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DEPARTMENT OF AGRICULTURE

Office of the Secretary

9 CFR Parts 101 through 118, 123, and 124

[Docket No: USDA-2026-0298]

Modernization of Regulations Under 9 CFR Parts 101–118 and 123–124

AGENCY: Office of the Secretary, U.S. Department of Agriculture.

ACTION: Request for Information

SUMMARY: The U.S. Department of Agriculture (USDA) proffers this Request for Information (RFI) to solicit the public's input on regulatory considerations related to 9 CFR parts 101-118, 123-124. The regulations are issued primarily pursuant to Section 154 of the Virus-Serum-Toxin Act (VSTA). USDA intends to evaluate each part and subpart for its effectiveness at upholding the VSTA's statutory mandate to prohibit the preparation, sale, barter, or exchange of "worthless, contaminated, dangerous, or harmful" viruses, serums, toxins, or analogous products intended for the use in the treatment of domestic animals, i.e., all animals, other than man, including poultry. The current regulations reflect decades of incremental amendments, technical updates, and revisions adopted at different points in time to address specific scientific, operational, and/or programmatic needs; in recent history, USDA has not holistically reformed the regulations implementing the VSTA. Comprehensive modernization of the regulations will ensure that the framework remains coherent, consistent, and responsive to contemporary technologies, innovation, and practices while continuing to fulfill the statutory requirements of the VSTA.

DATES: We will consider all comments that we receive on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: USDA invites public comments on this RFI and encourages stakeholders, including farmers, industry representatives, and state and local governments, to provide input.

You may submit comments, identified by docket number USDA-2026-0298, in the Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. All comments will be posted without change and will be publicly available on www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Michael Poe, Office of the General Counsel, USDA, 1400 Independence Avenue SW, Washington, DC 20250-1400, (202) 769-8247.

SUPPLEMENTARY INFORMATION:

Background

Within the United States Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) Center for Veterinary Biologics (CVB) regulates veterinary biologics under the Virus-Serum-Toxin Act (VSTA).[1] The VSTA prohibits the preparation, sale, barter, exchange or shipment of "worthless, contaminated, dangerous, or harmful" viruses, serums, toxins, or analogous products.[2] The VSTA authorizes the Secretary of Agriculture (the Secretary) to examine and inspect all viruses, serums, toxins, and analogous products for use in the treatment of domestic animals, if the products are imported or offered for importation into the United States, to determine if the products are prohibited by the VSTA, and if they are, to deny entry. The VSTA further authorizes the Secretary to promulgate regulations to prevent the preparation, sale, barter, exchange, or shipment of such products. Within USDA, this authority has been delegated to CVB. Regulations established under the VSTA are contained in 9 CFR parts 101-118, 123-124.

The regulations in 9 CFR parts 101-118, 123-124 establish the terminology, technical requirements, and enforcement practices for CVB's administration of the VSTA. These parts collectively address a range of activities associated with veterinary biological products, including

[1] 21 U.S.C. §§ 151–159 (2023)
[2] 21 U.S.C. § 151.

product and establishment licensing;[3] the conditions for importation and experimental use;[4] and the procedures for suspension or revocation of USDA licenses and authorizations.[5] These regulations also include requirements related to facility design and operation,[6] equipment sanitation,[7] production controls,[8] testing and serial release procedures,[9] packaging and labeling specifications,[10] and recordkeeping and reporting practices.[11] Additional provisions address the management and use of animals at licensed establishments,[12] inspection authorities,[13] and the detention or disposition of non-compliant products.[14] Over time CVB has amended these regulations to incorporate updated laboratory methods and production technologies, resulting in a patchwork of incremental updates across multiple technical domains. The intent of this Request for Information (RFI) is to gather information that would assist USDA in modernizing 9 CFR parts 101-118, 123-124. Modifications will be considered to encourage innovation, protect animal health, and improve regulatory clarity, while ensuring fidelity to the text of the VSTA. Based on this background information, we solicit public comments regarding the following questions:

1. What modifications or streamlining of the regulations in 9 CFR parts 101-118, 123-124 would best respond to modern research and development (R&D), manufacturing, and distribution practices to improve animal health outcomes?
2. Please describe your experiences with regulation under 9 CFR parts 101-118, 123-124, including any areas that could be improved. In your view, do any provisions hinder market efficiency or innovation, and what costs do you incur when complying with or

[3] *See* 9 C.F.R. 102.
[4] *See* 9 C.F.R. 103-104.
[5] *See* 9 C.F.R. 105.
[6] *See* 9 C.F.R. 108.
[7] *See* 9 C.F.R. 109.
[8] *See* 9 C.F.R. 114.
[9] *See* 9 C.F.R. 113.
[10] *See* 9 C.F.R. 112.
[11] *See* 9 C.F.R. 116.
[12] *See* 9 C.F.R. 117.
[13] *See* 9 C.F.R. 115.
[14] *See* 9 C.F.R. 118.

navigating the regulatory requirements? Additionally, which aspects of 9 CFR parts 101-118, 123-124 function effectively as written?

3. How could CVB improve the clarity, organization, or interpretation of the regulations in 9 CFR parts 101-118, 123-124 to reduce ambiguity, enhance predictability, and support consistent compliance across the industry?
4. How could 9 CFR parts 101-118, 123-124 better align with the statutory authorities granted in the VSTA, particularly with respect to animal testing and handling requirements, facility requirements, and packaging and labeling requirements, among others?
5. Which regulatory processes within 9 CFR parts 101-118, 123-124, such as licensing, production updates, facility approvals, inspections, or reporting, could be streamlined to reduce administrative burden while preserving product quality, availability, and effectiveness?
6. How could CVB better align 9 CFR parts 101-118, 123-124 with international standards or regulatory frameworks to support and/or preserve global market access, reduce duplicative requirements, or improve regulatory harmonization? How could changes to 9 CFR parts 101-118, 123-124 impact domestic manufacturers and producers' ability to export to other markets?
7. How might CVB incorporate greater regulatory flexibility into 9 CFR parts 101-118, 123-124 to accommodate emerging technologies, novel product categories, or evolving production systems without compromising safety or effectiveness?
8. Are there any other specific issues or topics CVB should consider in modifying and modernizing the regulatory framework outlined in 9 CFR parts 101-118, 123-124?

We request that commentors:

1. Provide supporting data, case examples, or references that substantiate your recommendations.

2. If applicable, indicate whether your comments reflect the perspective of a manufacturer, distributor, veterinarian, academic/research institution, trade association, state regulatory officials, the public, or other stakeholder group.

When providing information to USDA, commenters must indicate what information provided is confidential business information. USDA will review this information to ensure that the provided information is not information that the submitter would ordinarily disclose to the public. USDA intends to protect confidential business information in accordance with legal and regulatory obligations and practices.

Authority: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.3.

Andrew Perry,

Office of the General Counsel.

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