

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Office of the Secretary

#### 7 CFR Part 1

[Docket No. APHIS–2009–0039]

#### Rules of Practice for Certain Adjudicatory Proceedings; Possession, Use, and Transfer of Select Agents and Toxins

**AGENCY:** Office of the Secretary, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the administrative regulations of the Office of the Secretary of Agriculture to provide that the rules of practice contained in those regulations shall be applicable to adjudicatory proceedings under the Animal and Plant Health Inspection Service's regulations pertaining to the possession, use, and transfer of select agents and toxins. This final rule is necessary to clarify the rules of practice that will apply to the adjudication of a violation of regulations pertaining to the regulation of select agents and toxins.

**DATES:** *Effective Date:* July 9, 2009.

**FOR FURTHER INFORMATION CONTACT:** Mr. Steve O'Neill, Chief, Regulatory Analysis and Development, PPD, APHIS, 4700 River Road Unit 118, Riverdale, MD 20737–1238; (301) 734–8682.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title II, "Enhancing Controls on Dangerous Biological Agents and Toxins" (sections 201 through 231), provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201–204) and the Department

of Agriculture (subtitle B, sections 211–213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). For the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) has been designated as the agency with primary responsibility for implementing the provisions of the Act; the Animal and Plant Health Inspection Service (APHIS) is the agency fulfilling that role for the Department of Agriculture.

In accordance with those statutory provisions, on August 12, 2002, APHIS published in the **Federal Register** (67 FR 52383–52389) an interim rule that established the initial lists of biological agents and toxins and set out the manner in which persons in possession of listed agents and toxins were to provide notice of such possession.

Section 212 of the Act also required the Secretary of Agriculture to provide by regulation for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of listed biological agents and toxins in order to protect animal and plant health, and animal and plant products. Specifically, sections 212(b) and (c) required that the Secretary:

- Establish and enforce safety procedures for listed agents and toxins, including measures to ensure proper training and appropriate skills to handle agents and toxins, and proper laboratory facilities to contain and dispose of agents and toxins;
- Establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose;
- Establish procedures to protect animal and plant health, and animal and plant products, in the event of a transfer or potential transfer of a listed agent or toxin in violation of the safety procedures and safeguard and security measures established by the Secretary; and
- Ensure appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

In an interim rule published in the **Federal Register** on December 13, 2002 (67 FR 76908–76938) and effective on February 11, 2003, APHIS established

regulations in 7 CFR part 331 and 9 CFR part 121 governing the possession, use, and transfer of biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal or plant products. APHIS adopted its December 2002 interim rule as a final rule in a document published in the **Federal Register** on March 18, 2005 (70 FR 13242–13292).

Section 212(i) of the Act provides that persons who violate the regulations are subject to civil penalties not to exceed \$250,000 in the case of an individual and \$500,000 in the case of any other person. APHIS is amending the administrative regulations of the Office of the Secretary in 7 CFR 1.31 to provide that the uniform rules of practice for the Department of Agriculture promulgated in 7 CFR part 1, subpart H, are applicable to adjudicatory, administrative proceedings to assess civil penalties for violations of APHIS' regulations governing the possession, use, and transfer of select agents and toxins.

This final rule also amends the regulations in 7 CFR 1.131 by removing references to statutory provisions that were repealed by the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*). Specifically, in paragraph (a) of that section we are removing the following references:

- Act of May 29, 1884, commonly known as the Animal Industry Act, section 7, as amended (21 U.S.C. 117),
- Act of August 30, 1890, section 6, as amended (21 U.S.C. 104),
- Act of February 2, 1903, commonly known as the Cattle Contagious Diseases Act of 1903, section 3, as amended (21 U.S.C. 122),
- Act of March 3, 1905, section 6, as amended (21 U.S.C. 127),
- Act of July 2, 1962, section 6(a), as amended (21 U.S.C. 134e), and
- Act of May 6, 1970, section 2, as amended (21 U.S.C. 135a).

Along those same lines, in paragraph (b) of § 1.131, we are replacing a reference to "the Animal Quarantine and Related Laws (21 U.S.C. 111 *et seq.*)" with a reference to the Animal Health Protection Act.

This rule relates to internal agency management. Therefore, this rule is exempt from the provisions of Executive Orders 12866 and 12988. Moreover,

pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required for this rule, and it may be made effective less than 30 days after publication in the **Federal Register**. In addition, under 5 U.S.C. 804, this rule is not subject to congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121. Finally, this action is not a rule as defined by 5 U.S.C. 601 *et seq.*, the Regulatory Flexibility Act, and thus is exempt from the provisions of that Act.

#### Paperwork Reduction Act

This final 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 7 CFR Part 1

Administrative practice and procedure, Agriculture, Antitrust, Claims, Cooperatives, Courts, Equal access to justice, Fraud, Freedom of information, Government employees, Lawyers, Motion pictures, Penalties, Privacy.

■ Accordingly, we are amending 7 CFR part 1 as follows:

#### PART 1—ADMINISTRATIVE REGULATIONS

■ 1. The authority citation for part 1 continues to read as follows:

**Authority:** 5 U.S.C. 301, unless otherwise noted.

#### Subpart H—Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes

##### § 1.131 [Amended]

■ 2. Section 1.131 is amended as follows:

■ a. In paragraph (a), by removing the entries for “Act of May 29, 1884, commonly known as the Animal Industry Act, section 7, as amended (21 U.S.C. 117).”, “Act of August 30, 1890, section 6, as amended (21 U.S.C. 104).”, “Act of February 2, 1903, commonly known as the Cattle Contagious Diseases Act of 1903, section 3, as amended (21 U.S.C. 122).”, “Act of March 3, 1905, section 6, as amended (21 U.S.C. 127).”, “Act of July 2, 1962, section 6(a), as amended (21 U.S.C. 134e).”, and “Act of May 6, 1970, section 2, as amended (21 U.S.C. 135a).”.

■ b. In paragraph (a), by adding, in alphabetical order, an entry for “Agricultural Bioterrorism Protection Act of 2002, section 212(i) (7 U.S.C. 8401(i)).”.

■ c. In paragraph (b)(2), by removing the words “Animal Quarantine and Related Laws (21 U.S.C. 111 *et seq.*)” and adding the words “Animal Health Protection Act (7 U.S.C. 8301 *et seq.*)” in their place.

Dated: June 29, 2009.

**Thomas J. Vilsack,**  
*Secretary of Agriculture.*

[FR Doc. E9–16195 Filed 7–8–09; 8:45 am]

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#### DEPARTMENT OF AGRICULTURE

#### Cooperative State Research, Education, and Extension Service

#### 7 CFR Part 3431

**RIN 0524–AA43**

#### Veterinary Medicine Loan Repayment Program (VMLRP)

**AGENCY:** Cooperative State Research, Education, and Extension Service, USDA.

**ACTION:** Interim final rule and request for comments.

**SUMMARY:** This interim final rule establishes the process and procedures for designating veterinarian shortage situations, specifically for the Veterinary Medicine Loan Repayment Program (VMLRP) authorized by the National Veterinary Medical Service Act (NVMSA) and administered by the Cooperative State Research, Education, and Extension Service (CSREES) of the U.S. Department of Agriculture. CSREES will designate geographic and practice areas that have a shortage of food supply veterinarians in order to carry out the VMLRP goals of strengthening the nation’s animal health infrastructure and supplementing the Federal response during animal health emergencies. CSREES will carry out NVMSA by entering into educational loan repayment agreements with veterinarians who agree to provide veterinary services in veterinarian shortage situations for a determined period of time. CSREES is establishing Subpart A for the designation of the veterinarian shortage situations and Subpart B for the administration of the VMLRP.

**DATES:** This rule is effective July 9, 2009. The Agency must receive comments by September 8, 2009 for them to be considered in the final rule.

**ADDRESSES:** You may submit comments, identified by RIN 0524–AA43, by any of the following methods:

**Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

**E-mail:** [vmrlrp@csrees.usda.gov](mailto:vmrlrp@csrees.usda.gov). Include Regulatory Information Number (RIN) number 0524–AA43 in the subject line of the message.

**Fax:** 202–401–7752.

**Mail:** Paper, disk or CD–ROM submissions should be submitted to Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture, STOP 2299, 1400 Independence Avenue, SW., Washington, DC 20250–2299.

**Hand Delivery/Courier:** Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Room 2258, Waterfront Centre, 800 9th Street, SW., Washington, DC 20240.

**Instructions:** All submissions received must include the agency name and the RIN for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Gary Sherman, National Program Leader, Veterinary Science, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2220, 1400 Independence Avenue, SW., Washington, DC 20250–2220; Voice: 202–401–4952; Fax: 202–401–6156; e-mail: [gsherman@csrees.usda.gov](mailto:gsherman@csrees.usda.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background and Purpose

In January 2003, the National Veterinary Medical Service Act (NVMSA) was passed into law, adding section 1415A to the National Agricultural Research, Extension, and Teaching Policy Act of 1997 (NARETPA). This law established a new Veterinary Medicine Loan Repayment Program (7 U.S.C. 3151a) authorizing the Secretary of Agriculture to carry out a program of entering into agreements with veterinarians under which they agree to provide veterinary services in veterinarian shortage situations. In November 2005, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006 (Pub. L. 109–97) appropriated \$495,000 for CSREES to implement the Veterinary Medicine Loan Repayment Program and represented the first time funds had been appropriated for this program. In February 2007, the Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110–5) appropriated an additional \$495,000 to CSREES for support of the program, and in December 2007, the