

effective line of defense against an introduction of highly pathogenic avian influenza.

Description of Respondents: Farms; Individuals or households; Federal Government.

Number of Respondents: 5,000.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 5,000.

Animal and Plant Health Inspection Service

Title: Karnal Bunt; Compensation for Custom Harvesters in Northern Texas.

OMB Control Number: 0579-0248.

Summary of Collection: Under the Plant Protection Act (PPA) (7 U.S.C. 7701-7772), the Animal and Plant Health Inspection Service (APHIS) has the responsibility and authorization to prohibit or restrict the importation, entry, or movement of plant and plant pests in the United States. The regulations regarding Karnal Bunt are set forth in 7 CFR Parts 301.89-1 through 301.89-16. APHIS amended the Karnal Bunt regulations to provide for the payment of compensation to custom harvesters for losses they incurred due to the requirement that their equipment be cleaned and disinfected after four counties in northern Texas were declared regulated areas for Karnal Bunt during the 2000-2001 crop season.

Need and Use of the Information: APHIS will collect information using PPQ 540, Certificate of Federal/State Domestic Plant Quarantines. The certificate is used for domestic movement of treated articles relating to quarantines. The information collected is critical to the mission of preventing the infestation of Karnal Bunt into non-infested areas of the United States.

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 40.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 8.

Sondra Blakey,

Departmental Information Collection Clearance Officer.

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BILLING CODE 3410-34-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04-071-1]

Notice of Request for Extension of Approval of an Information Collection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the Virus-Serum-Toxin Act and regulations.

DATES: We invite you to comment on this docket. We will consider all comments that we receive on or before October 12, 2004.

ADDRESSES: You may submit comments by any of the following methods:

• **Postal Mail/Commercial Delivery:**

Please send four copies of your comment (an original and three copies) to Docket No. 04-071-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 04-071-1.

• **E-mail:** Address your comment to 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. 04-071-1" on the subject line.

• **Agency Web Site:** Go to <http://www.aphis.usda.gov/ppd/rad/cominst.html> for a form you can use to submit an e-mail comment through the APHIS Web site.

Reading Room: You may read any comments that we receive 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.

Other Information: 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: For information on the Virus-Serum-Toxin Act and regulations, contact Dr. Albert Morgan, Section Leader, Operational Support Section, Center for Veterinary Biologics, VS, APHIS, 4700 River Road Unit 148, Riverdale MD 20737, (301) 734-8245. For copies of more detailed information on the information

collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

SUPPLEMENTARY INFORMATION:

Title: Virus-Serum-Toxin Act and Regulations.

OMB Number: 0579-0013.

Type of Request: Extension of approval of an information collection.

Abstract: The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is responsible for ensuring that veterinary biological products are pure, safe, potent, and effective. This program is conducted under the Virus-Serum-Toxin Act (21 U.S.C. 151, *et seq.*) and the regulations in 9 CFR, chapter I, subchapter E. Veterinary biological products are defined as all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, *e.g.*, antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term "biological products" includes, but is not limited to, vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components that are of natural or synthetic origin or that are derived from synthesizing or altering various substances or components of substances, such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

To accomplish its mission, APHIS issues licenses to qualified establishments that produce biological products and issues permits to importers of such products. We also enforce requirements concerning production, packaging, labeling, and shipping of these products and set standards for the testing of these products.

Fulfilling this responsibility requires us to use certain information collection activities such as establishment license applications, product license applications, product import permit applications, product and test report forms, and field study summaries. This information helps us to ensure that biological products used in the United States are pure, safe, potent, and effective. If we did not collect this information, we would be unable to carry out this mission.

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]

BILLING CODE 3410-34-P

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