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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS–2009–0070]

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: In a final rule that was published in the **Federal Register** on October 5, 2012, we amended and republished the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products; reorganized the list of select agents and toxins based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant, or animal health; and amended the regulations in order to add definitions and clarify language concerning security, training, biosafety, biocontainment, and incident response. In that final rule we neglected to precisely align all of our regulatory language with that used by the Centers for Disease Control and Prevention (CDC) in their regulations and, in some cases, did not align our language in the Animal and Plant Health Inspection Service (APHIS) regulations concerning plant health and plant products with that concerning animal health and animal products. As APHIS co-administers the select agent regulations with CDC, this document corrects inconsistencies in language between APHIS and CDC regulations. We are also correcting an improper term used in those sections of the regulations associated with identification of a viral strain or subspecies that is excluded from the requirements of the regulations, modifying the terms used when a select toxin is excluded from the regulations, clarifying those parts of the regulations that deal with temporary exemptions granted during periods of agricultural or public health emergencies, and adding language to specify that individuals not approved for access to registered space for activities not related to select agents or toxins (e.g., routine cleaning, maintenance, and repairs) would not have to be continuously escorted by an approved individual so long as those non-approved persons would not be able to gain access to select agents or toxins.

DATES: *Effective Date:* May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Dr. Charles L. Divan, Unit Director, APHIS Agriculture Select Agent Services, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737–1231; (301) 851–3300, option 3.

SUPPLEMENTARY INFORMATION: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (referred to below as the Bioterrorism Response Act) provides for the regulation of certain biological agents that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the U.S. Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins are those that have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to both human and animal health or animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services (HHS).

We use the term ''select agents and toxins'' throughout the preamble of this technical amendment. Unless otherwise specified, the term ''select agents and toxins'' will refer to all agents or toxins listed by APHIS. When it is necessary to specify the type of select agent or toxin, we will use the following terms: ''PPQ select agents and toxins'' (for the plant agents and toxins listed in 7 CFR 331.3), ''VS select agents and toxins'' (for the animal agents and toxins listed in 9 CFR 121.3), or ''overlap select agents and toxins'' (for the agents and toxins listed in both 9 CFR 121.4 and 42 CFR 73.4).

On October 5, 2012, we published in the **Federal Register** (77 FR 61056–61081, Docket No. APHIS–2009–0070) a final rule [1] that amended and republished the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products; reorganized the list of select agents and toxins based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant, or animal health; and amended the regulations in order to add definitions and clarify language concerning security, training, biosafety, biocontainment, and incident response. Concurrently, CDC published a final rule amending and republishing the list of select agents that have the potential to pose a severe threat to human health.

APHIS and CDC worked to establish identical language in their respective regulations wherever possible. Within APHIS, we also aimed to maintain consistency between the VS and PPQ select agent regulations. The current action is necessary to correct the discrepancies in language in order to fully harmonize the regulations.

We are also clarifying a term used in the PPQ select agents and toxins regulations in § 331.3(d)(3) and the VS and overlap select agents and toxins regulations in §§ 121.3(d)(3) and 121.4(d)(3), which addresses the circumstances in which a virus strain or agent subspecies is excluded from the requirements set out in the regulations. Specifically, these paragraphs do not

[1] To view the final rule, its preceding proposed rule, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0070.*

clearly identify those strains of viruses and subspecies of agents that we do not consider to have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. These sections allow the listed virus strains and agent subspecies to be excluded from the requirements of the regulations provided that an entity can verify that the virus or agent in their possession is within the listed strain or subspecies. In this amendment, we are replacing the word ''verify'' with the word ''identify,'' as identification must occur prior to verification of a viral strain or subspecies of agent.

Sections 331.3(e), 121.3(e), and 121.4(e) concern the circumstances under which attenuated strains of select agents or inactive select toxins may be excluded from the requirements of the regulations. In these sections, we are replacing the words ''inactive'' and ''inactivated'' with the phrase ''modified to be less toxic or potent.'' This is necessary in order to cover a broader category of toxins. A select toxin may be modified to be less toxic or potent in such a way that it loses some but not necessarily all functional activity. By comparison, an inactive select toxin is completely non-functional. A written request and supporting scientific information would have to be submitted for toxins that have been modified to be less toxic or potent and a determination of whether to exclude the submitted toxin would be made by the Administrator.

Paragraphs 121.6(e) and (f) involve temporary exemptions to all or part of the regulations concerning overlap select agents and toxins, which may be granted by the Administrator or requested by the HHS Secretary in the event of an agricultural or public health emergency. We are amending the language in order to clarify that entities do not have to request these exemptions, as is the case with the other potential exemptions listed in § 121.6, since the decision regarding whether to issue exemptions is predicated on an independent determination of the existence of such an emergency by the Administrator or HHS Secretary.

Finally, § 331.11(d)(2) and § 121.11(d)(2) require that individuals not approved by the Administrator or the HHS Secretary for access to registered space for activities not related to select agents or toxins (e.g., routine cleaning, maintenance, and repairs) be continuously escorted by an approved individual. We are adding language to clarify that continuous escort is required only if those non-approved persons could potentially gain access to select agents or toxins.

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:

TITLE 7—AGRICULTURE

PART 331— POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

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

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

§ 331.1 [Amended]

■ 2. Section 331.1 is amended as follows:

■ a. In paragraph (1) of the definition of *recombinant nucleic acids,* by removing the words ''(i.e., recombinant nucleic acids)''.

■ b. In the definition of *security barrier,* by removing the words '', animals, or materials''.

■ 3. Section 331.3 is amended as follows:

■ a. In paragraph (d)(3), by removing the word ''verify'' and adding the word ''identify'' in its place.

■ b. By revising paragraph (e) introductory text.

■ c. In paragraph (e)(2), by removing the word ''inactivated'' and adding the word ''modified'' in its place.

The revision reads as follows:

§ 331.3 PPQ select agents and toxins.

* * * * *

(e) An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or modified toxin does not pose a severe threat to plant health or plant products.

* * * * *

§ 331.11 [Amended]

■ 4. Section 331.11 is amended as follows:

■ a. In paragraph (d)(2), by adding the words ''if the potential to access to select agents or toxins exists'' after the words ''approved individual''.

■ b. In paragraph (g), by removing the word ''documents'' and adding the word ''document'' in its place.

§ 331.12 [Amended]

■ 5. In § 331.12, paragraph (a) is amended by adding the words ''(including arthropods)'' after the words ''including any animals''.

§ 331.13 [Amended]

■ 6. In § 331.13, paragraph (a) introductory text is amended by removing both commas.

TITLE 9—ANIMALS AND ANIMAL PRODUCTS

PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

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

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

■ 8. Section 121.3 is amended as follows:

■ a. In paragraph (d)(3), by removing the word ''verify'' and adding the word ''identify'' in its place.

■ b. By revising paragraph (e) introductory text.

■ c. In paragraph (e)(2), by removing the word ''inactivated'' and adding the word ''modified'' in its place.

The revision reads as follows:

§ 121.3 VS select agents and toxins.

* * * * *

(e) An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or modified toxin does not pose a severe threat to animal health or animal products.

* * * * *

■ 9. Section 121.4 is amended as follows:

■ a. In paragraph (d)(3), by removing the word ''verify'' and adding the word ''identify'' in its place.

■ b. By revising paragraph (e) introductory text.

■ c. In paragraph (e)(2) by removing the word ''inactivated'' and adding the word ''modified'' in its place.

■ d. In paragraph (f)(3)(i), first sentence, by removing the second occurrence of the word ''and'' and adding the word ''or'' in its place.

The revision reads as follows:

§ 121.4 Overlap select agents and toxins.

* * * * *

(e) An attenuated strain of a select agent or a select toxin modified to be

less potent or toxic may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or modified toxin does not pose a severe threat to public health and safety, animal health, or animal products.

* * * * *

§ 121.5 [Amended]

■ 10. In § 121.5, paragraph (a)(3)(i) is amended by removing the words ''and swine'' and adding the words ''or swine'' in their place.

■ 11. Section 121.6 is amended as follows:

■ a. In paragraph (a)(3)(i), by removing the second occurrence of the word ''and'' and adding the word ''or'' in its place.

■ b. By revising paragraphs (e) and (f).

The revisions read as follows:

§ 121.6 Exemptions for overlap select agents and toxins.

* * * * *

(e) If it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap select agent or toxin, the Administrator may exempt an individual or entity from the requirements, in whole or in part, of this part for up to 30 calendar days. The Administrator may extend the exemption once for an additional 30 days.

(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements, in whole or in part, of this part for up to 30 calendar days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap select agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

§ 121.9 [Amended]

■ 12. In § 121.9, paragraph (c)(1) is amended by removing the words ''and swine'' and adding the words ''or swine'' in their place.

§ 121.11 [Amended]

■ 13. Section 121.11 is amended as follows:

■ a. In paragraph (c)(2), by adding the words ''(including arthropods)'' after the word ''animals''.

■ b. In paragraph (d)(2), by adding the words ''if the potential to access to select agents or toxins exists'' after the words ''approved individual''.

■ c. In paragraph (g), by removing the word ''Internet'' and adding the words ''National Select Agent Registry'' in its place.

■ 14. Section 121.13 is amended as follows:

■ a. By revising paragraph (a).

■ b. By removing paragraph (b).

■ c. By redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

■ d. In newly redesignated paragraph (b), by removing the words ''paragraph (b)'' and adding the words ''paragraph (a)'' in their place.

■ e. In newly redesignated paragraph (c), by removing the words ''paragraph (b)'' and adding the words ''paragraph (a)'' in their place.

The revision reads as follows:

§ 121.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] <100 ng/kg body weight.

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Done in Washington, DC, this 1st day of May 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–10741 Filed 5–9–14; 8:45 am]

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

RIN 3038–AD88

Enhancing Protections Afforded Customers and Customer Funds Held by Futures Commission Merchants and Derivatives Clearing Organizations; Correction

AGENCY: Commodity Futures Trading Commission.

ACTION: Correcting amendments.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is correcting final rules published in the **Federal Register** of November 14, 2013 (78 FR 68506). Those rules, 17 CFR Parts 1, 3, 22, 30, and 140, took effect on January 13, 2014. This correction amends Appendix B to 17 CFR 1.20 and Appendix B to 17 CFR 1.26 by removing a phrase from both appendices.

DATES: Effective on May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Parisa Abadi, Attorney-Advisor, 202–418–6620, *pabadi@cftc.gov,* Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 14, 2013 (78 FR 68506), the Commission published final rules adopting new regulations and amending existing regulations to require enhanced customer protections, risk management programs, internal monitoring and controls, capital and liquidity standards, customer disclosures, and auditing and examination programs for futures commission merchants (''FCMs''). The final rules also address certain related issues concerning derivatives clearing organizations (''DCOs''), including the requirement that a DCO obtain a written acknowledgment from each depository or money market mutual fund with which the DCO holds or invests customer funds, in the form of a standard template letter set forth in Appendix B to 17 CFR 1.20—Derivatives Clearing Organization Acknowledgment Letter for CFTC Regulation 1.20 Customer Segregated Account, and in Appendix B to 17 CFR 1.26—Derivatives Clearing Organization Acknowledgment Letter for CFTC Regulation 1.26 Customer Segregated Money Market Mutual Fund Account, respectively (each an ''Acknowledgment Letter'').

The sixth full paragraph [1] of the body of the Acknowledgment Letter set forth in Appendix B to 17 CFR 1.20 and the seventh full paragraph of the body of the Acknowledgment Letter set forth in Appendix B to 17 CFR 1.26 address the depository's or money market mutual fund's obligations in the event of the bankruptcy of the DCO account holder. The provisions are intended to relate exclusively to the bankruptcy of the account holder and should not additionally refer to the bankruptcy of

[1] This paragraph, as revised, will become the seventh full paragraph of the body of the Acknowledgment Letter set forth in Appendix B to 17 CFR 1.20, after the format of that Acknowledgment Letter is conformed to the format of the Acknowledgment Letter set forth in Appendix B to 17 CFR 1.26.