



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-17-0080; NOP-17-09]

RIN 0581 AD78

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances for 2017 NOSB Recommendations (Livestock 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 to the National List for use in organic livestock production; and, reclassify potassium acid tartrate from a non-agricultural substance to an agricultural substance and require the organic form of the ingredient when commercially available.

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: Robert Pooler, 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-17-0080; NOP-17-09, and/or Regulatory Information Number (RIN) 0581-AD78 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 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: Robert Pooler, 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 nonsynthetic 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 presented 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 two NOSB recommendations on two amendments to the National List. These recommendations were submitted to the Secretary on November 7, 2017. Table 1 summarizes the proposed changes to the National List based on these NOSB recommendations.

Table 1. Substances being added to the National List or current listings being amended.

Substance	National List Section	Proposed rule action
Elemental sulfur	§ 205.603(b)	Add to National List
Potassium acid tartrate	§ 205.605 & § 205.606	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:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

This proposed rule would add one substance to § 205.603, synthetic substances allowed for use in organic livestock production.

Elemental Sulfur

The proposed rule would amend the National List to add elemental sulfur for use as a parasiticide to treat livestock and livestock housing. Table 2 illustrates the proposed listing.

Table 2. Proposed rule action for elemental sulfur.

Current rule:	N/A
Proposed rule action:	Add elemental sulfur to § 205.603(b).

On March 1, 2016, AMS received a petition¹ to add elemental sulfur to the National List in § 205.603 for use as a topical pesticide treatment in organic livestock production to repel mites, fleas, and ticks from livestock and livestock living quarters. Mites, fleas, and ticks are vectors of livestock diseases and under favorable conditions may heavily infest livestock and livestock living quarters. Elemental sulfur is dusted on and rubbed into the feathers and hair of livestock and applied to interior surfaces of livestock housing. The USDA organic regulations allow elemental sulfur for use in organic crop production as an insecticide (including mite control), § 205.601(e); as a plant disease control, § 205.601(i); and as a plant or soil amendment, § 205.601(j).

At its November 2, 2017 public meeting, the NOSB considered the petition to add elemental sulfur to the National List for use in organic livestock production and received public comment. In its review, the NOSB also considered a March 2017 technical evaluation report (technical report) on elemental sulfur² that described its manufacture, industry uses, regulation, and chemical properties.

In consideration of the petition, technical report, and public comments, the NOSB determined that the use of elemental sulfur as a topical pesticide for organic livestock satisfies OFPA evaluation criteria for National List substances and recommended adding elemental sulfur to § 205.603 as an external parasiticide in organic livestock production.³ AMS has reviewed and proposes to address this NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would

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>.

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

amend the National List by adding elemental sulfur to § 205.603(b) as an external parasiticide. This would permit the use of elemental sulfur on livestock and livestock housing when preventive measures have failed (§ 205.238).⁴

§ 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 move one substance, currently listed in § 205.605, to § 205.606.

Potassium acid tartrate

The proposed rule would amend the National List to reclassify potassium acid tartrate from a non-agricultural substance listed in § 205.605(b) to an agricultural substance listed in § 205.606.

Table 3. Proposed rule action for potassium acid tartrate.

Current rule:	§ 205.605(b), potassium acid tartrate.
Proposed rule action:	Remove potassium acid tartrate from § 205.605(b) and insert potassium acid tartrate under § 205.606.

Potassium acid tartrate is currently allowed as a synthetic substance for use in organic handling. The U.S. Food and Drug Administration (FDA) allows potassium acid tartrate to be used as a leavening agent, pH control agent, or antimicrobial agent. Other uses that are permitted by the FDA include as an anticaking agent, a formulation aid, a humectant, a stabilizer and thickener, and a surface-active agent (21 CFR 184.1077). Potassium acid tartrate has been on the National List since October 2002. During its

⁴ Section 205.238(b) permits organic producers to use synthetic medications which are allowed for use in § 205.603 when preventive practices are inadequate.

November 2017 public meeting, the NOSB considered the proposal to reclassify potassium acid tartrate as an agricultural substance. Specifically, the NOSB considered new information in an updated January 2017 technical report on potassium acid tartrate.⁵ This report described how potassium acid tartrate is a byproduct of the wine making process and is extracted with water. Prior to and during this meeting, the NOSB also received and considered public comment on the proposal. The NOSB determined that potassium acid tartrate meets the definition of an “agricultural product” in § 205.2 of the USDA organic regulations because it is derived from an agricultural product (grapes) and does not undergo a chemical change during extraction.⁶ This is consistent with the USDA organic regulations and the NOP guidance on classification of agricultural and nonagricultural materials.⁷ Therefore, the NOSB recommended reclassifying potassium acid tartrate as an agricultural substance and moving it to section 205.606 of the National List. This action would require organic handlers who use potassium tartrate to source an organic form of the ingredient. If the ingredient is not commercially available⁸, the nonorganic form may be used.

Consistent with the NOSB recommendation, this proposed rule would amend § 205.605 by removing potassium acid tartrate from § 205.605(b) and inserting it in § 205.606.

⁵ 2017 potassium acid tartrate technical report: <https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>. Under “P.”

⁶ The USDA organic regulations define “agricultural product” as: “Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketing in the United States for human or livestock consumption.”

⁷ NOP 5033, Classification of Materials: https://www.ams.usda.gov/sites/default/files/media/Program%20Handbk_TOC.pdf.

⁸ See 7 CFR 205.606 and 7 CFR 205.2 for definition of “Commercially available”

III. Related Documents

On May 30, 2017, a Notice was published in the Federal Register (82 FR 24659) announcing the fall 2017 NOSB meeting. The purpose of the meeting was to deliberate on recommendations on substances petitioned as amendments to the National List.

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, 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. The SBA has classified small 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.⁹ 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 \$700,000 sales threshold to qualify as a small business.

According to the NOP's Organic Integrity Database there are 9,633 certified handlers in the U.S.¹⁰ The Organic Trade Association's 2017 Organic Industry Survey has information about employment trends among organic manufacturers. The reported 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 82 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.

⁹ 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

¹⁰ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on March 23, 2018.

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 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 one substance 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, Animals, Archives and records, Imports, Labeling, 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 § 205.603 by redesignating paragraphs (b)(2) through (b)(8) as (b)(3) through (b)(9) and adding new paragraph (b)(2) to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(b) * * *

(2) Elemental sulfur—for treatment of livestock and livestock housing.

* * * * *

3. Amend § 205.605 paragraph (b) by removing “Potassium acid tartrate.”

4. Amend § 205.606, by redesignating paragraphs (o) through (t) as (p) through (u) and adding new paragraph (o) to read as follows:

**§ 205.606 Nonorganically produced agricultural products allowed as ingredients in
or on processed products labeled as “organic.”**

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(o) Potassium acid tartrate.

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Dated: April 24, 2018

Bruce Summers
Acting Administrator
Agricultural Marketing Service

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