



Review of Allowed and Prohibited Substances in Organic Production and Handling Questions and Answers

1. What substances are allowed and prohibited in organic production and handling?

Organic standards allow most natural substances in organic farming while prohibiting most synthetic substances. The [National List of Allowed and Prohibited Substances](#)—part of the USDA organic regulations—lists the exceptions to this basic rule, as well as the non-organic substances allowed in processed organic products.

The [National Organic Standards Board](#) (NOSB), a Federal Advisory Committee, advises USDA on which substances should be allowed or prohibited in organic farming and processing.

Organic crop and livestock production

Allowed:

- Natural substances unless specifically prohibited (see below)
Examples of allowed natural substances: compost, almond hulls, coffee grounds
- Synthetic substances that are specifically allowed in [crops](#) and [livestock](#) production
Examples of allowed synthetic substances: electrolytes, vitamins, and newspaper

Prohibited:

- Natural substances that are specifically prohibited in [crops](#) and [livestock](#) production
Examples of prohibited natural substances: arsenic, strychnine
- Synthetic substances that aren't specifically allowed (see above)

Processed organic products

Allowed:

- Certified organic ingredients
Examples include organic carrots, organic milk, or organic wild mushrooms
- Non-organic substances that are specifically allowed ([agricultural](#) and [non-agricultural](#))
Examples of allowed substances: baking soda, fish oil

Prohibited:

- Non-organic substances that aren't specifically allowed (see above)

All substances must meet criteria based on impact to human health, the environment, and other requirements under the [Organic Foods Production Act \(OFPA\)](#) and the [USDA organic regulations](#).

2. What if I want to suggest a change to the National List?

The USDA can change the National List through rulemaking, based on recommendations from the NOSB. The NOSB makes recommendations for changes to the National List. NOSB recommendations on proposed changes to the National List may be started through: (1) a petition to add, remove, or change the allowance of a substance and (2) the sunset process. Both options involve the NOSB's review, multiple public comment opportunities, and USDA rulemaking.

1. Petition to change the National List

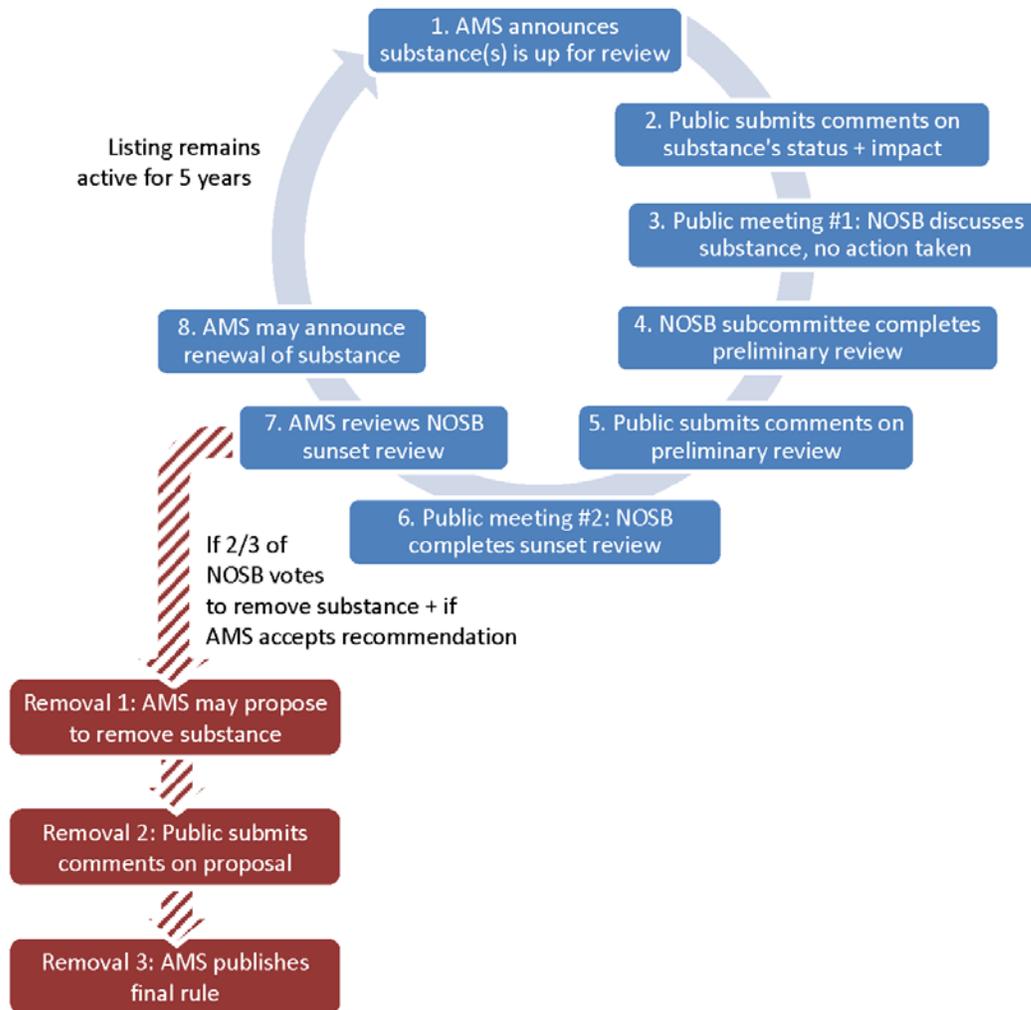
At any time, an individual or organization may submit a petition to add, remove, or change the allowance of a substance. The NOSB reviews the petition based upon the criteria specified in OFPA. The NOSB then makes a proposal to add, remove or change the allowance of a substance and request public comments. The NOSB reviews public comments and OFPA criteria. If two thirds of the NOSB members support the petition to add, remove, or change the allowance of the substance then a final recommendation is submitted to USDA. If the petition does not meet the threshold of a two-third vote of the Board, called a "decisive vote," then the process ends, and the proposed change to the List does not move forward. If the vote does pass, the USDA then reviews the NOSB's recommendation and may publish a proposed rule to change the National List with a request for public comments. View guidelines and process: www.ams.usda.gov/NOPFilingaPetition

2. Sunset review process

If a substance is added to the National List as a result of the rigorous review and rulemaking process described above, it is then subject to a review every five years to confirm that it continues to meet the criteria laid out in OFPA. For this review, called the "sunset process," the NOSB reviews the substance, public comments, and any new information concerning the substance. This could include, for example reviewing any new information about the substance's impact to human health or the environment, and any new proven, natural alternatives. As a result of this review, if the NOSB confirms that the substance no longer meets the OFPA criteria, the NOSB can make recommendations to remove the substance from the National List. As described above, changing the National List requires USDA to complete rulemaking, a process which includes another public comment opportunity.

On September 16, 2013, USDA clarified and enhanced this process to increase transparency, public engagement, and streamline its administration of the National List.

3. What is the clarified sunset process?



4. How is this different from the previous sunset process?

Method of notification

Previously, USDA published an “Advanced Notice of Proposed Rulemaking” in the Federal Register, which would (1) identify all substances scheduled to expire in a given year, and (2) request public comments.

The current process accomplishes the same two goals, but with a simpler Federal Register notice.

More opportunities for the public and the NOSB to consider substances against OFPA criteria

Previously, the NOSB typically evaluated a substance over the course of one public meeting.

The current process allows public comments to be submitted across two public meetings, allowing additional assessments, transparency, and public engagement.

No changes during sunset

From 2005-2010, the sunset review process only allowed a substance to be renewed or removed from the National List during the sunset process.

In 2011, the sunset review process was modified so that the NOSB could recommend additional clarifications or restrictions to the allowance of a substance during the sunset process. (For example, restricting the use of an approved substance to very specific applications or for very specific food categories.) USDA experienced a number of difficulties making changes to the allowance of a substance during the sunset process. These difficulties included inadequate public notification, and difficulties completing the rulemaking process prior to the sunset date.

The current process returns the process to the pre-2011 process and only allows a substance to be renewed or removed from the National List during the sunset process, based on the NOSB's review. The NOSB will evaluate changes to existing listings using the well-established petition process.

Streamlined rulemaking

Amending the USDA organic regulations (e.g. deleting a substance from the National List) requires rulemaking. Previously, USDA addressed all listings—removals and renewals—through rulemaking. On average, this regulatory process took 30 months from NOP's development of an ANPR through publication of a final rule on sunset substances. The new process will only involve rulemaking if two thirds of the NOSB votes to remove a substance from the National List. For all other substances, USDA would simply announce that the substance will remain on the National List without change for five years (announced via NOP Organic Insider and Federal Register).

Through the streamlined sunset process, NOP can complete the renewal of sunset substances through one action - a single Federal Register notice. This streamlined process is anticipated to shorten the timeline for this process from 30 months to approximately 6 months, which will allow NOP to spend the remaining time on other mission-critical rulemaking projects. Importantly, the new process also preserves transparency and the opportunity for public engagement.

NOSB Sunset Voting Procedure

Previously, the NOSB could vote on a motion to renew a substance on the National List during the sunset review process. If more than one-third of the NOSB members voted not to renew, the NOSB would recommend that the substance be removed from the National List. This voting process conflicted with the petition process, which requires a two-thirds majority to both add and remove a substance from the National List.

The current process provides for the NOSB to vote on a motion to remove a substance to align the sunset process with the petition process. If the vote to remove doesn't reach the required two-thirds majority, USDA may announce that the substance is renewed.

If NOSB members or the public would like to remove or further restrict the allowance of the substance, these actions can be proposed and evaluated through the petition process.

5. What are the benefits for organic farmers, processors, and other industry stakeholders?

Efficient use of USDA resources

Organic stakeholders have requested that USDA focus on several mission-critical standards, including clarifying the origin of livestock requirements and establishing practice standards for organic pet food, mushrooms, aquaculture, apiculture, and animal welfare. The streamlined sunset process will allow the National Organic Program to reinvest its limited resources into these important efforts.

Transparent sunset review process

AMS recognizes that removing a substance from the National List could negatively impact organic farmers or require organic processors to reformulate and/or relabel their products. This new sunset process provides two public comment opportunities before the NOSB's recommendation on each substance.

6. Does this process require a decisive vote to remove substances during sunset?

Yes. This change increases consistency and stability by requiring that two thirds of the NOSB support any change to the National List—whether during sunset or the petition process.

Before any substance is added to the National List, the NOSB reviews it and, after reviewing public comments, determines if the substance meets all criteria under OFPA. If it does, a rigorous rulemaking process is completed before it is added to the List. For example, if something is on the List as “allowed,” the NOSB previously concluded the substance was essential and didn't negatively impact human health or the environment. Then, USDA reviewed the NOSB's recommendation and did rulemaking—with another public comment period—to add the substance to the National List.

Once a substance is on the list, organic farmers and processors often invest significant time and money to update their organic system plans and adjust their product formulations to reflect the change. Given this in-depth process, and given the importance of the List to thousands of organic operators, there must be adequate information and careful consideration to justify removing a substance from the National List. To provide organic producers the stability needed to make long-range decisions, it must be as difficult to remove a previously approved substance from the List as it was to add it in the first place.

For example, new data showing environmental or health impacts or new proven, natural alternatives may support a removal of a substance on the National List. Given the rigor of the NOSB's initial review and public support during the rulemaking process, two thirds of the NOSB members must—based on this new information—agree to vote to remove the substance during the sunset process to ensure fairness in the evaluation process at both stages (addition and removal).

If two thirds of the Board agree with the new data and recommend the substance's removal based on that, USDA may then begin the rulemaking process to remove the substance from the National List. Without this decisive vote threshold, organic farmers and processors may conclude that the National List process doesn't support the long-term stability needed to make substantive



investments in organic production.

Any individual always has the opportunity to [submit a petition](#) to add, remove, or change the listing of a National List substance at any time. USDA supports the NOSB's continued efforts to streamline the petition process, especially to facilitate petitions to remove substances from the National List.

7. Why do two thirds of the NOSB have to vote to remove a substance?

OFPA states that "two-thirds of the votes cast at a meeting of the board at which a quorum is present shall be decisive of any motion" (7 U.S.C. Section 6518(i)). Therefore, a motion to remove a substance requires two thirds of the NOSB to vote "yes" and initiate rulemaking to remove the substance from the National List. Otherwise, the substance continues to be allowed for another 5 years.

8. Does this process meet the requirements in OFPA?

Yes. NOSB must review all National List substances every 5 years and can make recommendations to remove substances based on criteria specified in OFPA. These requirements are described in the sunset provision of OFPA (7 U.S.C. Section 6517):

- (e) SUNSET PROVISION. No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

The current process continues to meet the sunset provision, with NOSB reviewing substances every 5 years and USDA renewing substance listings based on the NOSB's review.

9. Does the current process apply to previous NOSB sunset recommendations?

No. The process applies on an ongoing basis, beginning with the fall 2013 NOSB meeting.

10. How do I provide comments or get involved?

Individual substances. The NOSB welcomes your written and in-person comments on sunset substances at two separate public meetings. Get notified of public comment opportunities by subscribing to the NOP Organic Insider at <http://bit.ly/NOPOrganicInsider>.



Sunset process. The public can provide feedback at any time: nopguidance@ams.usda.gov.

Petition process. Any individual or organization may submit a petition to add, remove, or amend the listing of a substance. Learn more at <http://www.ams.usda.gov/NOPFilingaPetition>.