USDA/APHIS
Draft Environmental Assessment

In response to Bayer CropScience Petition 06-234-01P seeking Extension of Determination of Non-regulated Status for Glufosinate Resistant rice, *Oryza sativa*, event LLRICE601

U.S. Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

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I. Summary

The Animal and Plant Health Inspection Service of the United States Department of Agriculture (USDA-APHIS), has prepared a draft Environmental Assessment (EA) in response to a request (APHIS Number 06-234-01p) from Bayer CropScience for an extension of a determination of non-regulated status issued for genetically engineered rice (*Oryza sativa* L.) lines LLRICE62 and LLRICE06 described in petition number 98-329-01p (AgrEvo 1998). Public comment is being solicited on this assessment. LLRICE62 and LLRICE06 contain the *bar* gene from *Streptomyces hygroscopicus* HP632 which confers resistance to the herbicide glufosinate ammonium. The Bayer CropScience request claims that an additional rice line, LLRICE601 does not present a plant pest risk, and therefore LLRICE601 and its progeny derived from crosses with other non-regulated rice should no longer be regulated articles under regulations at 7 CFR Part 340, based on its similarity to the antecedent organisms.

LLRICE601 was field tested under nine notifications issued by APHIS (see Table 3, pg. 12, petition 06-234-01p). Field tests were conducted from 1998-2001. According to the developer, LLRICE601 was being developed as a backup line for LLRICE62, but commercial development was subsequently dropped. There was no indication from field data reports to suggest that LLRICE601 would behave any differently than lines LLRICE62 and LLRICE06 under field conditions. After review of the submitted petition, APHIS has concluded that LLRICE601 is similar to LLRICE62 and LLRICE06, and therefore has made the preliminary decision to extend a determination of nonregulated status to LLRICE601.

II. Introduction

A. The Antecedent Organisms.

LLRICE06 and LLRICE62 were developed 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, respectively. The bar gene was derived from the soil-borne bacterium, *Streptomyces hygroscopicus* HP632. The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), an enzyme which inactivates the herbicide glufosinate ammonium. Therefore the rice field could be treated with this herbicide to control weeds without damaging the rice crop.

In 1999, APHIS granted a determination of nonregulated status to LLRICE62 (Unique Identifier ACS-OS ØØ2-5) and LLRICE06 (Unique Identifier ACS-OS ØØ1-4). An EA was prepared, (USDA-APHIS 1999) and during the 60-day public comment period in advance of the determination to deregulate these two lines, only four comments were received, all in support of deregulation. Bayer also conducted a full consultation with the FDA on both events (FDA 1999a, 1999b)

Although these lines were deregulated in 1999 and EPA registered glufosinate for use on rice in 2002, neither line has ever been distributed for commercial use.

In addition to the LLRICE62 and LLRICE06 events, APHIS has evaluated petitions for nonregulated status for other crop species expressing the *bar* gene. Since 1995, APHIS deregulated 4 corn events, 5 rapeseed events, and 1 cotton event containing the *bar* gene. In addition, the agency has deregulated 6 corn events, 2 rapeseed events, 7 soybean events, and 1 sugarbeet event containing the very similar *pat* gene derived from *Streptomyces viridochromogenes* which also encodes the PAT protein. The majority of these glufosinate herbicide tolerant crop lines were originally developed by AgrEvo, whose parent company Hoechst AG merged with Rhone-Poulenc to form Aventis in 1999. Aventis was acquired by Bayer in 2002. *Bar* and *Pat* genes have been licensed for use by Syngenta, Dow, and Pioneer. Transgenic corn, canola, and cotton containing *bar* or *pat* genes have been commercialized beginning in 1996.

B. **Phosphinothricin N-Acetyltransferase (PAT)**

This enzyme modifies glufosinate herbicides so that they are no longer toxic to plants (OECD 1999, OECD 2002). The gene is found in a wide range of microorganisms and encodes a well-characterized protein that has a history of safe use in agriculture. Reviews of 26 other events containing this protein have established the environmental safety of this protein (for more details see the preliminary risk assessment in Appendix 1.

C. The Extension Process.

The extension process developed from APHIS' expectation that many regulated articles will be developed that differ insignificantly from others that have already been reviewed and granted nonregulated status. The aim of making comparisons between regulated articles and their antecedent organisms is to ensure that the new regulated articles in question raise no serious new issues meriting full review under the petition process. To qualify for the extension process (7 C.F.R. 340.6(e)), the regulated article must be similar to the previously deregulated, antecedent organism. Introduction of genetic material into the same species, or by a different transformation method, or that differs only in regulatory sequences, are examples of regulated articles that qualify for extension (see APHIS website, http://www.aphis.usda.gov/brs/extback.html). In the extension process, the developer submits a petition comparing the subject organism to the antecedent organism(s) while APHIS evaluates this comparison and determines whether any differences pose a significant plant pest risk.

D. Comparison of LLRICE601 with deregulated events -06 and -62.

APHIS compared molecular and agronomic data from LLRICE601 to the previously deregulated rice events LLRICE06 and LLRICE62 as part of its preliminary risk assessment of the subject rice line (see Appendix 1). In summary, LLRICE601 is similar to LLRICE62 and 06. All contain the *bar* gene preceded by the 35S promoter, confer glufosinate tolerance, and exhibit no other significant phenotypic differences from the

corresponding parental comparator. There are a number of subtle differences listed in the preliminary risk assessment in Appendix 1, but none were deemed to be significant or to pose a plant pest risk.

E. USDA-APHIS Regulatory Authority

APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Plant Protection Act (7 U.S.C. 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. In this submission, the plants have been genetically engineered using recombinant DNA techniques, and *Agrobacterium tumefaciens* is the donor of the *nos* DNA regulatory sequence that facilitates the expression of the introduced gene in the engineered plants. The *nos* sequence is from the soil-inhabiting bacterial plant pathogen, *Agrobacterium*, which is one of the listed taxa in the 7 CFR § 340.

Section 340.6(e)(2) of the regulations, entitled "Extensions to determinations of nonregulated status," provides 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 articles in question.” If APHIS determines that the regulated article is sufficiently similar to an antecedent organism, the agency can grant the petition. In such a case, APHIS authorizations (i.e., permits or notifications) would no longer be required for field testing, importation, or interstate movement of the nonregulated article or its progeny.

This environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.C § 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR §§ 1500-1508); (3) USDA regulations and implementing NEPA (7 CFR § 1b); and (4) APHIS NEPA Implementing Procedures (7 CFR § 372).

F. Food and Drug Administration (FDA) Regulatory Authority

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. Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. For lines LLRICE06 and LLRICE62, Bayer completed a consultation with the FDA. LLRICE601, which was not intended for commercialization, was not submitted to FDA for evaluation under FDA’s voluntary biotechnology consultation process. However, according to the FDA, Bayer has provided information to FDA about the safety of the PAT protein, molecular characterization, and nutritional

composition of grain from LLRICE601. Based on the available data and information, FDA has concluded that the presence of this bioengineered rice variety in the food and feed supply poses no food or feed safety concerns(http://www.cfsan.fda.gov/~lrd/biorice.html).

III. PURPOSE and NEED

APHIS has prepared this EA before making a final determination on the status of LLRICE601 as a regulated article under APHIS regulations. In accordance with 7 CFR 340.6(e)(3) a preliminary decision based on this EA and preliminary risk assessment will be published in the Federal Register before the decision becomes final and effective. Additionally, the EA and Bayer petition requesting an extension of a determination of non-regulated status issued for genetically engineered rice(*Oryza sativa* L.) lines LLRICE62 and LLRICE06 will also be publicly available on the APHIS website.

IV. ALTERNATIVES

A. No Action Alternative

Under the "no action" alternative, APHIS would take no action with respect to this petition at this time. LLRICE601 would continue to be a regulated article under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of LLRICE601 plants. APHIS might choose this alternative if it concluded that it could not, under all the circumstances, evaluate the petition adequately and reach a preliminary decision.

B. Denial of Petition: Continuation as a Regulated Article

Under this alternative, APHIS would deny the petition. LLRICE601 would continue to be a regulated article under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of LLRICE601 plants. APHIS might choose this alternative if there were insufficient evidence to demonstrate the similarity of LLRICE601 to LLRICE62 or LLRICE06. If APHIS chooses this alternative, Bayer may subsequently submit a modified or separate petition for a determination of nonregulated status without prejudice. (7 C.F.R. 340.6 (e) (4)).

C. Determination that LLRICE601 plants are No Longer Regulated Articles

Under this alternative, LLRICE601 would no longer be a regulated article under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of glufosinate tolerant rice derived from LLRICE601. APHIS might choose this alternative if there were sufficient evidence to demonstrate the similarity of LLRICE601 to LLRICE62 or LLRICE06 for which the agency had previously concluded presented no greater plant pest risk than rice developed in traditional breeding programs.

D. Preferred Alternative

APHIS has chosen Alternative C as the preferred alternative. This is based upon the similarity of LLRICE601 to the antecedent organisms.

V. Affected Environment

A. Current Practices

In the United States, rice cultivation is concentrated in two regions:

1) the southern Mississippi River Valley, beginning in the Missouri "Bootheel" and moving south through Arkansas and Louisiana to the Gulf Coastal Plain into Texas

2) North Central California

In the South, long grain rice varieties are the principal types grown, whereas California grows primarily medium grain and short grain rice varieties. No GM varieties of rice are grown and distributed commercially. Herbicide tolerant rice lines resistant to imidazolinone herbicides have been developed by conventional mutation-induced breeding techniques. Marketed as Clearfield® varieties, the herbicide tolerant trait has been incorporated into long grain varieties for use in Southern states where red rice may be a weed pest. In 2006, Clearfield® varieties accounted for approximately 34% of the rice acreage grown in the South (Ouzts 2006). Crop rotation, irrigation management, and herbicides are used to control weeds in rice and no single weed management strategy is successful for control. A more detailed treatment of weed control can be found in Section E of the Developer's original petition (AgrEvo 1998). Glufosinate is a low toxicity, non-selective herbicide. Glufosinate use on rice is regulated by the EPA. It has been registered for use on rice since 2002.

B. Rice Biology

In this section of the environmental assessment, the biology of rice and plants related to rice are considered. Because the mechanism by which genes are moved from one flowering plant to another is through cross-pollination of sexually compatible plants, the plants with which rice can cross-pollinate are described. Below is an analysis of the biology of rice. This review focuses solely on rice in the United States. Other sources of information include a review prepared by the Organization for Economic Cooperation and Development (OECD), "Consensus Document on the Biology of *Oryza sativa* (Rice)" found at: http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)26 and the "Biology and Ecology of Rice (*Orzya sativa* L.) In Australia" found at http://www.ogtr.gov.au/pdf/ir/biologyrice.pdf

Cultivated rice is included in the genus *Oryza* of the grass family (Poaceae). The genus *Oryza* contains twenty two species distributed through the tropical and subtropical regions of Asia, Africa, Central and South America, and Australia. Two species are cultivated and twenty are wild (Morishima, 1984; Vaughan et al., 2003). *O. sativa* is commonly referred to as Asian rice and is cultivated worldwide. The word "rice" generally indicates a plant and a crop of this species. *O. glaberrima* is commonly referred

to as African rice and is cultivated in West and Central Africa. The genus *Oryza* is not native to the continental United States. One species, *Oryza latifolia* Desv. Broadleaf rice, is native to Puerto Rico. Only the single species, *Oryza sativa* is cultivated in the United States. Wild rice grown in the upper Midwest is another genus entirely and does not hybridize with Oryza.

Red rice is a weed complex associated with cultivated rice grown in the southern United States. It is a diverse complex of *Oryza sativa* ssp. *indica*, *O. sativa* ssp. *japonica*, *O. nivara* and *O. rufipogon* (Vaughan et al., 2001). Red rice has a red pericarp or seed coat, pubescent light-green leaves, pubescent seeds that are shed easily (shatter) and a dormancy mechanism that enables seed survival for extended periods under unfavorable soil and environmental conditions (Eastin, 1979; Diarra et al., 1985; Ladinsky, 1985). These characteristics are different from most cultivated rice which has a tan pericarp, does not shatter readily and has little if any seed dormancy. Red rice is also taller at maturity than most of the cultivars grown today. It can be a troublesome weed in rice growing operations in the southern United States.

C. Detection of LLRICE601 in commercial rice

Bayer CropScience has learned that samples of commercial long grain rice were found to contain low levels of an event containing the *bar* gene. Molecular characterization has indicated that the detected event was LLRICE601 and not LLRICE62 or LLRICE06. Aventis discontinued field testing LLRICE601 in 2001.

VI. POTENTIAL ENVIRONMENTAL IMPACTS

Potential impacts to be addressed in this EA are those that pertain to the use of LLRICE601 and its progeny in the absence of confinement.

1. Potential impacts from gene introgression from LLRICE601 into its sexually compatible relatives.

In assessing the risk of gene introgression from LLRICE601 into its sexually compatible relatives, APHIS considered two primary issues: 1) the potential for gene flow and introgression; and 2) the potential impact of introgression.

Rice is not sexually compatible with plant species outside of the *Oryza* genus. In the United States, there are no sexually compatible species of *Oryza* other than *Oryza sativa*. Rice is primarily self-pollinating, and outcrossing rates usually occur at a very low rate (generally less than 1%) (OECD, 1999). The floral structure of *O. sativa* and the short viability of its pollen present biological barriers to cross-pollination (Gealy et al., 2003). A rice floret opens only once for a short period of time, usually for approximately an hour or less, during which time fertilization can occur. The stigma is fertilized by pollen produced by the same floret, therefore rice flowers are typically self-pollinated. Pollen viability is for no longer than five to ten minutes, but the stigma can remain viable for two to four days and can be fertilized by foreign pollen if for some reason it is not fertilized by its own pollen (Gealy et al., 2003). Gene introgression into commercial rice

via pollen flow is therefore very unlikely. Due to the high selfing characteristic of rice, the Association of Official Seed Certifying Agencies (AOSCA) certified seed regulations for foundation seed require a minimum isolation distance from other rice varieties of at least ten feet when ground drilled and 50 feet if ground broadcast (AOSCA, 2003).

In addition, another mechanism for gene escape is outcrossing to weedy/red rice. Species in the red rice complex, sometimes associated with the cultivation of rice, are the only species likely to hybridize with LLRICE601, but their competitiveness requires the same specific environmental conditions that are used for cultivation of commercial rice. Therefore, red rice is not considered weedy in other environments. Offspring from hybridization between LLRICE601 and red rice will not have enhanced competitive abilities except for glufosinate resistance. As other chemical and mechanical control practices are available besides glufosinate application, LLRICE601 is unlikely to increase the weediness potential of red rice.

Because red rice is the only species likely to hybridize with glufosinate tolerant rice, and control practices are available to mitigate an increased plant pest risk should introgression occur, there would be no impact related to outcrossing from deregulating this line (Alternative C). There would also be no impact from continuing to regulate the line (Alternatives A and B).

2. Potential impacts based on the relative weediness of LLRICE601

Rice is a highly domesticated aquatic crop species, which grows exclusively in highly managed aquatic ecosystems. It is non-competitive with weed species and is self-pollinated. As a result, errant seed does not pose a threat to wild or managed, non-flooded ecosystems. Rice plants (*Oryza sativa*) growing unintentionally around rice growing areas are regarded as weeds (Vaughan and Morishima, 2003). Weedy rice can result from the escape of cultivated varieties into surrounding areas if conditions are suitable for establishment. It appears that weedy rice commonly evolves through the degeneration of domesticated rice (Vaughan et al., 2003). Weedy rice may be derived from hybridization between different cultivars, selection of weedy traits present in cultivars, relics of abandoned cultivars, or may have been brought into the growing region through contaminated seed stocks (Vaughan and Morishima, 2003). Weedy rice typically grows only as a component of agro-ecosystems where rice is grown or has been grown. It does not persist in environments inhospitable to rice cultivation.

Weedy red rice can be a major economic problem when it occurs in rice fields because it can lead to a loss in yield through competition with the desired cultivar as well as decreasing the value of the harvested grain. It is for this reason that many seed certification standards have a zero tolerance for red rice contamination in fields established for certified seed increases. For example see www.moseed.org/rice.htm.

No change in general agronomic traits (leaf color, shape, growth habit, days to pollen shed, days to maturity and seed germination rates) have been observed in LLRICE601 that might affect the plant's ability to persist in the environment (see Appendix 1). The presence of the *bar* gene in the rice seeds has not altered seed germination rates.

Because *O. sativa* does not persist in unmanaged ecosystems, it is only able to survive where rice is cultivated, and can be managed with existing cultural practices, there would be no weed impact from deregulating the genetically modified variety (Alternative C) and its subsequent release relative to the release of any conventional rice variety. There would also be no impact from continuing to regulate the line (Alternatives A and B).

3. Potential impact on non-target organisms, including beneficial organisms and threatened or endangered species

The PAT protein is not known to have any toxic properties. The EPA, based on submitted toxicological data, established an exemption from the requirement of a tolerance for residues of PAT and the genetic material necessary for its production in all plants (USEPA 1997). Furthermore, LLRICE601 produces lower levels of PAT protein than the antecedent organism LLRICE62 which had no reported non-target effects. The level of protein in LLRICE601 seed has been estimated to be 120 ng/g fw which is only 0.000034% of the crude rice protein.

Analysis of both qualitative and quantitative information from the petition and published data, supports the developer's conclusion that the unconfined release of LLRICE601 and its progeny would not harm any non-target or Federally listed (or proposed) threatened or endangered species. An analysis of Threatened and Endangered Species was conducted for the six major rice producing States (Arkansas, California, Louisiana, Mississippi, Missouri and Texas) and for three minor production States (Florida, Oklahoma, Tennessee) using the U.S. Fish and Wildlife database http://ecos.fws.gov/ecos/index.do and NatureServe database: http://www.natureserve.org/explorer/. The analysis found that there are a few plant species that are sometimes associated with rice fields in California. In California and the Gulf Coast States there are a number of Threatened and Endangered Animal species that could visit or inhabit rice fields from time to time. Most of these are various bird species that could feed in and around rice production areas. In California the Giant Garter Snake can live in rice fields and Vernal Pool Fairy Shrimp are known to inhabit rice fields. In Texas the Attwater's Greater Prairie Chicken is known to inhabit fallow rice fields. The engineered rice would not be expected to affect any of these species or other species that visit or inhabit rice fields since the PAT protein has been shown to be neither toxic nor allergenic (Hérouet, et al., 2005). Likewise, based on the phenotypic similarity to conventional rice varieties in all respects other than glufosinate tolerance, APHIS concluded that LLRICE601 would not have any more impact on habitat of listed species than conventional rice.

BRS has reviewed the data in accordance with a process mutually agreed upon with the U.S. Fish and Wildlife Service to determine when a consultation is needed as required under Section 7 of the Endangered Species Act. APHIS reached a determination that the release of LLRICE601 would have no effect to listed species and consequently a written concurrence or formal consultation with Fish and Wildlife Service is not required for this EA.

Under any of the alternatives, there would be no impact on nontarget organisms or Federally-listed endangered species.

4. Potential impacts on biodiversity

Analysis of available information indicates that LLRICE601 exhibits no traits that would cause increased weediness and that its unconfined cultivation should not lead to increased weediness of other cultivated rice or other sexually compatible relatives. LLRICE601 line exhibited no change in disease susceptibility, and it is unlikely to harm non-target organisms common to the agricultural ecosystem or threatened or endangered species recognized by the U.S. Fish and Wildlife Service. Based on this analysis, there is no apparent potential for significant impact to biodiversity. If APHIS chooses alternative A or B, there would also be no impact on biodiversity

5. Potential impacts on agricultural practices

If LLRICE601 were to be grown commercially, the effect from introducing LLRICE601 into the environment on agricultural practices would be no different than for the deregulated lines. As the trait expressed is resistance to glufosinate and the level of resistance is similar to that of the other two lines, there should be no difference in impact on standard agricultural practices in rice cultivation and controlling volunteer rice. See Appendix I for more details.

6. Potential impacts on organic farming

The National Organic Program (NOP) is administered by USDA's Agricultural Marketing Service (AMS). Organic production operations must develop and maintain an organic production system plan approved by their accredited certifying agent in order to obtain certification. Organic certification of a production or handling operation is a process claim, not a product claim. Organic certification involves oversight by an accredited certifying agent of the materials and practices used to produce or handle an organic agricultural product. Oversight by a certifying agent includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records.

The organic system plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods, unless a certifying agent has reasonable suspicion that a prohibited substance or excluded method was used. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards. Planting of genetically-modified seed would render the organic crop non-organic and require it to be sold as conventional. The status of the organic operation depends on the operator's foreknowledge of the origin and status of the seed planted. The duty of an organic grower to develop and maintain an organic production system that meets the relevant regulatory standards will not change regardless of which alternative is selected. Therefore, granting the extension of nonregulated status

(alternative C) will have no significant impact on organic farming. Likewise there will be no significant impact from alternatives A and B.

7. Potential impacts on raw or processed agricultural commodities

APHIS analysis of data on agronomic performance, disease and insect susceptibility, and compositional profiles of LLRICE601 and its parent variety indicate no significant differences between the two that would be expected to cause either a direct or indirect plant pest effect on any raw or processed plant commodity from deregulation of LLRICE601. Similarly, there were no significant differences between LLRICE62 and LLRICE06 and their corresponding parent varieties. There would be no impacts on raw or processed agricultural commodities from deregulating the genetically modified variety (Alternative B). There would also be no impact from regulating the line (Alternative A).

VII. CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

Executive Order (EO) 12898, "Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to conduct their programs, policies and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and significant human health or environmental effects. Each alternative was analyzed in its ability to affect minority and low-income populations. None of the alternatives was found to pose disproportionately high or significant human health or environmental effects to any specific minority or low-income group.

EO 13045, “Protection of Children from Environmental Health Risks and Safety Risks,” acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency’s mission) requires each Federal agency to identify, assess and address environmental health risks and safety risks that may disproportionately affect children. None of the alternatives are expected to have disproportionately high or significant human health or environmental effects on children.

EO 13112, “Invasive Species,” states that federal agencies take action to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological and human health impacts that invasive species cause. Rice is not invasive and is widely prevalent in the U.S. Based on the data submitted by the applicant and reviewed by APHIS, the engineered plant is not different in any fitness characteristics from its parent that might increase its invasive potential.

Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions" requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories and possessions that result from actions being taken. APHIS has given this due consideration and does not expect a significant environmental impact outside the United States should an extension of non-regulated status be granted for LLRICE601 or if one of the other alternatives is chosen. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new rice cultivars internationally, apply equally to those covered by an APHIS determination of non-regulated status under 7 CFR Part 340. Any international traffic of LLRICE601 subsequent to an extension of non-regulated status for LLRICE601 would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control" (https://www.ippc.int/IPP/En/default.jsp). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (137 countries as of April 2005). In April, 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11; Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk, and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for bioengineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The Cartagena Protocol on Biosafety is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003 and 134 countries are Parties to it as of July 13, 2006 (see http://www.biodiv.org/biosafety). Although the United States is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with domestic regulations that importing countries that are Parties to the Protocol have put in place to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation. LMOs

imported for food, feed or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (http://usbiotechreg.nbii.gov). This data will be available to the Biosafety Clearinghouse. APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the United States and in the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard for the *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (see http://www.nappo.org/Standards/Std-e.html). APHIS also participates in the North American Biotechnology Initiative (NABI), a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including: Argentina, Brazil, Japan, China, and Korea. Many countries, e.g. Argentina, Australia, Canada, China, Japan, Korea, Philippines, South Africa, Switzerland, the United Kingdom.

VIII. REFERENCES CITED

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XI. APPENDICES

Appendix I.

Summary of the evidence that the inadvertent release of

LLRICE601 poses no environmental concerns

Background

In 1999, APHIS granted a determination of nonregulated status to two herbicide tolerant rice transformation events designated LLRICE62 (Unique Identifier ACS-OSØØ2-5) and LLRICE06 (Unique Identifier ACS-OSØØ1-4). These lines were produced by inserting the *bar* gene from *Streptomyces hygroscopicus* HP632 which encodes the enzyme phosphinothricin N-acetyltransferase (PAT). PAT provides resistance to the herbicide glufosinate by metabolizing the active ingredient of the herbicide to an inactive form. During the 60-day public comment period in advance of the determination to deregulate these two lines, only four comments were received, all in support of deregulation. Although these lines were deregulated in 1999 and EPA registered glufosinate for use on rice in 2002, neither line has ever been distributed for commercial use.

In addition to the LLRICE62 and LLRICE06 events, APHIS has evaluated petitions for nonregulated status for other crop species expressing the *bar* gene. Since 1995, APHIS deregulated 4 corn events, 5 rapeseed events, and 1 cotton event, containing the *bar* gene. In addition, the agency has de-regulated 6 corn events, 2 rapeseed events, 7 soybean events, and 1 sugarbeet event containing the very similar *pat* gene derived from *Streptomyces viridochromogenes* which also encodes the PAT protein. The majority of these glufosinate herbicide tolerant crop lines were originally developed by AgrEvo, whose parent company Hoechst AG merged with Rhone-Poulenc to form Aventis in 1999. Aventis was acquired by Bayer in 2002.

Phosphinothricin N-Acetyltransferase (PAT)

This enzyme modifies glufosinate herbicides so that they are no longer toxic to plants (OECD 2002). The gene is found in a wide range of microorganisms and encodes a well characterized protein that has a history of safe use in agriculture. Reviews of 26 other events containing this protein have established the environmental safety of this protein. PAT protein lacks sequence homology to known toxins and is unlikely to be an allergen because it is rapidly digested in simulated gastric and intestinal fluids, is unstable to heat greater than 40^{o}C, and lacks glycosylation sites. Numerous feeding studies have been conducted in mice, birds, and rabbits which document that the protein is neither toxic to humans or animals (OECD 1999). As such the EPA, based on submitted toxicological data, established an exemption from the requirement of a tolerance for residues of the phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production in all plants. Thus, the potential for toxicity or allergenicity to humans or nontarget organisms for PAT protein expressed in rice lines containing event LLRICE601 is considered remote.

Comparison of LLRICE601 with deregulated events -06 and -62.

Rice lines LLRICE601, -06, and -62 were field tested under the appropriate APHIS authorizations over several growing seasons in the United States prior to the decision of the developer to seek nonregulated status for lines LLRICE06 and LLRICE62. LLRICE601 was maintained by the developer as a backup line. Field evaluations of LLRICE06 and 62 are described in documentation submitted by the developer in support of the petition to APHIS for a determination of nonregulated status (http://www.aphis.usda.gov/brs/aphisdocs/98_32901p.pdf). For these two lines it was specifically concluded that they posed no greater plant pest risk than rice developed in traditional breeding programs and were therefore granted nonregulated status by APHIS. APHIS further notes that since the date of the determination of nonregulated status for lines LLRICE06 and -62 in 1999, other regulatory authorities (Canada, Russia, and Argentina) have approved its use in the environment and/or as food and feed. Based on a comparison of the data submitted in the petition for granting nonregulated status to LLRICE06 and 62 and data submitted by Bayer on August 4, 2006, regarding the molecular characterization of event LLRICE601, APHIS has identified the following similarities and differences between the rice lines:

Similarities between rice lines LLRICE601 and -06; -62

1. Rice line LLRICE601 is similar to lines LLRICE06 and LLRICE62. All contain a single transgene, *bar* driven by the 35S CaMV (Cauliflower Mosaic Virus) promoter.
2. In no cases were antibiotic resistance markers (kanamycin for -06 and -62; spectinomycin for 601) from the respective plasmid vectors integrated into the genome.
3. Molecular and genetic characterization of all three lines indicate that the *bar* gene is stably inherited.
4. All are resistant to the herbicide glufosinate.

5. All differ from their traditional counterpart by only the addition of the *bar* gene sequence into the genome, and the expression of the PAT protein.
6. -601 and -62 produce a single anti-PAT immunoreactive peptide of the same apparent molecular weight when analyzed on Western blots.

Differences between rice lines LLRICE601, -06, and -62.

1. The DNA construct was introduced into the LLRICE06 and -62 by direct gene transfer but was introduced into -601 by *Agrobacterium*-mediated transformation. Both direct gene transfer and *Agrobacterium*-mediated transformation are standard practices for introduction of genetic material into plant genomes and therefore APHIS does not consider this difference significant. Both are well characterized transformation methods which integrates the donor genes into the chromosome of the recipient plant cell. The donor DNA sequences are stably and irreversibly integrated into the plant's chromosomal or organellar DNA, where they are maintained and inherited as any other genes of the plant cell.
2. The 35S CaMV promoter is slightly longer for -601 versus -06 and -62. APHIS does not consider this difference significant. The promoter in -601 has been used in other events where no unusual effects were observed and which have completed USDA and FDA regulatory review. The 35S CaMV promoter is among the most common gene sequences used in genetically engineered plants and has a history of safe use.
3. LLRICE601 uses the *nos* (nopaline synthase) terminator while -06 and -62 use the 35S CaMV terminator. APHIS does not consider this difference significant. The *nos* terminator does not encode a protein or functional RNA, is widely used in genetic engineering, and has been approved in a number of deregulated products, for example LLCotton25 and MON810 corn.
4. LLRICE06, -62, and -601 represent different varieties of rice which have each been transformed with the *bar* gene. LLRICE06 was transformed into the medium grain variety M202, LLRICE62 was transformed into the medium grain variety Bengal, and LLRICE601 was transformed into the long grain variety Cocodrie. APHIS does not consider this difference significant. During the evaluation of a petition for nonregulated status, APHIS considers the fact that a particular event may be crossed into other genetic backgrounds and grants nonregulated status to the subject of the petition and all progeny bred from the deregulated lines. Indeed LLRICE62 has been introgressed into other long grain varieties through conventional breeding and these all have nonregulated status.
5. There are minor differences in the level of PAT protein expressed between all three events (the two nonregulated events LLRICE06 and -62 and the regulated event -601). In the seed, the level of PAT protein in LLRICE601 is below the level in -06 and -62. In the leaf tissues, the level of PAT protein in -601 is much less than the level in -62 but is slightly higher than the level in -06. APHIS does not consider these differences significant. As the PAT protein levels of -601 are below those of -62 and no unintended effects were observed on non-target

organisms in –62, no unintended effects on non-target organisms due to differences in PAT expression levels are expected in -601.

6. The sequence of the PAT protein produced in LLRICE601 is identical to the sequence produced in the approved cotton line LLCotton25. These sequences vary from the LLRICE06 and -62 PAT proteins by a single amino acid at position 2 where the former have an aspartic acid residue and the latter have a serine. APHIS does not consider this difference to be significant because lines corresponding to both versions of the protein have completed USDA and FDA regulatory review.

Molecular Characterization of LLRICE601

Details on molecular characterization of LLRICE601 were submitted to APHIS in a report, Molecular Characterization of Glufosinate-Tolerant rice transformation event LLRICE601, dated August 4, 2006. Bayer included a Southern blot analysis of DNA from lines containing the event LLRICE601 consistent with the conclusion that only a single bar gene flanked by an intact 35S promoter and a truncated *nos* terminator were inserted into the genome. In addition, the Southern blot revealed extra bands for the 35S CaMV promoter suggesting a second copy of the promoter inserted elsewhere in the genome. The random insertion of an extra 35S promoter fragment in the rice genome is unlikely to have any consequence as the effectiveness of the promoter is dependent on it inserting close enough to DNA encoding a functional gene. At a low frequency, it could potentially insert near enough to another gene to alter the expression of a native rice gene. Alternatively, it could integrate within a native rice gene and disrupt its function. As submitted phenotypic data (see Whole Plant Evaluation below) revealed no apparent differences between LLRICE601 and the parent variety, if there are any changes in gene expression, those changes do not appear to pose a plant pest risk. Southern blots were provided that were consistent with the conclusion that no coding sequences from the vector, including the spectinomycin gene, were integrated into the rice genome.

To characterize the insertion site of the P35S-bar-nos gene, flanking DNA was sequenced and analyzed for the presence of transcriptional and translational regulatory elements (CART, TATA-boxes, ribosome binding sites, and polyadenylation signals). The absence of most or all of these regulatory elements in each putative open reading frame in the flanking regions is strong evidence that the expression of newly created proteins derived from the 5-prime or 3-prime junction region is highly unlikely. Sequence comparison of flanking DNA to genomic DNA conclusively identified the insertion site on chromosome 12. At the insertion site, no homology was found to any known gene, cDNA, or expressed sequence tag (EST) indicating that the insertion did not disrupt a native rice gene.

Stability of the inserted *bar* gene cassette was evaluated over multiple generations. The results obtained demonstrate the stability of the event LLRICE601 at the genomic level.

Whole plant evaluations of LLRICE601.

Details on field evaluations of lines LLRICE601-5001, -5201, -5401, and 5601 were submitted to APHIS in a report, Agronomic Performance of glufosinate-tolerant rice transformation event LLRICE601, dated August 4, 2006. At the T3 generation, these four inbred lines of LLRICE601 and the parent variety, Cocodrie, were tested for two seasons in multi-location replicated trials (AR, LA, MS, and TX). The last testing was completed in 2001. LLRICE601 exhibited consistent commercial level resistance to glufosinate whereas Cocodrie was sensitive. To measure response to rice pathogens sheath blight, panicle blight, and rotten neck blast, LLRICE601 was tested alongside Cypress, the standard for US long grain rice disease screening, and was found to have similar responses. For attributes related to weediness potential (seed germination, dormancy, and panicle shattering) LLRICE 601 and Cocodrie were virtually indistinguishable. Likewise, for all other agronomic properties measured including, panicle morphology, days to maturity, lodging tendency, yield, and grain characteristics (a total of 86 attributes were measured) LLRICE601 was comparable to Cocodrie. Thus, when grown in the field, LLRICE601 was nearly indistinguishable from Cocodrie. In field tests in 2000, LLRICE601 appeared to be shorter than Cocodrie. However the two lines were not significantly different in height during the 2001 growing season. Similarly, LLRICE62 and LLRICE06 were not significantly different from their respective parental comparators in any agronomic characters except for glufosinate tolerance. All the characteristics measured for LLRICE601, LLRICE06, and LLRICE62 were in the expected range of conventional rice except for the glufosinate resistance trait.

Compositional analysis of LLRICE601

Aventis looked at grain crude fat/oil, protein, ash, fiber, carbohydrates, minerals, vitamins, amino acids, and fatty acids. No significant differences were observed between transgenic rice, transgenic rice sprayed with herbicide, and non-transgenic rice for any of the parameters measured.

No evidence for inadvertent effects in LLRICE601.

Morphological and biochemical data reveal no significant differences between LLRICE601 and Cocodrie, indicating that the insertion of the CaMV35S promoter-*bar* gene- *nos* terminator and the additional 35S promoter have created no apparent unintended effects in LLRICE601.

Environmental Impacts from the introduction of LLRICE601

LLRICE601 grows normally and appears to interact with other organisms in the environment in ways that should not present plant pest risks or significant impacts on the environment. Given that the PAT protein is non-toxic, no increased risk to nontarget organisms or threatened and endangered species is anticipated by the introduction of LLRICE601. Rice is not listed as a common, serious, or principal weed or a weed of current or potential importance in the United States and Canada. Species in the red rice complex sometimes associated with the cultivation of rice, are the only species likely to hybridize with LLRICE601, but their competitiveness requires the same specific environmental conditions that are used for cultivation of commercial rice. Therefore, red

rice is not considered weedy in other environments. Offspring from hybridization between LLRICE601 and red rice will not have enhanced competitive abilities except for glufosinate resistance. As other chemical and mechanical control practices are available besides glufosinate application, LLRICE601 is unlikely to increase the weediness potential of red rice.

Effects on Agricultural Practices from the introduction of LLRICE601

Because this event is similar to the two approved lines (LLRICE62 and LLRICE06) the effect from introducing LLRICE601 into the environment on agricultural practices would be no different than for the deregulated lines. As the trait expressed is resistance to glufosinate and the level of resistance is similar to that of the other two lines, there should be no difference in impact on standard agricultural practices in rice cultivation and controlling volunteer rice. Specifically, if volunteer rice were to appear in agricultural fields it can be managed in the same way that any glufosinate-tolerant volunteers are currently managed. For example in rotation practices where a soybean crop might follow a rice crop, volunteer rice is usually treated with post-emergent soybean herbicides for controlling grasses. Herbicides such as quizalofop [Assure II], fluazifop [Fusilade]or sethoxydim [Poast] are commonly employed. Volunteer rice can also be controlled with preplant burndown applications of paraquat [Gramoxone Extra] and glyphosate [Roundup Ultra or Roundup WeatherMax]. LLRICE601 is also sensitive to the herbicides used in the Clearfield® system, including imazethapyr [Newpath] and imazamox [Beyond]. In the case where Roundup Ready® soybeans or cotton would follow a rice crop, glyphosate could be used.

In addition, because it was concluded in the review of LLRICE 62 or LLRICE06 that this trait does not contribute to increased weediness, and based on agronomic data supplied by the developer for LLRICE601, it can also be concluded that this identical trait does not contribute to increased weediness in line LLRICE601.

Conclusion

LLRICE601 has undergone extensive field testing and characterization.

1. It exhibits no plant pathogenic properties and is no more susceptible to disease than the reference rice variety, Cypress.
2. It is no more likely to become a weed than other herbicide tolerant rice varieties developed by traditional plant breeding. Rice is not a 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. While it is possible that the *bar* gene could be transmitted to red rice by pollen gene flow, control practices are available to mitigate an increased plant pest risk should introgression occur.
4. LLRICE601 is not toxic and exhibits no potential to harm organisms beneficial to the agricultural system. Likewise, it is not expected to harm threatened or endangered species.

5. LLRICE601 is not different than conventional rice with respect to a wide variety of morphological, agronomic, and biochemical attributes and therefore is no more likely to cause damage to raw or processed agricultural commodities than rice varieties developed by conventional breeding.
6. LLRICE601 has a high degree of similarity to two antecedent organisms (LLRICE06 and LLRICE62) which have been granted nonregulated status. All characteristics measured for LLRICE06, LLRICE62, and LLRICE601 were in the expected range of conventional rice with the exception of the glufosinate resistance trait.

APHIS believes that the available evidence stated above supports the conclusion that LLRICE601 is likely to be as safe as LLRICE06, -62, and conventionally bred rice lines. Therefore APHIS concludes that the inadvertent release of LLRICE601 poses no environmental concerns.

Selected resource materials:

USDA-APHIS documents:

- Petition submitted by the developer AgrEvo to APHIS in 1998 for LLRICE06 and LLRICE62. http://www.aphis.usda.gov/brs/aphisdocs/98_32901p.pdf

- APHIS decision documents at the time of the determination of nonregulated status in 1999. http://www.aphis.usda.gov/brs/aphisdocs2/98_32901p_com.pdf

EPA:

- USEPA. 1997. Phosphinothricin acetyltransferase and the genetic material necessary for its production in all plants-exemption from the requirement of a tolerance on all raw agricultural commodities. Federal Register: April 11, 1997, Volume 62, No. 70, pp. 17717-17720.

Food and Drug Administration documents for LLRICE06 and 62:

- Status: Consultation Completed
- Response Letter: http://www.cfsan.fda.gov/~rdb/bnfl063.html
- Summary Memo: http://vm.cfsan.fda.gov/~rdb/bnfm063.html

OECD 1999. Environmental Health and Safety Publications. Series on Harmonization of Regulatory Oversight in Biotechnology. No. 11.. Consensus Document on General Information Concerning the Genes and their Enzymes that Confer Tolerance to Phosphinothricin Herbicide. (http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)13)

OECD 2002**.** Environmental Health and Safety Publications. Series on Harmonization of Regulatory Oversight in Biotechnology. No. 25. Module II. Phophinothricin. (http://www.olis.oecd.org/olis/2002doc.nsf/43bb6130e5e86e5fc12569fa005d004c/c351fd9d795e54c1c1256bae0051a2a8/$FILE/JT00125605.PDF