



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-19-0023; NOP-19-01]

RIN 0581 AD83

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA's) organic regulations. This rule adds non-organic tamarind seed gum as an allowed ingredient in organic products when certified organic tamarind seed gum is not commercially available.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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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 allowed in organic farming and the nonsynthetic substances prohibited in

organic farming. The National List also identifies nonagricultural and nonorganic agricultural substances (ingredients) that may be used in organic handling.

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501–6524), and the USDA organic regulations (7 CFR part 205) specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List (7 CFR 205.601–205.606). Section 205.105 also requires that any nonorganic agricultural substance 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 final rule addresses one NOSB recommendation to amend the National List that was submitted to the Secretary on October 26, 2018. The amendment in this final rule is discussed in the section on Overview of Amendments below.

II. Overview of Amendments

The following provides an overview of the amendment to a designated section of the National List regulations. This rule adds tamarind seed gum to the National List. This rule does not add blood meal made with sodium citrate or natamycin to the National List, as proposed by AMS (84 FR 55866, October 18, 2019).

The background information on each substance and the basis for each NOSB recommendation was addressed in the proposed rule. The NOSB evaluated each substance by applying the OFPA substance evaluation criteria to determine if the substance was compatible with organic production and handling. For each substance, AMS reviewed the recommendation

submitted by the NOSB to the Secretary to determine if the OFPA evaluation criteria had been appropriately applied and whether the addition to or amendment of the National List would not supersede other federal regulations.

AMS received 45 comments on the proposed rule. After considering the comments, AMS determined that the addition of nonorganic tamarind seed gum to the National List for use in organic handling will be finalized as proposed. The proposed amendments to add blood meal made with sodium citrate and to prohibit the use of natamycin in organic production have not been finalized for the reasons discussed below. Section F of this final rule provides an overview of the comments received and AMS's response to these comments.

Tamarind seed gum

This rule amends the National List to allow nonorganic tamarind seed gum (by addition to § 205.606) in organic products when organic tamarind seed gum is not commercially available. Tamarind seed gum is used as a thickener, stabilizer, emulsifier or gelling agent in processed foods. The U.S. Food and Drug Administration (FDA) has been informed that tamarind seed is Generally Recognized as Safe (GRAS) for the above uses.¹ During its October 24 – 26, 2018, public meeting, the NOSB recommended adding tamarind seed gum as an allowed nonorganic agricultural ingredient to § 205.606 of the National List. As required by the USDA organic regulations (§ 205.606), the nonorganic form of the ingredient will only be permitted when organic tamarind seed gum is not commercially available.² To use nonorganic forms of ingredients listed at § 205.606, organic handling operations must demonstrate and

¹ Agency Response Letter GRAS Notice No. GRN 000503, August 12, 2014; <https://wayback.archive-it.org/7993/20171031004449/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm413748.htm>

² The USDA organic regulations (7 CFR 205.2) define “commercially available” as, “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.”

document that organic forms of the ingredient(s) are not commercially available. Certifying agents (“certifiers”) review the operation’s use of nonorganic ingredients for compliance with the regulations in the course of reviewing an organic operation’s organic system plan.

Amendments not Finalized in this Rule.

Based upon public comments received on the proposed rule, AMS is not finalizing the proposed amendments to (1) list blood meal made with sodium citrate as an allowed synthetic substance for organic crop production or (2) prohibit natamycin use in crop production. A summary of the comments received on the proposed rule and AMS’s responses to these comments are included in Section F of this final rule.

III. Related Documents

On October 18, 2019, AMS published in the Federal Register (84 FR 55866) a proposed rule to amend the National List to include blood meal made with sodium citrate; natamycin; and nonorganic tamarind seed gum. On August 9, 2018, AMS published a Notice in the Federal Register (83 FR 39376) announcing the fall 2018 NOSB meeting. One purpose of that meeting was to deliberate recommendations for the substances addressed in this rule.

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB (7 U.S.C. 6517(d)). 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 permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition

procedures from USDA. The current petition procedures published in the Federal Register (81 FR 12680, March 10, 2016) for amending the National List 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 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.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS)³ 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 \$1,00,000.

³ North American Industry Classification System: <https://www.census.gov/eos/www/naics/>.

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 \$16.5 million.

AMS has considered the economic impact of this proposed rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2017 Census of Agriculture, 18,166 organic farms in the United States reported sales of organic products and total farmgate sales in excess of \$7.2 billion.⁴ Based on that data, organic sales average \$400,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$1,000,000 sales threshold to qualify as a small business.

According to the NOP’s Organic Integrity Database, there are 19,764 organic handlers that are certified under the USDA organic regulations (10,492 of these handlers are based in the U.S).⁵ The Organic Trade Association’s 2018 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

⁴ U.S. Department of Agriculture, National Agricultural Statistics Service. 2017 Census of Agriculture. https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/. The number of organic farms includes both certified and exempt farms.

⁵ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on June 15, 2020.

to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

The USDA has 78 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 \$16.5 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 one substance in organic handling. Adding this substance to the National List would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. 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 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 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 (U.S. EPA) 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 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 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. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

F. Comments Received on Proposed Rule

During a 60-day comment period that closed on December 17, 2019, AMS received 45 comments on the proposed rule (84 FR 55866). These comments were submitted by organic farmers and handlers, certifying agents, researchers, trade associations, nonprofit organizations, and consumers. The comments can be viewed at <https://www.regulations.gov> by searching for docket ID “AMS-NOP-19-0023.”

Comments received on the proposed addition to § 205.601.

AMS received several comments on the proposed amendment to add blood meal made with sodium citrate to the National List for use in organic crop production. Most of these comments opposed the proposed listing. These comments argued that classifying blood meal made with sodium citrate as a synthetic substance contradicts guidance in NOP 5033 Classification of Materials and NOP 5034-1 Materials for Organic Crop Production, which lists blood meal as a nonsynthetic substance.⁶ Some comments noted that the use of anticoagulants,

⁶ NOP 5033 and NOP 5034-1 are available in the NOP Program Handbook: <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

such as sodium citrate, is part of the “standard of identity” of blood meal, and, therefore, blood meal made with anticoagulants should be considered a nonsynthetic substance. Some comments stated that the use of sodium citrate in the making of blood meal has no technical effect, does not transform the blood into a different substance through a chemical change, and is not present in the final product. A few comments stated that sodium citrate binds with calcium in blood, making blood meal processed with sodium citrate the same as blood meal derived from processed animal blood where no anticoagulant was used. These comments suggested that the blood meal processed with sodium citrate is not altered into a form that does not occur in nature and should be classified as nonsynthetic.

A few comments expressed concern about the potential impact of adding processing aids used to manufacture crop inputs to the National List. These comments postulate that adding blood meal made with sodium citrate to the National List sets a precedent for reviewing and approving processing aids that may be used in other currently approved inputs that are considered to be nonsynthetic, such as bone meal or feather meal, but which in turn, could become prohibited.

Several comments opposed or questioned the allowance of blood meal in organic production generally. A comment indicated that blood meal can be made without the use of sodium citrate and several comments were concerned that there are no restrictions on or required information about the source of the blood meal used in organic production, for example, to prohibit blood meal from nonorganic animals. One comment was concerned about disease transmission resulting from the use of blood meal and proposed that blood meal should be added to § 205.602 as a prohibited nonsynthetic substance.

AMS also received comments supporting the addition of blood meal made with sodium citrate to the National List. However, supporting comments noted concerns with potential impacts of the proposed action beyond blood meal and one suggested revising guidance as an alternative to rulemaking. One comment supported the listing with the caveat that there was public support for such action and acknowledged the potential broader implications of that action and regulatory uncertainty about reviewing substances used in the processing of inputs.

Comments received on the proposed addition to § 205.602.

Many of the public comments addressed the proposal to list natamycin as a prohibited substance in organic crop production. Many comments opposed natamycin's listing in § 205.602 as a prohibited nonsynthetic substance. These comments argued that the NOSB's determination that natamycin use could increase fungal resistance is flawed and is not supported by research. Several comments also included citations to specific research findings which conclude that natamycin use does not contribute to fungal resistance. Comments also stated that natamycin has been used for many years with no documented evidence of increased fungal resistance.

In addition to disputing fungal resistance, comments cited other concerns with prohibiting the use of natamycin, including reduced product shelf-life, economic loss, and fewer options for controlling diseases where options are already very limited. The comments also stated that natamycin is generally not used for treatment of human fungal infections.

AMS received several comments claiming that the proposed listing to prohibit natamycin, and the deliberations on the natamycin petition, did not meet requirements for prohibiting nonsynthetic substances stipulated in OFPA (7 U.S.C. 6517). To prohibit a nonsynthetic substance in organic crop or livestock production, OFPA requires that the USDA, in consultation with the U.S. Department of Health and Human Services and the U.S. Environmental Protection

Agency, determine that the substance is harmful to human health or the environment, or is inconsistent with organic farming. Comments stated that natamycin is not harmful to and has negligible impact on human health. In addition, comments argued that the NOSB did not conclude that the use of natamycin was inconsistent with organic farming. Some comments stated that the NOSB's recommendation to prohibit natamycin because it is "non-essential for organic production" is not valid because essentiality is not an evaluation criterion included in 7 U.S.C. 6517(c)(2) for prohibiting nonsynthetic substances.

AMS did receive some comments in support of adding natamycin to § 205.602 as a prohibited nonsynthetic substance. These comments agreed with the NOSB's recommendation to list natamycin as a prohibited nonsynthetic because of hazards to human health and the environment, and issues with essentiality for and compatibility with organic agriculture. Some comments argued that natamycin should be categorized as a synthetic substance because of the potential for synthetic substrates to be used in the fermentation process to produce natamycin. One comment requested guidance on determining whether the use of synthetic fermentation substrates in natamycin production would result in a nonsynthetic product. Another comment supporting the listing speculated on the possible impact natamycin use could have on soil fungi.

Comments received on the proposed addition to § 205.606.

AMS received five comments opposed to the addition of nonorganic tamarind seed gum to § 205.606 for use in organic handling. Comments argued that nonorganic ingredients should never be allowed in the processing and handling of organic products. Other comments indicated that tamarind seed gum is not essential for organic handling. Some comments argued for a focus on improved traceability of tamarind seed supply chains (as cited by the tamarind seed gum petitioner), noting that organic tamarind seed is available, but poor traceability makes

confirmation of the organic status of tamarind seed gum difficult. Other comments argued that the tamarind seed gum petition review process did not adequately determine whether tamarind seed gum is commercially available in organic form. One comment more broadly noted that the petition process for listing materials on § 205.606 should include a review of all barriers to the organic production and commercial availability of a substance, and that a substance should be listed only if those barriers are clearly shown to be insurmountable. This comment also challenged the NOSB review of tamarind seed gum, stating that the petition review was not robust enough.

AMS response to comments on blood meal made with sodium citrate and comments on natamycin.

Sodium citrate was the petitioned substance for use as a processing aid (anticoagulant) in spray-dried blood products, such as blood meal. The NOSB recommended adding sodium citrate to the National List as an allowed synthetic substance for that use and requested that AMS review sodium citrate to determine whether sodium citrate used to process blood meal must be on the National List in order for the resulting blood meal to be allowed in organic crop production. As such, AMS proposed adding blood meal made with sodium citrate as a synthetic substance to the National List for use in organic crop production.

Natamycin was petitioned to be classified as an allowed nonsynthetic substance for use as a post-harvest treatment to control fungal diseases on certain commodities. The NOSB determined that natamycin is nonsynthetic and that it should be prohibited in organic crop production because it is not essential, is inconsistent with sustainable agriculture, and has the potential to contribute to fungal resistance and the associated negative effects on human health.

Therefore, AMS proposed listing natamycin as a nonsynthetic substance that is prohibited in organic crop production.

AMS is not adopting two amendments in the proposed rule. These amendments would have listed (1) blood meal made with sodium citrate as an allowed synthetic substance in organic crop production and (2) natamycin as a prohibited nonsynthetic in organic crop production. Commenters raised significant concerns about each of these proposals.

Specifically, many comments opposed AMS's classification of blood meal made with sodium citrate as a synthetic substance and explained that there may be potential impacts of that action which had not been considered in the proposed rule. AMS does not agree that information presented in these comments conclusively shows that blood meal made with sodium citrate is a nonsynthetic substance. However, AMS does agree that classifying blood meal made with sodium citrate as synthetic may have negative implications for some other materials used in organic production and that such impacts were not anticipated or considered in the proposed rule.

Further, AMS is not finalizing the proposed amendment based in part on the fact that the NOSB did not specifically recommend adding blood meal made with sodium citrate as a synthetic to the National List. The NOSB recommended adding sodium citrate for use as an anticoagulant in the processing of blood meal, but did not determine that blood meal made with sodium citrate is a synthetic substance. Based on new information received in public comments about sodium citrate's action in blood meal, AMS determined that further discussion and deliberation by the NOSB are needed to determine whether or not the use of sodium citrate makes blood meal a synthetic substance. Therefore, in the absence of an NOSB recommendation that blood meal made with sodium citrate should be added to the National List as a synthetic substance and because information submitted in public comment raised new questions about the

proposed classification of blood meal made with sodium citrate as a synthetic substance, AMS is not adopting the proposed listing.

In regards to natamycin, several public comments also presented research findings to challenge the conclusions that natamycin use in organic crop production would increase fungal resistance to antimicrobials, have negative environmental or human health impacts, and that a prohibition meets the OFPA criteria for prohibiting natural substances. AMS agrees that these research findings should be considered as part of the totality of the information considered on natamycin, and that the merits of those findings should be discussed as part of any regulatory action. AMS has not assessed the validity of the research findings presented in public comment, and AMS believes that the availability of this information warrants consideration before finalizing a prohibition on natamycin in organic production. As a result, AMS is not finalizing the proposed amendment to add natamycin as a nonsynthetic substance prohibited for use in organic crop production.

AMS is not finalizing the proposed amendments for blood meal with sodium citrate and natamycin for reasons discussed above. The information presented in public comments opposing the proposed actions should be assessed before any new proposal for regulatory action. AMS may invite additional input from the NOSB on these topics; the NOSB's work may include conducting further study of the information and potential impacts and risks presented in public comments. AMS will not continue rulemaking on these two substances unless the NOSB forwards a new recommendation(s) on these topics to AMS.

AMS response to comments on tamarind seed gum.

This rule will add tamarind seed gum to the National List. AMS received few comments on tamarind seed gum. These comments expressed concern about the traceability of organic tamarind seed gum, and one comment argued that the NOSB did not conduct a robust review of the tamarind seed gum petition when determining organic tamarind seed gum availability. AMS disagrees with these comments. The NOSB comprehensively reviewed information on the potential sources of tamarind seed gum to determine if there were adequate sources of organic tamarind seed gum available to organic handlers in form, quantity, and quality. Based on the Organic INTEGRITY Database, which identifies no organic producers or handlers of tamarind seed gum, the NOSB determined there were insufficient sources of organic tamarind seed gum and recommended that tamarind seed gum be added to the National List in § 205.606. AMS agrees that the absence of organic tamarind seed gum handlers in the Organic INTEGRITY Database demonstrates that this ingredient is not currently commercially available in organic form. The USDA organic regulations require organic handlers to use organic agricultural ingredients when available before using any nonorganic agricultural ingredients that are included under § 205.606. Tamarind seed gum that is sold, labeled or represented as organic must be verified as organically produced and handled.

G. General Notice of Public Rulemaking

This final rule reflects recommendations submitted by the NOSB to the Secretary to add one substance to the National List.

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 part 205 is revised to read as follows:

Authority: 7 U.S.C. 6501–6522.

2. Amend § 205.606 by redesignating paragraphs (t) through (w) as paragraphs (u) through (x) and adding new paragraph (t) 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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(t) Tamarind seed gum.

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Bruce Summers,
Administrator,
Agricultural Marketing Service.