

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 1212**

[Document Number AMS–SC–16–0124]

Honey Packers and Importers Research, Promotion, Consumer Education and Industry Information Order; Change in Producer Eligibility Requirements and Implementation of Charges for Past Due Assessments**AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Final rule.

SUMMARY: This rule revises the eligibility requirements for producer representatives on the Honey Packers and Importers Board (Board) and prescribes late payment and interest charges on past due assessments under the Agricultural Marketing Service's (AMS) regulation regarding a national research and promotion program for honey and honey products. This rule reduces the minimum production requirement for producers to serve on the Board and thereby allow more producers to be eligible to serve on the Board. This rule also prescribes late payment and interest charges on past due assessments to help facilitate program administration.

DATES: Effective Date: April 13, 2018.

FOR FURTHER INFORMATION CONTACT: Sue Coleman, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202)378–2569; facsimile: (202) 205–2800; or electronic mail: Sue.Coleman@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This rule affecting 7 CFR part 1212 is authorized under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Orders 12866, 13563, and 13771

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 falls within a

category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. 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 OMB's 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).

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 would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

This 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 the entry of USDA's final ruling.

Background

This rule revises the eligibility requirements for producer representatives on the Board and prescribes late payment and interest charges on past due assessments under

the Honey Packers and Importers Research, Promotion, Consumer Education and Industry Information Order. The part is administered by the Board with oversight by USDA. Under the part, assessments are collected from first handlers and importers and used for research and promotion projects designed to maintain and expand the market for honey and honey products in the United States and abroad. This rule reduces the minimum production requirement for producers to serve on the Board from 150,000 to 50,000 pounds annually and thereby allow more producers to be eligible to serve on the Board. This rule also prescribes late payment and interest charges on past due assessments to help facilitate program administration. Both of these actions were unanimously recommended by the Board.

Producer Eligibility Requirements

Section 1212.46 of the part provides authority for the Board to recommend amendments to the part. Section 1212.40 of the part provides that the Board have ten members—three first handlers, two importers, one importer-handler, three producers, and one marketing cooperative representative. Currently, eligible producers must produce a minimum of 150,000 pounds of honey in the United States annually based on the best three-year average of the most recent five calendar years.

The Board has had difficulty over the past few years in identifying honey producers who meet the current eligibility requirement for production volume. U.S. honey production has decreased and fewer producers can meet the part's eligibility requirement. USDA's National Agricultural Statistics Service estimates U.S. honey production from producers with 5 or more colonies at 164 million pounds in 2008¹ and at 156 million pounds in 2015.² The Board has been having difficulties identifying producer nominees who produce over the 150,000 pound threshold.

Thus, the Board formed a subcommittee in October 2015 to review this issue. Over the following six months, the Board conducted outreach with beekeeping associations to gather input about the need and the level to reduce the annual production volume requirement for producers to serve on the Board. The recommendation from

¹ USDA, National Agricultural Statistics Service, Honey Final Estimates 2008–2012, September 2014, p. 4; <http://usda.mannlib.cornell.edu/usda/nass/SB1039/sb1039.pdf>.

² USDA, National Agricultural Statistics Service, Honey, March 22, 2017, p. 2, <http://usda.mannlib.cornell.edu/usda/current/Hone/Hone-03-22-2017.pdf>.

the associations to the subcommittee was that the minimum production requirement for producers be set at 50,000 pounds to increase the pool of eligible producers.

The Board met in April 2016 and unanimously recommended that the part's minimum production requirement for producers be reduced from 150,000 to 50,000 pounds. This should allow more producers to be eligible to serve on the Board. Section 1212.40 of the part is revised accordingly.

Charges on Past Due Assessments

Section 1212.52 of the part specifies that the Board will cover its expenses by levying an assessment on first handlers and importers. First handlers must pay their assessments to the Board on a monthly basis no later than the fifteenth day of the month following the month in which the honey or honey products were marketed. Importers must pay assessments to the Board on honey and honey products imported into the United States through the U.S. Customs and Border Protection (Customs). If Customs does not collect an assessment from an importer, the importer must pay the assessment directly to the Board.

The honey program also provides for two exemptions. Pursuant to § 1212.53, first handlers and importers who handle or import less than 250,000 pounds of honey or honey products annually, and first handlers and importers of organic honey and honey products are exempt from the payment of assessments.

Section 1212.52(g) of the part specifies that the Board shall impose a late payment charge on any first handler or importer who fails to pay their assessments to the Board on time. First handlers or importers subject to a late payment charge must also pay interest on the unpaid assessments for which they are liable. The late payment and interest charges must be prescribed in regulations issued by USDA.

Assessment funds are used by the Board for activities designed to benefit all industry members. Thus, it is important that all assessed entities pay their assessments in a timely manner. Entities who fail to pay their assessments on time would be able to reap the benefits of Board programs at the expense of others. In addition, they would be able to utilize funds for their own use that should otherwise be paid to the Board to finance Board programs.

Thus, the Board recommended that rates of late payment and interest charges for past due assessments be prescribed in the part's regulations. A late payment charge will be imposed upon first handlers and importers who fail to pay their assessments to the

Board within 30 calendar days of the date when assessments are due. This one-time late payment charge will be 10 percent of the assessments due before interest charges have accrued.

Additionally, interest at a rate of $\frac{2}{3}$ of 1 percent per month on the outstanding balance (which computes to an annual rate of 8 percent), including any late payment and accrued interest, will be added to any accounts for which payment has not been received within 30 calendar days of the date when assessments are due. Interest will continue to accrue monthly until the outstanding balance is paid to the Board.

This action is expected to help facilitate program administration by providing an incentive for entities to remit their assessments in a timely manner, with the intent of creating a fair and equitable process among all assessed entities. Accordingly, a new subpart C is added to the part's regulations regarding past due assessments, and a new § 1212.520 is added to subpart C.

Final 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 this 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 producers as those having annual receipts of no more than \$750,000, and small agricultural service firms (first handlers and importers) as those having annual receipts of no more than \$7.5 million.

The Board reported that there are about 752 importers and 41 first handlers of honey and honey products covered under the program during the 2016 fiscal period. Seventeen out of the 41 first handlers (41 percent) and 25 out of the 752 importers (3 percent) accounted for 90 percent of the assessments in their respective categories. Total assessments for 2016 were \$6.74 million, of which \$1.75 million (26 percent) came from first handlers and \$4.99 million (74 percent) was paid by importers. This data can be used to compute an estimate of average annual revenue from honey sales from each of these categories, which in turn helps to estimate the number of large

and small first handlers and importers. As mentioned above, 17 first handlers account for 90 percent of the domestic assessments. Multiplying first handler assessments in 2016 of \$1,750,155 by 0.9 and then dividing by 17 yields an average annual assessment of \$92,655 for the first handlers in this category. Dividing this figure (\$92,655) by the assessment rate of 1.5 cents per pound (\$0.015) yields an average quantity per first handler of 6.177 million pounds. Multiplying 6.177 million pounds by the average 2016 U.S. domestic price of \$2.08 per pound³ yields an average, annual honey revenue per handler of \$12.85 million, which is well above the SBA threshold of \$7.5 million. It should be noted that this revenue estimate is based on the average price at the producer level, and the \$12.85 million is an estimate of the total value at which the average size handler acquired the honey from producers. Therefore, most of the 17 first handlers that pay 90 percent of the domestic assessments are likely to be large firms according to the SBA definition.

An equivalent computation can be made for the 25 importers who paid 90 percent of the \$4,991,926 in assessments in 2016. Of the 25 importers, the average assessment per importer was \$179,709. Dividing the average assessment per importer by the assessment rate of \$0.015 per pound yields an average quantity per importer estimate of 11.981 million pounds.

For honey imports, the equivalent of the season average price for domestic honey is referred to as a "unit value." The unit value of \$1.24 per pound is computed by dividing annual imported honey value of \$417.31 million by average quantity of 335.69 million pounds (import data from the Foreign Agricultural Service). Multiplying the \$1.24 unit value by the average quantity of 11.981 million pounds yields average annual honey revenue per importer figure of \$14.856 million, almost two times the SBA threshold figure of \$7.5 million for a large firm. Therefore, the majority of the 25 importers that pay 90 percent of the assessments are large firms, according to the SBA definition.

Comparable computations can be made to determine the average 2016 honey revenue for the 24 first handlers and 727 importers that paid 10 percent of the assessments in the first handler and importer categories. The first handler and importer average annual honey revenue figures are approximately \$1,011,000 and \$57,000,

³ USDA, NASS, Honey, March 22, 2017, p. 3, <http://usda.mannlib.cornell.edu/usda/current/Hone/Hone-03-22-2017.pdf>.

respectively, indicating that the vast majority are small businesses (in terms of honey sales), under the SBA large business threshold of \$7.5 million in annual sales.

Based on the foregoing, the majority of first handlers and importers may be classified as small entities.

This rule relaxes the part's eligibility requirements for producer representatives on the Board as specified in section 1212.40 of the part. The program currently requires that producer representatives produce a minimum of 150,000 pounds of honey (based on the best three year average of the most recent five calendar years) in the United States annually. U.S. honey production has been decreasing and fewer producers can meet this eligibility requirement. Thus, the Board unanimously recommended reducing the minimum production requirement from 150,000 to 50,000 pounds annually. This will allow for a greater pool of producer nominees to be eligible to serve on the Board. Authority for this action is provided in § 1212.46(d) of the part.

This rule also prescribes charges for past due assessments under the part. A new § 1212.520 is added to the part specifying a one-time late payment charge of 10 percent of the assessments due and interest at a rate of $\frac{2}{3}$ of 1 percent per month (or 8 percent on an annual basis) on the outstanding balance, including any late payment and accrued interest. This section is included in a new subpart C—Past Due Assessments. Authority for this action is provided in § 1212.52(g) of the part and section 517(e) of the 1996 Act.

Regarding the economic impact of this rule on affected entities, relaxing the eligibility requirements for producer representatives on the Board is administrative in nature and will have no economic impact on entities covered under the program. This change will help increase the number of producers who will be eligible to serve on the Board. Eligible producers, first handlers and importers interested in serving on the Board will have to complete a background questionnaire. Those requirements are addressed later in this rule in the section titled *Reporting and Recordkeeping Requirements*.

Prescribing charges for past due assessments will impose no additional costs on first handlers and importers who pay their assessments on time. It merely provides an incentive for entities to remit their assessments in a timely manner. For all entities who are delinquent in paying assessments, both large and small, the charges will be applied uniformly. As for the impact on

the industry as a whole, this action will help facilitate program administration by providing an incentive for entities to remit their assessments in a timely manner, with the intent of creating a fair and equitable process for all assessed entities.

Additionally, as previously mentioned, the part also provides for two exemptions. First handlers and importers who handle or import less than 250,000 pounds of honey or honey products annually, and first handlers and importers of organic honey and honey products are exempt from the payment of assessments.

Regarding alternatives, one option to the action regarding producer eligibility would be to maintain the status quo and not reduce the production threshold for producers to be eligible to serve on the Board. However, the Board has been having difficulty identifying producer nominees who produce over 150,000 pounds of honey annually. After outreach to beekeeping associations, the Board concluded that reducing the minimum production requirement for producers from 150,000 to 50,000 pounds annually is appropriate to increase the pool of eligible producers.

Likewise, an alternative to the action to prescribe late payment and interest charges for past due assessments would be to maintain the status quo and not prescribe these charges. However, the Board determined that implementing such charges will help facilitate program administration by encouraging entities to pay their assessments in a timely manner. The Board reviewed rates of late payment and interest charges prescribed in other research and promotion programs and concluded that the late payment charge and the interest charge contained in this rule is appropriate.

Reporting and Recordkeeping Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection requirements that are imposed by the part have been previously approved by OMB under OMB control number 0581-0093. Additionally, Board nominees (including producers) must submit a Background Information form (AD-755) to ensure they are qualified to serve on the Board. The time to complete that form is estimated at 30 minutes per response. The background form is approved under OMB control no. 0505-0001. This rule will not result in a change to the information collection and recordkeeping requirements previously approved and will impose no additional reporting requirements and

recordkeeping burden on honey producers, first handlers or importers.

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 rule.

Regarding outreach efforts, as previously mentioned, this action was discussed at a subcommittee in October 2015. The Board conducted outreach over the following six months to beekeeping associations to gather input about the need to reduce the annual production volume requirement for eligible producers on the Board. The Board met in April 2016 and unanimously recommended reducing the production volume requirement from 150,000 to 50,000 pounds annually. The Board also recommended prescribing late payment charges and interest on past due assessments in the part's regulations. All of the Board's meetings are open to the public and interested persons are invited to participate and express their views.

A proposed rule concerning this action was published in the **Federal Register** on December 22, 2017 (82 FR 60687). The Board sent the proposed rule directly to beekeeping associations, the Board, and assessment payers. Additionally, the Board included notification about the proposal and internet links in its industry newsletter. Finally, the proposal was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending January 22, 2018, was provided to allow interested persons to submit comments.

Analysis of Comment

One comment was received in response to the proposed rule. The comment requested two public seats on the Board because of taxpayer dollars and environmental concerns. Currently, the plan does not authorize a Board public member. The national research and promotion program for honey and honey products is funded through assessments paid by honey first handlers and importers. This comment is considered outside the scope. These types of concerns can be presented to the Board for their consideration. In addition, all Board meetings are open to the public to attend. No changes have been made to the rule based on this comment.

After consideration of all relevant matters presented, including the information and recommendation

submitted by the Board and other available information, it is hereby found that this rule, as hereinafter set forth, is consistent with and will effectuate the purposes of the 1996 Act.

List of Subjects in 7 CFR Part 1212

Administrative practice and procedure, Advertising, Consumer information, Honey Packer and Importer promotion, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1212 is amended as follows:

PART 1212—HONEY PACKERS AND IMPORTERS RESEARCH, PROMOTION, CONSUMER EDUCATION AND INDUSTRY INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1212 continues to read as follows:

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

■ 2. Section 1212.40 is revised to read as follows:

§ 1212.40 Establishment and membership.

The Honey Packers and Importers Board is established to administer the terms and provisions of this part. The Board shall have ten members, composed of three first handler representatives, two importer representatives, one importer-handler representative, three producer representatives, and one marketing cooperative representative. The importer-handler representative must import at least 75 percent of the honey or honey products they market in the United States and handle at least 250,000 pounds annually. In addition, the producer representatives must produce a minimum of 50,000 pounds of honey in the United States annually based on the best three-year average of the most recent five calendar years, as certified by producers. The Secretary will appoint members to the Board from nominees submitted in accordance with § 1212.42. The Secretary shall also appoint an alternate for each member.

■ 3. Subpart C is added to read as follows:

Subpart C—Past Due Assessments

§ 1212.520 Late payment and interest charges for past due assessments.

(a) A late payment charge will be imposed on any first handler or importer who fails to make timely remittance to the Board of the total assessments for which they are liable. The late payment will be imposed on

any assessments not received within 30 calendar days of the date when assessments are due. This one-time late payment charge will be 10 percent of the assessments due before interest charges have accrued.

(b) In addition to the late payment charge, $\frac{2}{3}$ of 1 percent per month (or an annual rate of 8 percent) interest on the outstanding balance, including any late payment and accrued interest, will be added to any accounts for which payment has not been received within 30 calendar days of the date when assessments are due. Interest will continue to accrue monthly until the outstanding balance is paid to the Board.

Dated: March 8, 2018.

Bruce Summers,

Acting Administrator.

[FR Doc. 2018–05063 Filed 3–13–18; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 114

[Docket No. APHIS–2009–0028]

RIN 0579–AD06

Viruses, Serums, Toxins, and Analogous Products; Expiration Date Required for Serial and Subserials and Determination of Expiration Date of Product

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to clarify that the expiration date of a serial or subserial of a veterinary biologic should be computed from the date of the initiation of the first potency test. We are also requiring the expiration dating period (stability) of a product to be confirmed by conducting a real-time stability study with a stability-indicating assay, stability monitoring of products after licensing, and specifying a single standard for determining the expiration date for veterinary biologics

DATES: Effective April 13, 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 114 (referred to below as the regulations), contain requirements for computing expiration dates and determining expiration dating periods (stability) for veterinary biologics. Currently, § 114.12 of the regulations requires each serial or subserial of veterinary biological products prepared in a licensed establishment to be given an expiration date, and § 114.13 provides that the expiration date for each product shall be computed from the date of the initiation of the potency test.

Prior to licensure, licensees and permittees must submit preliminary information to support the dating period shown on its labeling. Products are licensed with the provision that the dating period must be confirmed by real-time stability testing at the end of the predicted shelf life. Currently, the requirement in § 114.13 of the regulations for confirming stability is contingent upon whether a product consists of viable or non-viable organisms. For products consisting of viable organisms, each serial must be tested for potency at release and at the approximate expiration date until a statistically valid stability record has been established. For products consisting of non-viable organisms, each serial presented in support of licensure (prelicensing serials) must be tested for potency at release and at or after the dating requested. Products with satisfactory potency tests at the beginning and end of dating are considered to be efficacious throughout the requested dating period. Current science, however, considers stability estimates based on potency tests conducted at the beginning and end of the dating (a two-point profile) to be inaccurate and imprecise.¹

To address this situation, on September 17, 2010, we published in the **Federal Register** (75 FR 56916–56919, Docket No. APHIS–2009–0028) a proposal² to amend the regulations by clarifying that the expiration date of a serial or subserial of a veterinary biologic should be computed from the date of the initiation of the first potency test. We also proposed to require the expiration dating period (stability) of a product to be confirmed by a real-time stability study with a stability-indicating assay; require stability

¹ Capen, R., *et al.* (2012). On the shelf life of pharmaceutical products. *AAPS PharmSciTech*. DOI: 10.1208/s12249-012-9815-2.

² To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2009-0028>.