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DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service

7 CFR Part 331
9 CFR Part 121

[Docket No. 02–082–2]

RIN 0579–AB47

Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule; technical amendment.

SUMMARY: In an interim rule published in the Federal Register and effective on August 12, 2002, we established regulations that listed biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products, and that required all persons in possession of any listed biological agent or toxin to notify the Secretary of such possession. The definitions provided in those regulations for the terms ‘biological agent’ and ‘toxin’ did not reflect the amendments made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (7 U.S.C. 8401). Thus, we referred to 18 U.S.C. 178 when preparing the definitions for those terms we included in the “Definitions” sections of both 7 CFR part 331 and 9 CFR part 121 (§§ 331.1 and 121.1, respectively).

We failed to note, however, that elsewhere in title II of Public Law 107–188 (section 231 of subtitle D, “Criminal Penalties Regarding Certain Biological Agents and Toxins,” specifically), the definitions of “biological agent” and “toxin” in 18 U.S.C. 178 had been amended. Therefore, in this document, we are amending 7 CFR 331.1 and 9 CFR 121.1 as established by our August 12, 2002, interim rule so that the definitions provided in those sections for the terms “biological agent” and “toxin” are consistent with the definitions for those terms in 18 U.S.C. 178, as amended by Public Law 107–188.

EFFECTIVE DATE: August 12, 2002.

FOR FURTHER INFORMATION CONTACT: For information concerning the regulations in 7 CFR part 331, contact Dr. Arnold T. Tschanz, Senior Staff Officer, Regulatory Coordination, Plant Health Programs, PPQ, APHIS, 4700 River Road Unit 141, Riverdale, MD 20737–1236, (301) 734–8790.

For information concerning the regulations in 9 CFR part 121, contact Dr. Denise Spencer, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1231, (301) 734–3277.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule published in the Federal Register and effective on August 12, 2002 (67 FR 52383–52389, Docket No. 02–082–1), we established regulations in 7 CFR part 331 and 9 CFR part 121 that listed biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products, and that required all persons in possession of any listed biological agent or toxin to notify the Secretary of such possession. The interim rule was published in accordance with the requirements of section 212 of subtitle B (Department of Agriculture), title II (Enhancing Controls on Dangerous Biological Agents and Toxins), of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188).

In subtitle B, section 212(1) provides that “[t]he terms ‘biological agent’ and ‘toxin’ have the meanings given such terms in section 178 of title 18, United States Code.” Thus, we referred to 18 U.S.C. 178 when preparing the definitions for those terms we included in the “Definitions” sections of both 7 CFR part 331 and 9 CFR part 121 (§§ 331.1 and 121.1, respectively).

We failed to note, however, that elsewhere in title II of Public Law 107–188 (section 231 of subtitle D, “Criminal Penalties Regarding Certain Biological Agents and Toxins,” specifically), the definitions of “biological agent” and “toxin” in 18 U.S.C. 178 had been amended. Therefore, in this document, we are amending 7 CFR 331.1 and 9 CFR 121.1 as established by our August 12, 2002, interim rule so that the definitions provided in those sections for the terms “biological agent” and “toxin” are consistent with the definitions for those terms in 18 U.S.C. 178, as amended by Public Law 107–188.

List of Subjects

7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we are amending 7 CFR part 331 and 9 CFR part 121 as follows:

PART 331—POSSESSION OF BIOLOGICAL AGENTS AND TOXINS

1. The authority citation for part 331 continues to read as follows:


2. In § 331.1, the definitions for biological agent and toxin are revised to read as follows:

§ 331.1 Definitions.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.
PART 121—POSSESSION OF BIOLOGICAL AGENTS AND TOXINS

3. The authority citation for part 121 continues to read as follows:


4. In §121.1, the definitions for biological agent and toxin are revised to read as follows:

§121.1 Definitions.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

Done in Washington, DC, this 20th day of September, 2002.

Peter Fernandez,
Acting Administrator, Animal and Plant Health Inspection Service.

For further information contact:

Mr. Tingen at (301) 415–4737, or by email to pdr@nrc.gov. The availability of the Regulatory Analysis, Environmental Assessment, and Resolution of Public Comments associated with this rulemaking is further discussed in Section 5 below under SUPPLEMENTARY INFORMATION.

For further information contact:

Stephen Tingen, Division of Engineering, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Alternatively, you may contact Mr. Tingen at (301) 415–1280, or via e-mail at: stingen@nrc.gov.

1. Background

On August 3, 2001 (66 FR 40626), the NRC published a Federal Register notice that presented a proposed rule to amend 10 CFR part 50, “Domestic Licensing of Production and Utilization Facilities.” The proposed rule would revise the requirements for construction, ISI, and IST of nuclear power plant components. For construction, the proposed rule would permit the use of Section III, Division 1, of the ASME BPV Code, 1997 Addenda, 1998 Edition, 1999 Addenda, and 2000 Addenda for Class 1, Class 2, and Class 3 components with no new modifications or limitations.

For ISI, the proposed rule would permit the use of Section XI, Division 1, of the ASME BPV Code, 1997 Addenda, 1998 Edition, 1999 Addenda, and 2000 Addenda for Class 1, Class 2, and Class 3 components with new modifications and limitations.

For IST, the proposed rule would permit the use of the ASME OM Code, 1997 Addenda, 1998 Edition, 1999 Addenda, and 2000 Addenda for Class 1, Class 2, and Class 3 pumps and valves with one new modification.

In the same Federal Register notice, the Commission withdrew a proposed rule (64 FR 22580; April 27, 1999) that would have eliminated the requirement for licensees to update their ISI and IST programs every 120 months beyond a