



BRS Stakeholder Update



Summer 2006

Message from the Deputy Administrator

Greetings! Every so often, you receive a stakeholder update from Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). Because we want to provide you with up-to-date, useful information, we're bringing exciting new changes to the look and content of the BRS stakeholder update. The update will now be sent out on a quarterly basis, and instead of focusing on one issue within BRS, it will include a variety of articles of interest to our stakeholders. We hope you find the new issues informative, and we welcome any suggestions you may have. Again, we greatly value our stakeholders and look forward to sharing interesting news with you through our quarterly stakeholder updates. If you have not previously registered with our on-line BRS stakeholder registry, please go to <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf> and sign up to ensure that you receive all future stakeholder updates.

Sincerely,

Cindy Smith
BRS Deputy Administrator

USDA Notified of Detection of GE Rice in Commercial Long Grain Rice

On August 18, USDA and the U.S. Food and Drug Administration (FDA) announced that they were notified by Bayer CropScience that the company detected trace amounts of regulated genetically engineered (GE) rice in samples taken from commercial long grain rice. USDA and FDA both reviewed the available scientific data and concluded that there are no human health, food safety, or environmental concerns associated with this GE rice.

Because the line of GE rice in question was regulated, APHIS is conducting an investigation to determine the circumstances surrounding the release and whether any violations of USDA regulations occurred. In addition, USDA is working closely with our trading partners to provide them with information about the safety of this product.

Bayer has developed many GE herbicide-tolerant products with the protein called Liberty Link, three of which are rice. The regulated line (LLRICE 601) uses the same protein as two deregulated lines that underwent thorough safety evaluations. FDA and APHIS deemed those lines safe for use in food and safe in the environment. This protein has been repeatedly and thoroughly scientifically reviewed and used safely in food and feed, cultivation, import and breeding in the United States, as well as nearly a dozen other countries around the world.

Bayer indicated it had no plans to market LLRICE 601 and therefore had not requested deregulation. However, based on reports that LLRICE 601 is in the marketplace, Bayer has petitioned APHIS to extend a determination of non-regulated status to LLRICE 601. The extension process can be used when a new GE crop variety is very similar to a previously deregulated GE variety.

APHIS has reviewed the information submitted by Bayer and has drafted an environmental assessment (EA) of the possible environmental impacts of extending non-regulated status to LLRICE601. On September 8, APHIS published in the *Federal Register*, the information submitted by Bayer, the EA, and a preliminary decision on whether to extend non-regulated status to this variety. APHIS will accept public comments on these documents for a 30-day comment period that will close on October 10. After considering the comments received, APHIS will publish a response to comments, a final EA, and a final decision. If granted, the extension of non-regulated status would become effective when the final decision is issued. Documents related to this subject are posted on the APHIS-BRS website as they become available at http://www.aphis.usda.gov/brs/brs_notices.html.

Creeping Bentgrass Peer Review Completed

Creeping Bentgrass is a widespread grass and the most utilized species for golf courses. BRS developed a "Perspective on Creeping Bentgrass, *Agrostis stolonifera* L." ("Perspective"), to summarize the known information about the biology of this species and to assist BRS in decisionmaking. Prior to this document, there was no thorough, general overview of the biology of this species. The "Perspective" has been referenced in several influential documents, and has played a role in several decisions made by BRS.

In April 2003, BRS received a petition seeking deregulation of GE glyphosate-tolerant creeping bentgrass. Due to several scientific issues surrounding this GE creeping bentgrass, including that it is a perennial and hybridizes with several wild and weedy relatives, BRS decided to prepare an environmental impact statement (EIS) in order to complete a comprehensive analysis of the impact of this product. The "Perspective" document played a fundamental role in BRS' decision to prepare an EIS, and comprised the basis for much of the agency's preliminary risk assessment of the strain. BRS decided to conduct a peer review of the document to ensure that relevant knowledge of the biology of creeping bentgrass is sufficiently understood. The process for peer review of this document was managed by the BRS Office of Science. In June of this year, BRS completed the peer review of the "Perspective" document, its first using new standards recommended by the Office of Management and Budget (OMB) for enhancing the peer review process of the federal government's science documents.

For the peer review, seven experts were asked to consider the document's scope and depth, clarity and focus, accuracy, objectivity, and whether it reflected current scientific thinking. The reviewers' comments covered a wide range of opinions. APHIS reviewed the comments and made appropriate changes to the "Perspective" document. A copy of the finalized "Perspective" document, as well as the peer reviewers' reports and BRS' response to the reviewers is available at http://www.aphis.usda.gov/about_aphis/creeping_bentgrass.shtml. The revised "Perspective" document is providing integral information for the glyphosate-tolerant creeping bentgrass EIS and will help inform future BRS decision making.

In August 2006, the Environmental Protection Agency (EPA), Oregon State University, and various individuals published a report entitled "Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in non-agronomic habitats" in *Molecular Ecology*. The report reviews the escape of GE glyphosate-tolerant creeping bentgrass from a bentgrass seed-control district in Oregon into wild populations. BRS appreciates this article, is carefully reviewing the information, and will consider it, along with the "Perspective" document, in making future decisions regarding glyphosate-tolerant creeping bentgrass.

ePermits News

In June, APHIS was named one of six Intergovernmental Solutions award winners by the Industry Advisory Council and the American Council for Technology. APHIS' ePermits, which BRS currently uses to process notification applications, was chosen because of the ease with which applicants can apply online and because it demonstrates innovative and effective use of technology. Congratulations to everyone within BRS and APHIS for their hard work in developing this system, and we look forward to offering our applicants future capabilities such as online permit applications.

In other ePermits news, while ePermits users require Level 2 access to use *all* of the program's features, BRS is provisionally allowing applicants with only Level 1 access to submit applications online. Whereas Level 1 access is available immediately upon completing an online application, Level 2 access requires independent verification of your identity. We hope that this interim measure will aid BRS applicants in taking advantage of the ePermits system. We encourage new users to apply for Level 2 access after obtaining Level 1 access. To obtain either Level 1 or Level 2 access, visit <http://www.eauth.egov.usda.gov/eauthWhatIsAccount.html>. To access ePermits, please visit <https://epermits.aphis.usda.gov/epermits>.

BRS: Playing an Active Role in International Standard Setting

Part of BRS' role in regulating biotechnology involves helping to develop international biotechnology standards to promote science-based policies that are aligned with U.S. safety standards and to ensure that GE products can be traded between nations. The World Trade Organization recognizes three international bodies that develop standards and guidelines to protect the health of consumers, animals, and plants and to ensure fair trade practices: the International Plant Protection Convention (IPPC), for the protection of plants in agriculture and the environment; the Codex Alimentarius Commission (Codex), for safety of food and feed; and the World Organization for Animal Health (OIE), for control of animal diseases and other animal health issues.

BRS has been actively involved for a number of years in the development of standards for GE plants in the IPPC and in the North American Plant Protection Organization (NAPPO), the regional standard-setting body for the United States, Canada, and Mexico. However, there has been increasing focus worldwide on GE animals, and BRS is working within Codex and the OIE in the development of standards and guidelines to ensure the safe use of GE animals for food and to protect the health of GE animals.

In 2005, Codex reformed an ad hoc Intergovernmental Task Force to focus on foods derived from biotechnology. The task force was first created in 1999 and completed its initial work in 2003, which resulted in the development of guidelines for risk assessment of GE plants and microorganisms to be used in food. One of the projects newly agreed to by the task force, of which BRS is a participant, is the development of guidelines for conducting food safety assessments for food derived from GE animals. Codex standards are internationally accepted and strongly influence national food safety legislation. BRS Deputy Administrator Cindy Smith has recently been appointed as the Alternate U.S. Delegate to the Task Force, which next meets in Japan in November 2006.

OIE has also formed an ad hoc biotechnology group to develop guidelines to ensure the health of animals produced using biotechnology. In April 2006, BRS participated in the first meeting of this group, which was held at OIE headquarters in Paris. During the meeting, the group established

the need to focus on the health and safety of animal clones and transgenic animals, as well as biotechnology-derived vaccines. Biotechnology-derived vaccines have not only significantly improved animal health, but have the potential to assist in addressing the issue of transmission of animal diseases to humans, such as the current concern over highly pathogenic avian influenza. As the complexity and scope of biotechnology grows and new GE organisms are rapidly developed, BRS must continue to ensure that biotechnology products are safely developed and field-tested.

BRS Employee Spotlight: Dr. Terri Dunahay

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

Position: Team Leader for International Policy in BRS.

Years with BRS: I joined APHIS in March 2002 as a biotechnology trade director in APHIS Plant Protection and Quarantine, then moved to BRS when the new program area was formed in August of that year.

Activities prior to joining BRS: After receiving my PhD, I worked for 7 years as a researcher at the National Renewable Energy Lab in Golden, Colorado. It was a very interesting project; we were trying to genetically engineer algae to increase their production of oil, with the goal of using these organisms as a source of biofuel. I came to DC on a Public Policy Fellowship through the American Association for the Advancement of Science. I worked one year at USDA Economic Research Service, then accepted a position working on biotechnology issues at USDA Foreign Agriculture Service.

Education: I have a BA in Aquatic Biology from the University of California, Santa Barbara, and a PhD in Molecular and Cellular Biology from the University of Colorado, in Boulder.

Job Description: I coordinate BRS' participation in international organizations, ensure that our international obligations are considered in domestic policies, and provide technical support to our overseas Posts and other governmental agencies with respect to biotechnology regulation and trade. I also represent BRS in international standard-setting bodies such as the International Plant Protection Convention and was recently appointed Chair of the Biotechnology Panel of the North American Plant Protection Organization.

Proudest Accomplishment: Professionally—my work in the International Plant Protection Convention and the North American Plant Protection Organization that has led to adoption of standards for genetically engineered plants. Personally—making a successful mid-life career switch that involved a cross-country move and a fresh start in my personal life as well.

What motivates you about your job: Biotechnology is a very exciting, and controversial, area, and I enjoy being involved in the formation of policies that could facilitate the adoption and safe use of products developed using genetic engineering. I'm also very detail oriented and service oriented, and I enjoy the responsibility of handling a large number of issues with a variety of stakeholders.

Administrative Update

BRS' Communications and Capacity Building Branch has two new members dedicated to keeping the communication lines open with our stakeholders. Dr. Clint Nesbitt serves as an outreach and communications specialist for the branch, while Dr. Catherine Preston is the new state liaison.

In his new position, Clint is responsible for developing and coordinating BRS' overall communication and outreach strategy. Clint is also providing leadership in new activities to educate and improve communication with stakeholders and the public. One significant initiative Clint is spearheading is the update and revision of BRS' guidance documents, to be consolidated for the first time in a single publication, the upcoming *BRS User's Guide*. You can reach Clint at (301) 734-5673 or by e-mail at Thomas.C.Nesbitt@aphis.usda.gov.

As State Liaison, Catherine will serve as the States' primary contact for BRS issues, including inquiries about policies and regulatory decisions. States have always been welcome to contact BRS staff, and Catherine will provide additional support when they are unsure of whom to contact. Catherine will also coordinate activities with various State agencies to further improve their productive relationship with BRS. You can reach Catherine at (301) 734-5874 or by e-mail at Catherine.A.Preston@aphis.usda.gov.

We would also like to welcome two new senior regulatory specialists to the BRS Compliance and Inspection Branch. Dr. Farrell Wise and Dr. Devaiah Muruvanda will work to ensure that companies and organizations maintain compliance with regulations by using set criteria to evaluate potential compliance infractions, performing targeted inspections of field tests, and working with companies and organizations to build self-reporting systems so that BRS is notified immediately when a compliance infraction occurs. Farrell and Devaiah will work directly with a responsible party to resolve a compliance infraction and promptly reestablish compliance. Both Farrell and Devaiah have industry experience and have taught at the college level. Farrell's educational background is in horticulture, while Devaiah's is in entomology.

Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting <http://jobsearch.usajobs.opm.gov> and searching for "Biotechnology Regulatory Services" (in quotes).

Year-to-Date Submissions through August 31, 2006	
<u>Notifications Acknowledged</u>	
111	Importation
225	Interstate Movement
215	Environmental Release
464	Combined Interstate Movement/Release
<u>Permits Issued</u>	
11	Importation
23	Interstate Movement
20	Environmental Release
245	Courtesy Permits
2 Petitions/Extensions to Grant Non-Regulated Status Received	

Have questions about BRS policy and regulations? E-mail us at biotechquery@aphis.usda.gov.