

BRS Stakeholder Updates
To:
cc:
Sent by: Judy A Garrison Subject: BRS Stakeholder Update

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August 5, 2005

Dear BRS Stakeholder:

The last time the U.S. Department of Agriculture's (USDA) Biotechnology Regulatory Services (BRS) sent out a Stakeholder Update, we announced a structural reorganization to address emerging needs, support key functions, and anticipate future growth. In our effort to keep current with evolving science and technology, we are continuing to make changes to our organizational structure.

The newly reorganized BRS includes a Compliance and Inspection Branch, a Communications and Capacity Building Branch, an Office of Science, as well as forecasting function helping BRS address challenges and keep pace with advances in science. In addition, we are emphasizing five priority areas to set program direction and provide the foundation for decisionmaking. I had the opportunity to present these priority areas at the National Agricultural Biotechnology Council (NABC) last month and would like to also share them with you.

The first priority is maintaining rigorous regulation supported by strong compliance and enforcement that thoroughly evaluates and ensures safety. In 2003, we strengthened permit conditions for pharmaceuticals and industrials resulting in stringent confinement measures and a greater government role. For example, our confinement measures now include increased isolation distances and fallow zones, and restrict the use of the same land to produce pharmaceutical and industrial crops from the production of food or feed crops. APHIS also requires developers of pharmaceutical and industrial crops to have dedicated equipment and storage facilities for those crops. We currently inspect every pharmaceutical and industrial site at least seven times before, during, and after production. In addition, in 2003, APHIS amended its regulations to require that industrials are tested under the permit system.

BRS' Compliance and Inspection Branch is dedicated exclusively to ensuring that researchers maintain compliance through defined procedures that include violation-prevention efforts, risk-based criteria for quality inspection, uniform enforcement, and thorough documentation of any compliance infractions. Compliance specialists and APHIS inspectors perform targeted inspections and audits of field tests and use established criteria to thoroughly evaluate all potential compliance infractions. We will be discussing the changes to our Compliance and Inspection Branch with states and other interested groups. If you are interested in learning more about our compliance initiatives, please call to schedule an appointment.

The second priority is ensuring that our regulatory process and decisionmaking are transparent to stakeholders and the public. Being transparent about our processes, decisions, and activities is critical for building public confidence in the regulatory system. We must meet the challenge of fulfilling this objective while also protecting developers' confidential business information. As part of this initiative, BRS makes available on its website all environmental assessments

conducted for plant-made pharmaceutical field tests and plant-made industrial field tests, and announces the assessments in the Federal Register followed by a comment period.

In another effort to ensure transparency, in 2004, we held multiple public meetings to discuss issues associated with the BRS proposal to revise our regulations. BRS met with 22 stakeholder groups and heard a wide range of viewpoints on the proposed revisions and provided clarification on some of our Agency's objectives. We will be holding monthly Stakeholder Meeting Days to hear stakeholders' views on issues related to the programmatic Environmental Impact Statement (EIS) currently in preparation and the prospective revised regulations for genetically engineered organisms. Interested stakeholders may request meetings with BRS over the coming months. More information about scheduling an appointment is provided below.

The third priority is maintaining a science-based system that supports regulatory decisionmaking and safety. To help achieve this goal, we have expanded our staff to include a diversified collection of scientific expertise in fields such as plant pathology, botany, entomology, ecology, animal science, virology, environmental science, biochemistry, and molecular biology. To keep pace with the ever-evolving technology, BRS staff host and attend scientific meetings and workshops, keep current with scientific literature, and interact with outside scientists, stakeholders, and the public. BRS established the Office of Science, which works with the research community to identify biosafety research priorities and to communicate biosafety research results for the use of regulators globally.

As part of its agenda, the Office of Science addresses scientific issues associated with pharmaceuticals and in August 2004, conducted a workshop on confinement that focused largely on these crops. More than 100 scientists and experts from six countries participated in this workshop. The Office of Science also helps maintain science as the centerpiece of regulatory decisionmaking amidst the challenges of diverse political, economic, and personal viewpoints associated with the technology. Also in an ongoing commitment to science, BRS recently announced its peer review plan for the "White paper: Perspective on Creeping Bentgrass, *Agrostis stolonifera* L." This is in relation to the EIS for the petition for deregulation of glyphosate-tolerant creeping bentgrass. More information about this is given below.

The fourth priority is maintaining communication, coordination, and collaboration with our full range of stakeholders. BRS works to meet the challenge of recognizing and reaching out to a broad range of stakeholders and interests. It is important to reach out to a broad diversity of stakeholders that includes not only the biotechnology industry and researchers, but also stakeholders such as, the food industry, commodity groups, public interest groups, and the states.

Finally, the fifth priority set forth by BRS is establishing international leadership to ensure that international biotechnology standards are science-based, international regulatory capacity building is supported, and international implications of domestic policy and regulatory decisions are considered. We must take into account the international implications of any domestic policy decisions that we make and ensure that the policies that we put in place domestically can be applied equally internationally.

Through our evolving regulatory structure, dedicated compliance function, focus on science and risk, increased transparency, and communication with a broad range of stakeholders, we are focused on all of these priorities and managing the challenges posed by new trends. As science progresses, we will continue to evaluate the implications of new technologies, enhance our processes and procedures, and develop appropriate regulations to meet the challenges posed by this new science while continuing to safeguard American agriculture, the nation's food supply, and the environment.

Sincerely,

Cindy Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service

BRS Stakeholder Update

Stakeholder Listening Sessions

The goal of these listening sessions is to create a venue for BRS to hear stakeholders' views on issues related to the programmatic EIS that is currently in preparation and the prospective revised regulations for genetically engineered organisms. Links to participant lists and transcripts of all meetings will be posted on the web. Interested stakeholders may request meetings with BRS over the coming months. Upcoming Stakeholder Meeting Days are Sept. 22, 2005 and October 20, 2005.

Because meeting times are limited, priority will be given based upon the order in which requests are received. Preference may also be given to stakeholders who have not participated previously. Meeting dates in upcoming months will be posted on our website (http://www.aphis.usda.gov/brs/brs_meetings.html).

Call Gail Jones at (301) 734-5710 for more information or to schedule a time. You will be asked for your stakeholder group's name, a list of specific issues that you wish to discuss, contact information (telephone number and e-mail), and availability for the dates listed above. Telephone or video conferences may be available on request.

White Paper on Creeping Bentgrass

APHIS has announced its peer review plan for the "White paper: Perspective on Creeping Bentgrass, *Agrostis stolonifera* L." This document is informing the EIS for a petition for non-regulated status on creeping bentgrass. The peer review plan was developed by BRS Office of Science as part of an initiative to be proactive in meeting new OMB guidelines requiring the scientific review of "highly influential scientific assessments." It has been posted on a new APHIS Peer Review website at http://www.aphis.usda.gov/peer_review/index.html. The public is invited to comment on the peer review plan.

Branch Chief for Plant Pathogens and Protectants Branch

Dr. Michael Watson was hired as the branch chief for the new Plant Pathogens and Protectants Branch in the Environmental Risk Analysis Division. He has extensive experience working as a Federal Regulator and a working knowledge of all three agencies involved in regulating biotech crops. For the past two years, Michael has been a senior biotechnologist at APHIS in BRS. Prior to coming to USDA, he worked as a Consumer Safety Officer with the FDA and before that he worked as a Plant Pathologist for the EPA. Michael received his B.S degree from the University of Maryland and his Ph.D. from the University of CA, Davis in plant pathology.