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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. CS: List 3 "inerts"

These comments to the National Organic Standards Board (NOSB) on its Fall 2016 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 the world.

In reviewing this substance, the NOSB must apply the criteria in the Organic Foods Production Act (OFPA), that its use—
(i) would not be harmful to human health or the environment;
(ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and
(iii) is consistent with organic farming and handling.[1]

As stated by the Crops Subcommittee (CS) in the Spring,

> This listing will be superseded by the annotation change approved by the NOSB for EPA List 4 and List inerts (§205.601(m)(1)). The NOSB is continuing the sunset review process for these EPA List 3 inerts in case that change cannot be implemented through rulemaking before the 11/03/2018 sunset of EPA List 3 inerts.

However, the sunset vote does more than is implied by this description. As recognized by the CS in its discussion of a future Nonylphenol Ethoxylates (NPE) annotation in the Spring, the annotation change recommended by the NOSB at the fall 2015 meeting may require a long time for implementation. Earlier, in response to the fall 2012 NOSB recommendation on List 4 "inerts," the NOP said,

[1] OFPA §6517(c)(1)(A). Further details at OFPA §6518(m).

> When the NOSB has completed their review process for inerts currently permitted in organic production, the NOP will then consider any recommendation(s) made by the Board for specific amendments to the language at §205.601(m) and §205.603(e). The NOP believes that any changes to these sections of the National List would be best addressed in conjunction with any outcomes of the NOSB inerts review.[2]

NOP issued the following response to the Fall 2015 NOSB recommendation:

> The NOP has reviewed the NOSB's recommendation and plans to collaborate further with EPA's Safer Choice Program to develop a program for inert ingredient review, and to initiate notice and comment rulemaking to revise the annotations for inert ingredients at 205.601(m) and 205.603(e).[3]

Thus, the review of List 3 "inerts" should be taken seriously by the NOSB. The decision, like other sunset decisions, will likely be in effect for another 5 years.

List 3 "inerts" should be delisted.

The NOSB has already recommended an expiration date for these chemicals.

In the spring of 2012, the NOSB passed a motion to change the listing to:

> 2) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until December 31, 2015, after which point they are subject to individual review under 205.601, unless already covered by a policy adopted by the NOP for all other inert ingredients.

NOP refused to codify this recommendation.

The identities of the former list 3 "inerts" are known, and they should be examined relative to OFPA criteria.

The CS proposal of spring 2012 identified the "inerts" formerly on List 3 that are covered by this listing. They are BHT (antioxidant), 2-Hydroxy-4-n-octyloxybenzophenone (UV absorber), and 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (UV stabilizer). 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

[2] Miles McEvoy, February 27, 2013 Memorandum to NOSB.
[3] Miles McEvoy, February 29, 2016 Memorandum to NOSB.

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.

We have submitted the following information to help the CS begin its review.

Butylated hydroxytoluene (BHT) (CAS# 128-37-0)

According to the TAP review performed in 2002,

> BHT is synthesized from p-cresol. The p-cresol is obtained from coal tar (25%), as a by-product of catalytic cracking of petroleum (11%), and by a number of synthetic processes (64%). A major synthetic route is by sulfonation of toluene followed by heating with sodium hydroxide. Toluene is obtained by distillation of petroleum (Fiege, 1987).
>
> The p-cresol is alkylated with isobutylene gas in an acid catalyzed reaction. Products and results are sensitive to the catalyst and conditions. In one process, p-cresol with 5% phosphoric acid is heated to 70°C. Isobutylene gas obtained by catalytic cracking and distillation of petroleum is bubbled through. The catalyst separates and is removed. The product is washed with sodium hydroxide. Crystals settle out in 46% yield (Stillson, 1947).
>
> In another process, p-cresol is heated to 40°C with 5% methanedisulfonic acid. Isobutylene is bubbled through for 6 hours. Upon cooling, the catalyst separates. The product is washed with sodium hydroxide solution. Crystals separate in 88% yield and are recrystallized from methanol (McConnell and Davis, 1963).[4]

Other reviews include the following:

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.

National Organic Standards Board Technical Advisory Panel Review, Compiled by OMRI for the USDA National Organic Program. Butylated Hydroxytoluene (BHT). September 30, 2002.

Human Health Risk Assessment of Isomate®-EGVM by the Pesticide and Environmental Toxicology Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. October 2010. Includes consideration of "inerts" bumetrizole and BHT.

Safety Review of Checkmate Chemicals, by Don't Spray California.
http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf

The substance's physical properties and chemical mode of action.

[4] Butylated Hydroxytoluene (BHT) TAP review September 30, 2002. Lines 60-71.

Chemical interactions with other substances, especially substances used in organic production
The TAP review of Butylated Hydroxytoluene (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.

Toxicity and environmental persistence
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.[5]

Environmental impacts from its use or manufacture
An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.[6] Another review cites classifications as hazardous.[7]

Effects on human health
"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 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)."[8]

Effects on soil organisms, crops, or livestock.

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[5] 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.
[6] 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.
[7] Safety Review of Checkmate Chemicals, by Don't Spray California.
http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf.
[8] Safety Review of Checkmate Chemicals, by Don't Spray California.
http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf.

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 (OHOBP, methanone) (CAS # 1843-05-6)

OHOBP is synthesized by reacting 2, 4-dihydroxybenzophenones with octyl bromide or octyl chloride (1-chlorooctane).[9] Little toxicological information is available concerning octyl bromide, but it is harmful if inhaled and causes eye, skin, and respiratory tract irritation.[10] 1-chlorooctane's production and use in the manufacture of organometallics, as a chemical intermediate, and as a stabilizer may result in its release to the environment through various waste streams. Because it is an aliphatic hydrocarbon, it is a central nervous system depressant and severe pulmonary irritant.[11]

Previous reviews include:

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.

Safety Review of Checkmate Chemicals, by Don’t Spray California.
http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf

Yoko Kawamura, Yuko Ogawa, Tetsuji Nishimura, Yutaka Kituchi, Jun-ichi Nishikawa, Tsutomu Nishihara, and Kenichi Tanamoto, 2003. Estrogenic activities of UV stabilizers used in food contact plastics and benzophenone derivatives tested by the yeast two-hybrid assay. Journal of Health Science, 49(3): 205-212.

K. Morohoshi, H. Yamamoto, R. Kamata, F. Shiraishi, T. Koda, M. Morita, 2005. Estrogenic activity of 37 components of commercial sunscreen lotions evaluated by in vitro assays. Toxicology in Vitro 19: 457–469.

The substance's physical properties and chemical mode of action.

Chemical interactions with other substances, especially substances used in organic production

We have not found information about chemical interactions with methanone.

Toxicity and environmental persistence

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[9] EPA Office of Prevention, Pesticides, and Toxic Substances. Memo from Keri Grinstead, Inert Ingredient Assessment Branch, to Pauline Wagner, Inert Ingredient Assessment Branch, Registration Division. July 10, 2006. Patent: US PATENT 3,098,842 http://www.google.com/patents/US3098842.

[10] MSDS: http://www.nwmissouri.edu/naturalsciences/sds/b/Bromooctane.pdf.

[11] Hazardous Substances Data Bank, 1-Chlorooctane. http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@rn+@rel+111-85-3.

2-Hydroxy-4-n-octyloxybenzophenone: Ciba submitted 3 adverse effects reports under TSCA for sensitization. It is not readily biodegradable.[12]

Environmental impacts from its use or manufacture

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.[13]

Effects on human health

"[R]elated compounds in the benzophenone family have been shown to form estrogenic photoproducts, upon exposure to UV or sunlight (Hayashi et al. 2006)." [14]

Effects on soil organisms, crops, or livestock.

We have not found any information on impacts on soil organisms, crops, or livestock.

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

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole was petitioned to be added to the National List, and a TAP review was performed in 2003. It says,

> The manufacturing method for Sumisorb is considered confidential business information (CBI) and was deleted from the petition copy received by the investigator. It is likely that Sumisorb is synthesized from ρ-cresol. Cresols are byproducts of petroleum distillation widely used by industry, and are commonly derived via catalytic and thermal cracking of naphtha fractions (ATSDR 1992). Benzotriazoles are produced by reacting substituted and unsubstituted aromatic amines with other nitrogen donors (OPPT 2002).
>
> A search of the US Patent Office yielded a disclosed process for the preparation of 1,2,3-benzotriazole (a less complex chemical precursor to Sumisorb) as follows: continuous addition of acetic acid and orthophenylenediamine to an aqueous solution of sodium nitrate over a period of 1-3 hours at 5-25ºC. This is followed by neutralization of the reaction mixture with sodium hydroxide, then separation of the product from the mixture thereby obtaining a product concentration of 15-25 percent by weight (Chan et al 1981).

Previous reviews include:

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[12] 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.

[13] 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.

[14] Safety Review of Checkmate Chemicals, by Don't Spray California. http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf

"Sumisorb 300" National Organic Standards Board Technical Advisory Panel Review compiled by University of California Sustainable Agriculture Research and Education Program (UC SAREP) for the USDA National Organic Program. April 3, 2003.

Human Health Risk Assessment of Isomate®-EGVM by the Pesticide and Environmental Toxicology Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. October 2010. Includes consideration of "inerts" bumetrizole and BHT.

The substance's physical properties and chemical mode of action.

Chemical interactions with other substances, especially substances used in organic production

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."

Toxicity and environmental persistence

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 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."

Environmental impacts from its use or manufacture

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, CO_2, NO_x, or HCl when heated to burning (MSDS)."

Effects on human health

2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole: TAP 6: "FDA has approved the use of Sumisorb incorporated into food packaging except with certain fat-containing and strongly alcoholic foodstuffs 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.[15]

Effects 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."

Conclusion

The NOSB must review the List 3 "inerts," rather than waiting for NOP to implement the Spring 2015 recommendation. Since the NOSB can no longer rely on EPA listing of inert ingredients, and given the standards for listing that are required under OFPA, delaying is no longer an option if the organic label is to maintain consumer and farmer trust. There are three List 3 "inerts" in use in organic production, and the NOSB can review them individually. We have submitted information about those chemicals and believe they should not be relisted.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

[15] http://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:2:0::NO:::