

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning these information collection activities. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 2.490576 hours per response.

Respondents: U.S. importers, exporters, and shippers of veterinary biological products; State veterinary authorities; and operators of establishments that produce or test veterinary biological products or that engage in product research and development.

Estimated annual number of respondents: 500.

Estimated annual number of responses per respondent: 39.9.

Estimated annual number of responses: 19,950.

Estimated total annual burden on respondents: 49,687 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 10th day of August, 2004.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04-18524 Filed 8-12-04; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04-010-2]

Mycogen c/o Dow; Availability of Determination of Nonregulated Status for Cotton Lines Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Mycogen Seeds c/o Dow AgroSciences LLC cotton lines designated as Cry1F cotton event 281-24-236 and Cry1Ac cotton event 3006-210-23, which have been genetically engineered for insect resistance, are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Mycogen Seeds c/o Dow AgroSciences LLC in its petitions for determinations of nonregulated status, our analysis of other scientific data, and comments received from the public in response to a previous notice. This notice also announces the availability of our written determination and our finding of no significant impact.

EFFECTIVE DATE: July 15, 2004.

ADDRESSES: You may read the petitions, the determination, the environmental assessment and finding of no significant impact, and all comments that we received on this docket 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.

You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Susan Koehler, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 734-4886. To obtain copies of the petitions or the environmental assessment and finding of no significant impact, contact Ms. Terry Hampton at

(301) 734-5715; e-mail:

Terry.A.Hampton@aphis.usda.gov. The petitions and the environmental assessment and finding of no significant impact are also available on the Internet at:

- http://www.aphis.usda.gov/brs/aphisdocs/03_03601p.pdf
- http://www.aphis.usda.gov/brs/aphisdocs/03_03601p_ea.pdf
- http://www.aphis.usda.gov/brs/aphisdocs/03_03602p.pdf
- http://www.aphis.usda.gov/brs/aphisdocs/03_03602p_ea.pdf

SUPPLEMENTARY INFORMATION:

Background

On February 5, 2003, the Animal and Plant Health Inspection Service (APHIS) received two petitions from Mycogen Seeds c/o Dow AgroSciences LLC (Mycogen/Dow) of Indianapolis, IN, requesting determinations of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum* L.) designated as Cry1F cotton event 281-24-236 (cotton event Cry1F) (APHIS Petition No. 03-036-01p) and Cry1Ac cotton event 3006-210-23 (cotton event Cry1Ac) (APHIS Petition No. 03-036-02p), which have been genetically engineered for resistance to certain lepidopteran insect pests. The Mycogen/Dow petitions state that the subject cotton events should not be regulated by APHIS because they do not present a plant pest risk.

On March 9, 2004, APHIS published a notice in the **Federal Register** (69 FR 10972-10973, Docket No. 04-010-1) announcing that the Mycogen/Dow petitions and an environmental assessment (EA) were available for public review and comment. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject cotton and food products developed from it. APHIS received six comments on the petitions and the EA during the 60-day comment period which ended May 10, 2004. The comments were from three individuals, an industry organization, a cotton farmer, and an academic research center. Four of the comments were in favor of deregulation for the subject cotton lines, based on predicted economic and environmental benefits resulting from higher yields and reduced pesticide use. The combination of the two subject cotton lines through breeding after deregulation was also seen as a means of reducing the potential for the development of resistance in lepidopteran populations. The one commenter opposed to deregulation for the subject cotton lines suggested the need for many more years

of testing and more stringent regulation of all genetically engineered crop plants. The remaining commenter expressed the opinion that a partial deregulation of the subject cotton lines should be approved, with restrictions imposed so that additional field tests and monitoring could be conducted to provide data in certain areas of concern. APHIS has carefully considered these comments and suggestions, and a response to the comments is included as an attachment to the finding of no significant impact (FONSI).

Cotton events Cry1F and Cry1Ac have been genetically engineered to express synthetic insecticidal proteins derived from the common soil bacterium *Bacillus thuringiensis* (Bt). The petitioner states that the Cry1F and Cry1Ac proteins are effective in providing protection from the feeding of lepidopteran insect pests such as tobacco budworm, beet armyworm, soybean looper, and cotton bollworm. The subject cotton events also express the *pat* gene derived from *Streptomyces viridochromogenes*, a non-pathogenic bacterium. The *pat* gene encodes the enzyme phosphinothricin acetyltransferase (PAT), which confers tolerance to glufosinate herbicides and is present in cotton events Cry1F and Cry1Ac as a selectable marker. The subject cotton events were developed through use of the *Agrobacterium*-mediated transformation method. Cotton events Cry1F and Cry1Ac were developed primarily so that they could be crossed to produce a cotton line which contains both the insecticidal proteins and thereby to maintain a range of effective control options for lepidopteran insect pests and to reduce the potential for the development of resistance to Bt insecticides.

Cotton events Cry1F and Cry1Ac have been considered regulated articles under the regulations in 7 CFR part 340 because they contain gene sequences from the plant pathogen *Agrobacterium tumefaciens*. These cotton events have 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 confinement or isolation, would not present a risk of plant pest introduction or dissemination.

Determination

Based on its analysis of the data submitted by Mycogen/Dow, a review of other scientific data, field tests of the

subject cotton, and comments submitted by the public, APHIS has determined that cotton event Cry1F and cotton event Cry1Ac: (1) Exhibit no plant pathogenic properties; (2) are no more likely to become weedy than the non-transgenic parental line or other cultivated cotton; (3) are unlikely to increase the weediness potential for any other cultivated or wild species with which they can interbreed; (4) will not cause damage to raw or processed agricultural commodities; (5) will not harm threatened or endangered species or organisms that are beneficial to agriculture; and (6) should not reduce the ability to control pests and weeds in cotton or other crops. Therefore, APHIS has concluded that the subject cotton events and any progeny derived from hybrid crosses with other nontransformed cotton varieties will be as safe to grow as cotton in traditional breeding programs that are not subject to regulation under 7 CFR part 340.

The effect of this determination is that Mycogen/Dow's Cry1F cotton event 281-24-236 and Cry1Ac cotton event 3006-210-23 are no longer considered regulated articles under APHIS' regulations in 7 CFR part 340. Therefore, the requirements pertaining to regulated articles under those regulations no longer apply to the subject cotton or its progeny. However, importation of cotton events Cry1F and Cry1Ac and seeds capable of propagation are still subject to the restrictions found in APHIS' foreign quarantine notices in 7 CFR part 319 and imported seed regulations in 7 CFR part 361.

An EA was prepared to examine the potential environmental impacts associated with the proposed determinations of nonregulated status for Mycogen/Dow's Cry1F cotton event 281-24-236 and Cry1Ac cotton event 3006-210-23. 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). Based on that EA, APHIS has reached a FONSI with regard to its determination that Cry1F cotton event 281-24-236 and Cry1Ac cotton event 3006-210-23 and lines developed from them are no longer regulated articles under its regulations in 7 CFR part 340. Copies of the EA and FONSI are available as indicated in the **FOR**

FURTHER INFORMATION CONTACT section of this notice.

Authority: 7 U.S.C. 1622n and 7701-7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 9th day of August 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 04-022N]

Codex Alimentarius Commission: Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: This notice informs the public that the Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS), are sponsoring a public meeting on September 9, 2004. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States' positions that will be discussed at the 26th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held in Bonn, Germany, November 1-5, 2004. The Under Secretary for Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the 26th Session of CCNFSDU and to address items on the agenda.

DATES: The public meeting is scheduled for Thursday, September 9, 2004, from 1 p.m. to 4 p.m.

ADDRESSES: The public meeting will be held in the Auditorium (1A003), Food and Drug Administration, Harvey Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD. To receive copies of the Codex documents pertaining to the agenda items for the 26th CCNFSDU session, contact the Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250. The documents will also be accessible