

USDA Summary of Changes Made in Final Rule

1. We are revising the format of the regulations in 7 CFR part 331 and 9 CFR part 121 so that the sections numbers and, to the extent possible, the section titles and the information contained in each section is the same in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73.

2. We are changing the terms "biological agents and/or toxins," "listed agents and/or toxins," and "high consequence livestock pathogens" to "select agents and toxins" or "select agents or toxins" throughout 7 CFR part 331 and 9 CFR part 121. In addition, in 9 CFR part 121, we are removing the term "overlap agents" each time it appears and adding "overlap select agents and/or toxins" in its place.

3. We are changing the title of 7 CFR part 331 and 9 CFR part 121 from "Possession, Use, and Transfer of Biological Agents and Toxins" to "Possession, Use, and Transfer of Select Agents and Toxins."

4. We are removing *Phakopsora pachyrhizi* and plum pox potyvirus from the list of PPQ select agents and toxins.

5. We are removing Newcastle disease virus (VVND) from the list of VS select agents and toxins and adding Newcastle disease virus (velogenic) in its place to make it clear that we are regulating all of the velogenic strains.

6. We are removing *Clostridium botulinum* from the list of overlap select agents and toxins but we are continuing to list *Botulinum neurotoxin* producing species of *Clostridium*.

7. We are adopting CDC's approach for genetic elements and, therefore, we will consider the following to be select agents and toxins:

Nucleic acids that can produce infectious forms of any of the select agent viruses listed in either 7 CFR part 331 or 9 CFR part 121;

Recombinant nucleic acids that encode for the functional forms of any toxin listed in either 7 CFR part 331 or 9 CFR part 121 if the nucleic acids: (1) Can be expressed in vivo or in vitro; or (2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; and

Select agents and toxins listed in either 7 CFR part 331 or 9 CFR part 121 that have been genetically modified.

8. We are broadening the scope of the overlap toxin exclusion to cover overlap toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor.

9. We are amending the exemption provisions by requiring, as another condition of exemption, that the select agent or toxin be secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin.

10. We are amending the exemption provisions in 9 CFR part 121 by requiring immediate reporting after identification of specified select agents and toxins; identification of the other select agents and toxins must be reported within 7 calendar days after identification.

11. We are amending the exemption provisions to allow the Administrator to make exceptions to the timeframes for transfer or destruction of a select agent or toxin, as necessary.

12. We are amending the registration sections to set out a new framework for submitting registration applications to APHIS or CDC.

13. We are amending the registration sections in 7 CFR part 331 and 9 CFR part 121 to provide:

Federal, State, or local governmental agencies, including public institutions of higher education, are exempt from the security risk assessment for the entity and the individual who owns or controls such entity.

For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual: (1) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock; or (2) is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

14. We are amending the registration sections to provide that a certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the responsible official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

15. We are amending the registration sections to require that, prior to any change, the responsible official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.

16. We are amending the registration sections to provide that an entity must immediately notify APHIS or CDC if it loses the services of its responsible official. An entity may continue to possess or use select agents or toxins only if it appoints as the responsible official another individual who has been approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of the regulations.

17. We are amending the sections pertaining to denial, revocation, and suspension of registration by requiring that, upon notification of suspension or revocation, an individual or entity must:

Immediately stop all use of each select agent or toxin covered by the revocation or suspension order;

Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and

Comply with all disposition instructions issued by the Administrator for each select agent or toxin covered by the revocation or suspension.

18. We are amending the responsible official sections to require the responsible official to report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification. We are also amending the responsible official section in 9 CFR 121.9 to require the responsible official to report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. 19. We are amending the provisions relating to access approvals to state that an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin.

20. We are amending the provisions pertaining to access approval to provide that an individual's access approval may be revoked if the individual is within any of the categories specified in the regulations.

21. We are amending the security sections to clarify that the security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

22. We are adding the provisions for restricted experiments to 7 CFR part 331 and we are amending these provisions in 7 CFR part 331 and 9 CFR part 121 to indicate that

these experiments must be conducted under any conditions prescribed by the Administrator.

23. We are amending the training sections to require that information and training on biocontainment/biosafety and security be provided to each individual with access approval from the Administrator or the HHS Secretary before he/she has access and to each individual not approved for access by the Administrator or the HHS Secretary before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.).

24. We are amending the transfer section in 9 CFR 121.16 to set out the requirements for transfer of a select agent or toxin contained in a specimen for proficiency testing.

25. We are amending the transfer sections to provide that, on a case-by-case basis, the Administrator may authorize a transfer of a select agent or toxin not otherwise eligible for transfer under the regulations under conditions prescribed by the Administrator.

26. We are amending the transfer sections to provide that an authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization changes (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).

27. We are amending the records sections to require the maintenance of an accurate, current inventory for each toxin held and for each select agent held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials).

28. We are amending the section pertaining to notification of theft, loss, or release in 7 CFR part 331 to require that APHIS or CDC be notified immediately upon discovery of a release of a select agent or toxin outside of the primary barriers of the biocontainment area and we are amending this section in 9 CFR part 121 to require that APHIS or CDC be notified immediately upon discovery of a release of a select agent or toxin causing occupational exposure or a release outside of the primary barriers of the biocontainment area.

29. We are amending the administrative review sections to allow an individual to appeal revocation of access approval.