



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

September 18, 2014

National Organic Standards Board
Fall 2014 Meeting
Louisville, KY

Re. CS, LS: “Inert” ingredients

These comments 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.

Once again, the NOSB agenda contains only an “update” on “inert ingredients.” The NOSB has unanimously agreed upon a plan of action, yet we see no action. Therefore, we request the following implementation measures be taken.

Implement the change in the listing as recommended unanimously by the National Organic Standards Board in October 2012:

Replace the language at sections 205.601(m) and 205.603(e) with:

As synthetic other (“inert”) ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
- (ii) Reserved (for list of approved other (“inert”) ingredients)

Under (ii) above, list all inerts known to be used in organic production, as determined by the Inerts Working Group, each annotated with an expiration date between June 27, 2018 and June 27, 2022, as indicated in Table 1, with the exception of the following, which will have an expiration date of June 27, 2017:

Alkylphenol ethoxylates (individual chemicals to be listed)

EDTA and its salts (individual chemicals to be listed)

“Inerts” formerly on List 3:¹

Butylated hydroxytoluene (BHT) (CAS# 128-37-0) preservative/antioxidant

2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6) UV absorber

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (CAS #3896-11-5)

We submit the following information concerning the substances for which we request a 2017 expiration date:

Alkylphenol ethoxylates:

(a) chemical interactions with other substances, especially substances used in organic production;

Alkylphenol ethoxylates (APEs) can react with chlorine to form chlorinated alkylphenols.² Bacteria help break down APEs to alkylphenols (APs) and other more toxic chemicals. In aerobic systems, more carboxylic acid compounds are produced.³

(b) toxicity and environmental persistence;

Breakdown products, especially APs are much more toxic than APEs;^{4,5} and are also estrogenic.^{11,6} EPA rates persistence medium to high; degradation products persistent and toxic.⁷

(c) environmental impacts from its use or manufacture;

Bacteria help break down APEs to alkylphenols (APs) and other more toxic chemicals. In aerobic systems, more carboxylic acid compounds are produced.⁸ The lowest concentration of APE found to inhibit growth of young terrestrial and aquatic plants or trees was 10 ug/L...APE are rapidly taken up by plants and metabolized to polar metabolites. Concentrations of 20-500 mg/L

¹ NOSB, Crops Committee. 2012 Sunset Recommendation, List 3 Inert Ingredients in Passive Pheromone Dispensers. <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5097802&acct=nosb>

² A. Michael Warhurst, 1995. An Environmental Assessment of Alkylphenol Ethoxylates and Alkylphenols, Friends of the Earth, UK.

³ P. Whitehouse, 2002. Environmental Impacts of Alkylphenol Ethoxylates and Carboxylates. Part 1: Proposals for the Development of Environmental Quality Standards. R&D Technical Report P2-115/TR3. Environment Agency, Rio House, Waterside Drive, Aztec West, Almondsbury, Bristol BS32 4UD.

⁴ EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

⁵ Andrea Lani, 2010. Basis Statement for Chapter 883, Designation of the Chemical Class Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical and Safer Chemicals Program Support Document for the Designation as a Priority Chemical of Nonylphenol and Nonylphenol Ethoxylates, Bureau of Remediation and Waste Management, Maine Department of Environmental Protection.

⁶ Mark R. Servos, 1999. Review of the Aquatic Toxicity, Estrogenic Responses and Bioaccumulation of Alkylphenols and Alkylphenol Polyethoxylates, Water Qual. Res. I. Canada, Volume 34, No. 1, 123-177. A support document for Environment Canada's environmental assessment under the Canadian Environmental Protection Act.

⁷ EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

⁸ P. Whitehouse, 2002. Environmental Impacts of Alkylphenol Ethoxylates and Carboxylates. Part 1: Proposals for the Development of Environmental Quality Standards. R&D Technical Report P2-115/TR3. Environment Agency, Rio House, Waterside Drive, Aztec West, Almondsbury, Bristol BS32 4UD.

inhibited or restricted growth of soil bacteria.⁹ Breakdown products, especially APs, are much more toxic than APEs;^{10,11} also estrogenic.¹¹

(d) effects on human health; and,

APs and APEs act as xenoestrogens in human cells.¹²

(e) effects on soil organisms, crops, or livestock.

Because they improve wetting, penetration, absorption, and water solubility characteristics, surfactants are used in formulations of foliar-applied agrochemicals as stabilizing, emulsifying, and dispersing agents. . .The lowest concentration of APE found to inhibit growth of young terrestrial and aquatic plants or trees was 10 ug/L. . .APE are rapidly taken up by plants and metabolized to polar metabolites. Concentrations of 20-500 mg/L inhibited or restricted growth of soil bacteria.¹³

EDTA and its salts:

Chelating agents interact with a wide range of metals and can create imbalances and/or deficiencies.¹⁴

(b) toxicity and environmental persistence;

The “toxic” effect of EDTA and its salts is related to its ability to chelate metals. “The persistence of EDTA chelates is greatly dependent on the chelated metal. EDTA is a strong organic acid (approximately 1000 times stronger than acetic acid), and does not appear to occur naturally. It has a high affinity for alkaline-earth ions (for example, calcium and magnesium) and heavy-metal ions (for example, lead and mercury). This affinity generally results in the formation of highly stable and soluble hexadentate chelate complexes.”¹⁵

⁹ Sylvia S. Talmage, 1994. Environmental And Human Safety Of Major Surfactants: Alcohol Ethoxylates and Alkylphenol Ethoxylates, A report to The Soap and Detergent Association, Lewis Publishers: Boca Raton, Ann Arbor, London, Tokyo. Pp. 288-289.

¹⁰ EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates

¹¹ Andrea Lani, 2010. Basis Statement for Chapter 883, Designation of the Chemical Class Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical and Safer Chemicals Program Support Document for the Designation as a Priority Chemical of Nonylphenol and Nonylphenol Ethoxylates, Bureau of Remediation and Waste Management, Maine Department of Environmental Protection.

¹² Mark R. Servos, 1999. Review of the Aquatic Toxicity, Estrogenic Responses and Bioaccumulation of Alkylphenols and Alkylphenol Polyethoxylates, Water Qual. Res. I. Canada, Volume 34, No. 1, 123-177. A support document for Environment Canada’s environmental assessment under the Canadian Environmental Protection Act.

¹³ Sylvia S. Talmage, 1994. Environmental And Human Safety Of Major Surfactants: Alcohol Ethoxylates and Alkylphenol Ethoxylates, A report to The Soap and Detergent Association, Lewis Publishers: Boca Raton, Ann Arbor, London, Tokyo. Pp. 288-289.

¹⁴ Technical Evaluation Report Compiled by the Technical Services Branch for the USDA National Organic Program. February 26, 2010. (S, S)-Ethylenediaminedisuccinic Acid (free acid), lines 627-632.

¹⁵ EPA Office of Prevention, Pesticides, and Toxic Substances, 2004. Memo from Betty Shackelford, Registration Division, to Peter Caulkins, Special Review and Registration Division concerning Lower Toxicity Pesticide Chemical Focus Group Decision Document for ethylenediaminetetraacetic acid (EDTA) and its salts.

<http://www.epa.gov/opprd001/inerts/edta.pdf>

(c) environmental impacts from its use or manufacture;

“When released to soil, EDTA is mobile and expected to complex trace metals and alkaline earth metals, thereby causing an increase in the total solubility of the metals. EDTA may eventually predominate as the Fe(III) chelate in acidic soils and as the Ca chelate in alkaline soils. EDTA and its chelates are expected to leach readily through soil. When released to water, EDTA is also expected to form soluble complexes with trace metals and alkaline earth metals. It would not be expected to sorb appreciably to sediments or suspended solids in water, and is known not to be retained or altered chemically in typical water treatment facilities.”¹⁶

(d) effects on human health; and,

“[T]he toxic effects of EDTA are considered to be related to metal deficiencies, especially a deficiency of zinc.”¹⁷

“EDTA has been demonstrated to affect inhibition of DNA synthesis in primary cultures of mammalian cells, which may be due to impairment of enzymes involved in DNA replication (Heindorff et al., 1983). EDTA has also been demonstrated to enhance mutagen-induced aberration frequencies in *Drosophila melanogaster*, *Chlamydomonas reinhardi*, *Neurospora crassa* and *Zea mays* by interfering with the DNA repair process that takes place after exposure to mutagens (Heindorff et al., 1983).”¹⁸

“Mutagenicity studies such as mouse lymphoma were negative for EDTA and its salts except for a few positive tests when administered with sterile distilled water. Genotoxicity studies for EDTA and its salts were mixed positive and negative results, depending on assay type and cell type (CCRIS 2003 and Genetox 2003).”¹⁹

(e) effects on soil organisms, crops, or livestock.

EDTA and its salts can mobilize heavy metals in contaminated soils, allowing them to be taken up by plants.²⁰

¹⁶ EPA Office of Prevention, Pesticides, and Toxic Substances, 2004. Memo from Betty Shackelford, Registration Division, to Peter Caulkins, Special Review and Registration Division concerning Lower Toxicity Pesticide Chemical Focus Group Decision Document for ethylenediaminetetraacetic acid (EDTA) and its salts.

<http://www.epa.gov/opprd001/inerts/edta.pdf>

¹⁷ EPA Office of Prevention, Pesticides, and Toxic Substances, 2004. Memo from Betty Shackelford, Registration Division, to Peter Caulkins, Special Review and Registration Division concerning Lower Toxicity Pesticide Chemical Focus Group Decision Document for ethylenediaminetetraacetic acid (EDTA) and its salts.

<http://www.epa.gov/opprd001/inerts/edta.pdf>

¹⁸ EPA Office of Prevention, Pesticides, and Toxic Substances, 2004. Memo from Betty Shackelford, Registration Division, to Peter Caulkins, Special Review and Registration Division concerning Lower Toxicity Pesticide Chemical Focus Group Decision Document for ethylenediaminetetraacetic acid (EDTA) and its salts.

<http://www.epa.gov/opprd001/inerts/edta.pdf>

¹⁹ EPA Office of Prevention, Pesticides, and Toxic Substances, 2004. Memo from Betty Shackelford, Registration Division, to Peter Caulkins, Special Review and Registration Division concerning Lower Toxicity Pesticide Chemical Focus Group Decision Document for ethylenediaminetetraacetic acid (EDTA) and its salts.

<http://www.epa.gov/opprd001/inerts/edta.pdf>

²⁰ T. Thayalakumaran, B.H. Robinson, I. Vogeler, D.R. Scotter, B.E. Clothier, and H.J. Percival, 2003. Plant uptake and leaching of copper during EDTA-enhanced phytoremediation of repacked and undisturbed soil. *Plant and Soil* 254:

“Inerts” formerly on List 3: Butylated hydroxytoluene (BHT) (CAS# 128-37-0) preservative/antioxidant, 2-Hydroxy-4-n-octyloxybenzophenone (OHOBP, methanone) (CAS # 1843-05-6) UV absorber, 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (Sumisorb, bumetrizole) (CAS #3896-11-5). (a) chemical interactions with other substances, especially substances used in organic production;

The TAP review of BHT (lines 141-145) said there is little potential for interaction because it is encased in plastic. All reviewers said application devices must be removed at end of season. We have not found information about chemical interactions with methanone. The TAP review of Sumisorb (p. 4) said there is little potential for chemical interaction because the material is encased in plastic and is not volatile at field temperatures, although reviewer 1 said (p. 8), “Millar et al. (1992) found that small amounts of UV stabilizers sometimes accumulate on the surface of field-aged pheromone dispensers.”

(b) toxicity and environmental persistence;

BHT: According to the TAP review of BHT (lines 348-351), “The dispenser products have undergone expedited review by the Environmental Protection Agency and therefore the mammalian toxicity, ecological effects, and environmental fate and groundwater data has for the most part been waived (40 CFR 180.1001(e) (7/1/91)). Therefore, little environmental information is available on the effects of BHT (used as an inert) to terrestrial invertebrates or aquatic invertebrates and vertebrates.” The TAP review (lines 155-158) says, “At least 10 non-volatile polar degradation products are formed by progressive oxidation. Major metabolites are formed by oxidation of the methyl group, forming a BHT alcohol, a BHT acid, and a BHT aldehyde. These are further metabolized at a slower rate completely to CO₂ and water. BHT and its degradation products are biodegradable and do not persistent in the soil environment (Mikami et al., 1979a).” An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.²¹

2-Hydroxy-4-n-octyloxybenzophenone: Ciba submitted 3 adverse effects reports under TSCA for sensitization. (See attachments.) It is not readily biodegradable.²²

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole: From the Sumisorb TAP, p. 4: It is “toxic in aquatic environments... The mortality rate is higher after 96 hours that after 48 hours, suggesting a cumulative toxic effect on fish.” P. 12: “Although this compound is reported to be quite stable, the electron-withdrawing properties (nitrogens and chlorine) of the bicyclic ring lead

415–423. Technical Evaluation Report Compiled by the Technical Services Branch for the USDA National Organic Program. February 26, 2010. (S, S)-Ethylenediaminedisuccinic Acid (free acid), lines 528-529.

²¹ EPA, Office of Prevention, Pesticides, and Toxic Substances. Memo from Pauline Wagner, Inert Ingredients Branch, to Lois Rossi, Registration Division. Inert Reassessment of Butylated Hydroxyanisole (250 13- 16-5) and Butylated Hydroxytoluene (128-37-0). September 29, 2005.

²² BASF MSDS.

http://worldaccount.basf.com/wa/NAFTA/Catalog/FunctionalPolymers/doc4/BASF/PRD/30472796/.pdf?title=&asset_type=msds/pdf&language=EN&validArea=US&urn=urn:documentum:ProductBase_EU:09007af880153312.pdf

one to postulate eventual cleavage of the bond connecting the monocyclic to the bicyclic ring. The chemistry of the conceivable chlorinated bicyclic products possibly produced upon incorporation into soil cannot be assumed to be innocuous.” P. 4: “[I]t appears that no information is available on the fate of Sumisorb specifically.” P. 5: “Benzotriazoles tend to persist in the environment for a very long time due to their UV stability and resistance to oxidation, and persistence in the soil ecosystem is likely.”

(c) environmental impacts from its use or manufacture;

BHT: An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.²³ Another review cites classifications as hazardous.²⁴

2-Hydroxy-4-n-octyloxybenzophenone: It is a solid up to 47-49°C, fairly insoluble in water, with a high octanol/water coefficient, and EPA expects its mobility to be low. EPA also states that its toxicity to mammals, aquatic animals, and plants is low.²⁵

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole: From the TAP, p. 5: “When used appropriately, Isomate dispensers have a low potential for environmental contamination.... Overapplication combined with a practice that destroys the integrity of the dispensers would exacerbate the effects of environmental contamination... According to inspectors from three prominent Western organic certifiers, Isomate dispensers tend to be left on orchard trees indefinitely, or they are shed during pruning. In the latter case, growers commonly incorporate exhausted dispensers into the soil with tree prunings. Occasionally, the prunings are burned (along with the dispensers) for disease control. This practice, while limited, presents a localized risk of exposure to toxins since the substance may generate CO, CO₂, NO_x, or HCl when heated to burning (MSDS).”

(d) effects on human health; and,

BHT: “Butylated Hydroxytoluene (BHT) is classified as irritating to the eyes, respiratory system, and skin under European classification. Allergic contact dermatitis and contact urticaria are associated with exposure to BHT (HAZ-MAP). It is currently listed as “unclassifiable” in regard to its carcinogenicity in humans (due to limited human test data), however a variety of in vitro and animal studies have shown it to have carcinogenic, tumorigenic, mutagenic, and teratogenic effects in animals as well as in human cells (Sigma-Aldrich MSDS). Studies have also confirmed

²³ EPA, Office of Prevention, Pesticides, and Toxic Substances. Memo from Pauline Wagner, Inert Ingredients Branch, to Lois Rossi, Registration Division. Inert Reassessment of Butylated Hydroxyanisole (250 13- 16-5) and Butylated Hydroxytoluene (128-37-0). September 29, 2005.

²⁴ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>

²⁵ EPA, Office of Prevention, Pesticides, and Toxic Substances. Memo from Pauline Wagner, Inert Ingredients Branch, to Lois Rossi, Registration Division. Reassessment of One Exemption from the Requirement of a Tolerance for 2-Hydroxy-4-n-Octoxybenzophenone (OH-OBP, CAS No. 1 843-05-6). July 10, 2006.

BHT to have estrogenic activity (Miller et al. 2001; Wada et al. 2004) and MSDS sheets state that chronic exposure to BHT may cause reproductive and fetal effects (Acros MSDS)."²⁶

2-Hydroxy-4-n-octyloxybenzophenone: "[R]elated compounds in the benzophenone family have been shown to form estrogenic photoproducts, upon exposure to UV or sunlight (Hayashi et al. 2006)."²⁷

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole: TAP P. 6: "FDA has approved the use of Sumisorb incorporated into food packaging except with certain fat-containing and strongly alcoholic foodstuffs." P. 8: "From a review of the toxicology, Stouten et al. (2000) concluded that 'benzotriazole should be considered a suspected human carcinogen.'" EPA lists it for nonfood use only.²⁸

(e) effects on soil organisms, crops, or livestock.

BHT: TAP review (lines 268-271): "Soil microbes, sunlight and air quickly metabolize BHT. About 85-90% is degraded within 24 hours (Mikami et al., 1979a). Amounts reaching the phylloplane or soil should be low due to its low vapor pressure and encapsulation within a polyethylene matrix. Adverse effects on soil organisms, crops and livestock should be negligible, since very little should escape the dispenser (PBC, 2002)."

2-Hydroxy-4-n-octyloxybenzophenone: We have not been able to find any information on impacts on soil organisms, crops, or livestock.

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole: The TAP review, p. 4, says: "From what is known about other benzotriazoles, it has toxic effects on plants."

Why we are making this request

So-called "inert" ingredients in pesticide products are neither chemically nor biologically inert. They are designed to enhance the pesticidal activity of pesticide products and can have toxic properties that do not meet the standards of the Organic Foods Production Act (OFPA).

Active ingredients in pesticide products have been carefully screened to ensure that they meet the requirements of OFPA. Because of the thorough investigation by the National Organic Standards Board and the additional scrutiny given by the public in written and oral comments, the active ingredients that are allowed in organic agriculture present little hazard to people and ecosystems, from their manufacture through their use and disposal.

So-called "inert" ingredients, on the other hand, have not received the same level of scrutiny to ensure that they meet OFPA standards. Reliance on the registration of pesticide products with

²⁶ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>

²⁷ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>

²⁸ <http://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:2:0::NO::>

inert ingredients by the U.S. Environmental Protection Agency does not ensure that the standards of OFPA are met, given that the reviews and use allowances under the agency's authorizing legislation (the Federal Insecticide, Fungicide and Rodenticide Act) are based on different, and often incompatible standards. In addition, many pesticide product formulations are composed of mostly "inert" ingredients. As a result, the most hazardous part of pesticide products used in organic production may actually be the so-called "inert" ingredients.

The NOSB recognizes these facts and has sought to address them. A short history was presented in the Fall 2012 Crops Subcommittee proposal:

In 2006, EPA reassessed all inert ingredients used in pesticide formulations allowed on food crops, including former Lists 3, 4A, and 4B inerts, to ensure that they met the tolerance reassessment requirements of the Food Quality Protection Act. Inerts allowed for use in EPA registered pesticides applied to food now must either have a residue tolerance level or an exemption from tolerance level codified at 40 CFR Part 180. As a result of this reclassification, NOP regulations concerning allowed inert ingredients are out-of-date when compared with current EPA regulations, since EPA eliminated its list categories when it completed its tolerance reassessment. The NOSB recommended in April 2010 that NOP establish a task force in collaboration with EPA and the NOSB to examine this problem and provide a recommendation to the Board for re-evaluation of former List 3 and List 4 inerts. In October 2010, the NOSB recommended the renewal until October 21, 2017 of the current exemption on the National List permitting former List 4 inerts "pending review by the program of inerts individually and as a class of materials." In May 2012, the NOSB recommended an expiration date of October 21, 2017 for the current exemption that permits former List 3 inerts in passive pheromone dispensers, to coincide with the sunset date for List 4 inerts.

The NOSB-NOP-EPA working group was established in June 2010, known as the Inerts Working Group (IWG). Current members include: Jay Feldman (NOSB), Zea Sonnabend (NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), and Lisa Brines (NOP). The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting.

At the fall 2012 NOSB meeting, the Board unanimously passed a recommendation that was to put in motion the long-anticipated review of "inert" or "other" ingredients in pesticide products used in organic production:

The NOSB proposes this language to replace the current listing at section 205.601(m) and 205.603(e). The NOSB recommends that this change, including the listing of any approved (inert) ingredients, be completed prior to the October 21, 2017 sunset date for List 4 inerts:

Current language at sections 205.601(m) and 205.603(e): As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic

substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

Replace the language at sections 205.601(m) and 205.603(e) with:

As synthetic other (“inert”) ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

- (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
- (ii) Reserved (for list of approved other (“inert”) ingredients)

And now, as “List 4 inerts” appear on the sunset review workplan for the Crops and Livestock Subcommittees, no progress has been made since the fall 2012 meeting. The NOP reported on meetings with EPA to engage the agency’s *Design for the Environment* program in the review of “inerts,” but despite the fact that the Inerts Working Group has now been working as an interagency group for four years, a memorandum of understanding authorizing this joint venture has only just been signed. Additionally, the National Organic Program (NOP) has not issued a notification to manufacturers and users of products with a request for information on current inert ingredients in use. This ‘data call-in notice’ was intended to capture inert ingredients that may not be on the comprehensive list of 126 priority “inert” ingredients and 87 “minimal risk” substances eligible for registration under FIFRA section 25(b) used in formulations allowed in organic production, which was generated by the Inerts Working Group based on data from Material Review Organizations. The notice is overdue and should be issued without further delay.

Since, as stated above, so-called “inert” ingredients likely pose more hazards than other materials used in organic production, their review deserves a higher priority. This petition is intended to raise the priority level of inerts review.

All so-called “inerts” –especially those not on EPA’s 25(b) list– are desperately in need of review in compliance with OFPA criteria. We have chosen three groups to request immediate attention. They are all important for toxicological, ecotoxicological, and practical reasons.

The alkylphenol ethoxylates (APEs) have received much attention because they, and the alkyl phenols to which they break down, are endocrine disruptors. APEs are surfactants, and EPA’s Design for the Environment has been investigating alternatives that are not endocrine disrupting chemicals.

Lack of review of EDTA and its salts has prevented the NOSB from addressing the crucial issues in ferric phosphate review. EDTA appears to be important to the function of ferric phosphate as a molluscicide, but the NOSB has been unable to address that issue in the context of ferric phosphate review (both petition and sunset) because EDTA has not been reviewed as an “inert.”

EPA's *Design for the Environment* program has designed criteria for evaluating chelating agents that may help identify alternatives to EDTA and its salts, if necessary.²⁹

The former "List 3 inerts," which were approved for use only in passive pheromone dispensers, have received special treatment –the law did not intend for "inerts" on List 3 to be allowed in organic production. The definition of "passive polymeric dispenser products" that was included in the spring 2012 NOSB recommendation was refused by the NOP. Therefore, this small group of chemicals has questionable status. From our review of these chemicals, we think it quite likely that at least some will be found to be acceptable when reviewed by the NOSB, but the existence of such an exceptional listing does not support the integrity of the organic label.

Although we identified these three groups as requiring immediate attention, it would violate the intention of the Board to allow the indefinite extension of the listing for any of the so-called "inerts." Therefore, we request that all other substances falling under these listings –that is, those listed in Table 1– be annotated with expiration dates as indicated in Table 1.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

²⁹ http://www.epa.gov/dfe/pubs/projects/gfcp/dfe_criteria_for_chelating_agents.pdf

Alkyl alcohols –Expire June 27, 2021
Alkyl alkoxyates –Expire June 27, 2018
Alkylphenol ethoxyates –Expire June 27, 2018
Dyes –Expire June 27, 2018
EDTA and salts
Fatty acid ethoxyates –Expire June 27, 2018
Fatty acids, esters and salts –Expire June 27, 2018
Low Risk Polymer as defined under 40 CFR 180.960 –Expire June 27, 2020
Mineral acids, bases, and inorganic (their) salts –Expire June 27, 2019
Nonsynthetic –Expire June 27, 2021
Organic acids and salts –Expire June 27, 2021
Polyalkoxyates and polyalkoxylated alkyl ethers –Expire June 27, 2020
Polysorbates –Expire June 27, 2020
Preservatives / Antioxidants –Expire June 27, 2020
Tall oil and terpene derivatives –Expire June 27, 2021
TBD –Expire June 27, 2022

Table 1³⁰

DRAFT

³⁰ NOSB, 2012. Formal Recommendation to NOP.
<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101281>