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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 900

[Doc. No. AMS–SC–17–0086; SC18–900–1 FR]

General Regulations for Federal Fruit, Vegetable, and Specialty Crop Marketing Agreements and Orders; Authority To Meet Via Electronic Communications

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the general regulations for Federal fruit, vegetable, and specialty crop marketing agreements and marketing orders (orders) and allows such programs to conduct meetings and vote using electronic means of communication.

DATES: Effective May 17, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Schmaedick, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, Post Office Box 952, Moab, UT 84532; Telephone: (202) 557–4783, Fax: (435) 259–1502, or Julie Santoboni, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Melissa.Schmaedick@ams.usda.gov* or *Julie.Santoboni@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202)720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule is issued under the general regulations for Federal marketing agreements and orders (7 CFR part 900), effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 12866, 13563, and 13175. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See the Office of Management and Budget's (OMB) Memorandum titled, ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule authorizes administrative bodies of Federal fruit, vegetable, and specialty crop orders that currently do not have authority to conduct meetings using electronic communication means to do so.

This action also stipulates that each program follow its respective quorum and voting requirements when conducting meetings via electronic communication. Lastly, this action allows administrative bodies to recommend, subject to approval by the Secretary of Agriculture (Secretary), new requirements specific to meetings and verifying votes made at meetings conducted other than in-person.

Adding this authority increases operating efficiencies by adding flexibility to the methods by which meetings may be held and decisions made. Additionally, time and travel costs of attending meetings will be reduced. Of the 29 fruit, vegetable, and specialty crop orders currently in effect, six either do not have authority to meet other than in person or are limited specifically to phone or mail voting as alternatives.

Administrative Procedure Act and Regulatory Flexibility Act

This final rule establishes agency rules of practice and procedure. Under the Administrative Procedure Act (APA), prior notice and opportunity for comment are not required for the promulgation of agency rules of practice and procedure. 5 U.S.C. 553 (b)(3)(A). Only substantive rules require publication 30 days prior to their effective date. 5 U.S.C. 553 (d). Therefore, this final rule is effective upon publication in the **Federal Register**.

In addition, because prior notice and opportunity for comment are not required to be provided for this final rule, this rule is exempt from the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously-mentioned address in

the **FOR FURTHER INFORMATION CONTACT** section.

List of Subjects in 7 CFR Part 900

Administrative practice and procedure, Freedom of information, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth above, 7 CFR part 900 is amended as follows:

PART 900—GENERAL REGULATIONS

■ 1. The authority citation for part 900 continues to read as follows:

Authority: 7 U.S.C. 601–674 and 7 U.S.C. 7401.

■ 2. Add § 900.83 to subpart E read as follows:

§ 900.83 Conducting Meetings via Electronic Communication or Otherwise.

Notwithstanding any other provisions of a marketing order in this part, administrative bodies of fruit, vegetable, and specialty crop marketing orders, and their committees/subcommittees may, upon due notice to all members and the public:

(a) Conduct meetings by any means of communication available, electronic or otherwise, that effectively assembles members and the public, and facilitates open communication.

(b) Vote by any means of communication available, electronic or otherwise; Provided, That votes cast are verifiable and that quorum and other procedural requirements of each respective marketing order are met.

(c) With the approval of the Secretary, each administrative body may prescribe any additional procedures necessary to carry out the objectives of paragraphs (a) and (b) of this section.

Dated: May 11, 2018.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2018–10487 Filed 5–16–18; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 116

[Docket No. APHIS–2014–0063]

RIN 0579–AE11

VSTA Records and Reports Specific to International Standards for Pharmacovigilance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations concerning records and reports. This change requires veterinary biologics licensees and permittees to record and submit reports concerning adverse events associated with the use of biological products they produce or distribute. The information that must be included in the adverse event reports submitted to the Animal and Plant Health Inspection Service (APHIS) will be provided in separate guidance documents. These records and reports will help ensure that APHIS can provide complete and accurate information to consumers regarding adverse reactions or other problems associated with the use of licensed biological products.

DATES: Effective June 18, 2018.

FOR FURTHER INFORMATION CONTACT: Dr. Donna L. Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 851–3426.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 116 (referred to below as the regulations) contain requirements for maintaining detailed records of information necessary to give a complete accounting of all the activities within a veterinary biologics establishment. These records include records and reports for unfavorable or unintended events that occur in animals after the use of a biological product.

On September 4, 2015, we published in the **Federal Register** (80 FR 53475–53478, Docket No. APHIS–2014–0063) a proposal [1] to amend the regulations by establishing definitions for the terms *adverse event* and *adverse event report* and by providing requirements for adverse event records and reports. The changes we proposed are consistent with guidelines set out by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH is a unique project conducted under the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. Regulatory authorities and industry experts from Australia, Canada, and New Zealand participate as observers.

The purpose of VICH is to harmonize technical requirements for veterinary medicinal products (both pharmaceuticals and biologics). As a VICH member, the Animal and Plant Health Inspection Service (APHIS) provides expertise on veterinary biological products and participates in efforts to enhance harmonization. Both APHIS and the animal health industry are committed to seek scientifically based harmonized technical requirements for the development and use of veterinary biological products. VICH Guideline GL42: Pharmacovigilance: Data Elements for Submission of Adverse Events Reports specifically addresses the information that should be included when submitting adverse event reports.[2]

We solicited comments concerning our proposal for 60 days ending November 3, 2015. We received four comments by that date. They were from industry associations, a manufacturer of veterinary biologics, and a private citizen. The commenters were generally supportive of the proposed rule but asked some questions and raised some concerns about the provisions. These comments are discussed below by topic.

General Comments

One commenter stated that the current system for detecting safety issues with products has historically worked well. The commenter did not believe there have been significant safety issues that have not been detected in a timely fashion.

APHIS agrees with the commenter that the existing system has worked well. However, we believe that this rule will significantly improve the existing system by enhancing our ability to monitor the observed performance of veterinary biologics. For example, currently each veterinary biologics manufacturer makes an independent determination concerning whether an adverse event report raises questions regarding purity, safety, potency, efficacy, preparation, testing, or distribution, and when and in what manner such a report of the adverse event will be provided to APHIS. Thus, without explicit reporting requirements concerning adverse events, reports that may signal problems concerning the use of veterinary biological products may not all be submitted to APHIS or may not be submitted in a timely manner.

[1] To view the proposed rule, supporting document, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0063.*

[2] The VICH pharmacovigilance guidelines can be accessed at *http://www.vichsec.org/guidelines/pharmacovigilance.html.*