

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. 98-032-1]

AgrEvo USA Co.; Extension of Determination of Nonregulated Status to Soybean Genetically Engineered for Glufosinate Herbicide Tolerance**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Notice.

SUMMARY: We are advising the public of our decision to extend to one additional soybean line our determination that certain soybean lines developed by AgrEvo USA Company, which 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 decision is based on our evaluation of data submitted by AgrEvo USA Company in its request for an extension of a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of an environmental assessment and finding of no significant impact.

EFFECTIVE DATE: June 8, 1998.

ADDRESSES: The extension request and an environmental assessment and finding of no significant impact 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 and Biological Analysis, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4882. To obtain a copy of the extension request or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734-4885; e-mail: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "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," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or

produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated article in question.

Background

On January 14, 1998, APHIS received a request for an extension of a determination of nonregulated status (APHIS No. 98-014-01p) from AgrEvo USA Company (AgrEvo) of Wilmington, DE, for a soybean line designated as transformation event A5547-127 (event A5547-127), which has been genetically engineered for resistance, or tolerance, to the herbicide glufosinate. The AgrEvo request seeks an extension of a determination of nonregulated status that was issued for certain lines of glufosinate tolerant soybean (antecedent organisms) in response to APHIS petition number 96-068-01p (61 FR 42581-42582, August 16, 1996, Docket No. 96-019-2). Based on the similarity of event A5547-127 to the antecedent organisms, AgrEvo requests a determination that glufosinate tolerant soybean event A5547-127 does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

Analysis

Event A5547-127 soybean contains 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 the plant pathogen cauliflower mosaic virus. While the subject soybean event contains fragments of the *bla* marker gene, tests indicate this gene is not expressed in the plant. The particle acceleration method was used to transfer the added genes into the parental *Glycine max* A5547 cultivar. Event A5547-127 soybean was transformed with the same plasmid vector and in the same manner as certain antecedent organisms described

in APHIS petition number 96-068-01p, and differs from them only in the copy number and extent of integrated DNA.

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

Determination

Based on an analysis of the data submitted by AgrEvo and a review of other scientific data and field tests of the subject soybean line, APHIS has determined that event A5547-127 soybean: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than soybean lines 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. Therefore, APHIS has concluded that the subject soybean line and any progeny derived from crosses with other 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 event A5547-127 soybean 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 field testing, importation, or interstate movement of the subject soybean line or its progeny. However, importation of the subject soybean line 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, as amended (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 event A5547-127 soybean 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 1st day of May 1998.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98-12126 Filed 5-6-98; 8:45 am]

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**Approval of AgrEvo Request (98-014-01p) Seeking Extension of Determination of
Non-regulated Status For Glufosinate Resistant Soybean Transformation Event
A5547-127**

**Environmental Assessment and
Finding of No Significant Impact**

April 1998

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), has prepared an environmental assessment (EA) prior to approving an extension (APHIS Number 98-014-01p) to the determination of nonregulated status granted for petition 96-068-01p received from AgrEvo USA Company under APHIS regulations at 7 CFR Part 340. The subject of the extension request 98-014-01p, glufosinate resistant soybean transformation event A5547-127 has been genetically engineered with a gene whose expression results in tolerance to the herbicide glufosinate. Based on the analysis carried out in the EA, APHIS has reached a finding of no significant impact (FONSI) to the environment from its determination that glufosinate resistant soybean transformation event A5547-127 shall no longer be considered a regulated article.

A handwritten signature in cursive script, appearing to read "Rebecca Bech" followed by "for".

**Rebecca Bech
Assistant Director
Scientific Services
Plant Protection and Quarantine
Animal and Plant Health Inspection Service
U.S. Department of Agriculture**

Date: APR 30 1998

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96-068-01p**

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I. THE REGULATED ARTICLE

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a request for an extension of determination of nonregulated status (APHIS number 98-014-01p) from AgrEvo USA Company (AgrEvo) regarding glufosinate resistant soybean transformation event A5547-127 and its progeny. AgrEvo request claims that soybean transformation event A5547-127 does not present a plant pest risk, and should therefore no longer be a regulated article under regulations at 7 CFR Part 340.

AgrEvo submitted its extension request after the completion of field tests of glufosinate resistant soybean transformation event A5447-127 at 67 sites within USA under notifications 96-032-03N, 96-071-14N, 96-099-07N, 96-338-01N, 97-020-09N, 97-077-07N, 97-077-08N, 97-077-09N, 97-077-10N, 97-077-11N, 97-077-12N, 97-077-13N, 97-080-06N, 97-098-02N, 97-098-05N, 97-111-05N and 97-120-01N. These field tests have demonstrated no deleterious effects on plants, nontarget organisms, threatened and endangered species, or the environment. Field tests in the United States were performed under conditions of physical and reproductive confinement.

Soybean transformation event A5547-127 has been genetically engineered to express a single copy of the synthetic *pat* gene isolated from a soil bacterium *Streptomyces viridochromogenes* that results in the expression of an enzyme phosphinothricin acetyl transferase (PAT), which confers resistance to glufosinate herbicide. In addition the glufosinate resistant soybean transformation event A5547-127 also contains partial copies of the bacterial selection marker gene *bla* that is not expressed.

The soybean transformation event A5547-127 has been transformed with a vector pB2/35SAcK (has the same backbone structure derived from pUC plasmids) that has only two functional genes, viz the phosphinothricin acetyl transferase *pat*, and *bla* coding for ampicillin resistance via the enzyme β -lactamase. Only the *pat* is fully intact and functional in the plants whereas the *bla* gene is not. The *pat* gene is under the influence of 35S cauliflower mosaic virus promoter and terminator.

II. THE ANTECEDENT ORGANISM(S)

The antecedent organism(s) are those genetically engineered lines for which a determination have already been granted. The antecedent organisms that are relevant to this extension petition identified are the glufosinate resistant lines (GRS) lines A2704-12, A2704-21, and A5547-35 described in Appendix A and B. The antecedent organisms expressed *pat* (synthetic version of *bar* gene) originally isolated from a soil bacterium *Streptomyces viridochromogenes*. The genes code for the same enzyme PAT that confers resistance to the herbicide glufosinate. GRS lines showed 1-3 copies of the *pat* gene. The vector system used for transferring the genetic chimera had the same

backbone DNA drawn from pUC19 plasmid. The GRS lines were developed by the biolistic microprojectile bombardment technique (for more details see Appendix A).

III. SIMILARITIES AND DIFFERENCES BETWEEN ANTECEDENT ORGANISMS AND A5547-127

Glufosinate resistant soybean transformation event A5547-127 is significantly similar to the antecedent organisms described in the AgrEvo petition 96-068-01p except that it was developed by a new transformation event using the same biolistic particle bombardment technique. A5547-127 is tolerant to the herbicide glufosinate and exhibits the identical agronomic characteristics as the antecedent organisms.

A5547-127 contains broken *bla* gene which is not expressed and all the regulatory sequences used to express the *pat* gene come from the cauliflower mosaic virus, a well known plant pest. The vector used for transformation also has the same backbone drawn from pUC family of vectors. In addition, A5547-127 contains a single copy of the *pat* gene where as the antecedent organisms had 3 copies of the same. There is no *gus* gene in A5547-127.

IV. POTENTIAL ENVIRONMENTAL IMPACTS

APHIS has considered all the information provided by AgrEvo in its petition and other scientific data relating to the potential plant pest risk of glufosinate resistant soybean transformation event A5547-127 and its progeny. A thorough evaluation of the potential for significant impact to the human environment through the unconfined agricultural use of glufosinate resistant soybean transformation event A5547-127 leads APHIS to a Finding of No Significant Impact (FONSI). This conclusion is based upon (1) the purpose of the genetic modification; (2) the fact that this modification will not increase the weediness of soybean or any sexually compatible plants; and (3) the fact that this modification will not negatively effect any nontarget organisms, threatened and endangered species including beneficials.

In conjunction with the FONSI, APHIS has made the determination that the glufosinate resistant soybean transformation event A5547-127 and its progeny have no potential to pose a plant pest risk, and therefore are no longer considered regulated articles (see Appendix A attached to the EA of 96-068-01p).

Because the regulated article A5547-127 is agronomically similar in expressing the herbicide tolerance trait as that of the antecedent organisms, it does not present any new potential environmental impact issues other than addressed in the EA associated with determination 96-068-01p. Therefore, this EA is tiered to the original EA of 96-068-01p (see Appendix A) in which potential for impacts to the human environment through unrestricted use in agriculture of glufosinate resistant soybean transformation event A5547-127 and its progeny have been addressed in detail.

V. CONCLUSIONS

In accordance with the requirements of National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et. Seq.*) APHIS has considered the potential for significant impact on the environment of a proposed action, i.e, reaching the determination that A5547-127 and its progeny have no potential to present a plant pest risk, and therefore 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 determine that A5547-127 and its progeny 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 A5547-127 and its progeny will have impacts no different from traditional soybean varieties that are not regulated articles in the regulations at 7 CFR Part 340 before they enter agriculture. All the factors that were considered for the determination of nonregulated status of A5547-127 and its progeny are found in APPENDIX B. The following key points were considered for a FONSI:

1. The regulated article in question A5547-127 and its progeny are similar to the antecedent organisms as all of them have been genetically engineered with a gene that confers resistance to the herbicide glufosinate, and that all of them exhibit similar agronomic characteristics.
2. Neither the glufosinate resistance gene nor its product, the associated marker gene, or the regulatory sequences confer on A5547-127 line or its progeny any plant pest characteristic. The *pat* gene that confers tolerance to the herbicide glufosinate has been inserted into a soybean chromosome in A5547-127 soybean line. 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.

3. The gene that confers tolerance to the herbicide, glufosinate, will not provide A5547-127 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 A5547-127 lines exhibit any increased weediness relative to that of traditional varieties or the unmodified parental lines.

4. There is no reason to believe that the use of A5547-127 line or its progeny in agriculture will have a significant impact on any beneficial organisms in the environment or on any threatened or endangered species.

VI REVIEWERS

Biotechnology and Biological Analysis

Rebecca Bech, Assistant Director
Subhash Gupta, Ph.D., Biotechnologist (Reviewer)
David S. Heron, Ph.D., Biotechnologist (Reviewer)
Susan Koehler, Ph.D., Biotechnologist (Reviewer)
James Lackey, Ph.D., Biological Safety Officer (Reviewer)
Sivramiah Shantharam, Ph.D., Senior Manager, (Principal Reviewer)
James L. White, Ph.D., Senior Manager (Reviewer)
Shirley Ingebritsen (Reviewer)

VII AGENCY CONTACT

Ms. Kay Peterson, Regulatory Analyst
Biotechnology and Scientific Services
USDA, APHIS, BSS
4700 River Road, Unit 147
Riverdale, MD 20737-1237

Phone: (301) 734-4885
Fax: (301) 734-8669
mkpeterson@aphis.usda.gov