



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

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National Organic Program: USDA Organic Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: 2019 Sunset Review and Substance Renewals.

SUMMARY: This document announces the renewal of substance exemptions as listed 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 2019 sunset review process and addresses 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 action is effective October 30, 2019.

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SUPPLEMENTARY INFORMATION:

I. Background

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 the synthetic substances allowed to be used and nonsynthetic substances prohibited from use in organic farming. The National List also identifies synthetic and nonsynthetic nonagricultural (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 an exemption for using the synthetic substance is provided on the National List. Section 205.105 of the USDA organic regulations also requires that any nonorganic agricultural substance and any nonagricultural substance used in organic handling be listed as allowed on the National List.

The OFPA at § 6578 authorizes the NOSB, operating in accordance with the Federal Advisory Committee Act (§ 1 et seq., 5 U.S.C. App.2), as amended, to assist in evaluating substances to be allowed or prohibited for organic production and handling and to advise the Secretary on the USDA organic regulations. The OFPA sunset provision (§ 6517(e)) also requires a review of all substance exemptions 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. The NOSB subsequently votes to remove a substance allowance or prohibition from the National List.

The Agricultural Improvement Act of 2018 amended the OFPA at § 6518(i)(2) to specify that any vote on a motion proposing to amend the National List requires 2/3 of the votes cast at a

meeting of the NOSB at which a quorum is present to prevail. A substance allowance or prohibition remains listed on the National List unless an NOSB motion to remove such substance carries with 2/3 of votes cast, and the Secretary renews or amends the listing for such substance. The NOSB submits its sunset review and recommendations to the Secretary where, as delegated by the Secretary, AMS evaluates the sunset review and recommendations for compliance with the National List substance evaluation criteria in § 6518(m) and other federal statutes or regulations. AMS also considers public comments submitted in association with a specific sunset review process.

AMS published an updated sunset review process in the Federal Register on September 16, 2013 (78 FR 56811). In accordance with the sunset review process, AMS published two notices in the Federal Register announcing the NOSB meetings on April 19 – 21, 2017, and October 31 – November 2, 2017, and inviting public comments on the 2019 sunset review process (November 25, 2016 (81 FR 85205) and May 30, 2017 (82 FR 24659)). AMS also hosted two public webinars (April 13, 2017 and, October 24 and 26, 2017), to provide additional opportunities for public comment. The NOSB received additional comment during the public meetings. At these public meetings, the NOSB reviewed substance exemptions scheduled to sunset from the National List and recommended these exemptions not be removed. Table 1 shows the current listings for these substance exemptions.

AMS has reviewed and accepted the NOSB's 2019 sunset review recommendations and is renewing the listing of these substance exemptions until 2024.¹ AMS has determined that the substance allowances listed in this notice continue to be necessary for organic production and/or organic handling because of the unavailability of organic forms or wholly natural substitutes for

¹ National List Sunset Dates, NOP 5611, <https://www.ams.usda.gov/sites/default/files/media/NOP-SunsetDates.pdf>.

the specified uses (§ 6517(c)(1)(A)(ii)). The renewal of these substance allowances will avoid potential disruptions to the organic industry and consumers that may otherwise result from removal from the National List. AMS also has determined that the nonsynthetic substance prohibitions listed in this notice continue to be necessary because use of the two substances is inconsistent with organic production and/or organic handling (§ 6517(c)(2)(A)(ii)).

Five additional substance allowances were also reviewed and subsequently recommended for renewal by the NOSB: micronutrients, § 205.601(j); chlorhexidine, § 205.603(a); lidocaine, § 205.603(b); chlorine materials, § 205.605(b); and potassium acid tartrate, § 205.605(b). These five substance allowances are not included in this renewal notice, because these substances were already amended on the National List as a result of final rules published on December 27, 2018 (83 FR 66559) and on April 30, 2019 (84 FR 18133). The sunset date for micronutrients, § 205.601(j); chlorhexidine, § 205.603(a); lidocaine, § 205.603(b); and chlorine materials, § 205.605(b) is January 28, 2024. The sunset date for potassium acid tartrate, § 205.605(b), is May 30, 2024.

The NOSB also reviewed and subsequently recommended to the Secretary the removal of the listed exemptions for use of vitamin B₁ (§ 205.601), oxytocin (§ 205.603), procaine (§ 205.603), and konjac flour (§ 205.606). AMS is reviewing the NOSB recommendations to remove these substance allowances from the National List. Any removals from the National List would be addressed in a separate notice and comment rulemaking. AMS plans to take action on these substances before their sunset date of March 15, 2022.

Table 1 lists the substance exemptions being renewed through this document. These specific substance allowances and prohibitions continue as listed on the National List with a new sunset date of October 30, 2024.

Table 1: National List Substances Renewed in 2019 Sunset Review

Substance	Use Conditions
§ 205.601 Synthetic substances allowed for use in organic crop production.	
Chlorine materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite.	As described under § 205.601(a)(2)(i, ii and iv).
Herbicides, soap-based.	As described under § 205.601(b)(1).
Mulches: Biodegradable biobased mulch film.	As described under § 205.601(b)(2)(iii).
Boric acid.	As described under § 205.601(e)(3).
Sticky traps / barriers.	As described under § 205.601(e)(9).
Coppers, fixed.	As described under § 205.601(i)(2).
Copper sulfate.	As described under § 205.601(i)(3).
Humic acids.	As described under § 205.601(j)(3).
Vitamins, C, and E.	As described in § 205.601(j)(9).
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production	
Lead salts.	As described under § 205.602(d).
Tobacco dust (nicotine sulfate).	As described under § 205.602(j).
§ 205.603 Synthetic substances allowed for use in organic livestock production.	
Chlorine materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite.	As described under § 205.603(a)(10)(i, ii and iv).
Glucose.	As described under § 205.603(a)(13).
Tolazoline (CAS # 59-98-3).	As described under § 205.603(a)(29).
Copper sulfate.	As described under § 205.603(b)(1).
§ 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)).”	
Attapulgate.	As described under § 205.605(a).
Bentonite.	As described under § 205.605(a).
Diatomaceous earth.	As described under § 205.605(a).
Nitrogen.	As described under § 205.605(a).
Sodium carbonate.	As described under § 205.605(a).
Acidified sodium chlorite.	As described under § 205.605(b).
Carbon dioxide.	As described under § 205.605(b).
Magnesium chloride.	As described under § 205.605(b).
Sodium phosphates.	As described under § 205.605(b).
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on	

processed products labeled as “organic.”	
Casings.	As described under § 205.606(b).
Pectin.	As described under § 205.606(p).

Authority: 7 U.S.C. 6501–6524.

Dated: September 25, 2019

Bruce Summers
 Administrator
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