



BEYOND PESTICIDES

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October 3, 2014

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: 2016 Sunset: Egg White Lysozyme

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 agenda are submitted on behalf of 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, Beyond Pesticides 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.

Beyond Pesticides opposes the relisting of egg white lysozyme, based on the information available to us and the Handling Subcommittee (HS). We submit new information that has not been considered in past decisions, but which should have been requested. We note that the principal document available to the committee is a technical review (TR) of enzymes, which addresses egg white lysozyme, but not in the detail one would expect from a review of the material itself.

Our role as public interest commenters on the NOSB materials review process is to ensure that NOSB decisions are based on OFPA criteria, backed up with adequate documentation. We are disappointed that given the inadequacies of the documentation, the HS has not requested a supplemental TR to document environmental and health impacts as well as the need for the material. Nor has it requested any information from the industry or public. This lack of information and failure to request more information is especially disturbing because any information received after this meeting will be considered “untimely” according to the new NOP sunset policy.

1. Environmental and health impacts

Egg white lysozyme is isolated from the whites of hens’ eggs. It is most likely derived from nonorganic factory-farmed eggs from chickens kept in confinement, fed feed made from genetically engineered corn and soybeans treated with pesticides, and given antibiotics and arsenic to kill parasites. The health and environmental impacts of producing eggs in nonorganic factory farms are legion and include damage to streams from runoff from both egg producing facilities and the farms producing the feed, increasing antibiotic resistance, and arsenic contamination of land and water. Genetically engineered corn and soybeans are responsible for decreases in biodiversity. Seed treatments on nonorganic corn and soybeans lead to decimated populations of pollinators.

Yet none of these impacts are addressed in the technical review (TR) that will form the basis of the Handling Subcommittee's recommendation.

2. Essentiality

The TR is also lacking in documentation on essentiality. It does not address alternative materials or practices.

According to the TR, egg white lysozyme is a preservative. §205.600(b)(4) establishes as a criterion for listing of a material, "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law." Hence it is not essential.

3. Compatibility with organic and sustainable agriculture and handling.

Egg white lysozyme is used as a preservative, which is not consistent with organic handling practices. It relies on industrial egg production, which is not consistent with organic and sustainable agriculture practices.

4. Ancillary Substances

According to the recommendation passed by the NOSB in the spring of 2013, the board defined "ancillary substances" as "additives added during the manufacturing of a non-organic substance and **not** removed."

The NOSB went on to recommend the following policy:

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and nonsynthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

Ancillary substances in general product categories that are currently on §205.605 and §205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

The ancillary substances associated with this material have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material during sunset.

5. Conclusion

Although there is a lack of information on essentiality, it is clear that egg white lysozyme fails the criteria for no adverse impacts on health and environment, and compatibility with organic and sustainable agriculture and handling. Therefore, we urge the Board to not to relist egg white lysozyme.

A word about the process of the Handling Subcommittee. it is critical that the subcommittee and Board prepare a more robust review for public discussion at the first meeting on a Sunset 2016 material. Since the Fall 2014 meeting is scheduled to be the only public NOSB meeting during which the Handling Subcommittee and Board members can share its thinking and receive “timely” public input on the checklist and assessment of the material in accordance with OFPA criteria, the lack of prepared written analysis by the subcommittee for this meeting makes for an incomplete and truncated assessment process. Had this been done, the Subcommittee would have discovered that it needed a more complete TR to enable a complete assessment in accordance with OFPA criteria. Or, conversely, with a written prepared review, the subcommittee would have been able to share with the organic community its thinking on its decision on TR sufficiency and compliance with OFPA criteria.

Under the current process, information brought to the Board at the Spring 2015 meeting will be considered “untimely.” While we recognize that the Board has embarked on a new two-stage process, the first stage, or first meeting on sunset materials, must be a more robust review process if the Board’s assessment of exempt prohibited materials, like this one, on the National List is to be viewed by the public, including users and consumers, as credible. The process requires this, if there is to be continuing and building public trust in the assessment process and the organic food label. We have attached a checklist in which we provide the Board with answers to questions, based on the available technical review and other information, that are required to be considered as a part of a sunset review that is in compliance with the Organic Foods Production Act (OFPA) and the implementing regulations.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
Egg White Lysozyme**

[Date of Vote]

Summary of Proposed Action:

[Insert narrative describing vote, review of material, discussion, etc.]

Evaluation Criteria (see attached checklist for criteria in each category)

- | | Criteria Satisfied? |
|---|---|
| 1. Impact on Humans and Environment
N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 2. Essential & Availability Criteria | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| 3. Compatibility & Consistency
N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable
N/A
as Organic (only for §205.606) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |

Substance Fails Criteria Category: [] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify [substance] as [synthetic, nonsynthetic, agricultural]

Motion by:

Seconded by:

Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: Move to list [substance] on section **205.6xx** of the National List [with the annotation]

Motion by:

Seconded by:

Yes: # No: # Absent: # Abstain: # Recuse: #

Proposed Annotation (if any):

Basis for annotation: To meet criteria above Other regulatory criteria Citation

Notes:

Approved by Subcommittee Chair to Transmit to NOSB

Name, Subcommittee Chair

Date

NOSB Evaluation Criteria for Substances Added To the National List Handling

Category 1. Adverse impacts on humans or the environment? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	X			Non-organic egg production produces ammonia and arsenic-laden manure that when over-applied pollutes streams. It increases antibiotic resistance through non-therapeutic use of antibiotics. ¹
3. Are there any adverse impacts on biodiversity? (§205.200)	X			Non-organic chickens are fed mostly GMO corn and soybeans, grown in a system that decreases biodiversity. Runoff to streams can decrease biodiversity.
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]			X	
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			Arsenic fed to non-organic chickens persists in the environment.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	?			TR (lines 768-771): It is unlikely that the use of egg white lysozyme would cause harm to human health. The FDA has determined that there is insufficient current information to establish whether the ingestion of egg white lysozyme elicits an allergic response when consumed by sensitive individuals (FDA, 2000).
7. Is the substance, and any ancillary substances, GRAS when used according to FDA’s good manufacturing practices?	?			TR (lines 245-248): Egg white lysozyme was included as part of the tentative final rule (21 CFR 184) on direct food substances

¹ H. Xin ,R. S. Gates , A. R. Green , F. M. Mitloehner , P. A. Moore Jr. , and C. M. Wathes, 2011. Environmental impacts and sustainability of egg production systems. Poultry Science 90 :263–277. Emily Main, 2010. Organic Eggs: Worth the Cost? Yes! <http://www.rodalenews.com/organic-eggs>

[§205.600(b)(5)]			affirmed as GRAS in 1998. In 2000, a GRAS petition was submitted to FDA for egg white lysozyme. FDA follow up was identified; however, it is unknown if a conclusion was made on the GRAS status of egg white lysozyme (FDA, 2000).
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]	?		TR (lines 710-717): The Food Chemicals Codex, places the following limits on residues in enzymes used in food production and processing: Arsenic (As): not more than 3 ppm; Coliforms: not more than 30 per gram; Heavy metals as lead: not more than 0.004 percent; Lead (Pb): not more than 10 ppm; <i>Salmonella</i> spp: negative by test.

**NOSB Evaluation Criteria for Substances Added To the National List
Handling**

Category 2. Is the Substance Essential for Organic Production? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	?			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		TR lines 483-488: To manufacture egg white lysozyme, the lysozyme is extracted from fresh egg white by mixing in an inert polymer resin that binds to the lysozyme. The resin carrying the lysozyme is separated from the egg white. The lysozyme is then removed from the resin through the addition of salts. The lysozyme is then concentrated, purified, and dried. Although the resulting purified protein, on a dry, basis is almost 100 percent lysozyme, small amounts of other egg white proteins may be present (FDA, 2000).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		The creation is natural, but the extraction is not. (TR lines 483-488)
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			TR lines 565-567: Lysozymes are present in bacteria, fungi, plants, and animal tissues; high concentrations are found in milk, saliva, mucus, and tears. Egg white lysozyme is found specifically in the egg whites of domestic laying hens (FDA, 2000).
6. Is there an organic substitute? [§205.600(b)(1)]		X		TR lines 842-844: It is unclear whether egg white lysozyme is obtained commercially from eggs labeled as organic. However, due to the high cost of organic eggs, this process is unlikely since it would significantly increase the cost of production (USDA, 2009).
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		Egg white lysozyme is a preservative. (TR lines 634-635.) §205.600(b)(4) establishes as a criterion for listing of a material, "The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law." Hence it is not essential.
8. Is there a wholly natural substitute	?			The TR did not identify wholly natural

product? [§6517(c)(1)(A)(ii)]				substitutes.
9. Are there any alternative substances? [§6518(m)(6)]	?			The TR did not identify wholly natural substitutes.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	?			
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		Ancillary substances have not been reviewed. TR lines 483-485: To manufacture egg white lysozyme, the lysozyme is extracted from fresh egg white by mixing in an inert polymer resin that binds to the lysozyme. The resin carrying the lysozyme is separated from the egg white. The lysozyme is then removed from the resin through the addition of salts.

**NOSB Evaluation Criteria for Substances Added To the National List
Handling**

Category 3. Is the substance compatible with organic handling practices? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Preservative
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		Nonorganic egg production is not compatible with organic practices.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Nonorganic egg production is not compatible with sustainable agriculture.
4. Are the ancillary substances reviewed compatible with organic handling [?]	?			Ancillary substances have not been reviewed.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
6. Is the primary use as a preservative? [§205.600(b)(4)]	X			
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		

**NOSB Evaluation Criteria for Substances Added To the National List: Handling
 Category 4. Is the commercial supply of an organic agricultural substance fragile or
 potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance:****

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			Organic eggs are expensive. Not clear why <u>any</u> egg white lysozyme is needed.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?				
5. Does the industry information about unavailability include (but is not limited to) the following?:				
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Other issues which may present a challenge to a consistent supply?				