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**DEPARTMENT OF AGRICULTURE**

**Agricultural Marketing Service**

**7 CFR Part 205**

**[Document Number AMS-NOP-13-0057; NOP-13-03]**

**National Organic Program – Sunset Process**

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

**ACTION:** Notification of sunset process.

**SUMMARY:** This document describes the sunset review and renewal process for substances on the National List of Allowed and Prohibited Substances (National List), a subpart of the U.S.

Department of Agriculture (USDA) organic regulations. The Organic Foods Production Act of 1990 (OFPA) requires that the National Organic Standards Board (NOSB), a 15-member federal advisory committee, review all substances and that the Secretary of Agriculture (Secretary) renew these substances, within 5 years of their addition to or renewal on the National List. This action of NOSB review and USDA renewal is commonly referred to as the “Sunset Process.”

This document informs stakeholders about the process that the NOSB will use to complete their responsibility to review substances under OFPA’s sunset provision. This document also informs stakeholders about the process that the Secretary and the Agricultural Marketing Service’s (AMS) National Organic Program (NOP) will use to complete the USDA’s responsibilities under OFPA’s sunset provision.

**DATES:** The process announced by this document is effective on **[INSERT DATE 1 DAY AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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**SUPPLEMENTARY INFORMATION:**

I. Background

What is the National List?

The OFPA authorized the establishment of a National List of Allowed and Prohibited Substances (National List) (7 U.S.C. 6517). The National List, a subpart of the USDA organic regulations, identifies the synthetic substances that are allowed (exemptions) and the nonsynthetic (natural) substances that are not allowed (prohibitions) in organic production (7 CFR 205.601-604). Nonsynthetic substances are generally permitted to be used in organic production and are not required to be included on the National List. The 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 (§ 205.105). The National List also identifies the nonorganic substances that may be used in organic handling (§§ 205.605-205.606). Any nonorganic substance used in organic handling must also be included on the National List (§ 205.105).

Changes to the National List may be requested by any individual or organization through the National List Petition Process. Petitioners may submit a petition requesting the addition of a substance, the removal of a substance, or an amendment to a substance already on the National List. Section 205.607 of the USDA organic regulations addresses amending the National List. In addition, AMS published in the Federal Register guidelines regarding the submission of petitions for the National List on January 18, 2007 (72 FR 2167). This information can also be accessed through the NOP website at <http://www.ams.usda.gov/nop>.

### What is the National Organic Standards Board?

The NOSB is a 15-member Federal Advisory Committee that assists in the development of standards for substances to be used in organic production and handling (7 U.S.C. 6518(a)). The NOSB is responsible for developing proposed amendments to the National List for submission to the Secretary (7 U.S.C. 6518(k)(2)). Specifically, the NOSB reviews petitions received through the National List Petition Process and evaluates petitioned substances using specific criteria in OFPA (7 U.S.C. 6518(m)) and the USDA organic regulations (§ 205.600). These criteria address the impact of the use of the substance on human health and the environment, the necessity of the substance, and its compatibility with organic production and handling. Depending on the petitioned use of the substance, the petition will be reviewed by an NOSB subcommittee: crops, livestock, or handling. Proposals from the subcommittees are posted for public comment prior to the NOSB issuing a final recommendation. In developing their final recommendation, NOSB considers information from the petition, third party technical information, and written and in-person comments at public meetings. After NOSB provides a final recommendation to the Secretary, AMS reviews the recommendation and, if warranted, considers action to amend the National List through rulemaking. Under the authority of OFPA, the Secretary can amend the National List based on proposed amendments developed by the NOSB (7 U.S.C. 6517(d)(1)).

### What is the Sunset Process?

OFPA specifies that the NOSB must review all substances on the National List and that the Secretary renew substances within 5 years of their addition to or renewal on the National List. This action of NOSB review and USDA renewal is commonly referred to as the “Sunset Process.” It is essential for the NOSB to complete this review and the Secretary to complete any

renewals in a timely manner because these substances are critical to the production and handling of a wide array of raw and processed organic agricultural products. Failure to complete this process could cause disruption of well-established and accepted organic production, handling, and processing systems.

The NOSB has previously evaluated and determined that all substances currently on the National List are consistent with OFPA and the USDA organic regulations. As of publication of this document, the NOSB has completed five Sunset reviews since the establishment of the National List in October 21, 2002. AMS has addressed these reviews through multiple rulemaking actions. A complete list of Federal Register notices pertinent to NOSB reviews and AMS rules that address NOSB's Sunset Reviews is available on the NOP website at:

[www.ams.usda.gov/nopfederalregisternotices](http://www.ams.usda.gov/nopfederalregisternotices).

#### What does this document do?

This document describes the process that NOSB will use to complete its responsibility to review substances on the National List under OFPA's sunset provision. This document also describes the process that AMS' National Organic Program (NOP) will use to complete the Secretary's responsibility to renew the National List under OFPA's sunset provision.

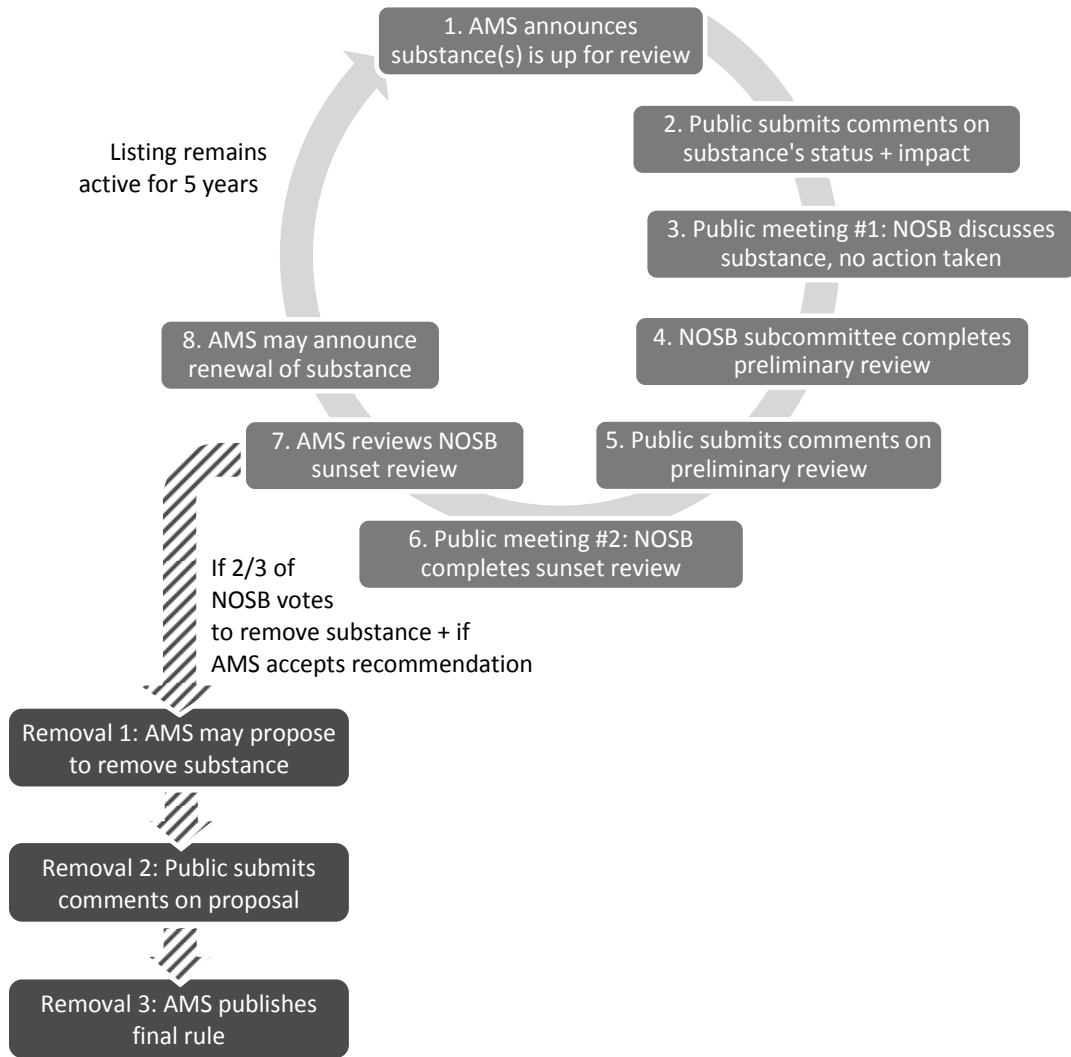
The Sunset Process described in this document will be used for future Sunset reviews and renewals, unless AMS replaces or updates this document. This document replaces the process that AMS described in the first Advanced Notice of Proposed Rulemaking (ANPR) for Sunset Review published in the Federal Register on June 17, 2005 (70 FR 35177).

#### II. The Sunset Process

The Sunset Process is comprised of two components: (1) the NOSB review and (2) USDA action on substances within 5 years of their addition to or renewal on the National List.

The Sunset Process is completed for each substance through the steps shown in Figure 1 and described below.

Figure 1. The Sunset Process



### Step 1 – AMS announces substance(s) for sunset review

AMS will publish a list of substances that will be undergoing the sunset review and renewal process in a given calendar year. The list will be published on the NOP website with enough lead time (e.g. two years) to provide for both NOSB review and USDA action on these substances. The list will be divided by subcommittee and provides the following information for each substance: current listing, use description, references to past technical reports, past NOSB actions, and regulatory history (e.g. links to proposed and final rules), as applicable. An example of the structure and content of this type of list is available at: [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop).

### Step 2 – Public submits comments on substance’s status and impact

AMS will also publish a Federal Register document announcing an NOSB meeting and request public comments on each substance under sunset review. This request for comments will direct the public to provide information that aids in NOSB review of the substance against the criteria in OFPA and under the USDA organic regulations. This request is for new information about a substance since its addition to the National List or its previous Sunset Review. Such information could include research or data that may support a change in the NOSB’s determination for a substance. This may include information on a substance’s impact on human health and the environment, its necessity, and its continued compatibility with organic production and handling.

In advance of the NOSB meeting, the public can submit written comments on the substances undergoing sunset review. At the NOSB meeting, the public can also provide in-person comments to NOSB on these substances. Members of the public interested in providing in-person comments may request a slot in advance. Instructions for such requests are available in the Federal Register document announcing the NOSB meeting.

### Step 3 – Public meeting #1: NOSB discusses substance, no action taken

At the first public meeting, each NOSB Subcommittee presents a brief background summary for each substance and describes any public comments received. The NOSB does not take action on this substance at this meeting. Instead, the purpose of the first meeting is for the NOSB to hear about any new information about each substance under review. Through the process of public comment, NOSB may identify and discuss key issues about a substance that needs further examination. Each Subcommittee will consider these issues as it develops its preliminary sunset review for the next public NOSB meeting.

### Step 4 – NOSB Subcommittee completes preliminary review

After the first public meeting, the NOSB Subcommittees will review public comment and technical information to draft a preliminary review of substances undergoing sunset review in a given year. AMS will publish this preliminary review on the NOP website. For substances that continue to meet the criteria for substances on the National List, the Subcommittee will summarize relevant information regarding its review of this substance. The review will also summarize information from any available technical report(s) on the substance and describe any new information pertaining to substance's impact on human health and the environment, its necessity, and its compatibility with organic production and handling. If the Subcommittee determines that a substance should remain on the National List, and there are no proposals to remove the substance, then the Subcommittee's preliminary review moves to the next step in this process. The Subcommittee does not vote on a motion to retain a substance on the National List.

As part of this review, the Subcommittee may identify new information that merits consideration of a substance for removal from the National List. If warranted, the NOSB Subcommittees can develop proposals to remove substances as part of their preliminary review.

Any proposals to remove a substance must be justified using the evaluation criteria in OFPA and the USDA organic regulations. Proposals to remove a substance must be part of the preliminary review that is posted in advance of the NOSB meeting.

If the Subcommittee identifies new information that it believes merits reconsideration of a use restriction for a substance (e.g., to expand its use, further restrict its use, or correct its restrictive annotation), then a member of the Subcommittee or a member of the public can file a petition to change the use of a substance through the National List Petition Process. Changes to or addition of annotations to substances already on the National List cannot be proposed during the Sunset Process. Additional information in support of this procedure is described below under Discussion.

#### Step 5 – Public submits comments on preliminary review

AMS will publish a Federal Register document announcing the second NOSB meeting and request public comments on each Subcommittee’s preliminary review. This request for comments will again direct the public to provide information that aids in NOSB review of each substance against the criteria in OFPA and under the USDA organic regulations. This request is for new information on the status of a substance since its addition to the National List or its previous Sunset Review. Such information could include research or data that may support a change in the NOSB’s determination for a substance. This may include information on a substance’s impact on human health and the environment, its necessity, and its continued compatibility with organic production and handling.

In advance of the second NOSB meeting, the public can respond to this Federal Register document by submitting written comments on the substances undergoing review. At the NOSB meeting, the public can also provide in-person comments to NOSB on these substances.



Members of the public interested in providing in-person comments may request a slot in advance. Instructions for such requests are available in the Federal Register document announcing the NOSB meeting.

#### Step 6 – Public meeting #2: NOSB completes Sunset Review

At the second public meeting, each Subcommittee will present a brief background summary of its preliminary review and summarize any public comments received. Each Subcommittee Chair leads the full NOSB discussion on that Subcommittee's preliminary reviews and any associated proposals to remove substances from the National List.

After NOSB discussion of each preliminary review and any proposals, the NOSB will vote on any motions to remove substances from the National List. If a Subcommittee had published a proposal to remove a substance, then a member of the NOSB can make a motion to remove that substance from the National List. As specified by OFPA, two-thirds of the votes cast at the meeting shall be decisive of any motion (7 U.S.C. 6518(i)). For motions to remove a substance, this means that two-thirds of votes cast must be in favor of removal of the substance. A motion to remove a substance that does not receive two-thirds of the votes cast fails, and the substance will remain on the National List.

Proposals to remove substances from the National List can only be considered by the NOSB if they were published as part of the Subcommittee's preliminary review for public comment in advance of the NOSB meeting. If the Subcommittee identifies new information at the meeting that it believes merits reconsideration of the conclusions presented in the preliminary review, that information will be considered untimely for purposes of the Sunset Review process. However, a member of the Subcommittee or a member of the public then can file a petition for removal or changes to the use of a substance through the National List Petition Process.

After NOSB votes on any proposals to remove substances, the NOSB discusses the overall review of substances under their consideration. At the conclusion of this discussion, the NOSB Chair confirms that the NOSB review is complete. The NOSB Chair compiles the preliminary reviews from each Subcommittee and any NOSB recommendations for removals into a comprehensive NOSB Sunset Review document. The NOSB Chair accepts this document as complete and transmits this document to AMS for consideration and for public posting on the NOP website at [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop). This action completes the NOSB's responsibility to review substances on the National List through OFPA's sunset provision (7 U.S.C. 6517(e)).

#### Step 7 – AMS reviews NOSB Sunset Review

Upon receipt of the NOSB's Sunset Review document, AMS reviews the outcome for each substance to consider AMS' next action and to ensure accuracy and completeness of the document.

#### Step 8 – AMS announces renewal of substance

After AMS' review, AMS may publish a document in the Federal Register listing all the substances that will remain on the National List until the next five year sunset review. This action addresses the Secretary's responsibility to renew substances on the National List through OFPA's sunset provision (7 U.S.C. 6517(e)). If the NOSB has recommended removal of any substance from the National List, then AMS may take the following actions to remove the substance:

#### Removal 1 – AMS proposes to remove substance

AMS will review any NOSB recommendations to remove a substance from the National List. If warranted, AMS will publish a proposed rule in the Federal Register to propose removal of these substances from the National List.

### Removal 2 – Public submits comments on proposal

AMS will request comments on the proposed rule for any removals. AMS may specifically request comments on the NOSB's justification for removal of the substance, information on the availability of alternatives to the substance (e.g., other substances, cultural or management practices), and information on the potential impacts (benefits and costs) of removing the substance from the National List.

### Removal 3 – AMS publishes final rule

AMS will review the comments received on the proposed rule and determine whether to finalize the rule as proposed. If AMS publishes a final rule to remove one or more substances, then these substances will be removed from the National List on the effective date of the final rule. On this date, their authorized use or prohibition in organic production or handling expires.

## III. Discussion

### What are the benefits of this action?

The Sunset Process described in this document is designed to improve public participation and transparency and ensure well-informed decision making about substances that are critical in organic production and handling.

Over the last few Sunset Reviews, AMS identified a number of ways that the process could be improved by:

- Increasing opportunities for the public to submit comments directly to NOSB;
- Clarifying the NOSB's voting approach and requirements for decisive votes under OFPA; and
- Ensuring that NOSB proposals are exposed to robust public comment and can be addressed in a timely manner through the AMS' process.

Therefore, the Sunset Process described in this document will create greater efficiency and will ensure that:

- Members of the public receive the full benefit of public comment on NOSB Sunset decisions over the course of two public meetings;
- There is consistency in NOSB review of substances across the Sunset Process and the National List Petition Process; and
- There is flexibility in the regulatory process to provide the organic industry with the regulatory certainty required for successful production and marketing of organic products.

How does this Sunset Process enhance public participation?

Since the NOSB represents all sectors of the organic community, the NOSB's review provides AMS with critical information about which substances should be allowed or prohibited in organic agriculture. This Sunset Process enhances the NOSB's ability to thoroughly review sunset substances over the course of two public meetings. The first meeting enables the public to provide NOSB Subcommittees with new information about substances under review and may prompt their requests for additional technical information. The second meeting enables the public to comment specifically on the outcomes of the NOSB Subcommittee's preliminary review, including any proposals to remove substances from the National List. The AMS rulemaking process provides an additional opportunity for the public to comment on any NOSB recommendation to remove a substance from the National List.

Can NOSB recommend a change to or addition of an annotation to a substance during Sunset Review? Can the NOSB recommend moving a substance to a different section of the National List during the Sunset Review?

No. For substances already on the National List, changes to or addition of annotations, or changes to the location of a substance on the National List (e.g., agricultural versus nonagricultural), cannot be proposed during the Sunset Process. In the past, NOSB made recommendations to further restrict the use of substances during Sunset Review. At times, these recommendations have not been exposed to robust public comment and have been difficult for AMS to implement through rulemaking actions by the sunset date. The difficulties with implementing these recommendations include the level of analysis required to assess how organic stakeholders may be affected by the recommendation and the deadline for completion of the Sunset Process.

If the NOSB identifies new information that it believes merits reconsideration of a use restriction on a substance (e.g., to expand its use, further restrict its use, or correct its restrictive annotation) or the location of a substance on the National List, then a member of the NOSB or a member of the public can file a petition for changes to the use or classification of a substance through the National List Petition Process ([www.ams.usda.gov/nop](http://www.ams.usda.gov/nop)).

Do all NOSB members have to agree to recommend removal of a substance during the Sunset Process?

No. Two-thirds of the votes cast at the meeting must be in favor of removal for a motion to remove to pass (7 U.S.C. 6518(i)). A motion to remove a substance that does not receive two-thirds of the votes cast fails to be “decisive” under OFPA and the substance will remain on the National List.

How does this document clarify the requirements for decisive votes under OFPA and the NOSB’s voting approach for Sunset review?

The “decisive votes” provision in OFPA states that two-thirds of the votes cast by NOSB is decisive of any motion (7 U.S.C. 6518(i)). Through this document, AMS is clarifying that removal of a substance during Sunset Review requires a two-thirds majority or “decisive” vote. In the past, the NOSB voted on a motion to “renew” each substance under Sunset Review. If a two-thirds majority wasn’t reached on a motion to renew a substance, then the outcome, by default, was considered an NOSB recommendation to remove the substance from the National List. Ensuring that a two-thirds majority vote is reached for any decisive action (e.g. removal of a substance) would bring greater consistency with OFPA.

The previous approach also was not aligned with the National List Petition Process, a process by which stakeholders can request removal of a substance from the National List. For the petition review, a two-thirds majority vote is required for the NOSB to recommend removal of a substance. Under the process described in this Federal Register document, the NOSB voting approach requires that, regardless of whether the substance is under Sunset Review or petition review, the NOSB will need a two-thirds majority vote to recommend removal of a substance from the National List.

What is the importance of submitting public comments to the NOSB at their first public meeting?

It is important for the public to engage in the Sunset Process early because the Subcommittees will use comments from their first public meeting to develop any proposals for removal of substances leading up to the second public meeting. As discussed in Step 6, proposals to remove substances from the National List can only be considered by the NOSB if they were published as part of the Subcommittee’s preliminary review for public comment in advance of the second NOSB meeting. Allowing changes to proposals or addition of new proposals at the

public meeting does not provide stakeholders who submitted written comments in advance of this meeting any opportunity to comment on substantive changes or additions that occur at the in-person meeting. Therefore, public participation during the first public meeting of this Sunset Process will provide the NOSB with the greatest amount of information available to aid in a thorough review.

Authority: 7 U.S.C. 6501 – 6522.

Dated: September 10, 2013.

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Agricultural Marketing Service

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