



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-17-0085; NOP-17-05]

National Organic Program: USDA Organic Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notification of 2018 Sunset Review.

SUMMARY: This document announces the renewal of 17 substances on the National List of Allowed and Prohibited Substances (National List) within the U.S. Department of Agriculture's (USDA) organic regulations. This document reflects the outcome of the 2018 sunset review process and addresses the recommendations submitted to the Secretary of Agriculture (Secretary), through the USDA's Agricultural Marketing Service (AMS), by the National Organic Standards Board (NOSB).

DATES: This document is effective May 29, 2018.

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SUPPLEMENTARY INFORMATION:

I. Background

The USDA 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 - 6524). The regulations implementing the NOP, also referred to as the USDA organic regulations (7 CFR Part 205), were published on December 21, 2000 (65 FR 80548) and became effective on

October 21, 2002. Through these regulations, AMS oversees national organic 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 of the USDA organic regulations 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 NOSB, operating in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.), to assist in the evaluation of substances to be allowed or prohibited for organic production and handling and to advise the Secretary on the USDA organic regulations. The OFPA also requires a review of all substances included on the National List within five years of their addition to or renewal on the list. During this sunset review, the NOSB considers any new information pertaining to a substance's impact on human health and the environment, its necessity due to the unavailability of wholly natural substances, and its consistency with organic production and handling. 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.

AMS published a revision of the sunset review process in the Federal Register on September 16, 2013 (78 FR 56811). This revised process provides public notice on the renewal of National List substances. This renewal occurs after the NOSB review.

In accordance with the sunset review process, AMS published two notices in the Federal Register announcing the NOSB meetings and inviting public comments pertinent to this renewal notification: March 16, 2016 (81 FR 14079) and August 1, 2016 (81 FR 50460). The NOSB also conducted two public webinars (April 19, 2016 and November 3, 2016), to provide opportunities for public comment. The NOSB received additional public comment during the face-to-face meetings on April 25-27, 2016 and November 16-18, 2016.

At these public meetings, the NOSB reviewed 17 substances with a 2018 sunset date. Table 1 shows the current listings for these substances. The NOSB recommended removing one substance, carrageenan, and completed its sunset review for the 16 other substances. The NOSB recommended removing carrageenan because they determined that alternative materials, such as gellan gum, guar gum, or xanthan gum, are available for use in organic products.

AMS has reviewed NOSB's sunset review document and decided to renew all 17 substances, including carrageenan. AMS found sufficient evidence in public comments to the NOSB that carrageenan continues to be necessary for handling agricultural products because of the unavailability of wholly natural substitutes (§ 6517(c)(1)(ii)). Carrageenan has specific uses in an array of agricultural products, and public comments reported that potential substitutes do not adequately replicate the functions of carrageenan across the broad scope of use. Therefore, carrageenan continues to meet the OFPA criteria for inclusion on the National List. The renewal of these 17 substances will avoid potential disruptions to the organic industry and the public that may otherwise result from their removal from the National List.

Table 1 lists the 17 synthetic and nonsynthetic substances on the National List that are being renewed. These substances continue to be included on the National List with a new sunset date of May 29, 2023.

Table 1: Substances Renewed in 2018 Sunset Review

National List Section	Substance Listing
§ 205.601	<u>Synthetic substances allowed for use in organic crop production.</u>
(a)	As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
(3)	Copper Sulfate —for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent
(5)	Ozone gas —for use as an irrigation system cleaner only.
(6)	Peracetic acid —for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.
(e)	As insecticides (including acaricides or mite control).
(4)	Copper Sulfate —for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.
(i)	As plant disease control
(8)	Peracetic acid —for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.
(m)	As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(2)	EPA List 3 —Inerts of unknown toxicity—for use only in passive pheromone dispensers
§ 205.602	<u>Nonsynthetic substances prohibited for use in organic crop production</u>
(c)	Calcium chloride , brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake
§ 205.605	<u>Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”</u>
(a)	Nonsynthetics allowed:
	Agar-agar

	Animal enzymes — (Rennet-animals derived; Catalase-bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin)
	Calcium sulfate —mined
	Carrageenan
	Glucono delta-lactone —production by the oxidation of D-glucose with bromine water is prohibited
	Tartaric acid —made from grape wine
(b)	Synthetics allowed:
	Cellulose —for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.
	Potassium hydroxide —prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches
	Silicon dioxide —Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”	
Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.	
(c)	Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.
(2)	Beta-carotene extract color —derived from carrots or algae (pigment CAS# 7235-40-7).

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Authority: 7 U.S.C. 6501–6524.

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