



## **DEPARTMENT OF AGRICULTURE**

### **Agricultural Marketing Service**

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

**[Document Number AMS-NOP-16-0052; NOP-16-03]**

**RIN 0581-AD52**

### **National Organic Program (NOP); Sunset 2017 Amendments to the National List**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the National List of Allowed and Prohibited Substances (National List) within the U.S. Department of Agriculture's (USDA) organic regulations, to prohibit the use of 8 substances in organic production and handling after June 27, 2017: Lignin sulfonate (for use as a floating agent); furosemide; magnesium carbonate; and the nonorganic forms of chia, dillweed oil, frozen galangal, frozen lemongrass, and chipotle chile peppers. This action also renews 3 substances on the National List to continue to allow nonorganic forms of inulin-oligofructose enriched, Turkish bay leaves, and whey protein concentrate in organic products. This action addresses eleven recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) following its October 2015 meeting. These recommendations pertain to the NOSB's 2017 sunset review of a portion of the substances on the National List.

**DATES:** This final rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The renewal of the substances inulin-oligofructose enriched, Turkish bay leaves, and whey protein concentrate for inclusion on

the National List is applicable beginning on June 27, 2017.

**FOR FURTHER INFORMATION CONTACT:** Paul Lewis, Ph.D., Director,  
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**SUPPLEMENTARY INFORMATION:**

I. Background

The USDA Agricultural Marketing Service (AMS) administers the National Organic Program (NOP), under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 - 6522). The 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, AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products.

Since October 2002, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606. The National List identifies synthetic substances that may be used and the nonsynthetic substances that must 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 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 substance and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

The OFPA authorizes the National Organic Standards Board (NOSB), operating

in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.), to develop recommendations to amend the National List. The NOSB assists in the evaluation of substances for organic production and handling and advises 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 valid. This periodic review of National List substances is referred to as “sunset review.” 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 sunset review of substances on the National List includes 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. Recommendations to either continue or discontinue an authorized exempted synthetic substance (7 U.S.C. 6517(c)(1)) are developed by the NOSB based on evaluation of technical information, public comments, and supporting evidence that demonstrate that 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 final rule would amend the National List to remove eight substances as recommended to the Secretary by the NOSB on October 29, 2015. Additionally, this final rule would renew three substances allowed for use in

organic products based on information that there is a continued need for these materials.

## II. Overview of Amendments

### Removals

This final rule amends the National List to remove eight exemptions (allowances) for: lignin sulfonate, furosemide, magnesium carbonate, chia, dillweed oil, frozen galangal, frozen lemongrass, and chipotle chile peppers. The NOSB recommended that these substances should be removed from the National List based on its 2017 sunset review. In summary, the NOSB concluded that these substances are no longer needed in organic production or handling because there are alternative practices or materials. AMS concurs with these recommendations for removal as described below.

The NOSB considered public comments and other information to determine whether these substances continue to meet the OFPA criteria (7 U.S.C. 6517(c) and 6518(m)) for inclusion on the National List. With regard to (i) lignin sulfonate (§ 205.601(1)(l) - synthetic substance allowed as a floating agent in post-harvest handling), (ii) furosemide (§ 205.603(a) - synthetic substance allowed for livestock medical treatment), and (iii) magnesium carbonate (§ 205.605(b) - synthetic ingredient allowed in or on organic processed products), the NOSB concluded that these three substances are no longer necessary for organic production or postharvest handling and alternative substances are available.

AMS received no public comments concerning the proposed removal of lignin sulfonate (as a floating agent in post-harvest handling), furosemide, and magnesium carbonate from the National List. AMS has reviewed and accepts the NOSB recommendations to remove these substances from the National List when the listings are

due to sunset, or expire. Therefore, after June 27, 2017, lignin sulfonate (as as floating agent in post-harvest handling), furosemide, and magnesium carbonate will no longer be allowed for use in organic production or handling.<sup>1</sup>

With regard to chia (*Salvia hispanica* L.), dillweed oil, galangal (frozen), lemongrass (frozen), and peppers (chipotle chile), the NOSB considered public comments and other information to determine whether these five substances continue to meet the OFPA criteria for inclusion on the National List. These substances appear in section 205.606 of the National List which allows the use of nonorganic forms of these substances when the organic form is not commercially available<sup>2</sup>. The NOSB recommended that these substances be removed because adequate organic sources are available in the supply chain and nonorganic forms are not needed.

AMS received no public comments concerning the proposed removal of chia, dillweed oil, frozen galangal, frozen lemongrass, and chipotle chile peppers from the National List. AMS has reviewed and accepts the NOSB recommendations to remove these substances from the National List when the listings are due to sunset, or expire. Therefore, after June 27, 2017, nonorganic forms of chia, dillweed oil, frozen galangal, frozen lemongrass, and chipotle chile peppers will no longer be allowed for use in organic products.

### III. Related Documents

Two notices announcing NOSB public meetings were published in the Federal Register on March 12, 2015 (80 FR 12975) and on September 8, 2015 (80 FR 53759).

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<sup>1</sup> The allowance for lignin sulfonate as a chelating agent or dust suppressant for plant or soil amendments in organic crop production remains on the National List (§ 205.601(j)(4)).

<sup>2</sup> Definition of Commercially Available (§ 205.2): The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

These notices invited the public to provide comments to the NOSB for the 2017 sunset review. The notices informed the public that the listings discussed in this final rule would expire from the National List on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary.

On January 18, 2017, AMS published a proposed rule in the Federal Register (82 FR 5431) to notify the public and solicit comments on AMS' proposed action to remove eleven substances from the National List based on the NOSB's 2017 sunset recommendations. The comment period for the proposed rule was extended an additional 30 days to April 19, 2017, per a Federal Register document published on February 17, 2017 (82 FR 10967).

#### 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 removal from the National List. The National List petition process is implemented under § 205.607 of the USDA organic regulations. The National List Petition Guidelines (NOP 3011) are published in the NOP Handbook which is available on the AMS website, <http://www.ams.usda.gov/nop>. The guidelines describe the information to be included for all types of petitions submitted to amend the National List. AMS published a revised sunset review process in the Federal Register on September 16, 2013 (78 FR 56811).

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

This rule does not meet the definition of a significant regulatory action contained in section 3(f) of Executive Order 12866, and is not subject to review by the Office of Management and Budget (OMB). 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).

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 rule would be to prohibit the use of eight substances that have limited public support and may no longer be used because alternatives to these substances have been developed and implemented by organic producers or organic

handlers (food processors). AMS concludes that the economic impact of removing lignin sulfonate, furosemide, magnesium carbonate, chia, dillweed oil, frozen galangal, frozen lemongrass, and chipotle chile peppers from the National List would be minimal to small agricultural firms because alternative practices or substances are commercially available. As such, these substances are to be removed from the National List under this rule.

This rule would also allow for the continued use of three nonorganic agricultural substances: Turkish bay leaves, inulin-oligofructose enriched, and whey protein concentrate. AMS concludes that renewing these three ingredients would minimize impact to small agricultural firms because alternative products or organic forms of these ingredients are not commercially available and handlers need to use the nonorganic forms. 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) as those having annual receipts of less than \$7,500,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000. See 13 CFR 121.201.

According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 24,669 in March 2017. The list of certified operations is available on the AMS NOP website at <http://www.ams.usda.gov/nop>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. In addition, the USDA has 81 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.

#### 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.

Pursuant to section 6519(f) of OFPA, 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 the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136-136(y)).

#### C. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this 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.

#### E. Comments received on Proposed Rule AMS-NOP-16-0052; NOP-16-03

AMS received seven public comments from ingredient manufacturers, organic handlers, and a trade association on the proposal to remove the following three substances from the National List: Turkish bay leaves, inulin-oligofructose enriched, and whey protein concentrate. These substances are listed in section 205.606 of the National List, which allows nonorganic forms to be used in organic products when organic forms are not commercially available. Removing these substances from the National List would mean that only organic forms of these ingredients could be used in organic products.

#### Changes Made Based on Comments

AMS received public comments which opposed the removal of Turkish bay leaves from the National List. These public comments stated that organic Turkish bay leaves are not available in the quantity or quality needed to meet organic handling needs. The comments explained that the different flavor profile of ground organic Turkish bay leaves would negatively impact finished products. Comments requested that AMS maintain the allowance for nonorganic Turkish bay leaves while suppliers pursue sources of organic Turkish bay leaves in sufficient quality and quantity to meet industry needs.

AMS also received public comments opposing the proposed removal of inulin-oligofructose enriched from the National List. Comments acknowledged that there are organic or alternate forms of inulin available, such as inulin from organic agave and fructooligosaccharides, but explained that these are not equivalent to inulin-oligofructose

enriched, which is sourced only from chicory root and provides unique functionality for use as a prebiotic in organic infant formula. The comments indicated that an adequate supply of organic chicory root is not commercially available.

AMS received public comment opposing the removal of whey protein concentrate from the National List. Whey protein concentrate is used as an ingredient in various products including bakery, confectionary, processed meat, infant formula, and dairy products. Public comments submitted indicated that whey protein concentrate is essential to organic processed products and is not commercially available in organic form at this time.

In consideration of the new information presented in public comments, AMS has determined that nonorganic forms of Turkish bay leaves, inulin-oligofructose enriched, and whey protein concentrate are essential to organic production and handling and should remain on the National List. The USDA organic regulations may allow the use of nonorganic substances that are not commercially available in organic form, quality, or quantity, and are necessary to organic handling. As with other substances in section 205.606 of the National List, organic handlers are permitted to use the nonorganic substance only if the organic substance is not commercially available. Handlers will need to demonstrate, and certifiers will need to verify, that the organic substance is not available in the form, quality or quantity needed. Further, any member of the public may petition to remove an agricultural substance from the National List if an organic substance becomes commercially available.<sup>3</sup>

#### List of Subjects in 7 CFR Part 205

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<sup>3</sup> The AMS website describes how to submit a petition: <https://www.ams.usda.gov/rules-regulations/organic/national-list/filing-petition>. See also NOP 3011 National List Petition Guidelines.

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. Amend § 205.601 by revising paragraph (l) to read as follows:

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

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(l) As floating agents in postharvest handling. Sodium silicate – for tree fruit and fiber processing.

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§ 205.603 [Amended]

3. Amend § 205.603 by:

a. Removing paragraph (a)(10); and

b. Redesignating paragraphs (a)(11) through (23) as paragraphs (a)(10) through (22).

§ 205.605 [Amended]

4. Amend § 205.605(b) by removing the substance “Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.”

§ 205.606 [Amended]

5. Amend § 205.606 by:

a. Removing paragraphs (c), (e), (h), (o), and (s); and

b. Redesignating paragraphs (d), (f), (g), (i) through (n), (p) through (r), and (t)

through (y) as paragraphs (c) through (t), respectively.

Dated: June 28, 2017.

Bruce Summers,  
Acting Administrator, Agricultural Marketing Service.

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