

*hygrosopicus*, strain ATCC21705. The *bar* gene encodes phosphinothricin-N-acetyltransferase (PAT), and the PAT enzyme catalyzes the conversion of L-phosphinothricin, the active ingredient in glufosinate, to an inactive form, thus conferring resistance to the herbicide. Expression of the added genes is controlled in part by gene sequences from the plant pathogens cauliflower mosaic virus and *Agrobacterium tumefaciens*. *Agrobacterium*-mediated gene transfer was used to transfer the added genes into the recipient Coker 312 cotton variety.

LLCotton25 has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. This cotton has been field tested since 1999 in the United States under APHIS notifications. In the process of reviewing the notifications for field trials of the subject cotton, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical containment or isolation, would not present a risk of plant pest introduction or dissemination.

In § 403 of the Plant Protection Act (7 U.S.C. 7701–7772), “plant pest” is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which genetically modified plants allow for a new use of a pesticide or involve a different use pattern for the pesticide, EPA must approve the new or different use. Accordingly, Aventis has submitted a pesticide petition to EPA to expand the registration of glufosinate to include use on LLCotton25.

When the use of the pesticide on the genetically modified plant would result

in an increase in the residues in a food or feed crop for which the pesticide is currently registered, or in new residues in a crop for which the pesticide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). The FDA statement of policy includes a discussion of FDA’s authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering. The petitioner has begun consultation with FDA on the subject cotton.

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for determination of nonregulated status from interested persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested persons on the environmental assessment (EA) prepared to provide the public with documentation of APHIS’ review and analysis of any potential environmental impacts and plant pest risk associated with a proposed determination of nonregulated status for Aventis’ LLCotton25.

The EA was prepared in accordance with (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS’ NEPA Implementing Procedures (7 CFR part 372). The petition and the environmental assessment and any comments received are available for public review, and copies of the petition and the environmental assessment may be ordered (see the **FOR FURTHER INFORMATION CONTACT** section of this notice).

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period,

and any other relevant information. After reviewing and evaluating the comments on the petition and the environmental assessment and other data and information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Aventis’ herbicide-tolerant LLCotton25 and the availability of APHIS’ written decision.

**Authority:** 7 U.S.C. 166, 1622n, 7756, and 7761–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 10th day of December 2002.

**Peter Fernandez,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 02–102–1]

#### Draft Guideline on Testing for the Detection of Mycoplasma Contamination

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** A draft guideline titled “Testing for the Detection of Mycoplasma Contamination” has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The draft guideline provides procedures for the testing of some veterinary biologics to detect mycoplasma contamination. Since the draft guideline applies to veterinary biological products regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency’s comments to the VICH Steering Committee.

**DATES:** We will consider all comments on the draft guideline that we receive on or before February 14, 2003.

**ADDRESSES:** You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and

three copies) to: Docket No. 02-102-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 02-102-1. If you use e-mail, address your comment to [regulations@aphis.usda.gov](mailto:regulations@aphis.usda.gov). Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-102-1" on the subject line.

You may read any comments that we receive on the draft guideline in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/vs/rep.html>.

You may request a copy of the draft guideline "Testing for the Detection of Mycoplasma Contamination" by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. The draft guideline is also available on the Internet at <http://www.aphis.usda.gov/vs/cvb/lpd/notices>.

**FOR FURTHER INFORMATION CONTACT:** For information regarding VICH, contact Dr. Richard E. Hill, Director, Center for Veterinary Biologics-Licensing and Policy Development, VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010; (515) 232-5785. For information regarding the draft guideline "Testing for the Detection of Mycoplasma Contamination," contact Dr. Donna M. Gatewood at the same address and telephone number.

**SUPPLEMENTARY INFORMATION:** The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand

participate as observers. The VICH initiative is conducted under the auspices of the International Office of Epizootics. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L'Industrie de la Sante Animale) provides the secretarial support for VICH activities. The U.S. Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise regarding veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, FDA and APHIS participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

This notice informs the public that a draft document, "Testing for the Detection of Mycoplasma Contamination" (VICH Topic GL34), has been made available for comments by the VICH Steering Committee. The draft guideline is intended to provide an international testing standard for the detection of mycoplasma contamination in veterinary biologics. Because the draft guideline applies to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act, we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

The draft document reflects current APHIS thinking on testing veterinary biologics for the detection of mycoplasma contamination. In accordance with the VICH process, once a final draft of "Testing for the Detection of Mycoplasma Contamination" has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, the final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, a VICH guideline specifically provides for the use of alternative approaches if those approaches are proven to be equivalent by scientifically accepted criteria.

Ultimately, APHIS intends to consider the VICH Steering Committee's final

guidance document for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, APHIS will consider its use as a basis for testing veterinary biologics for mycoplasma contamination under 9 CFR 113.28. APHIS may also use the final guidance document as the basis for proposed additions or amendments to its regulations in 9 CFR chapter I, subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Because we anticipate that applicable provisions of the final version of "Testing for the Detection of Mycoplasma Contamination" may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft version.

**Authority:** 21 U.S.C. 151 *et seq.*

Done in Washington, DC, this 10th day of December 2002 .

**Peter Fernandez,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Information Collection; Reinstatement, Without Change, of Previously Approved information Collection That Has Expired for Stewardship Incentive Program

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the reinstatement, without change, of a previously approved, but now expired, information collection required for participation of non-industrial private forest owners in the State and Private Forestry Stewardship Incentive Program. The collected information identifies (1) the Stewardship Incentive Program assignment of payment, (2) Internal Revenue Service income reporting requirements for participants, and (3) the participants' delegated power of attorney.

**DATES:** Comments must be received in writing on or before February 14, 2003.

**ADDRESSES:** Written comments concerning this notice should be addressed to Forest Service, USDA, Attn: Stewardship Coordinator, Cooperative Forestry Staff, Mail Stop