the glufosinate resistance gene are derived from organisms that are on the list of regulated articles.

10. Despite the presence of certain pathogen-derived sequences in the GRS genome, no crown gall or CaMV or AMV disease symptoms were observed by AgrEvo in any GRS lines during greenhouse or field studies. Furthermore, AgrEvo provides evidence that expression of the introduced gene does not result in disease symptoms or the syntehsis of products toxic to other organisms. AgrEvo also has monitored GRS lines field tests to verify that the severity of any disease or insect infestation of the transgenic plants did not differ from that of the parental line. No difference in disease and insect susceptibility was observed at any field test site where GRS lines were tested in the United States and Puerto Rico. In addition, greenhouse studies did not reveal any differences in the sensitivity of GRS lines to soybean cyst nematode from the parental lines.

There is no published evidence for the existence of any mechanism, other than sexual crossing of compatible *Glycine* species, by which these genetic sequences can be transferred to other organisms. Comparative analyses of numerous gene sequences from microorganisms and plants have never, to our knowledge, yielded any published evidence of strong inter-kingdom gene homologies that would be indicative of recent or frequent gene exchanges between plants and microorganisms, except for *Agrobacterium*-mediated gene transfers. A certain amount of information can be found in the scientific literature (e.g., Carlson and Chelm,1986; Wakabayashi et al., 1986; Doolittle et al, 1990) that provides a suggestion that transfer of genes from plants to microorganisms may have occurred over evolutionary time, i.e., in the eons since the various times of divergence between the kingdoms. A single report (Bryngelsson et al., 1988) has suggested that plant DNA can be taken up by a parasitic fungus, but no evidence has ever been forthcoming that such DNA uptake has resulted in the frequent transfer of a functional DNA sequence. Even if a rare plant-to-microbe gene transfer were to take place, there is no reason to believe that such a transfer of any of the sequences would pose any plant pest risk. We conclude

that concerns regarding DNA transfer from GRS lines to microorganisms are, at best, highly putative and speculative.

GRS Lines Have No Significant Potential To Become Weeds.

Baker (1965) developed a list of attributes most commonly found in many weeds. Soybean possesses few of the characteristics of plants that are notably successful weeds. It is an annual crop and is considered to be a highly domesticated, well-characterized crop plant that is not persistent in undisturbed environments without human intervention. The parental lines are not considered a weed, and introduction of the glufosinate resistance trait should not impart any new weedy characteristics. GRS lines are likely to be grown mostly in areas that are currently under soybean cultivation, i.e., in typical growing regions for the crop.

AgrEvo has designed experiments and collected data from greenhouse and field trials that support the contention that the glufosinate resistant soybean has little potential to become a serious or successful weed. Data provided in the petition indicate clearly that the applicant has not observed any significant changes in the number of seeds produced, germination characteristcs, final stand, over-wintering capability, or pathogen susceptibility.

GRS Lines Will Not Increase The Weediness Potential Of Any Other Plant With Which They Can Breed.

The only wild species that cross with the cultivated soybean are members of the genus *Glycine*. Soybean is not reported to cross with any extra-generic relatives (Hymowitz and Singh, 1987). Some members of the wild perennial species of subgenus *Glycine* may be found in United States territories in the Pacific (Hermann, 1962; Hymowitz and Singh, 1987; Newell and Hymowitz, 1978); however, there are no known reports of successful natural hybridization between cultivated soybean and the wild perennial species. Hybridization is known only in *vitro* culture, i.e., under human intervention, and hence the probability of natural gene transfer is very low. Even when hybridization is achieved, the F1 plants obtained are generally sterile. Only the nearest wild relative of cultivated soybean, *G. Soja*, is listed as a common weed in Japan by Holm et al (1979). However, texts on weeds found in Japan place it neither among the harmful weeds on cultivated lands (Kasahara, 1982), nor among the weeds of pastures and meadows (Nemoto, 1982). Although natural hybridization is known to occur between cultivated soybean and the wild, annual species *G. Soja* (Kwon et al, 1972), the latter is not found in the United States or its territories.

Cultivated soybeans are almost completely self-pollinated, with hybridization reported generally at less than 1%. Honey bees are responsible for the occasional cross-pollination, while thrips are ineffective pollination vectors (Caviness, 1970). Thus, soybean can be grown adjacent to other soybean cultivars for the purposes of maintaining purity of lines as long as the distance between cultivars is adequate to prevent mechanical mixing.

Should movement of genetic material take place to any receptive plants, and glufosinate resistance be transferred, no competitive advantage would be conferred because glufosinate is not used with these plants when they are found in non-agricultural areas. In agricultural areas such plants would be controlled by normal agronomic practices.

GRS Lines Will Not Cause Damage To Raw Or Processed Agricultural Commodities.

Information provided by AgrEvo regarding the components and processing characteristics of GRS lines revealed no differences in any component that could have a direct or indirect plant pest effect on any raw or processed commodity.

GRS Lines Are 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 GRS lines. The PAT enzyme, expressed in GRS lines of soybean, is not known to have any toxic properties. Field observations of GRS lines revealed no negative effects on nontarget organisms, suggesting that the relatively higher levels of PAT enzyme in the tissues of the line are 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 PAT for its substrate makes it unlikely that PAT would metabolize endogenous substrates to produce compounds toxic to beneficial organisms. APHIS has not identified any other potential mechanisms for deleterious effects on beneficial organisms.

V. CONCLUSION

APHIS has determined that GRS lines developed by AgrEvo will no longer be considered regulated artricles 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 GRS lines or their progeny. Importation of GRS 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.

Arnold Foudin for John H. Payne

John H. Payne, Ph. D.
Acting Director
Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
United States Department of Agriculture
Date: JUL 31 1995

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