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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. 01-036-1]

Requirements for Recognizing the Animal Health Status of Foreign Regions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations that set out our procedures for recognizing the animal health status of regions. Specifically, we propose to require regions that have been granted status under the regulations to provide information, or allow us to access information, to confirm the regions' animal health status when we request it. We believe this action is necessary to help prevent the introduction of foreign animal health diseases into the United States.

DATES: We will consider all comments that we receive on or before May 5, 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. 01-036-1, 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. 01-036-1. If you use 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. 01-036-1" on the subject line.

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.

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/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92, "Importation of Animals and Animal Products: Procedures for Requesting Recognition of Regions" (referred to below as the regulations), set out the process by which a foreign government may request recognition of the animal health status of a region or approval to export animals or animal products to the United States based on the risk associated with animals or animal products from that region. As provided in § 92.2, each request must include information about the region, including information on the authority, organization, and infrastructure of the veterinary services organization of the region; the extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity for such movements; livestock demographics and marketing practices in the region; diagnostic laboratory capabilities in the region; and the region's policies and infrastructure for animal disease control, *i.e.*, the region's emergency response capacity.

Recognition by the Animal and Plant Health Inspection Service (APHIS) of a region's animal health status makes exports of animals and animal products from that region subject to a certain set of import conditions, depending on that region's animal health status. These conditions are intended to ensure that animals and animal products imported from the region will not introduce animal diseases into the United States. However, once a region has been granted a particular animal health status for a specified disease, the regulations provide no mechanism for APHIS to verify that the assigned import conditions remain appropriate and

effective over time. We believe that such verification is sometimes necessary and appropriate to ensure continued protection from the introduction of foreign animal diseases into the United States.

Therefore, we are proposing to add a paragraph to § 92.2 that would require, at the discretion of the Administrator, that regions submit, or allow the collection of, information we believe is necessary to ensure that the animal health status of the region has been maintained. For example, we may determine that a site visit is necessary to verify information provided by the region, or we may require information to confirm that the import requirements of the region have not changed. Similarly, if a region with recognized animal health status borders a region that reports an outbreak of an animal health disease, we may require information regarding security along that border. These listed examples are simply that—examples of information we may require. Specific information collection activities, if determined necessary, will vary based on the information required to adequately assess a region's animal health status.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to amend the regulations that set out our procedures for recognizing the animal health status of regions. Specifically, we propose to require regions that have been granted status under the regulations to provide information, or allow us to access information, to confirm and/or assess the regions' animal health status when we request to do so. We believe this action is necessary to help prevent the introduction of foreign animal health diseases into the United States. We do not expect that this action will result in any economic effects, positive or negative.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and

regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 01-036-1. Please send a copy of your comments to: (1) Docket No. 01-036-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed 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 (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 40 hours per response.

Respondents: Veterinary authorities in regions that have been granted a particular animal health status for a specified animal disease.

Estimated annual number of respondents: 3.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 3.

Estimated total annual burden on respondents: 120 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.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects in 9 CFR part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Region, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 92 as follows:

PART 92—IMPORTATION ANIMALS AND ANIMAL PRODUCTS; PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS

1. The authority citation for part 92 would continue to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. Section 92.2 would be amended by redesignating paragraph (a)(1) as paragraph (a) and adding a new paragraph (g) to read as follows:

§ 92.2 Application for recognition of the animal health status of a region.

* * * * *

(g) If a region is granted animal health status under the provisions of this section, that region may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order for that region to maintain its animal health status.

Done in Washington, DC, this 28th day of February 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03-5280 Filed 3-5-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N-0276]

[RIN 0910-AC40]

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of proposed rulemaking that appeared in the **Federal Register** of February 3, 2003 (68 FR 5378). The document proposed a regulation that would require domestic and foreign facilities that manufacture, process, pack, or hold food for human and animal consumption in the United States to register with FDA by December 12, 2003. Due to a printing error, the document was published with inadvertent errors in the appendix. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03-2443, appearing on page 5378, at page 5421, in the **Federal Register** of Monday, February 3, 2003, the appendix, which is a draft food facility registration form, has several errors. For the convenience of the reader, we are republishing the appendix.

Dated: February 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

Note: The following appendix will not appear in the Code of Federal Regulations.

BILLING CODE 4160-01-C