Proposed Rules

Federal Register
Vol. 68, No. 121
Tuesday, June 24, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. 02–001–1]

RIN 0579–AB53

Procedures for Reestablishing a Region as Free of a Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to establish procedures that we will follow when a region that we recognize as free of a disease experiences an outbreak of that disease. The procedures include steps we would take to prevent the introduction of disease from that region and steps we would take to further assess the region's animal health status. The procedures would allow for timely reinstatement of the region's disease-free status if supported by the reassessment.

DATES: We will consider all comments that we receive on or before August 25, 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. 02–001–1, 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. 02–001–1. 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. 02–001–1'' 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, Assistant Director, 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 from a region based on the disease 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 disease 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 import conditions are intended to ensure that animals and animal products imported from the region will not introduce animal diseases into the United States.

Recently, we have been asked if the requirements in § 92.2 apply to regions that wish to have their previous disease-free status restored after they have experienced and eradicated an outbreak of the disease. As explained in a final rule published on November 5, 2001, regarding the status of France and Ireland for foot-and-mouth disease (66 FR 55872–55876, Docket No. 01–031–2), we do not intend for the regulations in § 92.2 to apply in these circumstances.

In this document, we propose to add to part 92 procedures that we will follow when a region recognized as free of a disease experiences an outbreak. The procedures include steps we will take to protect the United States from disease, as well as steps we will take to reassess the animal health status of the region and, when appropriate, to restore the region's previous disease-free status.

If a region that we recognize as free of a specified animal disease experiences an outbreak of that disease, we will take immediate action to prohibit or restrict imports of animals and animal products from that region to protect U.S. livestock. Such action may include publishing an interim rule prescribing the prohibitions or restrictions that may initially be announced administratively. The interim rule may be given an effective date earlier than the date of signature or publication to affirm our authority for issuing previous administrative orders. We believe such immediate actions are necessary to prevent the introduction of foreign animal diseases into the United States.

If the outbreak is confined to a limited area of the region we previously recognized as free of a disease, the interim rule we publish may impose prohibitions or restrictions on only a portion of the region. This is because we will already have information about the region, including information on the authority, organization, and infrastructure of the veterinary services organization of the region; the extent to which movements of animals and animal products are 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. This information would have provided the basis for our previous recognition of the disease-free status of the region. Our obligations under international trade agreements compel us to take only actions necessary to prevent the introduction of disease; therefore, unless we determine that this information is no longer reliable, it provides a rational basis for our determination that a region can effectively control an outbreak within a smaller region. In these cases, we will provide information to the public as soon as possible regarding the basis for our decision to prohibit or restrict imports from the smaller area of a region previously recognized as free.

Following publication of an interim rule, we will reassess the disease status of the region in the context of the standards of the Office International des Epizooties (OIE) to determine whether it is necessary to continue the interim prohibitions or restrictions. As part of the reassessment process, we will consider all public comments we receive on the interim rule, as well as any additional information relevant to a decision to change the disease status of the region, including information collected by or submitted to us. Prior to taking any action to relieve or finalize prohibitions or restrictions imposed by the interim rule, we will make information regarding our reassessment of the region's disease status available to the public for comment. We will announce the availability of this information by publishing a notice in the **Federal Register**. Based on the reassessment, including the comments we receive in response to the notice we publish, we will publish one of the following:

- A final rule that reinstates the disease-free status of the region, or a portion of the region covered by the interim rule;
- An affirmation of the interim rule that imposed prohibitions or restrictions on imports of animals and animal products from that region;
- Another document in the **Federal Register** for comment, if neither a final rule or interim rule is considered appropriate at that time (*e.g.*, we could publish a notice providing additional information for comment).

The initial interim rule is intended solely to serve as a temporary measure to provide the United States immediate protection from the introduction of foreign animal diseases. Also, the interim rule gives us an opportunity to evaluate the effectiveness of the region's emergency response measures and to determine whether the outbreak is indeed a temporary situation or indicates a fundamental change in the region's disease status. If a region takes immediate and effective steps to control and stamp out the disease, we believe the region's disease-free status should be restored as quickly as possible once the region has met OIE requirements.

Previously, the procedures we followed to restore the disease-free status of a region were lengthier. We typically did not receive adverse comments regarding the interim rule that revoked a region's status, so following the close of the comment period, we would publish an affirmation of the interim rule. Then, in order to restore the region's previous disease-free status, we would begin a new rulemaking with the publication of a proposed rule. After considering any comments we received during the comment period for the proposed rule, we would publish a final rule.

We believe that we can improve the regulatory process for restoring a region's disease free status by using the procedures described above, while still providing opportunity for public participation. For example, we removed France, Northern Ireland, the Netherlands, and Ireland from the list of regions considered to be free of rinderpest and foot-and-mouth disease (FMD) in two interim rules published in the **Federal Register** on March 14, 2001 (66 FR 14825–14826, Docket No. 01–018–1), and June 1, 2001 (66 FR 29686–29689, Docket No. 01–031–1). In those interim rules we stated that we intended to reassess the disease situations in these countries at a future date in accordance with OIE standards, and that as part of that reassessment process, we would consider all comments received regarding the interim rules. Additionally, we stated that the future reassessments would enable us to determine whether it was necessary to continue to prohibit or restrict the importation of specific regulated articles, or whether we could restore the disease-free status of some or all of those regions, or part of those regions. We subsequently reassessed the disease status of those regions, taking into consideration information provided to us by those regions, and our own site visits. We restored the disease-free status of France, Ireland, the Netherlands, and Northern Ireland in two final rules published in the **Federal Register** on November 5, 2001 (66 FR 55872–55876, Docket No. 01–031–2), and January 9, 2002 (67 FR 1072–1074, Docket No. 01–031–3). Our findings, including site visit reports, were made available to the public at the time the final rules were published.

Based on comments we received regarding those rulemakings, we decided in the future to make our findings available to the public for comment prior to taking any final action. Recently, following our reassessment of the FMD-status of Great Britain, we published a notice of availability of our findings in the **Federal Register** for comment (67 FR 54164, Docket 01–018–3, published August 21, 2002). Following the close of the comment period on that notice, and after considering the information provided by commenters, we published a final rule to restore the FMD-free status of Great Britain on December 17, 2002 (67 FR 77148–77152, Docket 01–018–4).

This proposed rule would codify in the regulations the procedures that we will follow to reassess the animal health status of regions that we recognize as free of disease, and that experience an outbreak of that disease. It would establish a transparent and more effective process for restoring the disease-free status of a region, or portion of that region, while acting to protect against the introduction of foreign animal diseases into the United States. It would also improve our current procedures by making information regarding our reassessment available for comment before taking final action.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Below is a summary of the economic analysis for this proposal. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866 and an analysis of the potential economic effects on small entities as required by the Regulatory Flexibility Act. A copy of the full economic analysis is available for review at the location listed in the **ADDRESSES** section at the beginning of this document or may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.**

We are proposing to establish procedures that we will follow when a region that we recognize as free of a disease experiences an outbreak of that disease. The procedures include steps we would take to prevent the introduction of disease from that region and steps we would take to further

assess the region's animal health status. The procedures would allow for timely reinstatement of the disease-free status of a region, or portion of a region, if supported by the reassessment.

As in the past, if a region that we recognize as free of a specified animal disease experiences an outbreak of that disease, we will take immediate action to prohibit or restrict imports of animals and animal products from that region to protect U.S. livestock. Restrictions and/or prohibitions may at first be announced administratively but are generally followed by an interim rule.

Previously, following the close of the comment period on the interim rule, we would publish an affirmation of the interim rule. Then, in order to restore the region's previous disease-free status, we would begin a new rulemaking with the publication of a proposed rule. After considering any comments we received during the comment period for the proposed rule, we would publish a final rule.

Under our new procedures, we will not proceed directly to an affirmation of the interim rule following the close of the comment period. Rather, we will reassess the disease status of the region in the context of the standards of the Office International des Epizooties (OIE) to determine whether it is necessary to continue the interim prohibitions or restrictions. As part of the reassessment process, we will consider all public comments we receive on the interim rule, as well as any additional information relevant to a decision to change the disease status of the region, including information collected by or submitted to us. Prior to taking any action to relieve or finalize prohibitions or restrictions imposed by the interim rule, we will make information regarding our reassessment of the region's disease status available to the public for comment. We will announce the availability of this information by publishing a notice in the **Federal Register**. Based on the reassessment, including the comments we receive in response to the notice we publish, we will publish one of the following:

- A final rule that reinstates the disease-free status of the region, or a portion of the region covered by the interim rule;
- An affirmation of the interim rule that imposed prohibitions or restrictions on imports of animals and animal products from that region;
- Another document in the **Federal Register** for comment, if neither a final rule or interim rule is considered appropriate at that time (*e.g.*, we could publish a notice providing additional information for comment).

The new procedures will improve the process for reinstating a region's disease-free status while still providing an effective opportunity for public participation.

U.S. entities potentially affected by these changes in procedures include importers, domestic producers, and consumers. In particular, importers and consumers could benefit because imports affected by the change in disease status could resume earlier than under previous procedures. Domestic producers of close substitutes, who may have benefitted during the period when imports were restricted or prohibited, could incur losses associated with a resumption of imports that could occur sooner than under past procedures. Because import levels of potentially regulated commodities from the majority of disease-free foreign regions are low relative to total imports and domestic availability of those commodities, the new procedures will likely not lead to significant benefits or losses. This projection is based on a review of economic analyses we prepared for recent rulemakings revoking and reinstating the disease-free status of foreign regions, as well as an analysis of the types and volumes of commodities currently imported from regions we currently recognize as free of specified diseases. We believe that the main benefits associated with the change in procedures will be improved trade relations between the U.S. and foreign governments.

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 13988, 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

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 OF 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. A new section 92.4 would be added to read as follows:

§ 92.4 Reestablishment of a region's disease-free status.

This section applies to regions that are designated in subchapter D of this chapter as free of a specific animal disease and then experience an outbreak of that disease.

(a) *Interim designation.* If a region recognized as free of a specified animal disease in subchapter D of this chapter experiences an outbreak of that disease, APHIS will take immediate action to prohibit or restrict imports of animals and animal products from that region. Such action may include publishing an interim rule that imposes prohibitions or restrictions that may be announced initially administratively. The interim rule may be given an effective date earlier than the date of signature or publication to affirm our authority for issuing previous administrative orders. The interim rule may impose prohibitions or restrictions on only a portion of the region previously recognized as free of a disease. In these cases, APHIS will provide information to the public as soon as possible regarding the basis for its decision to prohibit or restrict imports from the smaller area of that region previously recognized as free.

(b) *Reassessment of the disease situation.* (1) Following publication of an interim rule as described in paragraph (a) of this section, APHIS will reassess the disease situation in that region in accordance with standards of the Office International des Epizooties to determine whether it is necessary to continue the interim prohibitions or restrictions. As part of the reassessment process, APHIS will consider all public comments received on the interim rule, as well as any other information collected by or submitted to APHIS.

(2) Prior to taking any action to relieve or finalize prohibitions or restrictions imposed by the interim rule, APHIS will make information regarding its reassessment of the region's disease

status available to the public for comment. APHIS will announce the availability of this information by publishing a notice in the **Federal Register**.

(c) *Determination.* Based on the reassessment conducted in accordance with paragraph (b) of this section, including comments regarding the reassessment information, APHIS will take one of the following actions:

(1) Publish a final rule that reinstates the disease-free status of the region, or a portion of the region, covered by the interim rule;

(2) Publish an affirmation of the interim rule that imposed prohibitions or restrictions on the imports of animals and animal products from that region; or

(3) Publish another document in the **Federal Register** for comment.

Done in Washington, DC, this 19th day of June, 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 03–15907 Filed 6–23–03; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 63

[Docket No. PRM–63–1]

State of Nevada; Denial of a Petition for Rulemaking; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: denial; correction.

SUMMARY: On February 27, 2003 (68 FR 9023), the U.S. Nuclear Regulatory Commission (NRC) published a notice of denial of a petition for rulemaking. The petition for rulemaking, dated July 12, 2002, had been filed with the Commission by the State of Nevada, and assigned Docket No. PRM–63–1. The petitioner had requested that the NRC amend its regulations governing the disposal of high-level radioactive waste in a proposed geologic repository at Yucca Mountain, Nevada. This action corrects a sentence in the notice of denial by restoring a word that was mistakenly omitted from the published document. This action also corrects an erroneous citation and a typographical error in the body of the notice.

FOR FURTHER INFORMATION CONTACT: Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7285 or Toll Free: 1–800–368–5642, e-mail: *tjm3@nrc.gov;* or Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7163 or Toll Free: 1–800–368–5642, e-mail: *MTL@nrc.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–4625, published on February 27, 2003 (68 FR 9023), the following corrections are made.

1. On page 9025, in the third column, the second heading is corrected to read as follows:

a. 10 CFR part 63 Is in Accord With NWPA Requirements.

2. On page 9026, in the third column, the third sentence from the bottom of the column is corrected to read as follows:

The Commission decided to reexamine its implementation of a multiple barrier approach and propose a regulation which required a system of multiple barriers, but which did not set numerical goals for the performance of individual barriers.

3. On page 9032, in the fifth line, the words ''Swedish Nuclear Power Inspectorate'' are replaced by the words ''Swedish Nuclear Fuel and Waste Management Company''.

Dated at Rockville, Maryland, this 18th day of June, 2003.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 03–15861 Filed 6–23–03; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1306

[Docket No. DEA–202P]

RIN 1117–AA68

Authority for Practitioners To Dispense or Prescribe Approved Narcotic (Opioid) Controlled Substances for Maintenance or Detoxification Treatment

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA proposes to amend its regulations to allow qualified practitioners to dispense and prescribe to narcotic (opioid) dependent persons Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment. These practitioners would not need to obtain a separate DEA registration as a narcotic treatment program to legally dispense or prescribe these drugs. Such practitioners, however, must be deemed ''qualifying physicians'' by the Secretary, Department of Health and Human Services. This notice of proposed rulemaking is in response to the recent amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA), title XXXV of the Children's Health Act of 2000 (Pub. L. 106–310), that are designed to expand and improve treatment of opioid addiction. The proposed regulations are intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration specifically for maintenance/detoxification treatment.

DATES: Written comments must be postmarked on or before September 22, 2003.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

What Change in the Current Regulations Is This Notice Proposing?

With passage of the Drug Addiction Treatment Act of 2000 (DATA), title XXXV of the Children's Health Act of 2000 (Pub. L. 106–310; 116 Stat. 1222), this notice of proposed rulemaking proposes to amend the regulations affecting maintenance and detoxification treatment for narcotic (opioid) addiction. The Controlled Substances Act (CSA) and current regulations require that practitioners who want to conduct maintenance or detoxification treatment using narcotic (opioid) controlled drugs be registered with DEA as narcotic treatment programs (NTPs) in addition to the practitioners' personal registrations. The separate NTP registrations authorize the practitioners to dispense or administer, but not prescribe, narcotic (opioid) controlled drugs.

Proposed § 1301.27 would establish an exemption from the separate registration requirement for qualified