

March 4, 2010

MEMORANDUM FOR THE CHAIRPERSON OF THE NATIONAL ORGANIC STANDARDS BOARD (NOSB)

FROM: Miles McEvoy
Deputy Administrator
National Organic Program (NOP)



SUBJECT: Sunset Review Under the National Organic Program (NOP)

The sunset provision (USC Section 6517) of the Organic Food Production Act (OFPA) requires the National Organic Standards Board (NOSB) to review all materials on the National List every 5 years.

(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 NOSB has the responsibility and authority to add substances to the National List of Allowed and Prohibited Substances. Both approved and prohibited substances that appear on the National List must be reviewed every 5 years by the NOSB to either renew the listing or recommend that the substances are removed from the National List. The NOP believes that organic production and handling could be disrupted if materials are not renewed in a timely manner. The NOP stated in the 2005 Advanced Notice of Proposed Rulemaking:

“Because these substances may be critical to the production and handling of a wide array of raw and processed organic agricultural products, their expiration could cause disruption of well-established and accepted organic production, handling, and processing systems.”

The NOSB has the responsibility to review materials in a timely manner. The NOSB is responsible for making a recommendation regarding whether the listing of an exempted material should be **renewed or removed** during the sunset review. In the absence of a recommendation, the NOP will initiate rulemaking to remove the substance from the National List. During the sunset review process the NOSB may:

- 1) Consider old Technical Advisory Panels (TAPs), Technical Reviews (TR), and new information submitted in public comment or that they obtain through their own expertise.
- 2) Request a new TAP or TR.
- 3) Recommend the removal of an exempted material from the National List due to a lack of public comment substantiating the importance of a continued listing.

Annotations

There is nothing in OFPA to prohibit the NOSB from making a recommendation to modify or amend an annotation during the sunset review process. However, the NOSB Policy Manual states in the sunset review procedures that amending or creating new annotations is not part of the sunset review process. The NOSB would need to amend their sunset review policy in order to recommend amending annotations during the sunset review process. No annotation can be changed without going through the rulemaking process.

Public comments

Public comments in support of renewing the substance or that request removal of the substance from the National List should provide clear reasons and documentation.

In order to support the **renewal** of a substance on the National List the comments should demonstrate that the material is:

- 1) Not harmful to human health or the environment;
- 2) Necessary because alternative materials or practices are not available;
- 3) Consistent and compatible with organic practices.

In order to support the **removal** of a substance on the National List the comments should demonstrate that the material is:

- 1) Harmful to human health or the environment;
- 2) No longer necessary because alternative materials or practices are available;
- 3) No longer consistent and compatible with organic practices.

In summary, it is the responsibility of:

- The public to provide the evidence regarding the importance of the renewal or removal of a material on the National List.
- The NOSB to thoughtfully review and weigh the evidence regarding the renewal or removal of a material on the National List.

Addendum: History of Sunset Review Interpretation in the National Organic Program (NOP)

The Organic Foods Production Act of 1990 (OFPA) Provides for Sunset Review under SEC. 2118 U.S.C. 6517 NATIONAL LIST. It clearly states that no exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed and renewed the exemptions or prohibitions. The NOSB must act to retain the exemptions or prohibitions; without action by the NOSB, those exemptions and prohibitions will expire.

(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.

December 2000 – The NOP Final Rule - The Preamble to NOP Final Rule published December 21, 2000 (65 FR 80637), states that the petition process is not described in the regulation to provide

maximum flexibility to change and clarify the petition process during the implementation of the NOP. Sunset review is not mentioned in the preamble or the regulation.

“(12) National List Petition Process as Part of the Final Rule. Commenters have requested that the National List Petition Process, approved by the NOSB at its June 2000 meeting (and published in the Federal Register on July 13, 2000), be included in the final rule. We do not agree with the commenters, and we have retained the National List Petition Process regulation language from the proposed rule. We have separated the specific petition process from the regulation to provide for maximum flexibility to change and clarify the petition process to accommodate new considerations developed during the NOP implementation. If this process were part of this final rule, updates to the petition process would require notice and comment rulemaking. Any changes in the National List that may be a result of the petition process, however, would require notice and comment rulemaking.”

June 2005 - Advanced Notice of Proposed Rulemaking (ANPR) for Sunset Review (sunset) – The sunset review procedures and reasoning of the first iteration of the national list of allowed and prohibited substances was described in the June 2005 ANPR on Sunset Review. The concern was raised in the first ANPR that the expiration of materials from the national list could disrupt the industry, and it was necessary for the public to weigh in well in advance regarding this process.

“Because these substances may be critical to the production and handling of a wide array of raw and processed organic agricultural products, their expiration could cause disruption of well-established and accepted organic production, handling, and processing systems. Therefore, the NOP is initiating the sunset review and renewal process now, in order to provide ample opportunity for you to make your views known.”

There are also some assumptions expressed in the ANPR that “that exemptions were originally recommended by the NOSB based on evidence available to the NOSB at the time of review which demonstrated that the substances were found to be:

- (1) Not harmful to human health or the environment,
- (2) Necessary because of the unavailability of wholly nonsynthetic alternatives [or practices], and
- (3) Consistent and compatible with organic practices.”

The ANPR indicates that public comments in support of or in opposition to the continued listing of material, should provide clear reasons and any relevant documentation, especially if the public comments are in opposition to a current listing. The commenter should demonstrate that the material is: (1) harmful to human health or the environment, (2) no longer necessary because alternative materials or practices are available; (3) no longer consistent and compatible with organic practices.

NOSB Policy & Procedures Manual (PPM) - The procedures and intent have been further described in the Policy & Procedures Manual (PPM) for the National Organic Standards Board (NOSB).

SUNSET REVIEW PROCESS

Background

Sunset is a regulatory process for determining the continued listing of a material already approved or prohibited on the National List for use in organic agriculture production and handling. It is not used to petition to add a new substance nor is it used to change an existing annotation. If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited.

Since sunset is defined as the reviewing of regulations to ensure the continued relevance and not the creation of new regulation, all substance must be renewed as listed. If there is a need to consider changing an annotation or moving a material from one list to another, this may be accomplished through the existing procedures for petition.

- 1) Decisions made through the Sunset review must be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.
- 2) An NOSB's committee's review and "...recommendation to the entire Board [is] for the material's removal or renewal.

The review is conducted based on "Force of Evidence" as presented by Board members, public comments, and scientific data from other sources (see Chart 3). This includes the original recommendation from the Board to list. The committee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR."