This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of entry of USDA’s final ruling.

Background

This interim rule invites comments on revising the time frame for continuance referenda under the Order. The Order is administered by the Board with oversight by the U.S. Department of Agriculture (USDA). The Order requires USDA to conduct a continuance referendum five years after the program took effect (2011). This action revises this time frame from five years (2016) to no later than seven years (2018). This will allow time for USDA to complete a separate rulemaking action on the Order’s exemption threshold. That rulemaking is being initiated in response to a federal district court decision in Resolute Forest Products Inc., v. USDA, et al. (Resolute). Once USDA completes that action, a continuance referendum will be conducted. The results of the exemption threshold rulemaking could impact who votes in the referendum and who pays assessments under the Order.

DATES: Effective August 31, 2016. Comments received by October 31, 2016 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this interim rule. Comments may be submitted on the Internet at: http://www.regulations.gov or to the Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., Room 1406–S, Stop 0244, Washington, DC 20250–0244; facsimile: (202) 205–2800. All comments should reference the document number and the date and page number of this issue of the Federal Register and will be made available for public inspection, including name and address, if provided, in the above office during regular business hours or it can be viewed at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:
Maureen T. Pello, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, P.O. Box 831, Beavercreek, Oregon 97004; telephone: (503) 632–8848; facsimile (503) 632–8852; or electronic mail: Maureen.Pello@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This interim rule is issued under the Order (7 CFR part 1217). The Order is authorized under the Commodity Promotion, Research and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This action has been designated as a “non-significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has waived the review process.

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of entry of USDA’s final ruling.

Background

This interim rule invites comments on revising the time frame for continuance referenda under the Order. The Order is administered by the Board with oversight by the U.S. Department of Agriculture (USDA). The Order requires USDA to conduct a continuance referendum five years after the program took effect (2011). This action revises this time frame from five years (2016) to no later than seven years (2018). This will allow time for USDA to complete a separate rulemaking action on the Order’s exemption threshold. That rulemaking is being initiated in response to a federal district court decision in Resolute Forest Products Inc., v. USDA, et al. (Resolute). Once USDA completes that action, a continuance referendum will be conducted. The results of the exemption threshold rulemaking could impact who votes in the referendum and who pays assessments under the Order.

DATES: Effective August 31, 2016. Comments received by October 31, 2016 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this interim rule. Comments may be submitted on the Internet at: http://www.regulations.gov or to the Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., Room 1406–S, Stop 0244, Washington, DC 20250–0244; facsimile: (202) 205–2800. All comments should reference the document number and the date and page number of this issue of the Federal Register and will be made available for public inspection, including name and address, if provided, in the above office during regular business hours or it can be viewed at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:
Maureen T. Pello, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, P.O. Box 831, Beavercreek, Oregon 97004; telephone: (503) 632–8848; facsimile (503) 632–8852; or electronic mail: Maureen.Pello@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This interim rule is issued under the Order (7 CFR part 1217). The Order is authorized under the Commodity Promotion, Research and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This action has been designated as a “non-significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has waived the review process.

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Executive Order 12988

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of entry of USDA’s final ruling.

Background

This interim rule invites comments on revising the time frame for continuance referenda under the Order. The Order is administered by the Board with oversight by the U.S. Department of Agriculture (USDA). The Order requires USDA to conduct a continuance referendum five years after the program took effect (2011). This action revises this time frame from five years (2016) to no later than seven years (2018). This will allow time for USDA to complete a separate rulemaking action on the Order’s exemption threshold. That rulemaking is being initiated in response to a federal district court decision in Resolute Forest Products Inc., v. USDA, et al. (Resolute). Once USDA completes that action, a continuance referendum will be conducted. The results of the exemption threshold rulemaking could impact who votes in the referendum and who pays assessments under the Order.
The softwood lumber program was promulgated in 2011. Assessment collection began in January 2012. Under the Order, assessments are collected from U.S. manufacturers (domestic) and importers and used for projects designed to increase the demand for softwood lumber within the United States. Softwood lumber is used in products like flooring, siding and framing. Entities that domestically ship or import less than 15 million board feet annually are exempt from paying assessments.

Authorities and Action

Section 518 of the 1996 Act (7 U.S.C. 7417) authorizes continuance referenda. Paragraph (b) of that section requires USDA to conduct a referendum not later than seven years after assessments first begin under an order. Under §1217.81(b)(2) of the softwood lumber Order, USDA must conduct a referendum five years after the program took effect to determine whether persons subject to assessment favor continuance of the Order, and then every five years thereafter. A referendum was initially scheduled for August 2016.

USDA is conducting an analysis on the 15 million board foot exemption threshold under the Order, as specified in paragraphs (a) and (b) of section 1217.53. USDA is analyzing this threshold based on recent data and will publish the results of its analysis for public comment in a future rulemaking action. Once this rulemaking is completed, USDA will conduct a referendum. The results of that rulemaking could impact who votes in the referendum and who pays assessments under the program.

USDA will be initiating the future rulemaking action on the Order’s exemption threshold in response to a May 2016 federal district court decision in Resolute. All program obligations, including the collection of assessments and filing of reports, remain in effect.

Therefore, USDA has postponed the August 2016 referendum and is revising paragraph (2) in section 1217.81(b) to specify that a referendum must be conducted no later than seven years (2018) after the program took effect. This will allow time for USDA to complete the rulemaking action on the exemption threshold under the program and conduct a referendum. Section 1217.81(b)(2) is revised accordingly. Authority for USDA to amend the Order is provided in section 1217.87 of the Order and in section 514(d) of the 1996 Act (7 U.S.C. 7413).

Initial Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS is required to examine the impact of the rule on small entities. Accordingly, AMS has considered the economic impact of this action on such entities.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. The Small Business Administration defines, in 13 CFR part 121, small agricultural service firms (domestic manufacturers and importers) as those having annual receipts of no more than $7.5 million. Based on 2015 Board data, it is estimated that there are about 375 domestic manufacturers of softwood lumber in the United States. Using an average price of $330 per thousand board feet, a domestic manufacturer who ships less than about 23 million board feet per year would be considered a small entity. It is estimated that fewer than 240 domestic manufacturers, or 64 percent, ship under 23 million board feet annually.

Likewise, based on 2015 U.S. Customs and Border Protection (Customs) data, it is estimated there are 890 importers of softwood lumber. About 790 importers, or 89 percent, each imported less than $7.5 million worth of softwood lumber annually. Thus, for purposes of the RFA, the majority of domestic manufacturers and importers of softwood lumber would be considered small entities.

Regarding value of the commodity, with domestic consumption estimated at 43.9 billion board feet in 2015 and using a price of $330 per thousand board feet, the annual domestic value for softwood lumber is about $14.5 billion. According to 2015 Customs data, the annual value for softwood lumber imports is about $5.0 billion. This interim rule invites comments on revising the time frame for continuance referenda under the Order. The Order is administered by the Board with oversight by USDA. Section 1217.81(b)(2) of the Order requires USDA to conduct a continuance referendum five years after the program took effect (2011). This action revises this section to change the time frame from five years (2016) to no later than seven years (2018). This will allow time for USDA to complete a separate rulemaking action on the Order’s exemption threshold. That rulemaking is being initiated in response to a federal district court decision in Resolute. Once USDA completes that action, a referendum will be conducted. The results of that rulemaking could impact who votes in the referendum and who pays assessments under the program.

Regulatory alternatives, conducting the referendum as initially planned in 2016 would cause confusion in the industry. USDA is currently conducting an analysis on the exemption threshold under the Order and will publish the results in a separate rulemaking action. That action is being initiated in response to Resolute. Once USDA completes that action, a referendum will be conducted. The results of that rulemaking could impact who votes in the referendum.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements that are imposed by the Order have been approved previously under OMB control number 0581–0093. This interim rule imposes no additional reporting and recordkeeping burden on domestic manufacturer and importers of softwood lumber.

As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. Finally, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this interim rule.

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.

Regarding outreach efforts, USDA announced at the Board’s meeting on May 25, 2016, that the referendum scheduled for August 2016 would be postponed to a future to-be-determined date. USDA also announced at the meeting that it would publish a notice in the Federal Register on the postponement. After the meeting, the Board issued a newsflash to industry members advising them accordingly.

A 60-day comment period is provided to allow interested persons to respond to this interim rule. All written comments received in response to this rule by the date specified will be considered prior to finalizing this action.

After consideration of all relevant material presented, and other information, it is found that this interim rule, as hereinafter set forth, will tend to effectuate the declared purposes of the 1996 Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the Federal Register because: (1) This interim rule extends the time frame for USDA to conduct a referendum under the Order from five years (2016) after the program took effect to no later than seven years (2016) after the program took effect; (2) postponing the 2016 referendum will give USDA time to complete a separate rulemaking action on the Order’s exemption threshold that is being initiated in response to a May 2016 federal district court decision in Resolute; (3) USDA announced at the Board’s meeting on May 25, 2016, that the 2016 referendum would be postponed, and the Board subsequently issued a newsflash to industry members advising them of the postponed referendum; and (4) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 1217

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Promotion, Reporting and recordkeeping requirements, Softwood lumber.

For the reasons set forth in the preamble, 7 CFR part 1217 is amended as follows:

PART 1217—SOFTWARE LUMBER RESEARCH, PROMOTION, CONSUMER EDUCATION AND INDUSTRY INFORMATION ORDER

1. The authority citation for 7 CFR part 1217 continues to read as follows:


2. In §1217.81, revise paragraph (b)(2) to read as follows:

§1217.81 Referenda.

* * * * *

(b) * * * *

(2) No later than seven years after this Order becomes effective and every five years thereafter, to determine whether softwood lumber manufacturers for the U.S. market favor the continuation of the Order. The Order shall continue if it is favored by a majority of domestic manufacturers and importers voting in the referendum who also represent a majority of the volume of softwood lumber represented in the referendum who, during a representative period determined by the Secretary, have been engaged in the domestic manufacturing or importation of softwood lumber;

* * * * *


Elanor Starmer,
Administrator.

[FR Doc. 2016–20805 Filed 8–29–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101, 103, 112, 113, and 114

[Docket No. APHIS–2008–0008]

RIN 0579–AD19

Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations regarding the packaging and labeling of veterinary biological products to provide for the use of an abbreviated true name on small final container labeling for veterinary biologics; require labeling to bear a consumer contact telephone number; change the format used to show the establishment or permit number on labeling and require such labeling to show the product code number; change the storage temperature recommended in labeling for veterinary biologics; require vaccination and revaccination recommendations in labeling to be consistent with licensing data; require labeling information placed on carton tray covers to appear on the outside face of the tray cover; remove the restriction requiring multiple-dose final containers of veterinary biologics to be packaged in individual cartons; require labeling for bovine virus diarrhea vaccine containing modified live virus to bear a statement warning against use in pregnant animals; reduce the number of copies of each finished final container label, carton label, or enclosure required to be submitted for review and approval; require labels for autogenous biologics to specify the organism(s) and/or antigen(s) they contain; and require labeling for conditionally licensed veterinary biologics to bear a statement concerning efficacy and potency requirements. In addition, we are also amending the regulations concerning the number of labels or label sketches for experimental products required to be submitted for review and approval, and the recommended storage temperature for veterinary biologics at licensed establishments. These changes are necessary in order to update and clarify labeling requirements and to ensure that information provided in labeling is accurate with regard to the expected performance of the product.

DATES: Effective October 31, 2016.

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

Under the Virus-Serum-Toxin Act (the Act, 21 U.S.C. 151–159) and regulations issued under the Act, the Animal and Plant Health Inspection Service (APHIS) grants licenses or permits for biological products which are pure, safe, potent, and efficacious when used according to label instructions. The regulations in 9 CFR part 112, “Packaging and Labeling” (referred to below as the regulations), prescribe requirements for the packaging and labeling of veterinary biological products including requirements applicable to final container labels, carton labels, and enclosures. The main purpose of the