



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-18-0051; NOP-18-02]

RIN 0581 AD80

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances for April 2018 NOSB Recommendations (Crops and Handling)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA's) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule proposes to add elemental sulfur for use as a molluscicide in organic crop production, add polyoxin D zinc salt to control fungal diseases in organic crop production, and reclassify magnesium chloride from an allowed synthetic to an allowed nonsynthetic ingredient in organic handling.

DATES: Comments must be received by (INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER).

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Valerie Frances, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-S., Ag Stop 0268, Washington, DC 20250-0268. Telephone: (202) 720-3252.

Instructions: All submissions received must include the docket number AMS-NOP-18-0051; NOP-18-02, and/or Regulatory Information Number (RIN) 0581-XXXX for this rulemaking. When submitting a comment, clearly indicate the proposed rule topic and section number to which the comment refers. In addition, comments should clearly indicate whether or not the commenter supports the action being proposed and also clearly indicate the reason(s) for the position. Comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. Comments should also offer any recommended language change(s) that would be appropriate to the position. Please include relevant information and data to support the position such as scientific, environmental, manufacturing, industry, or impact information, or similar sources. Only relevant material supporting the position should be submitted. All comments received will be posted without change to <http://www.regulations.gov>.

Document: To access the document and read background documents, or comments received, go to <http://www.regulations.gov>. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2642-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through

Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Valerie Frances, Standards Division, National Organic Program. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established the National List within part 205 of the USDA organic regulations (7 CFR § 205.600 through 205.607). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling.

The Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501- 6522) (OFPA), and § 205.105 of the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonagricultural substance used in organic handling be on the National List. Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations developed by the NOSB. Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, USDA's Agricultural Marketing Service (AMS) has published multiple rules amending the National List.

This proposed rule would amend the National List to implement three NOSB recommendations. These recommendations were submitted to the Secretary on April 27, 2018. Table 1 summarizes the proposed changes to the National List based on these NOSB recommendations.

Table 1. Proposed amendments to the National List.

Substance	National List Section	Proposed rule action
Elemental Sulfur	§ 205.601(h)	Add to National List
Polyoxin D Zinc Salt	§ 205.601(i)	Add to National List
Magnesium Chloride (MgCl)	§ 205.605(b) to § 205.605(a)	Reclassify listing and move within National List

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

§ 205.601 Synthetic substances allowed for use in organic crop production.

This proposed rule would add two substances to § 205.601, synthetic substances allowed for use in organic crop production.

Elemental Sulfur

The proposed rule would amend the National List to add elemental sulfur to § 205.601(h) for use as a molluscicide bait to control slugs and snails. Table 2 illustrates the proposed rule action.

Table 2. Proposed rule action for elemental sulfur.

Current rule:	N/A
Proposed rule action:	Add elemental sulfur to § 205.601(h) as slug or snail bait.

On May 25, 2017, AMS received a petition¹ to add elemental sulfur to the National List in § 205.601(h) for use as a slug or snail bait. Currently, the USDA organic regulations allow elemental sulfur for use in organic crop production as an insecticide (including mite control) in § 205.601(e); as a plant disease control in § 205.601(i); and as a plant or soil amendment in § 205.601(j).

At its April 2018 public meeting, the NOSB considered the petition to add elemental sulfur to the National List for use in organic crop production as a molluscicide. Increased adoption of low tillage and no tillage agricultural practices can increase the abundance of snails and slugs, which can reduce crop yields. The availability of a molluscicide as a new tool will help prevent crop losses. In its review, the NOSB considered a March 2017 technical report on elemental sulfur² that described its manufacture, industry uses, regulation, and chemical properties. Prior to and during this meeting, the NOSB received and considered public comment on the proposal.

In consideration of the petition, technical report, and public comments, the NOSB determined that the use of elemental sulfur as a slug or snail bait for organic crop production satisfies OFPA evaluation criteria for National List substances and recommended adding elemental sulfur to § 205.601(h) as a slug or snail bait for organic crop production.³

AMS has reviewed and agrees that the NOSB has considered the petitions, technical report, and public comments sufficiently, and that elemental sulfur used as a

¹ Elemental sulfur petition: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. Under “S.”

² The technical report for elemental sulfur is available on the AMS website, organized in alphabetical order: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. Under “S.”

³ NOSB 2018 Spring meeting elemental sulfur recommendation: <https://www.ams.usda.gov/sites/default/files/media/CSSulfurMolluscicideRec.pdf>

slug or snail bait satisfies the OFPA criteria for National List substances. AMS proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the National List by adding elemental sulfur to § 205.601(h) as a slug or snail bait. This would permit the use of elemental sulfur-based bait, providing an additional tool to organic producers to control slugs and snails when other required preventive measures have failed to provide sufficient control (§ 205.206(e)).

Polyoxin D Zinc Salt

The proposed rule would amend the National List to add polyoxin D zinc salt to control fungal diseases at § 205.601(i). Table 3 illustrates the proposed rule change.

Table 3. Proposed rule action for polyoxin D zinc salt.

Current rule:	N/A
Proposed rule action:	Add polyoxin D zinc salt to § 205.601(i) as plant disease control.

Two petitions to add polyoxin D zinc salt for use in organic crop production were submitted to the National Organic Program: one in March 2012 and the other in May 2016. Both petitions and an addendum in February 2018 proposed to amend 7 CFR 205.601 to add polyoxin D zinc salt as a synthetic substance allowed for use in organic crop production.⁴

In consideration of the information in the March 2012 petition, the September 2012 technical report, and public comments, the NOSB determined that the use of

⁴ Polyoxin D zinc salt 2012 and 2016 petitions along with addendums found under “P”:
<https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. Details regarding the consideration of the 2012 petition can be found in the April 2013 NOSB Recommendation, available here:
<https://www.ams.usda.gov/event/spring-nosb-meeting-2013-or>.

polyoxin D zinc salt to control fungal diseases in organic crop production did not satisfy the OFPA evaluation criteria for National List substances and did not recommend the addition of polyoxin D zinc salt to the National List in 2013.⁵

However, in May 2016, a new petition brought forward new data which indicated that polyoxin D zinc salt was not harmful to beneficial soil organisms and insects. This was supported by a limited scope technical report in December 2017. The petitioner also provided an analysis of grower need for this material. On February 2, 2018, the petitioner provided an addendum that more precisely specified that the requested amendment is for 7 CFR 205.601(i).

According to the 2012 and 2017 technical reports⁶ and the March 2012 and May 2016 petitions, polyoxin D zinc salt is a synthetic biofungicide. The National List provides several materials that organic producers may use to control fungal diseases. However, the NOSB determined that polyoxin D zinc salt is more efficacious than other allowed materials against a broader range of fungal diseases, such as cottonball disease on cranberries; black rot, downy mildew, powdery mildew and bunch rot on grapes; mummyberry on blueberries; phomopsis leaf spot on strawberries; downy mildew on basil; and other fungal diseases on fruits.

In consideration of the March 2012 and May 2016 petitions, the February 2018 addendum, the 2012 and 2017 technical reports, and public comments, the NOSB determined that the use of polyoxin D zinc salt to control fungal diseases in organic crop

⁵ NOSB recommendation on the 2012 petition to add polyoxin D zinc salt to the National List: <https://www.ams.usda.gov/sites/default/files/media/Polyoxin%20D%20NOSB%20final%20recommendation.pdf>

⁶ The technical report for polyoxin D zinc salt is available on the AMS website, organized in alphabetical order: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. Under “P.”

production satisfies OFPA evaluation criteria for National List substances and recommended adding polyoxin D zinc salt to § 205.601(i) for plant disease control in organic crop production.⁷

AMS has reviewed and agrees that the NOSB has considered all of the petitions, technical reports, and public comments sufficiently, and that polyoxin D zinc salt satisfies the OFPA criteria for National List substances. AMS proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the National List by adding polyoxin D zinc salt to § 205.601(i) for plant disease control. This would permit the use of polyoxin D zinc salt in crop production to address fungal diseases when preventive measures have failed (§ 205.206(e)).

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

This proposed rule would reclassify one substance from an allowed synthetic ingredient in § 205.605(b), to an allowed nonsynthetic ingredient in § 205.605(a).

Magnesium Chloride

This proposed rule would reclassify magnesium chloride as a nonsynthetic substance that may be used in organic handling. It would also remove the annotation that magnesium chloride must be “derived from sea water.” Table 4 illustrates the proposed rule change.

Table 4. Proposed rule action for magnesium chloride.

⁷ NOSB Recommendations 2018 Spring Meeting:
<https://www.ams.usda.gov/sites/default/files/media/CSPolyoxinDZincSaltRec.pdf>

Current rule:	§ 205.605(b) magnesium chloride —derived from sea water.
Proposed rule action:	Remove magnesium chloride from § 205.605(b) and insert magnesium chloride under § 205.605(a) without annotation.

Magnesium chloride derived from sea water is currently listed at § 205.605(b) as a nonagricultural (nonorganic) synthetic substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” The primary uses of magnesium chloride in organic food processing are as a firming agent in tofu processing and as a source of the essential mineral magnesium in organic infant formula. During the NOSB’s 2015 sunset review of magnesium chloride, the Board requested public comment on whether this material should be reclassified as nonsynthetic because it can be derived from sea water by brine drying with no ancillary substances. Public comments supported the reclassification of magnesium chloride as nonsynthetic and moving it from § 205.605(b) to § 205.605(a). To consider the reclassification of magnesium chloride on the National List, the NOSB requested a technical report on magnesium which was made available in November 2016.

Magnesium chloride is the simple salt of the halogen chlorine and the alkaline earth metal magnesium. The November 2016 technical report describes many different sources and processes to produce nonsynthetic forms of magnesium chloride which are widely commercially available.⁸ This substance is nonsynthetic when derived from natural sources and manufactured in a way that does not chemically change the substance (see § 205.2 definitions of *nonsynthetic (natural)* and *synthetic*). Public comments at the April 2018 NOSB meeting supported the reclassification of magnesium chloride as

⁸ The technical report for magnesium chloride is available on the AMS website, organized in alphabetical order under “M”: <https://www.ams.usda.gov/rules-regulations/organic/national-list/m>

nonsynthetic and moving it from § 205.605(b) to § 205.605(a). No public comments were received indicating any concern with procuring nonsynthetic forms of magnesium chloride.⁹

In consideration of the new information provided in the November 2016 technical report and the public comments provided at both the 2015 and 2018 NOSB meetings, the NOSB unanimously recommended moving magnesium chloride to § 205.605(a) to more accurately reflect that nonsynthetic forms of this material are widely available. The NOSB also recommended that the annotation “derived from seawater” be removed when it is moved to §205.605(a) because natural sources of magnesium chloride can be derived from terminal lake brines, subsurface brine deposits, and mined mineral deposits as well as seawater.¹⁰

Organic handlers who use magnesium chloride will need to ensure that the product complies with the nonsynthetic classification, the regulations and the listing at §205.605(a) by obtaining details about the source of the magnesium chloride and its full manufacturing process. The NOP Program Handbook guidance documents NOP 5033, *Classification of Materials*, and NOP 5033-1, the *Decision Tree for the Classification of Materials as Synthetic or Nonsynthetic*¹¹, can be used if additional clarification is needed. Synthetic forms of magnesium chloride would be prohibited in organic handling.

AMS has reviewed and agrees that the NOSB has sufficiently considered the new information provided in the November 2016 technical report and the public comments

⁹ <https://www.ams.usda.gov/sites/default/files/media/TranscriptsSpring2018NOSBmeeting.pdf>

¹⁰ NOSB Recommendations 2018 Spring Meeting:
<https://www.ams.usda.gov/sites/default/files/media/HSMagnesiumChlorideReclassRec.pdf>

¹¹ NOP 5033 *Classification of Materials* & NOP 5033-1 *Decision Tree for the Classification of Materials as Synthetic or Nonsynthetic*:
https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf

provided at the 2015 and 2018 NOSB meetings in alignment with the OFPA criteria for National List substances and the NOP Program Handbook guidance documents NOP 5033 & NOP 5033-1¹².

AMS proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend § 205.605(b) by removing magnesium chloride and inserting it in § 205.605(a) to more accurately reflect that this substance is available in nonsynthetic form. This proposed rule would also remove the annotation “derived from seaweed”.

III. Related Documents

On January 17, 2018, a Notice was published in the Federal Register (83 FR 2373) announcing the spring 2018 NOSB meeting. One purpose of the meeting was to deliberate on recommendations on current substances on the National List, and substances petitioned as amendments.

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607 of the USDA organic regulations sets forth the National List petition process. The current petition process (81 FR 12680,

¹² NOP 5033 *Classification of Materials* & NOP 5033-1 *Decision Tree for the Classification of Materials as Synthetic or Nonsynthetic*
https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf

March 10, 2016) can be accessed through the NOP Program Handbook on the NOP Web site at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

A. Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866. Additionally, because this proposal 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).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS), to delineate which operations qualify as small businesses.¹³ The SBA has classified small

¹³ U. S. Small Business Administration regulations: https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121_1104

agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$750,000. Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector, “All other professional, scientific and technical services.” For this category, the small business threshold is average annual receipts of less than \$15 million.

AMS has considered the economic impact of this proposed rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the U.S. would be considered small entities. According to the 2016 Certified Organic NASS Survey, 13,954 certified organic farms in the U.S. reported sales of organic products and total farmgate sales in excess of \$7.5 billion.¹⁴ Based on that data, organic sales average \$541,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$750,000 sales threshold to qualify as a small business.

According to the NOP’s Organic Integrity Database, there are 9,919 certified handlers in the U.S.¹⁵ The Organic Trade Association’s 2017 Organic Industry Survey has information about employment trends among organic manufacturers. The reported

¹⁴ U.S. Department of Agriculture, National Agricultural Statistics Service. September 2017. Certified Organic Survey, 2016 Summary. http://usda.mannlib.cornell.edu/usda/current/OrganicProduction/OrganicProduction-09-20-2017_correction.pdf.

¹⁵ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on July 5, 2018.

data are stratified into three groups by the number of employees per company: less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

The USDA has approximately 80 accredited certifying agents, who provide organic certification services to producers and handlers. The certifying agent that reports the most certified operations, nearly 3,500, would need to charge approximately \$4,200 in certification fees in order to exceed the SBA's small business threshold of \$15 million. The costs for certification generally range from \$500 to \$3,500, depending on the complexity of the operation. Therefore, AMS expects that most of the accredited certifying agents would qualify as small entities under the SBA criteria.

The economic impact on entities affected by this rule would not be significant. The effect of this rule, if implemented as final, would be to allow the use of additional and widely commercially available substances in organic crop or livestock production and organic handling. This action would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. AMS concludes that the economic impact of this addition, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly

burdening the court system. This proposed rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this proposed rule would not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the

authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

C. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule 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.

F. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to add two substances to the National List and to reclassify one substance on the National List. A 60-day period for interested persons to comment on this rule is provided.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Archives and records, Crops, Imports, Labeling, National List, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, subpart G is proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501 – 6522.

2. Amend §205.601 as follows:

a. Revise paragraph (h) and add new paragraphs (h)(1) and (h)(2),

b. Add new paragraph (i)(11).

The revision and additions to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(h) As slug or snail bait.

(1) Ferric phosphate (CAS # 10045-86-0).

(2) Elemental sulfur.

* * * * *

(i) * * *

(11) Polyoxin D zinc salt.

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3. Amend § 205.605 as follows:

a. In paragraph (a), add in alphabetical order, an entry for “magnesium chloride.”

b. In paragraph (b), remove the entry for “magnesium chloride—derived from seawater.”

The addition to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

* * *

(a) * * *

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Magnesium chloride.

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Dated: February 12, 2019

Bruce Summers
Administrator
Agricultural Marketing Service

BILLING CODE 3410-02 P

[FR Doc. 2019-02518 Filed: 2/14/2019 8:45 am; Publication Date: 2/15/2019]