



BEYOND PESTICIDES

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September, 2013

National Organic Standards Board
Fall 2013 Meeting
Louisville, KY

Re. CS, LS, HS: Sunset

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

These comments will address the sunset process, actions by the NOP, and sunset materials.

1. Sunset Process

a. History

7 USC §6517(e) of the Organic Foods Production Act (OFPA) states,
(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 Preamble to the National Organic Program (NOP) Final Rule, published December 21, 2000, states:

(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.

Sunset review is not mentioned in the preamble or regulation.

In June 2005, the Advanced Notice of Proposed Rulemaking for the first sunset says comments should present clear reasons, citing OFPA criteria, especially if the comments oppose relisting.

In a March 4, 2010 memorandum, the NOP stated, “The NOSB has the responsibility and authority to add substances to the National List...The NOSB is responsible for making a recommendation regarding whether the listing 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.”

On the topic of annotations during sunset, the memo said, “There is nothing in OFPA to prevent the NOSB from making a recommendation to modify or amend an annotation during the sunset 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 policy was amended in October 2010. The sunset review policy and procedures can be found in the Policy and Procedures Manual (PPM), April 2012 edition, starting on page 56.

The prescribed steps in the sunset review process as adopted by the NOSB are the following:

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 forwarded 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.

In addition, the PPM states, "As a norm, a motion for a petitioned material or sunset review should always be presented in the affirmative."

The policy addressing the process for voting on annotations in sunset was adopted at the October 2010 meeting of the NOSB in Madison, WI. The sunset policy, as adopted, contains a primary and backup motion. There was an extensive discussion leading up to and at the Madison meeting on the purpose of the backup motion, developed in collaboration with Deputy Administrator Miles McEvoy and NOP staff, and taking into account the regulatory time requirements. The written record on the backup motion from the Madison meeting demonstrates that it is intended to allow NOP the time necessary for a continuation of the current use of a substance if it is not possible to amend the annotation during the normal sunset rulemaking deadline.

On September 27, 2012, Mr. McEvoy sent a memo to the NOSB that confirmed the NOSB policy that was adopted by the Board at its October 2010 meeting:

The NOSB recommended amending annotations for three of the six substances (summarized in Table 1.) For each of these three substances, the NOSB also recommended to renew the existing listing. The NOSB recommendations to renew listings are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during the sunset rulemaking.

At the April 2013 NOSB meeting, the Deputy Administrator stated,

I just wanted to clarify our thinking around the annotations in sunset, kind of add a little bit to that. There have been a number of annotation changes that have been recommended during the sunset process and we have found that that has been incredibly difficult to meet the deadlines, the time frames of sunset, when we're making annotation changes because it complicates the rulemaking process.

So what we're requesting is to move forward with these reviews and making recommendations about the annotation changes, but to have any rulemaking that we conduct to make annotation changes be separate some sunset so that we don't run into these very difficult deadline problems, and that the annotation changes could be made through a separate rulemaking process.¹

b. May 3 Federal Register Notice

In its proposed rule of May 3, 2013 (78 FR 25879), the Agricultural Marketing Service (AMS) proposed adoption of the backup motion and rejected the NOSB's primary motion and reasoning for changing the annotation to carrageenan, and similarly proposed adoption of backup motions only for List 3 inerts and cellulose for reasons other than those allowed.

¹ April 2013 NOSB meeting transcript, page 1087, lines 3-21.

c. Issues Concerning the May 3 Federal Register Notice

i. The NOP proposal is illegal and a breach of trust with the NOSB and the public.

The Organic Foods Production Act §6517(d) states,

(d) Procedure for establishing National List

(1) In general

The National List established by the Secretary shall be based upon a proposed national list or proposed amendments to the National List developed by the National Organic Standards Board.

(2) No additions

The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.

The NOP proposal to adopt the “second recommendation” for carrageenan, cellulose, and List 3 inerts is a breach of trust with the NOSB and the public and violates the standards and process that have established a collaborative process between the NOSB and NOP, consistent with OFPA and the Federal Advisory Committee Act. It is a violation comparable to the proposal in USDA’s original draft regulations to allow sewage sludge, genetically engineered organisms, and radiation. In addition, in making this proposal, NOP ignores OFPA standards.

In these three cases, the NOSB proposed restrictive annotations to materials being considered under Sunset. NOSB policy calls for backup motions in these cases to allow the material to be continued to be used when the bureaucracy is unable to process a change in the listing in the timeframe before the material sunsets. There was an extensive discussion at the 2010 NOSB meeting of the purpose of the backup motion and Deputy Administrator Miles McEvoy, along with other NOP staff participated in that conversation. Although the purpose of the “second motion” did not, make its way into the final recommendation as printed, the record from the Madison meeting makes it very clear that the backup motion was not designed to give USDA the option of ignoring the NOSB action or choosing which motion to enforce --only to fill the time that it takes the action to be implemented.² In addition, there is nothing in the record from the Albuquerque NOSB meeting that indicates that the Board was giving the NOP the option of not enforcing the Board's decisions.³

Furthermore, in the NOP response to the NOSB meeting, NOP acknowledges the purpose of the second sunset vote: "For each of these three substances the NOSB also recommended to renew the existing listing. The NOSB recommendations to renew the listings are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during the sunset rulemaking."⁴

² Transcript of October 2010 NOSB meeting, October 26 pages 450-485 and October 28 pages 314-348.

³ Transcript of May 2012 NOSB meeting, pages zzz.

⁴ Miles McEvoy, September 27, 2012 “Memorandum to the National Organic Standards Board.”

However, instead of honoring the NOSB decision to phase-out certain uses (e.g. carrageenan in infant formula, and microcrystalline cellulose) and establish a rigorous timeframe for reviewing List 3 “inerts,” NOP made the following statement: "AMS is accepting NOSB's second recommendations rather than the NOSB's first recommendations to add or amend restrictive annotations for the following substances under Sunset review: EPA List 3 Inerts, carrageenan, and cellulose."

The reasons given by the Program for adopting the “second” (that is, backup) motions are not consistent with the Board policy as recognized by Mr. McEvoy in the memo cited above. They also raise concerns because in the Organic Program, the NOP/USDA should not rely on standards of safety that are contained under other statutes, such as the Federal Food, Drug and Cosmetic Act, as the basis for meeting the standards under OFPA. Those concerns will be addressed below.

Carrageenan

"Because the NOSB's sole justification for restricting the allowance of carrageenan was on the basis of food safety concerns, despite the fact that FDA regulations provide for its use as a safe food additive when used in accordance with 21 CFR 172.5, 21 CFR 172.620 and 21 CFR 172.626, AMS is renewing carrageenan as codified based on the NOSB's second recommendation."

Cellulose

"The NOSB. . . recommended changing the annotation to explicitly state which forms are allowed, thereby prohibiting the use of the microcrystalline form. Concurrent with Sunset Review policy, the NOSB also issued a second recommendation to renew the existing listing for cellulose. . . However, AMS needs more information from the industry to confirm that the microcrystalline form of cellulose is not currently in use in organic processed products. Therefore, through this proposed rule, AMS is proposing to address the NOSB's second recommendation to renew the exemption for cellulose as currently listed at section 205.605(b) and is seeking public comments on the NOSB's first recommendation to restrict its use in organic processed products. This approach would meet the timeframe required by the Sunset provision of OFPA and, based on the public comment, enable AMS to consider a restriction on its use for a future rulemaking."

List 3 Inerts

"AMS recognizes the recommendation's intent to address the complex challenges presented by the out-of-date listings in a timely manner. However, a rulemaking action to add an expiration date at this time may be problematic in the event that the timeline for inerts review takes longer than the projected four years; therefore, we are not proposing the addition of an expiration date to the exemption for EPA List 3 Inerts."

In none of the explanations quoted above, does the NOP cite the allowed reason for using the backup motion, which Mr. McEvoy cited in his September 27, 2012 memo. Because each backup motion effectively includes the assumed conditional, “if it is not possible to amend the annotation during rulemaking,” the NOP action would, if promulgated, be an exemption not

proposed by the NOSB, and therefore illegal violation. In addition, this action is a breach of the trust that must be present if the NOSB and NOP are to work cooperatively to carry out the Organic Program and promote organic production. It is also a breach of trust with the public, which relies on the collaborative efforts of the NOSB and NOP to deliver food meeting consumer expectations of the organic label. Ultimately, the failure of NOP to follow agreed upon and legal process requirements only serves to undermine the value of the USDA organic label.

ii. The NOP proposal improperly applies weaker standards in violation of OFPA.

In each of the cases, the NOP cites reasons for adopting the backup resolution that are not compatible with OFPA criteria. The statements on carrageenan provide a clear example.

Carrageenan

The NOP states, “The NOSB’s recommendation to prohibit the use of carrageenan in infant formula was based solely on food safety concerns despite carrageenan’s status as a safe food additive when used as specified by FDA regulations and despite FDA’s review of carrageenan in infant formula formulations under the FFDCFA. Therefore, AMS is not implementing this recommendation.”

The NOSB received extensive comments about the health effects of carrageenan and debated them at length. OFPA was created because other environmental and health standards were not seen as adequate for organic food. The fact that the NOSB cited food safety concerns does not mean that those concerns were limited to those addressed by other statutes, or that the Board saw the standards of those statutes as being adequate. The NOP does not have the option of disregarding the NOSB’s recommendation that was made following consideration of the evidence in compliance with NOP rules and oversight. NOP technical staff attended every meeting of the Handling Committee, attended the NOSB meeting, had access to the Technical Review, and never questioned the ability of the Board to make its determination, let alone disclose that it intended to overrule the board’s determination on the acceptability of a National List material. If the Program had evidence of harm caused by use allowed by the NOSB recommendation, it could restrict the use of carrageenan, but it cannot allow use not permitted by the NOSB recommendation.

Cellulose

The NOP says it needs more time to determine whether microcrystalline cellulose is currently in use in organic processed products. The concerns raised to the board related to the health and environmental impacts of microcrystalline cellulose, and its incompatibility with organic production. (See the transcript p. 303 and comments submitted by Beyond Pesticides and Cornucopia Institute.) OMRI’s opinion is that microcrystalline cellulose is not allowed under the current listing. Industry speakers supported the annotation prohibiting microcrystalline cellulose. Under the circumstances, the question that NOP needs to investigate seems irrelevant to the board decision. Again, the NOSB made a finding after a lengthy review process

in compliance with NOP rules and under NOP's oversight, and the NOP needs to respect the NOSB decision and the reasons behind it.

But perhaps the NOP is attempting, in this case, to use the backup vote for its intended purpose. If that is the case, it has not been done so correctly. Instead of proposing the backup motion and asking for comments on the NOSB proposal, the NOP should have proposed the NOSB proposal with the amended annotation, giving the justification for that proposal. Then the NOP should have said something like, "The NOSB also passed a backup recommendation renewing the existing listing. NOSB's backup recommendations to renew listings are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during sunset rulemaking. In order to meet its obligations to the Office of Management and Budget, NOP needs more information from the industry to confirm that the microcrystalline form of cellulose is not currently in use in organic processed products. Therefore, in the event that the NOP cannot obtain the needed information in time, the final rule will contain the backup renewal language, which will be replaced by the NOSB proposal when the required clearances are obtained."

List 3 "Inerts"

NOP says, "[A] rulemaking action to add an expiration date at this time may be problematic in the event that the timeline for inerts review takes longer than the projected four years; therefore, we are not proposing the addition of an expiration date to the exemption for EPA List 3 Inerts." In making this statement, the Program ignores some important facts: (1) There are only four materials formerly listed as List 3 "inerts," and (2) the NOP controls the subcommittee workplan. If the NOP wants those four materials to have high priority, all it needs to do is make them a high priority. In fact, the NOP should make the consideration of all "inerts" a priority. When this motion was passed, the NOP was asked to respond to the first motion contained in the recommendation, "Be it Resolved, It is the understanding of the NOSB that the NOP is committed to expediting the review of all inert ingredients as soon as possible and will support the NOSB in creating a plan for inerts review and accompanying workplan for the crops committee to complete this work." The NOP responded:⁵

Melissa Bailey: Okay, so I think what we, our understanding, if I could restate it back, is that the, the Program, agrees to support the, the Inerts Working Group process to move forward on inerts review. That may, depending on what kind of proposal the Working Group comes out with, the individual, any individual review of List 3 inerts may not actually occur first. It could occur later on in the process because of prioritizing inerts in however those maybe reviewed, according to the Working Group for List 4. So, that we certainly support and would provide the, the resources and support to get there. That is my understanding. ...

Miles McEvoy: Yeah. Just to clarify, we definitely can commit that, that this is important and we will move that forward. In context of all of the other things that we are moving

⁵ Transcript of May 2012 meeting, p. 180.

forward as well. So, is a lot on our work plan, a lot on your work plan, you know what is important, we will move it forward.

The proposed action is a reneging of that commitment to move ahead with the consideration of individual inert ingredients.

iii. Conclusion

The language in the proposed rule regarding use of the "second recommendation" betrays the process and undermines the NOP's credibility and by association organic integrity and people's trust in the process. Is NOP saying, and does it really believe, that it was the intent of the sunset policy and the NOSB decision making process to offer the NOP two choices (by identifying the "two recommendations"), rather than a mechanism to facilitate a process for implementing the NOSB's authority to authorize and deauthorize materials on the National List?

d. September 16, 2013 Announcement

On September 16, 2013, the NOP issued an announcement in the Federal Register (78 FR 56811) of a new sunset policy, to supersede and reverse policy adopted by the NOSB. Elements of the policy are:

- The NOSB will vote on sunset motions only if a motion opposing relisting is proposed by the subcommittee. If the subcommittee does not want to oppose relisting, then no motion will come from the subcommittee, and the NOSB will not vote.
- A motion opposing relisting will require a 2/3 majority to pass.
- The NOSB may not add annotations to a listing during sunset.
- The NOP will act to relist in the absence of any board action.

e. Issues Concerning September 16 Announcement

The September 16 announcement has a number of implications, some of which may not have been considered by the NOP:

- Because a subcommittee will be allowed to decide to relist a material in sunset –if the subcommittee does not produce a proposal opposing relisting, it is deciding to relist— subcommittee meetings must be open to the public under FACA.
- The announcement states that NOP will, on its own, without consideration of the material by the full board, relist a material. This is contrary to OFPA §6517(d)(2), which states, “The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.”
- The requirement that a 2/3 majority (a decisive vote under OFPA) is required to prevent relisting, rather than to allow relisting, during sunset is a reversal from the policy that has been followed since the original implementation of OFPA. It conflicts with the meaning of sunset, “a provision of a law that it will automatically be terminated after a

fixed period unless it is extended by law.”⁶ The NOP analogy equating sunset with a petition to remove a substance from the National List is therefore backwards, since a sunset requires action to keep it in effect. In both cases, re-listing at sunset and listing in response to a petition, a decisive or 2/3’s vote is required of the NOSB.

- The NOSB-passed policy allowing annotation during sunset was supported by the NOP when it was passed. The NOP has recently raised issues with annotation during sunset, mostly involving timing (which was set in collaboration with the NOP), but has not tried to work with the NOSB to resolve the difficulties.
- Annotations during sunset enable the NOSB to respond to specific concerns and fine tune listings without removing materials from the National List.

f. Recommendations to NOSB and NOP

i. To the NOSB

OFPA gives the NOSB responsibility for managing the National List. The NOP has usurped that authority. There will be litigation challenging the legality of NOP’s actions. Meanwhile, however, the NOSB should use every opportunity to assert its authority. This includes refusing to approve petitions because they may prove to be irrevocable and unmodifiable in the near future.

ii. To the NOP

The NOP’s actions clearly violate the standards and practices of OFPA. It is unfortunate for the organic community that a great deal of resources may need to be expended in establishing the illegality of NOP actions and correcting them. The NOP and USDA should consider the impact of their actions on the organic marketplace. Trusting USDA to regulate organic production has been an issue since a national organic label was envisioned. The credibility of the organic label depends on the existence and functioning of an independent board that makes decisions concerning the materials allowed to be used in organic production and advises the Secretary of Agriculture on all issues regarding the implementation of OFPA. The board was given clear statutory authority beyond a typical board organized under the Federal Advisory Committee Act (FACA). In fact, under FACA, the underlying principle of an appointing agency not influencing the advice of the advisory board is being violated by the NOP, which has stifled and undermined the board process of bringing concerns of the organic community to the Secretary. Without the NOSB performing its prescribed functions at its intended level, standards are called into question, public trust is violated, and there can be no national organic marketplace.

The NOP must step away from its mandated changes in sunset policy and allow the NOSB to follow its policies.

⁶ *Collins English Dictionary*, <http://www.collinsdictionary.com/dictionary/english/sunset-clause> We consulted several other legal and plain language dictionaries, and all gave similar definitions.

2. Sunset Materials

We address sunset materials in separate comments. However, we urge NOSB subcommittees to pass motions supporting removal from the National List because under the new policies, that is the only way that the full NOSB may perform its mandated duty to review all materials at sunset.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is written in a cursive style with a horizontal line at the end.

Terry Shistar, Ph.D.
Board of Directors