

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: **October 28, 2010**

Subject: **Sunset Review Process**

Chair: **Daniel G. Giacomini**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action
Guidance Statement
Other X

Statement of the Recommendation (Including Recount of Vote):

The proposed sunset policy seeks to clarify the authority and procedures of the NOSB in the sunset review of materials to include (i) a thorough review of the previous and updated scientific assessments and essentiality determination, and (ii) modifications or amendments to annotations, to the extent necessary to meet the statutory standards. Since the sunset review process is an assessment of National List substances to ensure their continued compliance with regulatory standards, the NOSB may determine that new restrictions in the form of annotations are necessary given changes in use patterns and scientific understanding. An annotation to expand the use of a substance does not fall within the purview of the sunset process and must only be considered through the petition process. The vote of the board was unanimous in favor of the motion.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The Organic Foods Production Act of 1990 (OFPA) authorized a National List of Allowed and Prohibited Substances (Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition 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 and the Secretary has reviewed such exemption or prohibition.”

The ability to add or change annotations (restrictions) on applicable National

List materials may be important to the Board's sunset decision, given changes in the use patterns of allowed materials and scientific understanding.

NOSB Vote:

Moved: Jay Feldman	Second: Katrina Heinze			
Yes: 14	No: 0	Abstain: 0	Absent: 0	Recusal: 0

**National Organic Standards Board
Policy Development Committee
Sunset Review Process – Policy Proposal**

October 28, 2010

Introduction

This document discusses the Policy Development Committee's proposed policy on Sunset Review, regarding the need for clarification and adjustment to the process of review by the NOSB. The proposed policy will be presented at the Fall 2010 Board meeting for a vote.

Background

The current process for Sunset Review is guided by statutory language in the Organic Foods Production Act, Sec. 2118(e),¹ the NOSB Policy and Procedures Manual (PPM),² and several Federal Register³ notices that describe the process.

While the statute does not define the process for validating an exemption or prohibition, it requires the NOSB to review "as provided in" Section 2118 of the act. In the strict sense of the law, this language would seem to require that the National List to be reevaluated to ensure that the list is in conformance with the standards as spelled out in Section 2118; "that the use of such substances – (i) would not be harmful to human health or the environment; (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and, (iii) is consistent with organic farming and handling." This reasoning would extend to the other provisions of this section as it applies to prohibitions and exemptions reviewed in the sunset process.

The Federal Register notices reinforce the notion that the sunset process is a complete review that assesses those materials on the list in accordance with the standards of Section 2118. As a result, the notices seek public input in three categories: "Category 1. Adverse impacts on humans or the environment?; Category 2. Is the substance essential for organic production?, and; Category 3. Is the substance compatible with organic production practices?"⁴

¹ **§2118 [7 U.S.C. 6517] NATIONAL LIST.** (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.

² NOSB: Policy and Procedures Manual (Revised May, 2006), pp.56-59.

³ 70FR35177 (2005), 72FR73668 (2008).

⁴ See Evaluation Criteria for Substances Added to the National List, 72FR73670 (Dec. 28, 2007)

The document entitled “Sunset and the National List of Allowed and Prohibited Substances” (NOSB Materials Committee Draft) includes in its section on background the following: “We consider the Congressionally-mandated sunset of exemptions and prohibitions contained in the National List to be a similar review and renewal process – that of the conditions that justified the exemption or prohibition in the first instance.”

The NOP has previously taken the position that the Board has narrow authority under the sunset process. As such, the PPM establishes limitations on the sunset process not found in the other documents. The PPM clearly states the following:

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 [sic] 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.

In a February 16, 2010 document entitled “Sunset Review Under the National Organic Program (NOP),” the program has provided an interpretation of OFPA that enables broader Board authority to modify and amend annotations, and a shifting of the burden of proof to the public to retain exempted materials. With respect to burden of proof, NOP states that, “During the sunset review process, the NOSB may: . . .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.” NOP cites that public comments should demonstrate that the renewal of removal of a substance on the National List meets the standards of Section 2118, OFPA. In addition, most importantly, NOP concurs with those who have interpreted a broad authority for the Board under the sunset process. NOP says,

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.

There is general agreement that the sunset review process must be informed a the outset by input from the public.

The proposed sunset policy seeks to clarify the authority and procedures of the NOSB in the sunset review of materials to include (i) a thorough review of the previous and updated scientific assessments and essentiality determination, and (ii) modifications or amendments to annotations, to the extent necessary to meet the statutory standards.

Relevant Areas in NOSB Policy and Procedures Manual and OFPA

Sunset Review Process (pp56-59, PPM), 7 U.S.C. 6517, NATIONAL LIST. (e) Sunset Provision. **§2118 [7 U.S.C. 6517] NATIONAL LIST.** (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.

Discussion

There is agreement that the sunset process should not be disruptive to the organic market. In this context, there are two key factors that drive the analysis under the sunset review process, the burden of materials review and the limitations on material use. First, should those in the organic market (users) be required to justify (or defend) current materials on the list (burden of proof)? Second, to what extent can the limitations on the use of the listed materials be changed to reflect current information (revised annotations)?

The statute embraces the idea that if the system of organic farming and handling is based on risk or hazard avoidance, then it should avoid reliance on synthetic inputs to the greatest extent possible. It is in this spirit that the law mandates a periodic sunset review that consistently updates the analysis that supports the listing. So, the review should not allow the use of a material just because it meets a prescribed health and environmental standard, as is the case with environmental or health laws. Rather, OFPA requires an assessment of essentiality. As a result, the evaluation criteria ask, “Is there another practice that would make the substance unnecessary,” and other questions of compatibility. This process should be constantly asking how or if the reliance on listed materials can be reduced. Those requiring the use of the inputs on the list should supply the NOSB with a specific justification for why continued use of the listed material is essential. At the same time, to the extent that the previous Board decisions do not have a complete record of review, clarity is needed on an appropriate process to fill the documented gaps in knowledge.

Once a material is defended or data is received that questions the listing, the process should allow for the amending of annotations. Since the statute subjects the sunset process to the same review standards as the original National List process, it follows that the same tools for restricting the use of those materials should be available to the Board. In an attempt to best protect against disruption in the organic market, annotations rather than complete prohibitions are called for in the face of available data.

In its Federal Register notices on sunset, the NOP stated at the outset, “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 sunset process is the statutory mandate to periodically question what is established and accepted and reaffirm or alter previous decisions as needed.

The sunset process to be optimally effective requires close collaboration with and resources of the NOP. Ultimately, the effectiveness of this process reflects on the credibility, integrity, and growth of the organic market. Organic agriculture represents a dramatic difference from conventionally produced food, both because of the organic systems plan and the strict limitation on allowable synthetic materials. The Committee notes that the statute holds that synthetics should not be easy to get on the National List, nor should they be easy to keep on the National List. To be truly responsive and to truly fulfill the mission of protecting consumers and ultimately farmers, the NOSB should be able to regulate the use of a material with annotations during the sunset process.

The recommendation addresses three areas of attention that are central to a comprehensive sunset review.

1. Thorough and comprehensive review.

Sunset review must be a rigorous and comprehensive review process that is supported by a technical review document and public input that reevaluates and updates previous findings to ensure that a decision to renew or restrict a currently listed material is fully informed and in compliance with the statutory standards.

2. Listed materials subject to sunset review.

Allowed materials under §205.601 and §205.603, §205.605, and §205.606 are sunsetted or removed from the National List unless the Board takes affirmative action to retain their uses. Similarly, prohibited uses under sections §205.602 and §205.604 will sunset unless the the Board takes action to relist.

3. Annotations.

The ability to add or change annotations (restrictions) on applicable National List materials may be important to the Board's sunset decision, given changes in the use patterns of allowed materials and scientific understanding. Sunset decisions by the Board are arrived at through a two-step consecutive process that separates the decision on annotations from the final sunset decision. Under this process, first the assigned committee and then the Board reviews the technical review document(s) and public input to determine whether the material continues to comply with the statutory standards. If the committee identifies the need for a use restriction or clarification, it may propose the annotation in the form of an amendment to a motion to renew. The committee and subsequently the Board will first take up the annotation amendment and then vote on the material's renewal. The public will have an opportunity to comment on the proposed final sunset decision. An annotation to expand the use of a substance cannot be done through the sunset review process.

Recommendation

The Policy Development Committee recommends that the section entitled "SUNSET REVIEW PROCESS" (NOSB Policy and Procedures Manual, pages 56-57) be amended as follows (text in italics indicates proposed new language, and text in parenthesis indicates language to be deleted).

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) *or new uses of a listed substance*. 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.)

Since the sunset review process is an assessment of National List substances to ensure their continued compliance with regulatory standards, the NOSB may determine that new restrictions in the form of annotations are necessary given changes in use patterns and scientific understanding. An annotation to expand the use of a substance does not fall within the purview of the sunset process and must only be considered through the petition process.

The Organic Foods Production Act of 1990 (OFPA) authorized a National List of Allowed and Prohibited Substances (Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition 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 and the Secretary has reviewed such exemption or prohibition.”

The National List that was implemented in October 21, 2002 contained over 200 substances. The first sunset review of listed materials was completed in October, 2007. 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.

Steps followed in Sunset Process

Not all listed materials reach sunset status at the same time, but the review process includes these steps:

1. A public notice is placed in the Federal register (Advance Notice of Proposed Rule Making or ANPR) of the pending sunset of the listed materials. The public has 60 days after the publication date to provide written comment (see Chart 1 below). The committee may request a third party technical review in anticipation of scientific evidence and claims likely to be made during public comment to the ANPR.
2. Public comments are collected and forward to the NOSB (see Chart 2).
3. The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material's removal, renewal,

or renewal with the addition of an annotation. 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.

4. The reviewing NOSB committee provides its recommendation to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
 - (i). Simple motion to remove, add, or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
 - (ii). Simple motion to renew the existing listing.
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the committee’s recommendation.
6. The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website.

The NOP will review public comment and draft the final rule. The final rule will proceed through interagency (i.e. OGC , OMB, and departmental) and congressional review, and upon receiving clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register. The final rule process is illustrated in Chart 4.

Committee Vote:

Motion: Jay Feldman	Second: Barry Flamm		
Yes: 5	No: 0	Abstain: 0	Absent: 0