Formal Recommendation From: National Organic Standards Board (NOSB) To: the National Organic Program (NOP)

Date: November 18, 2016

Subject: Sunset Review Efficient Work Load Reorganization

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following: (mark with an X)

Rulemaking Action:

Guidance Statement:

Other: X

Statement of the Recommendation:

The board unanimously passed this proposal to impartially and efficiently redistribute material reviews across several years. This should lead to efficient and reasonable use of resources and board time.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

This recommendation is compliant with 7 U.S.C. 6517(e), requiring NOSB review of all National List substances "within 5 years" of adoption or review and renewal.

NOSB Vote:

Motion:

Motion to accept this proposal on Sunset Review Efficient Work Load Reorganization Motion by: Tom Chapman Seconded by: Jean Richardson Yes: 14 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion Passed

National Organic Standards Board Policy Development Subcommittee Proposal Sunset Review - Efficient Work Load Reorganization August 9, 2016

INTRODUCTION:

At present, the National Organic Standards Board (NOSB) conducts sunset reviews of materials according to the same schedule that the materials were added to the National List. Since the majority of materials on the National List were first included when the organic regulations were published in 2002, the number of materials reviewed each year by the NOSB is radically disproportionate. The peak of required reviews occurs in the 2/7 review cycle¹ (2022/2027) with 187 material listings (estimated), and corresponds to the date that most materials were added on the National List with the promulgation of the final rule in 2002. In contrast the 4/9 cycle (2019/2024) which has only 1 material set for review. The sum of materials for all years other than the 2/7 cycle is 31 (estimated). Reviewing 196 materials in one year and 27 materials over 4 years is an inefficient use of resources and board time.

BACKGROUND:

The National List identifies synthetic substances that may be used in organic production and nonsynthetic (natural) substances that may not be used. It also includes non-organic substances that may be used in or on processed organic products.

As provided for by the "sunset provision" of the Organic Foods Production Act, (OFPA) "No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition...within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition (7 U.S.C. 6517(e))."

The National Organic Standards Board (NOSB) reviews materials on the National List on a schedule that ensures each material is reviewed prior to the end of this five-year period. By giving each material its due consideration, the NOSB can offer recommendations to the Secretary (via USDA National Organic Program) as to whether materials should be removed from the National List. The review of each material can be significant, as it involves research (including completion of technical reports by a third party, upon NOSB's request), debate among the NOSB, public comment periods, and public meetings. Public comment includes considerable time and resources by a wide array of stakeholders, including thousands of pages of detailed written reports for every material, often prepared in a very short period of time. The NOP currently allows for approximately two years for each material to complete the sunset review cycle; i.e. materials that "sunset" in 2018 are being considered in 2016 by the NOSB.

¹ A Note of terminology used to talk about sunset review cycles. Sunset review cycles occur every five years in a predictable pattern. To facilitate brevity, in this document the review cycle will termed by the last year digits – so an item on the current 2018 sunset review would be part of the 3/8 sunset review cycle.

Terminology used	Current Sunset Cycle	Next Sunset Review year
0/5 cycle	2020 (reviewed in 2018)	2025 (reviewed in 2023)
1/6 cycle	2021 (reviewed in 2019)	2026 (reviewed in 2024)
2/7 cycle	2022 (reviewed in 2020)	2027 (reviewed in 2025)
3/8 cycle	2018 (reviewed in 2016)	2023 (reviewed in 2021)
4/9 cycle	2019 (reviewed in 2017)	2024 (reviewed in 2022)

The advantages of a more even distribution of this work include:

- More balanced attention for individual materials, regardless of the date it was added to the National List
- Predictable and balanced materials workload for NOSB
- Reduced strain on NOP in supporting the NOSB's reviews during peak years, including coordination and review of technical reports and rulemaking actions
- Greater efficiencies in time and staff resources at NOP
- More reasonable number of items for the public to comment on in the limited time provided under the regulations.

Advancing the review of materials is the only way to resolve the distribution problem. Without any change, the disproportionate number of materials that sunset in 2017 will again come up for review in 2022. Since the review workload is lighter in all other years of the five year cycle than 2017, the NOSB could achieve an even load most quickly by advancing review as soon as possible after the 2017 materials have completed the renewal process.

RELEVANT AREAS OF OFPA:

No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition...within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition (7 U.S.C. 6517(e))."

DISCUSSION:

The following will be observed to complete early review of 2/7 sunset items:

<u>3/8 cycle excluded</u> – Items will not be moved from the 2/7 to the 3/8 due to timing - items would need to be included in the 2016 review occurring concurrent to this discussion document. Additionally, items should be "reviewed" after the program has "renewed" items on the national list. This renewal step will take place no later than 3/17/2017 when the first 2017 material reached 5 years from its last renewal. Since reviews occur 2 years prior to the sunset review date, 2018 materials need to be reviewed prior to 3/17/2017.

<u>Only materials on the 2/7 cycle are subject to early review</u>- Only items from the 2/7 cycle are being evaluated for an early review. Items on other cycles will remain where they are even if an earlier review would led to a more efficient review. Since materials may be added or removed from the list in any year, a perfectly even work load in unrealistic.

<u>Materials voted for removal during 2016 and 2017 Sunset Review Excluded</u>. Items voted for removal under the 2016 and 2017 sunset review are excluded from this process and accounting of materials since these materials should be removed from the National List prior to implementation of these proposals. <u>Early Review</u> – A list of the materials to be reviewed early are listed below as part of attachment A. 2/7 cycle materials will be added to the work agenda in spring of each year prior to the review year by request of the PDS. All other materials will remain on their current timelines. The materials will then be referred to the respective subcommittees. Work will cease for any material whose sunset date is modified from the 2/7 sunset cycle due to rulemaking, until such rulemaking, the subcommittees shall continue to work against the earlier review date. An early review of materials will be based on current information and known alternatives that are commercially available in the year they will be reviewed, and not on alternatives that may be available in 2022. If not mentioned below, sunset review shall occur along with the normal sunset materials for that cycle.

<u>Material Removals</u> – Farmers, livestock operations and handling operations need to operate under a predictable business environment. These businesses are planning operations and researching new

alternative materials on a 5-year cycle. Items reviewed early under the reorganization plan should be allowed to sunset on their original timeline in 2022. To do this, the NOSB will modify their sunset review documents to specify a 2022 removal and work in collaboration with the program to delay rulemaking until 2022.

<u>Workload</u> – Workload should be roughly evenly distributed amongst the 4 years. Materials should be split by subcommittee to even the workload of each subcommittee. Since materials may be added or removed from the list in any year, a perfectly even work load in unrealistic.

<u>Impartial and Efficient</u> - The process of reorganization should be as impartial and non-political as possible while also being efficient. Similar items are grouped together (i.e. chlorine materials) as best as can be keeping in mind the restrictions above, and then sequentially distributed into each of the 4 years. Any grouping will be put in the year where the first item in the group is numbered. The PDS believes this proposal achieves efficiency by grouping like items for review, allowing for TRs to be coordinated across subcommittees and for reviews to take into account all facets of allowed usages across the organic industry. At the same time, the reorganization is impartial and blind to bias by using sequential reordering.

Vote in Subcommittee

Motion to accept this proposal on Sunset review efficient work load reorganization Motion by: Tom Chapman Seconded by: Jean Richardson Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Attachment A

NL Section	Substance	Current Sunset Date	Sub Committee	Next Projected	Proposed Sunset Review Year
205.601(a)	Calcium	6/27/2017	CS	2022	2019
205.601(a)	Chlorine dioxide	6/27/2017	CS	2022	2019
205.601(a)	Ethanol	6/27/2017	CS	2022	2020
205.601(a)	Hydrogen peroxide	6/27/2017	CS	2022	2021
205.601(a)	Isopropanol	6/27/2017	CS	2022	2020
205.601(a)	Sodium hypochlorite	6/27/2017	CS	2022	2019
205.601(b)	Herbicides, soap-based	6/27/2017	CS	2022	2019
205.601(b)	Newspaper or other recycled paper	6/27/2017	CS	2022	2020
205.601(b)	Plastic mulch and covers (petroleum- based other than polyvinylchlorid e (PVC))	6/27/2017	CS	2022	2020
205.601(c)	Newspaper or other recycled paper	6/27/2017	CS	2022	2020
205.601(d)	Soaps, ammonium	6/27/2017	CS	2022	2021
205.601(e)	Boric acid	6/27/2017	CS	2022	2019
205.601(e)	Elemental sulfur	6/27/2017	CS	2022	2020
205.601(e)	Lime sulfur	6/27/2017	CS	2022	2020
205.601(e)	Oils, horticultural	6/27/2017	CS	2022	2021
205.601(e)	Sticky traps/barriers	6/27/2017	CS	2022	2019
205.601(e)	Sucrose octanoate esters	6/27/2017	CS	2022	2020
205.601(f)	Pheromones	6/27/2017	CS	2022	2021
205.601(i)	Copper sulfate	6/27/2017	CS	2022	2019
205.601(i)	Coppers, fixed	6/27/2017	CS	2022	2019
205.601(i)	Elemental sulfur	6/27/2017	CS	2022	2020
205.601(i)	Hydrated lime	6/27/2017	CS	2022	2020
205.601(i)	Hydrogen peroxide	6/27/2017	CS	2022	2021

205.601(i)	Lime sulfur	6/27/2017	CS	2022	2020
205.601(i)	Oils, horticultural	6/27/2017	CS	2022	2021
205.601(i)	Potassium bicarbonate	6/27/2017	CS	2022	2021
205.601(j)	Elemental sulfur	6/27/2017	CS	2022	2020
205.601(j)	Humic acids	6/27/2017	CS	2022	2019
205.601(j)	Liquid fish products	6/27/2017	CS	2022	2020
205.601(j)	Magnesium sulfate	6/27/2017	CS	2022	2021
205.601(j)	Soluble boron products	6/27/2017	CS	2022	2019
205.601(j)	Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt	6/27/2017	CS	2022	2019
205.601(j)	Vitamin B1	6/27/2017	CS	2022	2019
205.601(j)	Vitamin C	6/27/2017	CS	2022	2019
205.601(j)	Vitamin E	6/27/2017	CS	2022	2019
205.601(k)	Ethylene	6/27/2017	CS	2022	2020
205.601(I)	Lignin sulfonate	6/27/2017	CS	2022	2021
205.601(o)	Microcrystalline cheesewax	3/15/2017	CS	2022	2020
205.602(a)	Ash from manure burning	6/27/2017	CS	2022	2021
205.602(d)	Lead salts	6/27/2017	CS	2022	2019
205.602(e)	Potassium chloride	6/27/2017	CS	2022	2020
205.602(f)	Sodium fluoaluminate	6/27/2017	CS	2022	2021
205.602(i)	Tobacco dust (nicotine sulfate)	6/27/2017	CS	2022	2019
205.603(a)	Aspirin	6/27/2017	LS	2022	2020
205.603(a)	Atropine	6/27/2017	LS	2022	2021
205.603(a)	Calcium hypochlorite	6/27/2017	LS	2022	2019
205.603(a)	Chlorhexidine	6/27/2017	LS	2022	2019
205.603(a)	Chlorine dioxide	6/27/2017	LS	2022	2019

205.603(a)	Electrolytes	6/27/2017	LS	2022	2020
205.603(a)	Ethanol	6/27/2017	LS	2022	2020
205.603(a)	Fenbendazole	5/16/2017	LS	2022	2021
205.603(a)	Glucose	6/27/2017	LS	2022	2019
205.603(a)	Glycerine	6/27/2017	LS	2022	2020
205.603(a)	Hydrogen peroxide	6/27/2017	LS	2022	2021
205.603(a)	Iodine	6/27/2017	LS	2022	2021
205.603(a)	Isopropanol	6/27/2017	LS	2022	2020
205.603(a)	Ivermectin	6/27/2017	LS	2022	2021
205.603(a)	Magnesium sulfate	6/27/2017	LS	2022	2021
205.603(a)	Moxidectin	5/16/2017	LS	2022	2021
205.603(a)	Oxytocin	6/27/2017	LS	2022	2019
205.603(a)	Peracetic acid	6/27/2017	LS	2022	2021
205.603(a)	Phosphoric acid	6/27/2017	LS	2022	2020
205.603(a)	Sodium hypochlorite	6/27/2017	LS	2022	2019
205.603(a)	Tolazoline	6/27/2017	LS	2022	2019
205.603(a)	Vaccines	6/27/2017	LS	2022	2020
205.603(a)	Xylazine	6/27/2017	LS	2022	2021
205.603(b)	Copper sulfate	6/27/2017	LS	2022	2019
205.603(b)	Hydrated lime	6/27/2017	LS	2022	2020
205.603(b)	Iodine	6/27/2017	LS	2022	2021
205.603(b)	Lidocaine	6/27/2017	LS	2022	2019
205.603(b)	Mineral oil	6/27/2017	LS	2022	2020
205.603(b)	Procaine	6/27/2017	LS	2022	2019
205.603(b)	Sucrose octanoate esters	6/27/2017	LS	2022	2020
205.603(d)	Methionine	10/2/2017	LS	2022	2021
205.603(d)	Trace minerals	6/27/2017	LS	2022	2021
205.603(d)	Vitamins	6/27/2017	LS	2022	2021
205.605(a)	Alginic acid	6/27/2017	HS	2022	2021
205.605(a)	Attapulgite	8/3/2017	HS	2022	2019
205.605(a)	Bentonite	6/27/2017	HS	2022	2019
205.605(a)	Calcium carbonate	6/27/2017	HS	2022	2020
205.605(a)	Calcium chloride	6/27/2017	HS	2022	2021
205.605(a)	Citric acid	6/27/2017	HS	2022	2021
205.605(a)	Dairy cultures	6/27/2017	HS	2022	2021
205.605(a)	Diatomaceous earth	6/27/2017	HS	2022	2019
205.605(a)	Enzymes	6/27/2017	HS	2022	2021
205.605(a)	Flavors	6/27/2017	HS	2022	2020
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205.605(a)	Lactic acid	6/27/2017	HS	2022	2021
205.605(a)	Magnesium sulfate	6/27/2017	HS	2022	2021
205.605(a)	Nitrogen	6/27/2017	HS	2022	2019
205.605(a)	Oxygen	6/27/2017	HS	2022	2020
205.605(a)	Perlite	6/27/2017	HS	2022	2021
205.605(a)	Potassium chloride	6/27/2017	HS	2022	2020
205.605(a)	Potassium iodide	6/27/2017	HS	2022	2021
205.605(a)	Sodium carbonate	6/27/2017	HS	2022	2019
205.605(a)	Yeast	10/21/2017	HS	2022	2021
205.605(b)	Acidified sodium chlorite	3/15/2017	HS	2022	2019
205.605(b)	Alginates	6/27/2017	HS	2022	2020
205.605(b)	Ascorbic acid	6/27/2017	HS	2022	2021
205.605(b)	Calcium citrate	6/27/2017	HS	2022	2021
205.605(b)	Calcium hydroxide	6/27/2017	HS	2022	2020
205.605(b)	Calcium hypochlorite	6/27/2017	HS	2022	2019
205.605(b)	Carbon dioxide	6/27/2017	HS	2022	2019
205.605(b)	Chlorine dioxide	6/27/2017	HS	2022	2019
205.605(b)	Diglycerides	6/27/2017	HS	2022	2020
205.605(b)	Ethylene	6/27/2017	HS	2022	2020
205.605(b)	Ferrous sulfate	6/27/2017	HS	2022	2021
205.605(b)	Hydrogen peroxide	6/27/2017	HS	2022	2021
205.605(b)	Magnesium chloride	6/27/2017	HS	2022	2019
205.605(b)	Magnesium stearate	6/27/2017	HS	2022	2020
205.605(b)	Monoglycerides	6/27/2017	HS	2022	2020
205.605(b)	Nutrient vitamins and minerals	10/21/2017	HS	2022	2021
205.605(b)	Phosphoric acid	6/27/2017	HS	2022	2020
205.605(b)	Potassium acid tartrate	6/27/2017	HS	2022	2019
205.605(b)	Potassium carbonate	6/27/2017	HS	2022	2020
205.605(b)	Potassium citrate	6/27/2017	HS	2022	2021
205.605(b)	Potassium phosphate	6/27/2017	HS	2022	2021

205.605(b)	Sodium citrate	6/27/2017	HS	2022	2021
205.605(b)	Sodium hypochlorite	6/27/2017	HS	2022	2019
205.605(b)	Sodium phosphates	6/27/2017	HS	2022	2019
205.605(b)	Sulfur dioxide	6/27/2017	HS	2022	2020
205.605(b)	Tocopherols	6/27/2017	HS	2022	2021
205.605(b)	Xanthan gum	6/27/2017	HS	2022	2020
205.606	Arabic gum	6/27/2017	HS	2022	2020
205.606	Carob bean gum	6/27/2017	HS	2022	2020
205.606	Casings	6/27/2017	HS	2022	2019
205.606	Celery powder	6/27/2017	HS	2022	2021
205.606	Fish oil	6/27/2017	HS	2022	2021
205.606	Fructooligosacc harides	6/27/2017	HS	2022	2020
205.606	Gelatin	6/27/2017	HS	2022	2021
205.606	Guar gum	6/27/2017	HS	2022	2020
205.606	Konjac flour	6/27/2017	HS	2022	2019
205.606	Lecithin—de- oiled	3/15/2017	HS	2022	2020
205.606	Locust bean gum	6/27/2017	HS	2022	2020
205.606	Orange pulp, dried	3/15/2017	HS	2022	2021
205.606	Pectin (non- amidated forms only)	6/27/2017	HS	2022	2019
205.606	Seaweed, Pacific kombu	3/15/2017	HS	2022	2021
205.606	Wakame seaweed (Undaria pinnatifida)	6/27/2017	HS	2022	2021