Notices

Federal Register
Vol. 64, No. 80
Tuesday, April 27, 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. 98-126-2]

AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Rice 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 rice transformation events developed by AgrEvo USA Company, which have been genetically engineered for tolerance to the herbicide glufosinate, 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, our 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: April 15, 1999.

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 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David Heron, Biotechnology and Biological Analysis, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-5141. 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 November 25, 1998, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 98-329-01p) from AgrEvo USA Company (AgrEvo) of Wilmington, DE, seeking a determination that rice (*Oryza sativa* L.) designated as Liberty Link® Rice Transformation Events LLRICE06 and LLRICE62 (rice transformation events LLRICE06 and LLRICE62), which have been genetically engineered for 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 January 26, 1999, APHIS published a notice in the **Federal Register** (64 FR 3924-3925, Docket No. 98-126-1) 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 rice transformation events and food products derived from them. In the notice, APHIS solicited written comments from the public as to whether rice transformation events LLRICE06 and LLRICE62 posed a plant pest risk. The comments were to have been received by APHIS on or before March 29, 1999. APHIS received four comments on the subject petition during the designated 60-day comment period from the following: a farmers rice cooperative; a State rice growers association; a State rice research board; and a State university rice research station. All of the comments were in support of the subject petition.

Analysis

Rice transformation events LLRICE06 and LLRICE62 have been genetically engineered to contain a *bar* gene derived from *Streptomyces hygroscopicus* strain HP632. The *bar* gene encodes the enzyme phosphinothricin-N-acetyltransferase (PAT), which confers tolerance to the herbicide glufosinate. Expression of the *bar* gene is controlled by 35S promoter and terminator sequences derived from the plant pathogen cauliflower mosaic virus. The direct gene transfer method was used to transfer the added genes into the parental rice varieties M202 (LLRICE06) and Bengal (LLRICE62).

The subject rice transformation events have been considered regulated articles under APHIS' regulations in 7 CFR part 340 because they contain gene sequences derived from a plant pathogen. However, evaluation of field data reports from field tests of these rice transformation events conducted under APHIS notifications since 1997 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the environmental release of rice transformation events LLRICE06 and LLRICE62.

Determination

Based on its analysis of the data submitted by AgrEvo, and a review of other scientific data and field tests of the subject rice transformation events, APHIS has determined that rice transformation events LLRICE06 and LLRICE62: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weeds than rice varieties developed by traditional plant breeding; (3) are unlikely to increase the weediness potential for any other cultivated or wild species with which they can interbreed; (4) will not harm threatened or endangered species or organisms that are recognized as beneficial to agriculture; and (5) will not cause damage to raw or processed agricultural commodities. Therefore, APHIS has concluded that the subject rice transformation events and any progeny derived from hybrid crosses with other rice varieties will be as safe to grow as rice in traditional breeding programs that are not subject to regulation under 7 CFR part 340.

The effect of this determination is that AgrEvo's rice transformation events LLRICE06 and LLRICE62 are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340.

AgrEvo USA Company Petition 98-329-01p
Determination of Nonregulated Status for Glufosinate Tolerant Rice
Transformation Events LLRICE06 and LLRICE62

Finding of No Significant Impact

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), has prepared an environmental assessment before issuing a determination of non-regulated status for genetically engineered rice transformation events designated as LLRICE06 and LLRICE62. These rice transformation events have been engineered to tolerate exposure to the herbicide glufosinate ammonium. APHIS received a petition (APHIS Number 98-329-01p) from AgrEvo USA Company regarding the status of LLRICE06 and LLRICE62 as regulated articles under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition, supporting documentation, and other relevant scientific information to reach a finding of no significant impact (FONSI) on the environment from the unconfined cultivation and agricultural use of rice transformation events LLRICE06 and LLRICE62 and their progeny. This conclusion is based on our analysis that rice transformation events LLRICE06 and LLRICE62: (1) exhibit no plant pathogenic properties; (2) are no more likely to become weeds than rice varieties developed by traditional plant breeding; (3) are unlikely to increase the weediness potential of any other cultivated or wild species with which they can interbreed; (4) will not harm threatened or endangered species or organisms that are recognized as beneficial to agriculture, and (5) will not cause damage to raw or processed agricultural commodities.

Therefore, after a review of the available evidence, including that provided by AgrEvo in its petition as well as other scientific data, APHIS believes that rice transformation events LLRICE06 and LLRICE62 should be just as safe to grow as rice varieties which are not subject to regulation under 7 CFR Part 340. APHIS concludes that there will be no significant impact on the environment if LLRICE06 and LLRICE62 and their progeny are no longer considered regulated articles under 7 CFR Part 340.

Sally L. McCammon
Acting Associate Director
Scientific Services
Plant Protection and Quarantine
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: 4/15/99

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ENVIRONMENTAL ASSESSMENT

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 98-329-01p) from AgrEvo USA Company (AgrEvo) of Wilmington, Delaware, in which AgrEvo has requested that APHIS determine that certain genetically engineered rice transformation events should no longer be considered as regulated articles under APHIS regulations found at 7 CFR Part 340. These transformation events, designated by AgrEvo as LLRICE06 and LLRICE62, have been engineered with a gene designed to confer tolerance to the herbicide glufosinate ammonium.

Transformation events LLRICE06 and LLRICE62 were obtained by transforming rice varieties M202 and Bengal, respectively, with the *bar* gene derived from the soil-borne bacterium *Streptomyces hygroscopicus*. The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), an enzyme which inactivates the herbicide glufosinate ammonium. The *bar* gene was introduced via a well characterized method which introduces DNA directly without the use of vector agents. Transformation events LLRICE06 and LLRICE62 have been considered regulated articles under APHIS regulations, because they were developed with DNA sequences derived from a plant pathogen.

As regulated articles, the interstate movement, importation, and field testing of LLRICE06 and LLRICE62 has been conducted under authorizations from APHIS. Field tests of regulated articles are conducted under conditions which confine the plants to the test site. AgrEvo's petition contains information which supports their contention that LLRICE06 and LLRICE62 do not present a plant pest risk and, therefore, should no longer be considered as regulated articles under these regulations.

This EA addresses the potential impacts associated with a determination that transformation events LLRICE06 and LLRICE62 and their progeny should no longer be considered as regulated articles under USDA regulations at 7 CFR Part 340.

Therefore, after a review of the available evidence, including that provided by AgrEvo in its petition as well as other scientific data, APHIS believes that rice transformation events LLRICE06 and LLRICE62 should be just as safe to grow as rice varieties which are not subject to regulation under 7 CFR Part 340.

II. BACKGROUND

Development of LLRICE06 and LLRICE62. AgrEvo developed rice transformation events LLRICE06 and LLRICE62 to tolerate exposure to the herbicide glufosinate ammonium, and thereby give rice growers another option for weed control during the growing season. Currently, rice growers in the United States control weeds through a combination of herbicides, crop rotation, and cultural practices such as flooding and tillage.

Transformation events LLRICE06 and LLRICE62 were developed by introducing a single gene, the *bar* gene, into the varieties M202 and Bengal. The *bar* gene was derived from the soil-borne bacterium *Streptomyces hygroscopicus*. The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), an enzyme which inactivates the herbicide glufosinate ammonium. The *bar* gene was introduced via a well characterized method which introduces DNA directly into plant tissues. Transformed tissues then were regenerated into whole plants which could be evaluated in the greenhouse and field for the desired characteristics. More detailed information can be found in this EA's appendix entitled "Determination of Nonregulated Status for Transgenic Rice Transformation Events LLRICE06 and LLRICE62."

APHIS received a petition from AgrEvo on November 25, 1998. The petition (assigned APHIS Number 98-329-01p) requested a determination from APHIS that genetically engineered rice transformation events LLRICE06 and LLRICE62 do not present a plant pest risk and therefore should no longer be considered regulated articles under the regulations at 7 CFR Part 340. AgrEvo has based its petition on information on the characterization of LLRICE06 and LLRICE62 with respect to their genetic modifications and their growth in field tests.

APHIS has authorized field tests of rice derived from LLRICE06 and LLRICE62 since 1997. In the course of these tests, AgrEvo confirmed its expectation that the plants would exhibit no deleterious effects, would not exhibit weedy characteristics, and would have no effect on nontarget organisms or the general environment. All field trials were performed under conditions of physical and reproductive confinement.

APHIS Regulatory Authority. APHIS regulations under 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, release into the environment, or any attempt thereat) of certain genetically engineered organisms and products. 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. Rice transformation events LLRICE06 and LLRICE62 have been considered regulated articles under Part 340 of the

regulations because they have been engineered to contain components from the known plant pest, cauliflower mosaic virus.

As regulated articles under APHIS regulations, introductions of rice transformation events LLRICE06 and LLRICE62 required authorizations from APHIS prior to importation, interstate movements, or planting them in field tests. APHIS regulations seek to limit introductions of transgenic plants into the environment until it is clear that the plants pose no more risk as plant pests than other varieties of that rice which are not subject to the regulations under 7 CFR Part 340.

The APHIS 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, release into the environment, or any attempt thereat) 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 subsection 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. 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.

In the Federal Plant Pest Act, as amended (7 U.S.C. 150aa-150jj), "plant pest" is defined as "any living stage of: Any 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 substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants." APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

Section 340.6 of the regulations, entitled "Petition 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 APHIS determines that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it is derived, the Agency may approve the petition in whole or in part. If the petition is approved, APHIS permits or notifications would no longer be required for field testing, importation, or interstate movement of that article or its progeny. Normal agronomic practices with the subject line, e.g., cultivation, propagation, movement, and cross-breeding also could be conducted without further APHIS approval.

Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Regulatory Authority. The EPA is responsible for the regulation of pesticides, including herbicides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides be registered for use on specific crops prior to distribution or sale. Residue tolerances for pesticides are established by the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*). The Food and Drug Administration (FDA) enforces tolerances set by the EPA under the FFDCA.

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. AgrEvo has completed its consultation with FDA regarding transformation events LLRICE06 and LLRICE62.

III. PURPOSE AND NEED

APHIS has prepared this EA before making a determination on the status of LLRICE06 and LLRICE62 as regulated articles under APHIS regulations cited above. This EA was prepared in compliance with the National Environmental Policy Act of 1969, as amended (NEPA)(42 USC 4321 *et seq.*) and the implementing regulations and procedures (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 the LLRICE06 and LLRICE62 are no longer regulated articles. Authorizations from APHIS would still be required for introductions of LLRICE06 and LLRICE62. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from uncontained cultivation of LLRICE06 and LLRICE62.

B. Determination that the LLRICE06 and LLRICE62 are no longer regulated articles.

Under this alternative, LLRICE06 and LLRICE62 would no longer be regulated articles. Authorizations from APHIS would no longer be required for introductions of LLRICE06 and LLRICE62 or their progeny.

V. POTENTIAL ENVIRONMENTAL IMPACTS

This EA considers the potential environmental impacts of each of the alternatives described above. If APHIS denies the petition, LLRICE06 and LLRICE62 and progeny derived from either of these would continue to be regulated by APHIS under 7 CFR Part 340. Interstate movement,

certain importations, and environmental releases of these rice transformation events could only be conducted under permits or notifications approved by APHIS that impose conditions of physical or reproductive confinement to prohibit persistence of LLRICE06 and LLRICE62 or their progeny in the environment. For example, to prevent out-crossing to sexually compatible species and persistence of any offspring, most rice field trials conducted under 7 CFR Part 340 require an isolation distance of ten feet from other commercial rice, control of sexually compatible wild or weedy relatives around the release site, strict harvesting measures, and post-harvest monitoring and termination treatments to control volunteers from the transgenic rice. AgrEvo would not be able to sell seed from LLRICE06 and LLRICE62 (or their progeny) to farmers for planting unless the farmers were able and willing to meet the conditions of the permit or notification. Farmers who might grow these rice transformation events commercially would find such conditions difficult, if not impossible, to meet.

APHIS has considered the characteristics of LLRICE06 and LLRICE62 and the potential environmental impacts that might be associated with their unconfined cultivation when no longer considered as regulated articles. To determine if rice transformation events LLRICE06 and LLRICE62 should continue to be considered as regulated articles, APHIS considered information on the biology of rice, data presented by AgrEvo, and scientific data on other topics relevant to a discussion of plant pest risk. APHIS concludes that transformation events LLRICE06 and LLRICE62 do not present a plant pest risk and should be just as safe to grow as rice varieties which are not subject to regulation under 7 CFR Part 340. This conclusion for the rice transformation events LLRICE06 and LLRICE62 is based upon findings in the following sections:

A. LLRICE06 and LLRICE62 exhibit no plant pathogenic properties.

Transformation events LLRICE06 and LLRICE62 were developed by introducing a single gene, the *bar* gene, into the varieties M202 and Bengal. The *bar* gene was derived from the soil-borne bacterium *Streptomyces hygroscopicus*, an organism which is not a plant pest. The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), an enzyme which inactivates the herbicide glufosinate ammonium. The *bar* gene was engineered into the rice with noncoding DNA regulatory sequences attached to the coding region of *bar*. The regulatory sequences are the 35*S* promoter and terminator sequences derived from cauliflower mosaic virus (CaMV), a well known plant pest. Even though the CaMV 35*S* regulatory sequences were derived from a plant pest, the presence of these sequences does not cause disease in the transformed plants. The use of these regulatory sequences in transgenic plants is well characterized, and there is no indication that the presence of these sequences pose a plant pest risk. After careful evaluation of previous experience and the specific plants being considered, there is no indication that the association of the CaMV 35*S* regulatory sequences with the *bar* gene in LLRICE06 and LLRICE62 causes plant disease or poses any plant pest risk. As expected, LLRICE06 and LLRICE62 exhibit no plant pathogenic properties.

The *bar* gene was introduced via a well characterized method which introduces DNA directly into plant tissues. Unlike some transformation protocols which use the plant pathogenic bacterium *Agrobacterium tumefaciens* as a vector agent to introduce DNA into plant cells, no vector agent was used for the transformation protocol used in the development of LLRICE06 and LLRICE62.

B. LLRICE06 and LLRICE62 are not likely to be more weedy than traditionally bred rice varieties.

APHIS evaluated whether rice transformation events LLRICE06 and LLRICE62 are any more likely to present a plant pest risk as weeds than nontransgenic rice. APHIS considered the wealth of experience in the cultivation with other varieties of rice and concluded that these transgenic lines are similar to other rice in that they are unlikely to be weed pests.

Rice is not listed as a common, serious or principal weed or a weed of current or potential importance in the United States or Canada. Expression of the *bar* gene in transformation events LLRICE06 and LLRICE62 will confer tolerance to the herbicide glufosinate ammonium, but will not confer tolerance to other herbicidal compounds. Expression of the *bar* gene will not confer characteristics which would cause these plants to become more "weedy" than nontransformed rice.

The physical characteristics, disease susceptibility, and insect susceptibility of rice transformation events LLRICE06 and LLRICE62 were compared to the attributes of nontransgenic rice during field trials. AgrEvo found no obvious differences between these transgenic plants and their nontransgenic counterparts with respect to the number of volunteers, emergence from seeds, and disease and insect susceptibility. These observations further support APHIS' conclusion that rice transformation events LLRICE06 and LLRICE62 are no more likely to present a plant pest risk as weeds than nontransgenic rice cultivars.

C. LLRICE06 and LLRICE62 are unlikely to increase the weediness potential for any other species with which they can interbreed.

After careful analysis, APHIS concludes that the unconfined cultivation of LLRICE06 and LLRICE62 is unlikely to result in an increased plant pest risk from their hybridization with the sexually-compatible species known as red rice, the only species which is likely to have a chance to hybridize with LLRICE06 and LLRICE62. Red rice is considered a weedy species in the cultivation of rice, but the competitiveness of red rice requires the specific environmental conditions (such as flooded fields) that are used for cultivation of commercial rice. Red rice is not considered weedy in other environments. APHIS examined whether red rice is likely to be more of a weed pest if red rice hybridizes with the glufosinate tolerant LLRICE06 and LLRICE62. Any offspring from such hybridizations will not have enhanced competitive capabilities, except for a possible tolerance to the herbicide glufosinate ammonium. However, these hybrid offspring will

still be sensitive to other registered herbicides. In addition, other weed control practices, such as tillage, should be just as effective on these plants as the practices are on red rice.

D. LLRICE06 and LLRICE62 will not harm threatened or endangered species or organisms that are recognized as beneficial to agriculture.

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for LLRICE06 and LLRICE62 and plant products derived from them to have damaging or toxic effects directly or indirectly on nontarget organisms. This includes those that are recognized as beneficial to agriculture and those that are recognized as threatened or endangered in the United States. APHIS also considered potential impacts on other "nontarget" pests, since such impacts could have an impact on the potential for changes in agricultural practices.

APHIS can find no reason to believe that deleterious effects or significant impacts on nontarget organisms, including threatened and endangered species or beneficial organisms, would result from the unconfined cultivation of rice transformation events LLRICE06 and LLRICE62. Other than the production of the PAT enzyme, these plants are the same as the commercial rice varieties from which they were produced. The PAT enzyme has been extensively studied, and there is no indication that it is toxic to organisms. Therefore it seems unlikely that the PAT enzyme will affect agriculturally beneficial organisms (e.g., earthworms and honeybees) or organisms which have been designated as threatened or endangered.

The EPA regulates the use of pesticides, including herbicides. In the course of pesticide registration, EPA considers the impact of pesticides on nontarget organisms. Application of the herbicide glufosinate ammonium to rice transformation events LLRICE06 and LLRICE62 or their progeny is regulated by the EPA.

APHIS concludes that the cultivation of rice transformation events LLRICE06 and LLRICE62 pose no harm to threatened and endangered species and nontarget organisms. Based on this analysis, APHIS concludes that the unconfined cultivation of LLRICE06 and LLRICE62 should be equivalent to nontransgenic rice cultivars in their potential to impact biodiversity of *Oryza* species.

E. LLRICE06 and LLRICE62 will not cause damage to raw or processed agricultural commodities.

Consistent with its statutory authority which defines plant pests as those organisms which cause direct or indirect damage to plants and plant products, APHIS evaluated whether LLRICE06 and LLRICE62 might indirectly impact agricultural practices or harm plant products such as some agricultural commodities.

After careful analysis, APHIS concludes that there is unlikely to be any significant adverse impact on agricultural practices associated with the use of LLRICE06 and LLRICE62. In addition, APHIS concludes that the characteristics of LLRICE06 and LLRICE62 reveal no difference in any trait or characteristic that could have an indirect plant pest effect on any processed agricultural commodity.

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 LLRICE06 and LLRICE62 outside the United States and its territories.

Our analysis of the biology of rice leads to the conclusion that the cultivation of LLRICE06 and LLRICE62 either domestically or abroad would not have an adverse impact on the environment. In all analyses conducted by AgrEvo, LLRICE06 and LLRICE62 displayed no significant differences from its parent line except for their tolerance to glufosinate.

It should be noted that all the existing national and international regulatory authorities and phytosanitary protocols that currently apply to introductions of new rice varieties internationally will apply to LLRICE06 and LLRICE62.

VI. CONCLUSIONS

APHIS has reviewed the information provided by AgrEvo in its petition as well as other scientific data in evaluating LLRICE06 and LLRICE62. After careful analysis of the available information, APHIS concludes that LLRICE06 and LLRICE62:

(1) exhibit no plant pathogenic properties;

(2) are no more likely to become weeds than rice lines developed by traditional plant breeding;

(3) are unlikely to increase the weediness potential of any other cultivated or wild species with which they can interbreed;

(4) will not harm threatened or endangered species or organisms that are recognized as beneficial to agriculture, and

(5) will not cause damage to raw or processed agricultural commodities.

Therefore, APHIS concludes that the LLRICE06 and LLRICE62 do not pose a plant pest risk. Rice transformation events LLRICE06 and LLRICE62 will be just as safe to grow as rice varieties that are not subject to regulation under 7 CFR Part 340.

VII. APPENDIX: DETERMINATION OF NONREGULATED STATUS FOR TRANSGENIC RICE TRANSFORMATION EVENTS LLRICE06 and LLRICE62.

A. SUMMARY

APHIS received a petition (APHIS Number 98-329-01p) from AgrEvo USA Company regarding the status of transgenic rice LLRICE06 and LLRICE62 as regulated articles under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition, supporting documentation, and other relevant scientific information to reach its determination that LLRICE06 and LLRICE62 and any new varieties developed from them should no longer be considered regulated articles. APHIS has determined that these plants should not present a plant pest risk, and they should be just as safe to grow as rice varieties which are not subject to regulation under 7 CFR Part 340.

On November 25, 1998, the Animal and Plant Health Inspection Service (APHIS) received a petition from the AgrEvo USA Company (hereafter referred to as AgrEvo) requesting a determination that rice derived from the transformation events designated as LLRICE06 and LLRICE62, which has been genetically engineered for tolerance to the herbicide glufosinate, does not pose a plant pest risk and therefore, should no longer be considered a regulated article. On January 26, 1999, APHIS announced receipt of the completed petition in the *Federal Register* (64 FR 3924-3925) and stated that the petition was available for public review. APHIS invited written comments on this proposed action, to be submitted on or before March 29, 1999. Based on a review of scientific data and literature, APHIS has determined that LLRICE06 and LLRICE62 rice do not present a plant pest risk and are therefore no longer regulated articles under the regulations found at 7 CFR Part 340. As a result of this determination, oversight by APHIS under 7 CFR Part 340 will no longer be required for field testing, importation, or interstate movement of LLRICE06 and LLRICE62 rice or their progeny.

This determination has been made based on an analysis that revealed that LLRICE06 and LLRICE62 rice plants: 1) exhibit no plant pathogenic properties, 2) are no more likely to become weeds than herbicide tolerant rice developed by traditional breeding, 3) are unlikely to increase the weediness potential of any other plant with which they can interbreed, 4) will not harm threatened or endangered species and organisms that are beneficial to agriculture, and 5) will not cause damage to raw or processed agricultural commodities. APHIS has also concluded that there is no reason to believe that new rice varieties derived from LLRICE06 and LLRICE62 will exhibit new plant pest properties; i.e., properties substantially different from any observed for the LLRICE06 and LLRICE62 rice lines already field tested, or those observed for rice in traditional breeding programs.

LLRICE06 and LLRICE62 rice are genetically engineered to express only one additional gene, the *bar* gene derived from the soil borne bacterium *Streptomyces hygroscopicus*. The *bar* gene

encodes the enzyme phosphinothricin-N-acetyltransferase (PAT), which confers tolerance to glufosinate herbicides. This gene has accompanying non-coding DNA regulatory sequences that modulate its expression. The DNA regulatory sequences were derived from the plant pathogen cauliflower mosaic virus (CaMV). The *bar* cassette, consisting of the coding region and aforementioned regulatory sequences, was introduced into rice using direct transformation. This technique has resulted in the incorporation of the intact (LLRICE06 and LLRICE62) and partial (LLRICE06) copies of the *bar* cassette into the plant genome. DNA from the vector backbone was not detected.

B. APHIS Regulatory Authority

APHIS regulations at 7 CFR 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, release into the environment, or any attempt thereat) of certain genetically engineered organisms and products. Under these regulations, a genetically engineered organism is deemed a regulated article if either 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. The FPPA gives the U.S. Department of Agriculture (USDA) the authority to regulate plant pests and other articles to prevent direct or indirect injury, disease, or damage to plants and plant products. In addition, the PQA provides an additional level of protection by enabling USDA to regulate the importation and movement of nursery stock and other plants that may harbor injurious pests.

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

An organism is not subject to the regulatory requirements of 7 CFR §340 when it is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition 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 approved, thereby allowing for unregulated introduction of the article in question. A petition may be approved in whole or in part.

LLRICE06 and LLRICE62 have been considered "regulated articles" under §340 of the regulations because certain noncoding regulatory sequences were derived from CaMV, a known plant pest.

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 a pest or that the plants or genes are pathogenic (McCammon and Medley, 1990). APHIS' approach to plant pest risk does not encompass only plant pathogens. Other traits, such as increased weediness, and harmful effects on beneficial organisms, such as earthworms and bees, are clearly included within what is meant by direct or indirect plant pest risk. In APHIS' regulations at 7 CFR §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."

C. PUBLIC COMMENTS

On January 26, 1999, APHIS announced in the Federal Register that the petition submission was available for public review and that the Agency would consider written comments received before the close of a 60-day comment period. APHIS received a total of four comments, all in favor of the petition for nonregulated status. APHIS considers these comments in addition to the petition submission and relevant information in the scientific literature.

D. DESCRIPTION OF LLRICE06 and LLRICE62

The rice transformation events LLRICE06 and LLRICE62 were developed to tolerate exposure to the herbicide glufosinate ammonium. In its petition, AgrEvo has provided information on the molecular genetic characterization of these plants. This information describes the transformation system, the DNA sequences incorporated into the plants, and the resultant gene products which are expressed. APHIS uses this and other information in its assessment to determine if these plants pose a plant pest risk.

Transformation protocol. Transformation was achieved via direct gene transfer, therefore no vector agent was used . AgrEvo has requested that the details of the methodology be maintained by APHIS as confidential business information. Tissues were transformed with a fragment of DNA which contained the *bar* gene and from the plasmid, then used this fragment to transform the rice callus tissue.

Genes introduced to develop LLRICE06 and LLRICE62. Transformation events LLRICE06 and LLRICE62 were developed by introducing a single gene, the *bar* gene, into the varieties M202

and Bengal. The *bar* gene was derived from the soil-borne bacterium *Streptomyces hygroscopicus*, an organism which is not a plant pest. The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), an enzyme which inactivates the herbicide glufosinate ammonium. The *bar* gene was engineered into the rice with noncoding DNA regulatory sequences attached to the coding region of *bar*. The regulatory sequences are the 35S promoter and terminator sequences derived from cauliflower mosaic virus. Neither the *bar* gene nor its associated noncoding DNA regulatory sequences cause plant disease or pose any plant pest risk.

Expression of genes introduced into lines LLRICE06 and LLRICE62. The rice transformation events LLRICE06 and LLRICE62 expressed the PAT protein encoded by the *bar* gene cassette. The PAT protein expressed in these plants was characterized and found to be equivalent to the previously characterized reference standards.

E. ASSESSMENT OF PLANT PEST POTENTIAL

In order to make a determination on the regulated status of LLRICE06 and LLRICE62, APHIS assessed whether they pose a plant pest risk which is greater than rice cultivars which are not subject to the APHIS regulations (7 CFR Part 340). The following sections summarize the components of the assessment.

1. The introduced genes do not present a plant pest risk in LLRICE06 AND LLRICE62.

LLRICE06 and LLRICE62 were obtained by transforming rice varieties M202 and Bengal, respectively, with a DNA fragment which contained the complete coding sequence of the *bar* gene and noncoding DNA regulatory sequences. The bar gene was derived from the soil borne bacterium *S. hygroscopicus* strain HP632 (Thompson et al., 1987). The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), and enzyme which inactivates glufosinate-ammonium herbicides by acetylating phosphinothricin, the active component. The native bar gene was modified in its codon usage to improve expression in plants.

Noncoding DNA regulatory sequences consisting of the 35S promoter and terminator sequences from CaMV were fused to the *bar* gene to form the *bar* cassette which was subsequently introduced into plants. CaMV is a double-stranded DNA caulimovirus with a host range restricted primarily to cruciferous plants. The region of the CaMV genome used corresponds to nucleotides 6909 through 7437 for the promoter and 7439 through 7632 for the terminator sequences (as described by Pietrzak et al., 1986). The 35S promoter and terminator have been used widely to effect high constitutive levels of gene expression in plants. There is no evidence that the presence of these sequences poses any plant pest risk. The *bar* gene is the only open reading frame present in the *bar* cassette.

ELISA (Enzyme Linked Immunosorbant Assay) was used to detect the bar gene product, phosphinothricin acetyl transferase (PAT), in grain of rice derived from transformation events LLRICE06 and LLRICE62. The assay detects both inactive and intact enzyme, so that positive detection does not necessarily indicate functional protein. These tests showed small amounts of the PAT protein in the grains of rice plants derived from both events LLRICE06 and LLRICE62, but not from the corresponding controls M202 and Bengal.

Expression of the PAT protein is not associated with disease or injury in rice derived from events LLRICE06 and LLRICE62. LLRICE06 and LLRICE62 rice has undergone 2 years of field testing in a several locations in the United States. AgrEvo described field tests which were performed in 1997 and 1998 to compare LLRICE06 AND LLRICE62 with their parental lines (M202 and Bengal, respectively). Plants were characterized with respect to agronomic features, seed characteristics, disease and pest characteristics, and compositional analysis.

2. LLRICE06 AND LLRICE62 are no more weedy than other cultivated rice, nor do they have any significant potential to become a weed or transmit weedy characteristics to other cultivated rice.

APHIS evaluated whether rice lines originating from LLRICE06 AND LLRICE62 were any more likely to become weed than corresponding nontransgenic rice lines, or other rice currently cultivated, by considering the characteristics the parent lines, and the new traits conferred upon them due to expression of the transgenes. APHIS also evaluated whether these transgenic lines of rice were any more likely to transmit weedy characteristic to other cultivated rice.

Most definitions of weediness stress the undesirable nature of weeds from the point of view of humans; individual definitions differ in approach and emphasis. Baker (1965) defines a plant as a weed if, in any specified geographical area, its populations grow entirely or predominantly in situations markedly disturbed by man (without, of course, being deliberately cultivated). He also described several ideal characteristics of weeds. Although Baker's characteristics have been criticized by some ecologists as nonpredictive, no more broadly accepted suite of characteristics has been defined by ecologists (Williamson, 1994). In our view, there is no formulation that is clearly superior at this time. 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.

Rice of the type commonly cultivated in the U.S. is not considered a weed. Rice is not listed as a noxious weed in the U.S. (USDA, 1995) nor is it listed anywhere else in the world. It is unlikely that the introduction of glufosinate tolerance in rice will result in increased weediness. Growth rate and growth habit have not been altered by the transformation. The transformed rice is an annual, does not shatter or disperse its seed, and has not acquired extended dormancy. Rice is not listed as a common, serious or principal weed or a weed of current or potential importance in the

United States or Canada in most weed literature (Holm et al., 1979; Muenscher, 1955; USDA, 1971; Weed Science Society of America, 1992). APHIS considered data and observations provided in the petition on the agronomic performance, general plant features, and disease and insect susceptibility of rice derived from LLRICE06 AND LLRICE62 evaluated in field tests in 1997 and 1998. No differences that would affect weediness were observed between rice derived from LLRICE06 AND LLRICE62 and the respective nontransgenic counterparts.

Expression of the *bar* gene conferring tolerance to L-phosphinothricin-based herbicides, in rice derived from LLRICE06 and LLRICE62 will not likely provide a competitive advantage sufficient to cause these to be any more "weedy" than other rice cultivars. APHIS knows of no advantage that rice producing the PAT enzyme other than resistance to the herbicide itself.

Expression of the *bar* gene in LLRICE06 and LLRICE62 will not likely provide a competitive advantage sufficient to cause these plants to be any more "weedy" than other rice cultivars. L-phosphinothricin (L- PPT) is a structural analogue of glutamate, the substrate of the enzyme glutamine synthetase. L-PPT exerts its herbicidal effect by competitively binding and displacing glutamate from the active site of the plant's glutamine synthetase enzyme (Bayer et al., 1972). The PAT enzyme encoded by the *bar* gene catalyzes the conversion of L-PPT to N-acetyl-L-PPT in the presence of acetyl-CoA as a co-substrate. This conversion leads to the inactivation of the herbicidal active ingredient because it can no longer bind to and inactivate glutamine synthetase. There is no reason to believe that the PAT enzyme or the N-acetyl-L-PPT reaction product would cause any changes in the characteristics of rice derived from LLRICE06 and LLRICE62 which would increase its weediness potential relative to other varieties of cultivated rice.

L-PPT is the active ingredient in the commercial herbicide formulations Basta® (Hoechst AG, Germany), Ignite®, Rely®, Liberty® (North America), Finale™ (Hoechst Holland N V., The Netherlands) and RadicaleX (Imex-Hulst B.V., The Netherlands). The L-PPT in these formulations is synthesized as an ammonium ion salt (common name, glufosinate ammonium [GA]). GA herbicides are used to control both annual and perennial weeds in tree fruits and vines, plantations, and nurseries, and prior to crop emergence in vegetables and field crops. It has recently been registered to control weeds in other crops which have been genetically-engineered for tolerance to GA by expression of the PAT enzyme, including corn and soybean lines which APHIS has deregulated. In the Gulf Coast and Delta rice-growing regions, rice is often grown in rotation with either grain sorghum or soybeans. When conditions are such that rice falls down before or during harvest, volunteer rice can be a problem in soybeans in the coming year. Volunteer rice is usually treated with post-emergence soybean herbicides for controlling grasses such as quizalofop (Assure II) fluazifop (Fusilade) , sethoxydim (Poast), or glyphosate in the case of Roundup Ready® soybeans. Tolerance to glufosinate should not change the effectiveness of these control measures. In California, 70 percent of rice is grown continuously without rotation. When rotations are used, off-year crops include corn, wheat, safflower, sunflower, tomatoes, dry beans, melons and vegetables. Volunteer rice is not considered to be a weed problem.

Gene introgression into other cultivated rice is possible. However, the biological characteristics of rice ensure that such outcrossing would occur only at a very low frequency if it occurred at all. Cultivated rice is primarily self pollinating, outcrossing at a rate less than one percent. The low rate is due to several botanical factors including both floral characteristics, inability of pollen to remain viable longer than a few minutes, and a lack of insect vectors for pollen spread. As an example the low propensity of rice to cross pollinate, the required separation distance of rice varieties for certified seed production in the U.S. is only 10 to 20 feet depending on the class of seed and the region. In the unlikely event that introgression into nearby varieties occurs, any glufosinate-tolerant volunteers resulting from the introgression could be controlled as describe above.

Based on this analysis, APHIS concludes that, with the exception of resistance to tolerance to GA herbicides, rice derived from LLRICE06 and LLRICE62 has agronomic traits similar to those of traditionally bred rice, and it does not exhibit traits that would cause increased weediness. Its cultivation should not lead to increased weediness of other cultivated rice.

3. Gene introgression from rice derived from LLRICE06 AND LLRICE62 into its sexually compatible relatives should not increase the weediness potential of resulting progeny any more than gene introgression from other rice varieties.

APHIS evaluated the potential for gene introgression to occur from rice derived from LLRICE06 and LLRICE62 into a sexually compatible wild relatives and then considered whether such introgression would result in increased weediness. The only known compatible wild species to cultivated rice in the U.S. are *O. rufipogon*, which has been found only in a single location in the Everglades of Florida, and red rice, a wild variant of cultivated *O. sativa*. Due to the restriction of *O. rufipogon* to the single locale which is not proximal to rice production, red rice is considered to be the only wild species that could receive genes from transgenic rice in the U.S.

The rate of gene introgression into red rice would likely be very low due to the botanical factors which include (1) flowering periods of the cultivated and wild rice which often do not overlap and (2) a height difference in which red rice is often taller while pollen tends to fall toward the ground. These barriers only tend to limit the rate of introgression. It is assumed that the *bar* gene conferring tolerance to glufosinate will introgress into red rice and could result in a glufosinate-tolerant red rice population. If this occurs, current weed control practices should be effective in controlling the weed.

Research on the conditions and consequences of gene flow into red rice has been performed by researchers at Louisiana State University, USDA-ARS, and the University of Arkansas. The data suggest the following:

- Gene flow from rice into red rice can occur. However, the rate is likely to be very low with levels being dependent on the degree of overlapping of flowering (Langevin, et al.).

- Inheritance of the bar gene in hybrids of red rice and cultivated white rice follows the predicted Mendelian pattern (Sankula et al.), and

- The presence of glufosinate tolerance in hybrid populations does not change the fitness characteristics (e.g. emergence vigor, final height, disease resistance, fecundity, shattering, and dormancy). No differences could be distinguished among any of the populations based on presence of the *bar* gene except for glufosinate tolerance.

APHIS considered potential impacts associated with the cultivation of glufosinate-ammonium tolerant rice derived from LLRICE06 AND LLRICE62 on current agricultural practices, in particular those used to control weeds. Rice in the United States is grown using mechanized practices. Transplants are not used. As with this production method in other temperate areas of the world, weed control is critical, and no single management strategy is successful. Practices which are used include planting of weed-free seeds, crop rotation to break weed cycles, precise land leveling for effective flooding, seed bed preparation, conservation tillage, irrigation management, and the application of one or more herbicides (Hill, Smith, and Bayer, 1994). Historically, the most important herbicide introductions for rice have been 2,4-D in the early 1950s and propanil in 1961. Several new herbicide registrations quickly followed. Recently, however, the number of available herbicides has been declining, especially in California, due primarily to concerns about residues in water. The phenoxy group of herbicides has been pulled in California because of carry-over toxicity to cotton which is grown in the rice-production areas. The petition provided detailed agronomic production programs for the Delta region (included standard and no-till dry seeding programs) and California (water seeded). These programs name at least 14 different herbicide (by generic name) registered for use on rice. The list included non-selective "burndown" herbicides for no-till use, as well as pre- and post-emergence herbicides. Additionally, imidazolinone-tolerant (IMI®) and glyphosate tolerant (Roundup Ready®) rice varieties are under development along with the glufosinate-tolerant (Liberty Link®) rice described in this petition. These host of herbicide alternatives will be important in the management of glufosinate tolerant red rice which may occur due to introgression.

The petition states that a stewardship program will be communicated and provided to growers through a grower's guide and targeted education. The program will emphasize strategies to minimize the occurrence of resistant weed populations. Experience gained from the development of resistance of barnyardgrass to propanil and sedges to bensulfuron taught us that resistance develops under continuous rice cultivation and no rotation to alternative herbicides. (Hill et al., 1994). The key points for glufosinate resistance management are as follows:

- Never allow red rice plants to set seed. For optimum weed control AgrEvo recommends using glufosinate twice at pre-flood and post-flood in the Delta. This should prevent any red rice from flowering at the same time as cultivated rice.

- Monitor for herbicide resistance. If glufosinate is used on transgenic glufosinate-tolerant soybeans in rotation after rice, red rice plants in the soybeans should be monitored for resistance. If survivors are noted, an alternative herbicides should be chosen. Several post-emergence herbicides are labeled for use in soybeans that will control red rice.

- Rotate crops and herbicides. The most effective time to control red rice is in the rotational crop in which effective grass control can be achieved without injury to the following white rice crop. In the third year of a rotation of rice with row crop or fallow, use a herbicide other than glufosinate on the non-rice crop.

- Red and white rice are resistant to some herbicides. Most herbicides have similar activity in white and red rice, therefore red rice which is resistant to some herbicides already exists. Knowledge of the biology of red rice and the of current weed control practices can be applied to help minimize the risk of resistant red rice occurring.

APHIS concludes that red rice is not likely to be more of a weed pest if red rice hybridizes with the glufosinate tolerant LLRICE06 and LLRICE62. Any offspring from such hybridizations will not have enhanced competitive capabilities, except for a possible tolerance to the herbicide glufosinate ammonium. However, these hybrid offspring will still be sensitive to other registered herbicides. In addition, other weed control practices, such as tillage, should be just as effective on these plants as the practices are on red rice.

4. Rice derived from LLRICE06 AND LLRICE62 exhibits no significant potential to harm non-target organisms.

Consistent with its statutory authority and requirements under NEPA, APHIS evaluated the potential for rice derived from LLRICE06 and LLRICE62 to have damaging or toxic effects directly or indirectly on nontarget organisms. This includes those that are recognized as beneficial to agriculture and those that are recognized as threatened or endangered in the United States.

Rice from transformation events LLRICE06 and LLRICE62 has been field tested at multiple sites in the U.S. and no toxicity or alteration of population levels have been observed for beneficial insects, birds, or other species that frequent the fields. There were no qualitative differences between beneficial species populations present on transgenic and nontransgenic plants. The *bar* gene is not toxic and encodes a protein which shares no homology with proteins known to be toxic. Levels of the three known antinutrients found in rice (trypsin inhibitor, lectin, and phytic acid) were found to be in the expected range for transgenic seeds. There is no reason to believe

that expression of PAT in rice derived from LLRICE06 and LLRICE62 would have deleterious effects or significant impacts on nontarget organisms, including beneficial organisms. Also, LLRICE06 and LLRICE62 should pose no harm to species which are recognized as threatened or endangered.

5. Use of rice derived from LLRICE06 and LLRICE62 should have no more adverse impacts on raw or processed agricultural commodities than the parent rice.

During field testing, rice derived form LLRICE06 and LLRICE62 exhibited the typical agronomic characteristics of the recipient plant, with the exception of the desired phenotype conferred by the *bar* genes. No unexpected differences were consistently observed in disease and pest susceptibilities during field observations. APHIS reviewed data supplied on the indirect effects of rice derived from LLRICE06 and LLRICE62 on other agricultural products.

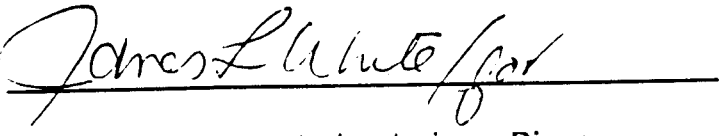
Rice is generally not consumed raw by humans, but rather is subjected to a number of processing steps followed by cooking. Studies by AgrEvo on the PAT enzyme indicate that it is both heat and acid labile. The enzyme loses 100% of its activity after cooking for 30 minutes at 75C . The enzyme is also inactivated after 30 minutes at a pH level of 4 or less. Should the enzyme not be destroyed by cooking, it would be subject to oral ingestion by humans. In addition, animals would be subject to oral ingestion via unprocessed grain or straw. It was shown that in 3 types of gastric juices representing livestock and in a simulated gastric juice representing humans, PAT was degraded within minutes.

The PAT enzyme does not have the characteristics of a toxin or an allergen. It is specific for L-phosphinothricin and has no homology to proteins other than to PAT genes from other organisms. Acetyl transferases as a group, however, are abundant and ubiquitous in nature where they share the common function of transferring an acetyl group from Acetyl CoA to a substrate. In summary, no adverse effects are predicted if the PAT enzyme is a minor constituent of human and animal food. APHIS notes that the use of glufosinate ammonium herbicides on rice derived from LLRICE06 and LLRICE62 are subject to regulations administered by the U.S. EPA, and food and feed use are subject to regulatory oversight by the FDA (see the Environmental Assessment)

G. DETERMINATION OF NONREGULATED STATUS

APHIS has determined that rice derived from transformation events LLRICE06 and LLRICE62 that has been field tested under APHIS authority, will no longer be considered a regulated article under regulations at 7 CFR Part 340. Permits or notifications acknowledged under those regulations will no longer be required from APHIS for field testing, importation, or interstate movement of transformation events LLRICE06 and LLRICE62 or their progeny. Importation of transformation events LLRICE06 and LLRICE62 seed is still, however, subject to the restrictions found in the Foreign Quarantine Notices (regulations at 7 CFR Part 319), just as they apply to any other importation of rice seeds. This determination has been made based on data collected from these approved field trials, laboratory analyses and literature references presented herein which demonstrate the following: (1) LLRICE06 and LLRICE62 exhibit no plant pathogenic properties. Although DNA from a plant pathogen was used in their development, these rice plants are not infected nor can these plants incite disease in other plants. (2) LLRICE06 and LLRICE62 are no more likely to become weeds than herbicide-tolerant rice which could potentially be developed by traditional breeding techniques. Rice is not a serious, principal or common weed pest in the U.S., and there is no reason to believe that resistance to glufosinate herbicides would enable rice to become a weed pest. (3) It is possible for LLRICE06 and LLRICE62 to transmit the *bar* gene via pollen to wild or cultivated sexually-compatible plants, although such transmission is likely to be rare. Even in the event of gene introgression, the resultant hybrid offspring will still be readily controlled by a range of commonly used weed management practices. Therefore, APHIS does not foresee that there will be an increased plant pest risk. (4) LLRICE06 and LLRICE62 are substantially equivalent with respect to a wide variety of agronomic properties and should have no adverse impacts on raw or processed agricultural commodities. (5) LLRICE06 and LLRICE62 are not toxic and they exhibit no potential to harm organisms beneficial to the agricultural ecosystem. Likewise, they should not affect threatened or endangered species.

APHIS has also concluded that there may be new varieties bred from transformation events LLRICE06 and LLRICE62; however, if such varieties are developed they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for rice already produced from transformation events LLRICE06 and LLRICE62 and field tested, or those observed for rice developed from traditional breeding.



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