Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AFRICAN DEVELOPMENT FOUNDATION

Sunshine Act Meeting; Board of Directors Meeting

TIME: 9:00 a.m.–12:00 noon.
PLACE: ADF Headquarters.
DATE: Wednesday, 10 December 1997.
STATUS: Open.

Agenda

Wednesday, 10 December 1997

9:00 a.m. Chairman's Report
10:00 a.m. President's Report
11:30 a.m. Executive Session (Closed)
12:00 noon Adjournment

If you have any questions or comments, please direct them to Ms. Janis McCollim, Executive Assistant to the President, who can be reached at (202) 673–3916.

William R. Ford,

President.

[FR Doc. 97–32101 Filed 12–3–97; 3:58 pm]

BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 97–088–1]

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 in support of the Virus-Serum-Toxin Act and regulations.

DATES: Comments on this notice must be received by February 3, 1998 to be assured of consideration.

ADDRESSES: Send comments regarding the accuracy of burden estimate, ways to minimize the burden (such as through the use of automated collection techniques or other forms of information technology), or any other aspect of this collection of information to: Docket No. 97–088–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please send an original and three copies, and state that your comments refer to Docket 97–088–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION: For information regarding the Virus-Serum-Toxin Act and regulations, contact Dr. David Espeseth, Director, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245 or e-mail despeseth@aphis.usda.gov. For copies of more detailed information on the information collection, contact Ms. Cheryl Jenkins, Agency Support Service Specialist, at (301) 734–5360.

SUPPLEMENTARY INFORMATION:

Title: Virus-Serum-Toxin Act and Regulations.

OMB Number: 0579–0013.

Expiration Date of Approval: March 31, 1998.

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 preventing the importation, preparation, sale, or shipment of worthless, contaminated, dangerous or harmful veterinary biological products. This program is conducted under the Virus-Serum-Toxin Act (21 U.S.C. 151, *et seq.*) and the regulations issued thereunder (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 this 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 employ a number of information-gathering tools such as establishment license applications, product license applications, product permit applications, product and test report forms, and field study summaries.

The information we obtain with the help of these documents enables 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 the continued use of this information collection activity.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. We need this outside input to help us:

(1) Evaluate whether the proposed 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 proposed collection of information, 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 collection of information 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 2.2063 hours per response.

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

Estimated number of respondents: 114.

Estimated number of responses per respondent: 298.73.

Estimated annual number of responses: 34,056.

Estimated total annual burden on respondents: 75,138 hours. (Due to rounding, the total annual burden hours may not equal the product of the annual number of responses multiplied by the average 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 28th day of November.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–31903 Filed 12–4–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 97–052–2]

Monsanto Co. and Dekalb Genetics Corp.; Availability of Determination of Nonregulated Status for Genetically Engineered Corn Line

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a corn line developed by Monsanto Company and Dekalb Genetics Corporation designated as GA21, which has been genetically engineered for tolerance to the herbicide glyphosate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Monsanto Company and Dekalb Genetics Corporation in their petition for a determination of nonregulated status and an analysis of other scientific data. This notice also announces the availability of our written determination document and its associated environmental assessment and finding of no significant impact.

EFFECTIVE DATE: November 18, 1997.

ADDRESSES: The determination, an environmental assessment and finding of no significant impact, the petition, and any written comments received regarding the petition may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are asked to call in advance of visiting at (202) 690–2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Ray Dobert, Biotechnology Evaluation, BSS, PPQ, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–8365. To obtain a copy of the determination or the environmental assessment and finding of no significant impact, contact Ms. Kay Peterson at (301) 734–4885; e-mail: mkpeterson@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 1997, the Animal and Plant Health Inspection Service (APHIS) received a petition (APHIS Petition No. 97–099–01p) from Monsanto Company of St. Louis, MO, and Dekalb Genetics Corporation of Mystic, CT (Monsanto/Dekalb), seeking a determination that a corn line designated as GA21, which has been genetically engineered for tolerance to the herbicide glyphosate, does not present a plant pest risk and, therefore, is not a regulated article under APHIS' regulations in 7 CFR part 340.

On August 13, 1997, APHIS published a notice in the **Federal Register** (62 FR 43311–43312, Docket No. 97–052–1) announcing that the Monsanto/Dekalb petition had been received and was available for public review. The notice also discussed the role of APHIS, the Environmental Protection Agency, and the Food and Drug Administration in regulating the subject corn line and food products derived from it. In the notice, APHIS solicited written comments from the public as to whether the subject corn line posed a plant pest risk. The comments were to have been received by APHIS on or before October 14, 1997. APHIS received no comments on the subject petition during the designated 60-day comment period.

Analysis

Corn line GA21 has been genetically engineered to contain a modified corn 5-enolpyruvylshikimate-3-phosphate-synthase (EPSPS) gene, which, when expressed in the plant, confers tolerance to the herbicide glyphosate. The modified corn EPSPS gene was introduced into the parental inbred corn line AT by the particle acceleration method, and its expression is controlled in part by the rice actin promoter and intron and the NOS 3′ termination sequence derived from the plant pathogen *Agrobacterium tumefaciens*.

Corn line GA21 has been considered a regulated article under APHIS' regulations in 7 CFR part 340 because it contains gene sequences derived from a plant pathogen. However, evaluation of field data reports from field tests of the subject corn line conducted under APHIS notifications since 1994 indicates that there were no deleterious effects on plants, nontarget organisms, or the environment as a result of the subject corn plants' release into the environment.

Determination

Based on its analysis of the data submitted by Monsanto/Dekalb, and a review of other scientific data and field tests of the subject corn line, APHIS has determined that corn line GA21: (1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than corn developed by traditional breeding techniques; (3) is unlikely to increase the weediness potential for any other cultivated or wild species with which it can interbreed; (4) will not harm other organisms, including agriculturally beneficial organisms and threatened and endangered species; and (5) should not cause damage to raw or processed agricultural commodities. Therefore, APHIS has concluded that corn line GA21 and any progeny derived from hybrid crosses with nontransformed corn varieties will be just as safe to grow as traditionally bred corn lines that are not regulated under 7 CFR part 340.

The effect of this determination is that the Monsanto/Dekalb corn line designated as GA21 is no longer considered a regulated article under APHIS' regulations in 7 CFR part 340.