

**BRS Stakeholder
Updates**

To:
cc:
Sent by: Judy A Garrison Subject: BRS Stakeholder Update, March 2006

03/10/2006 04:15 PM

Dear BRS Stakeholder:
March 10, 2006

Hello! We would like share some valuable news from Biotechnology Regulatory Services (BRS), a program within the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). BRS has been very busy lately, working to streamline and strengthen our comprehensive approach to regulating biotechnology. As a result of these efforts, BRS customers will soon be able to process notification applications online through the APHIS ePermits system. In addition, we plan to broaden this effort in the future to allow customers to utilize several other online applications and tools that are currently only available in a paper-based format. Through the new ePermits system, we expect that our customers will save a tremendous amount of time and effort.

The ePermits system is part of USDA's overall eGovernment initiative to transform and enhance the delivery of its programs, services, and information. Using ePermits, BRS applicants will be able to submit notifications online through a secure web server. Each organization will have the ability to designate certain individuals to prepare and submit information to ePermits, and only these individuals will have access to the organization's ePermits records. For applicants entering Confidential Business Information (CBI), ePermits will automatically generate a CBI and CBI-deleted version of the application from a single submission. In addition, organizations can set up an Organizational ID so that access to CBI is controlled.

The ePermits system will also provide BRS' applicants with enhanced tools to manage their applications. Applicants will be able to track the status of their submissions and will receive an email indicating whether an application has been accepted or denied. Organizations and their designees will be able to view previously submitted notification applications and copy them for use in creating new submissions. Additional capabilities include routing and tracking functions, as well as the availability of XML downloads through the secure Web site. Another benefit of ePermits is that APHIS regulatory officials will be able to issue and track notifications electronically in a single system, thus reducing data entry, processing, and delivery time and expense.

We expect this phase of the ePermits system to be accessible to our BRS customers in early April. A separate mailing will be used to notify you of the exact date you can begin submissions through ePermits. This information will also be posted on the BRS Web site.

User Registration

To ensure the security of the ePermits system, users are required to complete a registration process called eAuthentication. USDA Agencies use eAuthentication to enable individuals

access to certain USDA Web applications and services through the Internet. The Web-based service identifies and validates USDA customers before they can use participating USDA Web-based business applications. It provides a single credential that a USDA Web user can present to any participating USDA Web site, therefore reducing the burden on customers to register for and maintain separate identities with every online system. To learn more about USDA's eAuthentication, please visit <http://www.eauth.egov.usda.gov>. After completing eAuthentication, BRS customers will be able to access the ePermits system at <https://epermits.aphis.usda.gov/epermits>.

More Advances Underway

The ePermits system is an ongoing effort to improve citizens' knowledge of and access to USDA by enhancing service delivery and improving internal efficiency through technology-based solutions. It is a large initiative that has been in development for several years and is being implemented in multiple phases. The current phase of ePermits, which will allow the submission of notification applications online, will be available to our customers in April 2006. The next phase in the ePermits initiative will bring even more services to accommodate our customers. In late 2006, we plan to offer applicants the option of submitting permits online, currently done through the APHIS Form 2000 – Application for the Importation, Interstate Movement and Field Testing of Genetically Engineered Organisms.

We appreciate all of the input we received as we developed the new ePermits system, and look forward to working with our customers in the future as we further expand and enhance the system.

Other News

BRS will no longer be approving multi-year notifications. Under APHIS regulations, approval of a notification applies to field testing for 1 year from the date of introduction and may be renewed annually by submission of an additional notification to APHIS. Field trials are now only authorized until March 1, 2007. Applicants who are currently operating under a multi-year notification that is more than a year old must submit a new notification application by March 1, 2007, and must continue to submit a notification annually for each additional year they are requesting permission to field test a regulated article. Alternatively, applicants can apply for a multi-year permit, which is initially good for three years. The multi-year permit may then subsequently be extended for up to 5 years based on compliance history.

Again, we value our stakeholders and look forward to sharing other important information with you as we further enhance our regulatory program. If you have not previously registered with our on-line registry as a stakeholder with BRS, 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 J. Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service