

**National Organic Standards Board  
Policy Development Committee  
Sunset Review Process –Request for Public Comments  
March 1, 2010**

## **I. Introduction**

The PDC is soliciting comments from the NOP and public on the process that the NOSB will use in the future for sunset review. The input will be used to revise the directions in the NOSB Policy and Procedures Manual. This revision is intended to be presented as a recommendation for the Fall 2010 Board meeting.

## **II. Regulatory and Legal Background**

The current process for Sunset Review is guided by statutory language in the Organic Foods Production Act, Sec. 2118(e),<sup>1</sup> the NOSB Policy and Procedures Manual (PPM),<sup>2</sup> and several Federal Register<sup>3</sup> 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?”<sup>4</sup>

The document entitled “Sunset and the National List of Allowed and Prohibited Substances,” (NOSB Materials Committee Draft) finds in its section on background, “We consider the Congressionally-mandated sunset of exemptions and prohibitions contained in the National

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<sup>1</sup> **Sec. 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.

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

<sup>3</sup> 70FR35177 (2005), 72FR73668 (2008).

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

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.

More recently, NOP in a document entitled “Sunset Review Under the National Organic Program (NOP)” (February 16, 2010), 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 under for 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.

It should be stated that all the documents reviewing the sunset process state that public comments should inform the NOSB process of review at the front end.

The PDC is inclined to move as quickly as possible to establish through the sunset process procedures that (i) shift the burden of proof to those defending the renewal or removal of materials on the National List, and (ii) enable the Board to make recommendations to modify or amend annotations associated with listed materials. The committee is seeking public comments to inform its formulation of a revised PPM sunset policy for recommendation at the Fall 2010 NOSB meeting.

### **III. 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.

### **IV. Discussion**

There is agreement that the sunset process should not be disruptive to the organic market. In this context, there are two key questions that drive the analysis of the sunset process, including the burden of materials review and the limitations on their use that have been adopted to-date. 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, and a limited use of synthetics should reflect that scenario. 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, the NOSB should be able to regulate the use of a material with annotations during the sunset process.

## **Sunset Implementation Options**

### **1. Burden of proof on the industry to show that the material should remain on the National List of Allowed Substances.**

Background: This approach requires re-petitioning or some form of formal request from the industry (manufacturer, user). This approach conforms more closely to the traditional meaning of “sunset.” Items on the National List automatically go off the list in 5 years, unless they are petitioned to remain. Nonsynthetic substances prohibited for use in organic crop or livestock production remain prohibited unless petitioned to be allowed. In this sense, the sunset would not apply to 205.602 and 205.604. The NOSB would no longer be responsible for finding new information regarding a sunset material or determining if current information is sufficient. Instead, the NOSB will be provided with the necessary information, and can spend its time more wisely reviewing sunset materials, as OFPA intended. The burden of proof that a material should remain on the National List should not lie with the NOSB.

Pros:

- The approach is in compliance with the statutory framework.
- The burden for generating information to support re-listing is placed on those seeking to keep the material listed.
- “Allowed contaminants” are more likely to be removed.
- Increased consumer confidence in organic agriculture
- A systematic reduction in the number of synthetics allowed in organic production.
- NOSB time spent reviewing rather than looking up information
- The ability to deal with annotations during sunset will allow the NOSB & NOP to react more quickly and effectively to changing uses and developments in technology.

Cons:

- The review process is time-consuming.
- Those required to re-petition may object.

### **2. Burden of proof on the NOSB to show that the material should be delisted.**

#### **A. Policy and Procedures Manual Update: Sunset Procedures November 2008**

Background: This alternative should be considered by what it actually says and not necessarily by the Board’s present or past sunset actions. This approach does not mandate “evergreen.” The designated committee and finally the full Board have the ability and duty to recommend the removal or continued listing of a material. The PPM describes the review process as based on force of evidence presented by Board members, the original recommendation to list, scientific data from other sources, third party technical reviews, and public comment. This process when properly conducted should result in a fair determination

between keeping the material on or taking it off the N.L. However, the burden remains with the NOSB.

An important draw back of this approach is the lack of compiled records on the past deliberations of the committees and Board. It is especially difficult to ascertain the factual basis for the determinations for the original N.L. The PPM describes a general sunset process and steps, but does not describe the criteria to be used, records to be kept, or voting procedures, as is spelled out for the petition process.

Pros: This approach was recently adopted by the Board after public review and comment and has the agreement of the NOP. Following this approach should not be disruptive.

Cons: The burden is on the Board to determine the need and negatives of continued listing. The present policy does not allow a change or addition of an annotation. The current procedures fail to describe the detailed steps and criteria to be used in evaluating a sunset material. For example, review of a sunset material could follow the same review criteria used for petitioned materials.

## **B. “ Evergreen Approach”**

Background: This approach has a material staying on the National List, using the petition process to initiate removal of a substance. (see 7/28/2008 email from B. Robinson, NOP)

Pros: Requires less resources and time to implement, especially for industry. This approach ensures no disruption in the availability of materials that are currently available, including new formulations of those substances currently on the National List, and allows industry to continue using methods already approved.

Cons: Materials that have not been fully reviewed stay on the list indefinitely.. This approach is not in compliance with the statutory requirement for full review in accordance with evaluation criteria. There is less incentive for industry to develop alternate methods or seek organic substitutes. The National List will continue to lengthen, making the 5 year sunset review process increasingly onerous over time.

## **3. Sunset phase-out (hybrid) approach (combining the best of 1&2).**

Background: The sunset phase-out or hybrid approach enforces the notion that materials on the National List will phase-out unless they are defended by those who believe it is essential to organic production "because of the unavailability of wholly natural substitute products." This approach may eliminate the necessity for reviews of materials that are not defended and therefore presumed to be unnecessary. It enables the Board to continue to require the presentation of data in a re-listing petition that meets specific criteria and are uniformly presented to ensure consistency. This approach utilizes criteria that ensure consistent collection of data in key three categories required for decision making: adverse impacts on humans or the environment; essentiality for organic production, and; compatibility with organic production practices. The Board will continue to capture information from Board members, public comments, and scientific data from other sources to sustain or reverse prohibitions and exemptions. In recognizing that the statute requires a sunset review

equivalent to the initial National List review, the sunset phase-out approach allows the Board to adopt or amend annotations to ensure that use patterns meet the standards of the act.

Pros: To the extent that it is known that materials on the list are being phased-out unless defended, this approach creates market incentives to develop natural alternatives. The approach ensures public confidence that the most up-to-date analysis has been conducted in an effort to reduce and eliminate the use of synthetic materials to the maximum extent possible. The ability to utilize annotations in the sunset evaluation recognizes the complexity of use patterns and ensures the best restrictions with the least disruption. It will ensure the filling of gaps in information needed to make fully informed decisions on prohibitions and exemptions.

Cons: This approach may be more time consuming in reviewing petitions for continued listing, instead of simply assuming that unless a problem or question is raised, the list remains unchanged.

#### **V. Recommendation:**

The Policy Development Committee intends to make a recommendation on changes to the sunset review policy after the receipt of public comments on the issues outlined in this document.