



## **DEPARTMENT OF AGRICULTURE**

### **Agricultural Marketing Service**

#### **7 CFR Part 205**

**[Document Number AMS-NOP-15-0015; NOP-15-07]**

**RIN 0581-AD39**

#### **National Organic Program (NOP);**

Sunset 2015 Amendments to the National List

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would address recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) following their October 2014 meeting. These recommendations pertain to the 2015 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the recommendations from the NOSB, this proposed rule would remove two non-organic agricultural substances from the National List for use in organic handling, fortified cooking wines - marsala wine and sherry wine. This proposed rule would also remove two listings for synthetic substances allowed for use in organic crop production on the National List, streptomycin and tetracycline, as their use exemptions expired on October 21, 2014.

**DATES:** Comments must be received by [INSERT DATE 30 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-So., Ag Stop 0268, Washington, DC 20250-0268.

Instructions: All submissions received must include the docket number AMS-NOP-15-0015; NOP-15-07, and/or Regulatory Information Number (RIN) XXXX-XXXX for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (e.g. scientific, environmental, manufacturing, industry, impact information, etc.). Only relevant material supporting your position should be submitted. All comments received and any relevant background documents will be posted without change to <http://www.regulations.gov>.

Document: For access to the document and to 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, Telephone: (202) 720-3252; Fax: (202) 205-7808.

**SUPPLEMENTARY INFORMATION:**

I. Background

The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products. Since becoming fully effective, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606.

This National List identifies the synthetic substances that may be used and the nonsynthetic 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 OFPA and the USDA organic

regulations, as indicated in § 205.105, 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 substance and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

As stipulated by the OFPA, recommendations to propose amendment of the National List are developed by the 15 member NOSB, organized under the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.) to assist in the evaluation of substances to be used or not used in organic production and handling, and to advise the Secretary on the USDA organic regulations. The OFPA also requires a sunset review of all substances included on the National List within five years of their addition to or renewal on the list. If a listed substance is not reviewed by the NOSB and renewed by the USDA within the five year period, its allowance or prohibition on the National List is no longer in effect. Under the authority of the OFPA, the Secretary can amend the National List through rulemaking based upon proposed amendments recommended by the NOSB.

The NOSB's recommendations to continue existing exemptions and prohibitions are based on consideration of public comments and applicable supporting evidence that express a continued need for the use or prohibition of the substance(s) as required by the OFPA.

Concerning OFPA criteria used to make recommendations regarding the discontinuation of an authorized exempted synthetic substance (7 U.S.C. 6517(c)(1)), the NOSB's decision is based on consideration of public comments and applicable

supporting evidence that demonstrates the substance is: (a) harmful to human health or the environment; (b) no longer necessary for organic production due to the availability of alternative wholly nonsynthetic substitute products or practices; or (c) inconsistent with organic farming and handling practices.

In accordance with the sunset review process published in the Federal Register on September 16, 2013 (78 FR 61154), this proposed rule would amend the National List to reflect two recommendations submitted to the Secretary by the NOSB on October 30, 2014, to amend the National List to remove two substances, marsala wine and sherry wine, allowed as ingredients in or on processed products labeled as “organic.” This proposed rule would also remove listings of two substances, streptomycin and tetracycline, since their National List exemptions expired on October 21, 2014. The exemptions of each substance appearing on the National List for use in organic production and handling are evaluated by the NOSB using the evaluation criteria specified on the OFPA (7 U.S.C. 6517 – 6518).

## II Overview of Proposed Amendments

### Nonrenewals

After considering public comments and supporting documents, the NOSB determined that two substance exemptions on § 205.606 of the National List are no longer necessary for organic handling. AMS has reviewed and accepts the NOSB recommendations for removal. Based upon these NOSB recommendations, this action proposes to amend the National List to remove the exemptions as indicated for marsala wine and sherry wine.

### Marsala wine

The USDA organic regulations currently include an exemption on the National List for fortified cooking wines as an ingredient for use in organic processed products at § 205.606(g) as follows: Fortified cooking wines, (1) Marsala. In 2007, marsala wine was petitioned for addition to § 205.606 because it was considered a key flavor ingredient that was not commercially available in organic form and quantity. As required by the OFPA, the exemption for marsala wine was considered during the NOSB's 2015 sunset review. Two notices of the public meetings with request for comments were published in Federal Register on March 10, 2014 (79 FR 13272) and on September 8, 2014 (79 FR 53162) to notify the public that the marsala wine exemption discussed in this proposed rule would expire on December 14, 2015, if not reviewed by the NOSB and renewed by the Secretary. During their sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2015 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-14-0006 (March 2014 public meeting) and AMS-NOP-14-0063 (October 2014 public meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. As indicated on the National List and Petitioned Substance database on the NOP website, there is no technical report or technical advisory panel report on marsala wine. The NOSB did not request a new technical report for marsala wine for the 2015 sunset review.

The NOSB received no public comments supporting the continued need for the use of non-organic marsala wine in organic processed products. In addition, the NOSB

considered evidence that only a few operations use marsala wine as an ingredient in organic processed products. Based upon the lack of public comments requesting the continued use of marsala wine and supportive documents, the NOSB determined that the exemption for marsala wine on § 205.606 is no longer necessary or essential for organic processed products. Subsequently, the NOSB recommended removal of marsala wine from the National List.

AMS accepts the NOSB's recommendation on removing marsala wine from the National List. This proposed rule would amend § 205.606 by removing the substance exemption for marsala wine. This amendment would be effective on marsala wine's current sunset date, December 14, 2015.

#### Sherry wine

The USDA organic regulations currently include an exemption on the National List for fortified cooking wine, sherry wine, as an ingredient for use in organic processed products at § 205.606(g) as follows: Fortified cooking wines, (2) Sherry. In 2007, sherry wine was petitioned for addition to § 205.606 because it was considered a key flavor ingredient that was not commercially available in organic form or quantity. As required by the OFPA, the exemption for sherry wine was considered during the NOSB's 2015 sunset review. Two notices of the public meetings with request for comments were published in Federal Register on March 10, 2014 (79 FR 13272) and on September 8, 2014 (79 FR 53162) to notify the public that the sherry wine listing discussed in this proposed rule would expire on December 14, 2015, if not reviewed by the NOSB and renewed by the Secretary. During their sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance

exemptions included in the 2015 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–14–0006 (March 2014 meeting) and AMS–NOP–14–0063 (October 2014 meeting). The NOSB also considered oral comments received during these public meetings which are included in the meeting transcripts available on the NOP web site at <http://www.ams.usda.gov/nop>. As indicated on the National List and Petitioned Substance database on the NOP website, there is no technical report or technical advisory panel report on sherry wine. The NOSB did not request new technical report for sherry wine for the 2015 sunset review.

The NOSB received no public comments supporting the continued need for the use of non-organic sherry wine in organic processed products. In addition, the NOSB considered evidence that only a few operations use sherry wine as an ingredient in organic processed products. Based upon the lack of public comments requesting the continued use of sherry wine and supportive documents, the NOSB determined that the exemption for sherry wine on § 205.606 is no longer necessary or essential for organic processed products. Subsequently, the NOSB recommended removal of sherry wine from the National List.

AMS accepts the NOSB’s recommendation on removing sherry wine from the National List. This proposed rule would amend § 205.606 by removing the substance exemption for sherry wine. This amendment would be effective on sherry wine’s current sunset date, December 14, 2015.

This proposed rule would further amend § 205.606 by redesignating paragraphs (h) through (z) as (g) through (y), respectively.

## Expired Listings

### Streptomycin

This proposed rule would amend § 206.601 of the National List by removing the expired exemption for “Streptomycin, for fire blight control in apples and pears only until October 21, 2014.” Streptomycin was considered by the NOSB at their October 31 – November 4, 1995, meeting. At this 1995 meeting, the NOSB recommended adding streptomycin as a plant disease control to the National List and also indicated that the exemption listing should be reviewed in two years by the NOSB. The NOSB recommendation was accepted by the Secretary and streptomycin was included, as a plant disease control, in the initial final rule establishing the NOP that was published on December 21, 2000 (65 FR 80548). Subsequently, as recommended by the NOSB, the listing for streptomycin was amended on June 27, 2012 (77 FR 33290) to add an expiration date to the streptomycin annotation: Streptomycin, for fire blight control in apples and pears only until October 21, 2014. This proposed rule would remove the listing for streptomycin that expired on October 21, 2014 from § 205.601. Removal of this exempted substance from the National List has no new regulatory effect.

### Tetracycline

This proposed rule would amend § 206.601 of the National List by removing the expired exemption for “Tetracycline, for fire blight control in apples and pears only until October 21, 2014.” Tetracycline was considered by the NOSB at their October 31 – November 4, 1995, meeting. At this 1995 meeting, the NOSB recommended adding tetracycline as a plant disease control to the National List and also indicated that the exemption listing should be reviewed in two years by the NOSB. The NOSB recommendation was

accepted by the Secretary and tetracycline was included, as a plant disease control, in the initial final rule establishing the NOP that was published on December 21, 2000 (65 FR 80548). Subsequently, as recommended by the NOSB, the listing for tetracycline was amended on June 27, 2012 (77 FR 33290) to add an expiration date to the tetracycline annotation: Tetracycline, for fire blight control in apples and pears only until October 21, 2014. This proposed rule would remove the listing for tetracycline from section 205.601 that expired on October 21, 2014. Removal of this exempted substance from the National List has no new regulatory effect.

### III. Related Documents

Two notices of public meeting with request for comments were published in Federal Register on March 10, 2014 (79 FR 13272) and on September 8, 2014 (79 FR 53162) to notify the public that the 2015 sunset review listings discussed in this proposed rule would expire on December 14, 2015, if not reviewed by the NOSB and renewed by the Secretary. The listing for both streptomycin and tetracycline was added to the National List by the final rule (65 FR 80548) published in the Federal Register on December 21, 2000. Subsequently, an expiration date of October 21, 2014 was added to the streptomycin and tetracycline annotations on June 27, 2012 (77 FR 33290).

### IV. Statutory and Regulatory Authority.

OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed recommendations developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having

substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the USDA organic regulations. The current petition process was published on January 18, 2007 (72 FR 2167) and can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>. AMS published a revised sunset review process in the Federal Register on September 16, 2013 (78 FR 56811).

A. Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

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.

States and local jurisdictions are preempted under 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 2115(b) of OFPA (7 U.S.C. 6514(b)). States are also preempted under section 2104 through 2108 of OFPA (7 U.S.C. 6503 through 6507) 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 OFPA.

Pursuant to section 2108(b)(2) of OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of OFPA (7 U.S.C. 6519(f)), this proposed rule would not 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, 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. 301-399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136-136(y)).

Section 2121 of OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

### C. Regulatory Flexibility Act

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.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to prohibit the use of two non-organic agricultural products that may be available in organic form for use in organic processed products. AMS concludes that the economic impact of removing the nonorganic agricultural products, marsala wine and sherry wine, would be minimal to small agricultural firms since organic form of these agricultural products or organic forms of alternative agricultural products may be commercially available and, as such, their nonorganic forms are proposed to be removed from the National List under this rule. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration

(SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.5 million acres in 2011.<sup>1</sup> According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 19,470 in 2014. The list of certified operations is available on the NOP website at <http://apps.ams.usda.gov/nop/>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to \$39.1 billion in 2014, an 11.3 percent growth over 2013 sales.<sup>2</sup> In addition, the USDA has 80 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA. Certifying agents reported 27,810 certified operations worldwide in 2014.

#### D. 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 section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35, or OMB's implementing regulations at 5 CFR part 1320.

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<sup>1</sup> U.S. Department of Agriculture, National Agricultural Statistics Service. October 2012. 2011 Certified Organic Productions Survey.

<sup>2</sup> Organic Trade Association. 2014. Organic Industry Survey. [www.ota.com](http://www.ota.com).

#### E. 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 to the Secretary by the NOSB for substances on the National List of Allowed and Prohibited Substances that, under the Sunset review provisions of OFPA, would otherwise expire on December 14, 2015. A 30-day period for interested persons to comment on this rule is provided. Thirty days is deemed appropriate because the review of these listings was widely publicized through two NOSB meeting notices; the use or prohibition of these substances, as applicable, are critical to organic production and handling; and this rulemaking must be completed before the sunset date of December 14, 2015.

#### 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 is 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. Section 205.601 is amended by removing paragraphs (i)(11) and (i)(12).

3. Section 205.606 is amended by removing paragraph (g) and redesignating paragraphs (h) through (z) as (g) through (y).

Dated: July 27, 2015

Rex A. Barnes  
Associate Administrator  
Agricultural Marketing Service

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