



“Working Together to Make Trade Work

October 10, 2006

Via eRulemaking Portal:

Docket No. APHIS-2006-0140

Regulatory Analysis and Development, PPD

APHIS, Station 3A-03.8

4700 River Road Unit 118

Riverdale, MD 20737-1238

RE: Docket No. APHIS-2006-0140: *Bayer CropScience; Availability of an Environmental Assessment and a Preliminary Decision for an Extension of a Determination of Non-regulated Status for Rice Genetically Engineered for Glufosinate Herbicide Tolerance.*

[On July 31, 2006, Bayer CropScience (Bayer) of Research Triangle Park, NC notified the APHIS that trace levels of a genetically modified rice variety (LLRICE601) had been detected in long grain commercial rice. The LLRICE601 (LL601) event is substantially similar to two deregulated antecedent rice events, LLRICE62 and LLRICE06. Because LLRICE601 apparently never exhibited traits equivalent to the two more successful events, research on the LL601 line was stopped in 2001. In light of the discovery of trace levels of LLRICE601 in samples of marketed long grain rice, Bayer has petitioned APHIS for an extension of a determination of non-regulated status for LLRICE601. To this end, Bayer has supplied APHIS and the Food and Drug Administration (FDA) with information about the molecular characterization and agronomic performance of LLRICE601, enhancing the LL601 package with the full data packets of the more successful lines LLRICE62 and LLRICE06. APHIS has completed a preliminary risk assessment based on all the information and determined that LLRICE601 did not pose any environmental concerns.

On August 18, 2006, APHIS received a request for an extension of a determination of non-regulated status (APHIS No. 06-234-01p) from Bayer CropScience (Bayer) of Research Triangle Park, NC, for rice (*Oryza sativa*L.) designated as Liberty Link, Transformation Event LLRICE601, which has been genetically engineered for tolerance to the herbicide glufosinate. The request Bayer CropScience submitted seeks an extension of the determination of non-regulated status issued in response to APHIS petition number 98-329-01p for glufosinate-tolerant rice transformation events LLRICE06 and LLRICE62, the antecedent organisms. Because rice line LLRICE601 is similar to antecedent rice lines LLRICE06 and LLRICE62, Bayer CropScience requests a determination that rice line LLRICE601 does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.]

The North American Export Grain Association (NAEGA) appreciates this and other opportunities to provide comments to Agricultural Plant Health Inspection Service (APHIS) regarding its regulatory activities. APHIS actions that improve agricultural productivity and competitiveness and contribute to the national economy and the public health are critical to a sound agricultural economy and the provision of global food security.

The North American Export Grain Association, a not for profit trade association, established in 1912, consists of private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the bulk grain and oilseed exporting industry. NAEGA's mission is to promote and sustain

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the development of commercial export of grain and oilseed from the United States. NAEGA acts to accomplish this mission from its office in Washington D.C., and in markets throughout the world.

We have a direct interest in this rulemaking not only because of its impact on the trade of grain, but also because of the potentially precedent-setting nature in providing for science-based approach to address biotechnology regulation and influence appropriate actions from parties who are found responsible for the presence of a regulated genetically modified event in an agricultural commodity. Our particular concern is the impact of your decision making and that of those responsible parties on international regimes of influence to the trade of US agricultural commodities.

Comments:

1. **Circumstances like those that resulted in the proposed action are occurring far too frequently.** We encourage APHIS and other US Government Agencies involved in agricultural biotechnology regulation and market facilitation to re-double and strengthen efforts to provide for sound commercial practice and risk management as agriculture continues to utilize biotechnology.
2. **We agree with your conclusion** that rice line LLRICE601 is similar to the antecedent organisms in APHIS petition number 98-329-01p, and with your preliminary decision that rice line LLRICE601 should no longer be regulated under the regulations in 7 CFR part 340.
3. We consider the application of extension process being used for this deregulation action legal, appropriate and a welcome advancement in APHIS approach to its responsibility to establish and enforce regulations that protect American agriculture, the food supply, and the environment while allowing for the safe field testing of GE plants.
4. The trade disruption that has and will continue to result from findings of LLRICE601 is another example of a failure to accommodate the reality that any and all bulk commodity shipments “may contain” some coincidental amounts of commodities derived from modern biotechnology. Hence, policies and customer demands that include zero tolerance for GMO events in commercial production are impossible to meet.
5. The best way to overcome global controversy and trade disruption in bulk commodity shipments due to products derived from modern biotechnology is the adoption of a comprehensive, harmonized, global regulatory approval process that addresses key issues like Adventitious Presence (AP). Until such a process is in place, commercialization of new biotech products without prior approval by the governments in the major international markets for such products should be avoided.

6. Additional mandatory sampling and testing of commercial grains and oilseeds for genetic content such as is or will likely be put in place as a result of LLRICE610 unnecessarily increases costs, decreases competitiveness, and restricts liquidity of US origin production in global commodity markets and should be avoided. The US government should use federally appropriated funding to develop and gain international acceptance for sampling and testing procedures that do not impede commercial grain and oilseed export operations.
7. The US Government's and other regulatory procedures and statutory authority need to be thoroughly reviewed and updated on an ongoing basis to ensure that regulatory decisions reflect sound science, foster increased consumer confidence, and support a competitive commercial response to changing market conditions.
8. Technology providers must deploy exceptionally prudent and comprehensive risk management. Such effort is critical in light of the already controversial nature of the technology. Expanded effort and success to ensure that authorizations and major market approvals are secured and managed appropriately is necessary. Ultimately we call upon technology providers at all levels to apply best management practices from the research bench throughout the propagation and eventual crop marketing system to the point that the technology impacts its many beneficiaries.
9. **Technology providers responsible for the ultimate finding of the regulated event LLRICE601 in commercial supply bear principal corporate responsibility** for implementing effective and comprehensive quality-assurance practices that minimize trade disruptions resulting from shipments that may contain unauthorized biotechnology.
10. If APHIS proceeds with the deregulation of LL601, there will be a perception by many that Bayer has been rewarded for breaking the rules. That perception must be effectively dismissed by APHIS and USG government through the effective use of all the tools at their disposal.
11. A separate regulatory investigation is being conducted by APHIS. The investigation should result in a finding of how, when and where the LL601 event became mixed into the commercial rice supply. **While the investigation is independent of the deregulation process, the consequences of each can and should support the recovery of the market and further provide for sound commercial practice and risk management. Actions taken as a result of the investigation must, without regard to the extension of deregulation, cause responsible parties (company or institutions) to take remedial measures to**

counteract potential impacts to agriculture, the food supply, and the environment.

12. Since the findings of the investigation may lead to a stipulation settlement agreement, we strongly encourage the **stipulation agreement include provisions that cause responsible parties to accomplish “remedial measures to counteract potential impacts to agriculture”** by including commitments to :

- a. **Secure international regulatory approvals or appropriate regulatory acceptance for LLRICE 601.**
- b. Deploy best management practices or technical guideline to insure no contamination or cross contamination of biotech genes in the seed development and breeding programs ; and
- c. Deploy best management practices or technical guideline to identify, promptly address, and **implement corrective measures to resolve the market impact of the release of LLRICE601.** .

NAEGA appreciates your consideration of these comments. I would be pleased to respond to any questions the agency may have.

Sincerely,



Gary C. Martin
President and CEO