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National Organic Standards Board
USDA-AMS-NOP
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Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Docket ID # AMS-NOP-21-0038

Re. CS: Sunset

These comments to the National Organic Standards Board (NOSB) on its Fall 2021 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.

Copper sulfate

205.601(a)(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.
205.601(e)(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

205.601(a)(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.
205.601(e)(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited

to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Copper sulfate is hazardous to wildlife and the agroecosystem.

Rice paddies replace natural wetlands and provide alternative habitat for animals threatened by the loss of wetlands. Unfortunately, many of these animals are sensitive to copper. In addition, copper sulfate is toxic to aquatic animals that could provide some biological control for the algae the copper is used to kill. For example, one animal mentioned by the California Rice Commission as an inhabitant of rice fields is the western toad (*Bufo boreas*). Tadpoles of the western toad feed on filamentous algae, detritus, and may even scavenge carrion.[1] The LC50 for tadpoles of *Bufo boreas* is 47.49 parts per *billion* copper (0.04749 ppm).[2] According to the TAP review for copper sulfate (lines 680-683):

> Typical application rates in paddies to control algae appear to range from 0.25 ppm to 2.0 ppm. For treating tadpole shrimp, application rates appear to be "less than 10 ppm". With aquatic organisms showing detrimental effects at levels of about 0.4 ppm and above, this means that the application of $CuSO_4$ to rice paddies could kill mosquito fish, pond snails, and other organisms that could have beneficial properties.

Thus, application rates of copper sulfate exceed levels that are lethal to tadpoles of *Bufo boreas* by up to two orders of magnitude.

Similarly, tadpoles of the Pacific tree frog, another species found in rice fields, are suspension feeders, eating a variety of prey including algae, bacteria, protozoa and organic and inorganic debris.[3] A third species inhabiting rice fields is the bullfrog, whose tadpoles eat organic debris, algae, plant tissue, suspended matter and small aquatic invertebrates. [4]

In 2001, the NOSB adopted "Principles of Organic Production and Handling." The first of those principles is:

> Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

The particular impacts mentioned above—on amphibians found in rice fields—not only have a negative impact on biodiversity, but they also reduce possibilities for biological control of algae and tadpole shrimp. Thus, the use of copper sulfate in an aquatic environment like a rice field is inconsistent with a system of organic and sustainable agriculture.

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[1] AmphibiaWeb: Information on amphibian biology and conservation. [web application]. 2011. Berkeley, California: AmphibiaWeb. Available: http://amphibiaweb.org/. (Accessed: Jul 25, 2011).

[2] EPA, 2007. *Aquatic Life Ambient Freshwater Criteria—Copper*, Office of Water. EPA-822-R-07-001.

[3] http://www.californiaherps.com/frogs/pages/p.regilla.html.

[4] http://www.fs.fed.us/r4/amphibians/bullfrog.htm.

Copper sulfate is hazardous to humans.

Although the CS says, "Copper sulfate has been classified as a human carcinogen by the European Chemicals Agency (ECHA)," it appears that ECHA does not classify it as a human carcinogen, saying, "Available data on the genotoxicity and carcinogenicity of copper and its compounds have been considered against EU classification criteria. The available data for copper compounds do not meet the criteria requiring classification for carcinogenicity."[5] Nevertheless, copper sulfate is toxic, and workers are particularly at risk.[6] The CS points out a "specific concern for renal cancers (Buzio et al, 2002).[7] Chronic exposure to fungicidal sprays elevated the risk of renal cancers by almost 3 times." The Agency for Toxic Substances and Disease Registry (ATSDR) in the U.S. Department of Health and Human Services identifies damage to the gastrointestinal tract, liver, kidneys, and the immune system resulting from inhalation exposure. Respiratory effects have been seen in animals exposed to copper sulfate aerosols (such as might be experienced by workers). "Copper is considered the etiologic agent in the occupational disease referred to as 'vineyard sprayer's lung.'" [8] Copper sulfate is also a reproductive toxicant. [9]

Some issues need to be addressed by the CS.

The use restrictions in the annotations need to be clarified.

Do growers use the annotations to allow them to use copper sulfate every year – alternating use as algicide with use as insecticide? We have asked this question over repeated sunset cycles, without getting a clear answer. If copper sulfate is not removed from the National List, the annotations should be revised to clarify that use of copper sulfate for any purpose is limited to once in 2 years:

> **205.601(a)(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field for any purpose during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.**
>
> **205.601(e)(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field for any purpose during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.**

We have also heard that rice growers may consider algae (aka "scum") as a disease and use even more copper sulfate, justifying it with the plant disease listing at 205.601(i)(3). This is an obvious abuse that must not be allowed to continue.

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[5] https://echa.europa.eu/registration-dossier/-/registered-dossier/15562/7/8.

[6] https://pubchem.ncbi.nlm.nih.gov/source/hsdb/916#section=Non-Human-Toxicity-Excerpts-(Complete).

[7] Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.

[8] ATSDR, 2004. Toxicological Profile for Copper. https://www.atsdr.cdc.gov/ToxProfiles/tp132.pdf.

[9] http://npic.orst.edu/factsheets/archive/cuso4tech.html.

Are copper sulfate products allowed in organic rice production free of arsenic contamination?

Copper sulfate is often contaminated with arsenic. For example, the product Ecofusion copper sulfate pentahydrate granular (organic), Product #:1665-0018, is listed by the Washington State Department of Agriculture fertilizer database as containing 25% copper and 10.0 parts per million arsenic.[10]

Rice accumulates arsenic[11] and is the largest non-seafood source of arsenic in the American diet.[12] Organic rice is not immune to accumulating arsenic, and organic brown rice syrup has been identified as a vehicle for contaminating foods, including toddler formula, with arsenic.[13] Although the principal source of the arsenic has been identified as arsenic pesticides formerly used in areas now used for rice production,[14] it would be foolish to add still more arsenic to the water in rice paddies.

Is sodium carbonate peroxyhydrate an effective alternative?

Sodium carbonate peroxyhydrate (SCP) was added to the National List with the stipulation that it would reduce the use of copper sulfate as an algicide. Has it proved to be effective? If so, can the listing for copper sulfate as an algicide be eliminated? If not, then SCP should be removed from the National List.

What alternative practices would eliminate the need for copper sulfate?

During the 2011 sunset discussion of the use of copper sulfate in rice, the NOSB discussed rice production systems that eliminate the problems that copper sulfate is meant to address, and which cause us to ask, “Are tadpole shrimp and algae ‘pests’ only because of management practices?” Alternative systems –dryland drilling seed and transplanting seedlings—were documented by both the National Academy of Sciences and ATTRA Sustainable Agriculture Program. The NOSB should have investigated alternative management systems in the intervening years –or commissioned a Technical Review (TR) or Technical Advisory Panel (TAP) review to address these systems. This would be a good use of a TAP –to deliver different viewpoints on organic rice grown under different systems.

Has the NOSB recommendation for more research been heeded?

The NOSB addressed a need for research on the use of copper sulfate in rice at its fall 2011 meeting, saying in the presentation, “Research, this is one area where we have agreement. Everyone believes we need research in this area, and I think there's some analogy here to the antibiotics. This should not be used in aquatic environments.” What is the status of research in this area?

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[10] https://agr.wa.gov/departments/pesticides-and-fertilizers/fertilizers/fertilizer-database/fertilizer-product-lookup.

[11] http://www.dartmouth.edu/~toxmetal/research-projects/arsenic-in-plants.html.

[12] Yang, H.-C., Fu, H.-L., Lin, Y.-F., & Rosen, B. P. (2012). Pathways of Arsenic Uptake and Efflux. *Current Topics in Membranes*, *69*, 325–358. http://doi.org/10.1016/B978-0-12-394390-3.00012-4.

[13] Jackson BP, Taylor VF, Karagas MR, Punshon T, Cottingham KL. 2012. Arsenic, Organic Foods, and Brown Rice Syrup. Environ Health Perspect 120:623–626; http://dx.doi.org/10.1289/ehp.1104619.

[14] http://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm.

A research project on organic rice was announced as "a collaboration between researchers at Texas A&M University's AgriLife Research & Extension Center, Texas A&M Department of Soil and Crop Sciences, USDA's ARS Dale Bumpers National Rice Research Center, University of Arkansas Rice Research and Extension Center, University of Arkansas at Pine Bluff Department of Agriculture, and The Organic Center. It employs a multi-stakeholder research team to develop a multi-disciplinary approach to developing Integrated Pest Management strategies for organic rice production in the Southern United States."[15] *Has this project addressed alternatives to copper sulfate in controlling algae and tadpole shrimp? With what results?*

Data on accumulation in the soil, as required by the annotation, should be provided to the CS and the public.

The annotations on both listings for copper sulfate state, "Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent." Those who certify organic rice producers should be, therefore, obtaining test results for copper. As we have urged, these test results should have been requested by the CS and provided to the public—listings may remain anonymous—prior to the Fall 2021 meeting.

Copper sulfate should be sunsetted from organic rice production.

The annotation—which recognizes the toxicity of copper in the soil—is one indicator that copper sulfate should not remain on the National List forever. Even more important are the data on ecotoxicity and carcinogenicity presented above. The toxic effects on the aquatic and semi-aquatic organisms who inhabit rice paddies as a substitute for natural wetlands make copper sulfate incompatible with organic production and unacceptable to organic consumers. It is time to eliminate this toxic chemical from organic production.

Ozone gas

205.601(a)(5) Ozone gas—for use as an irrigation system cleaner only.

Ozone has high acute toxicity. Concentrations above 0.1 mg/L by volume average over an 8-hour period may cause nausea, chest pain, reduced visual acuity and pulmonary edema. Inhalation of >20 ppm for at least an hour may be fatal. In terms of chronic effects, ozone may have deleterious effects on the lungs and cause respiratory disease.[16] The use of ozone may be seriously detrimental to the health of humans who work with it, and those exposed indirectly, downwind of exposure. The use of a known and problematic air pollutant could make its consideration as a tool in organic farming questionable.[17] The Technical Review's (TR) summary of health effects may be useful to the Board (internal citations are deleted):

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[15] https://www.organic-center.org/our-projects/sustainable-and-profitable-strategies-for-ipm-in-southern-organic-rice/.

[16] Ozone TAP, lines 296-299. August 14, 2002.

[17] Ozone TAP, lines 695-697.

> Ozone is a respiratory irritant and may cause chronic lung disease. The pulmonary toxicity of ozone is due to its oxidation of lipid membranes, resulting in cell death and inflammatory cascades. Repeated exposure to gaseous ozone may result in lung damage and chronic lung conditions. The ability of ozone to oxidize DNA may also result in genetic changes and lung cancer. Exposure to ozone has also been reported to cause headaches, chest pain, and nausea. Due to the hazardous nature of ozone gas, the United States Occupation Health and Safety Administration (OSHA) limits 8-hour ozone exposure to levels of 0.1 ppm in 29 CRR 1910.1000.[18]

In addition, the TR describes how ozone contributes directly to air pollution and global climate change:

> As described in Evaluation Questions 3–8, ozone has a short environmental lifetime and leaves no residual contaminants. However, the reactive nature of ozone makes it a toxic substance capable of oxidizing most compounds. As discussed in the "Source or Origin of the Substance" section, tropospheric ozone is a major component of smog. Additionally, ozone is a more potent greenhouse gas than carbon dioxide, and tropospheric ozone contributes to global warming by trapping heat in the lower atmosphere. While stratospheric ozone is beneficial as it forms the ozone layer that protects the Earth from harmful ultraviolet rays, tropospheric ozone is harmful as both an oxidant and greenhouse gas. Moreover, ozone is denser than air, making it unlikely to migrate from the troposphere, where it is a harmful substance, to the stratosphere, where it is a beneficial substance.[19]

Regardless of onsite hazards, as pointed out by the TR, "[T]he production of ozone by on-site generators is an inefficient process in which approximately 75% of the applied electricity is lost to heat and light. Due to the energy-intensive nature of ozone production, environmental contamination may occur from its manufacture in the form of carbon dioxide emissions if electricity is generated by burning fossil fuels."[20]

If relisted, the broad "effectiveness" of ozone against soil organisms and chemical constituents, as documented in the recent technical review,[21] confirms the need for an annotation that does not allow application to soil.

We thank the Crops Subcommittee for requesting a TR that clarifies the hazards associated with use of ozone. The NOSB needs to take a comprehensive look at all sanitizers, their needs, and evaluate whether all needs can be met with materials that have low impacts on human health and the environment. **In view of the dangers associated with the use of ozone—including health effects, local air pollution, and global climate change—we ask that the NOSB vote to sunset ozone from §601.**

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[18] Ozone TR, lines 501-508.

[19] Ozone TR, lines 487-495.

[20] Ozone TR, lines 443-447.

[21] Ozone TR, lines 202-267; 429-437.

Peracetic acid

205.601(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.

205.601(i)(8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

Information from recent EPA reviews has not been incorporated into recent decisions about peracetic acid. The current annotation seems to indicate that peracetic acid is an "inert" ingredient, but it is not listed in EPA's InertFinder database. The annotation may arise from the fact that, "Because peracetic acid breaks down into hydrogen peroxide and acetic acid, it is almost always co-formulated with large quantities of hydrogen peroxide in order to drive the equilibrium towards maintaining the peracetic acid."[22] The process is described in Appendix B or the EPA Draft Health and Environmental Risk Assessment for Peroxy Compounds.[23]

EPA has efficacy data for peracetic acid products that indicate strong effectiveness on hard surfaces.[24] This makes us question the need for chlorine compounds for those uses.

In 2009, EPA opened a registration review docket and published a preliminary work plan for peroxy compounds. In March 2010, EPA issued a final work plan that described potential health and environmental risks and identified data needs. In December 2011, the agency issued a Data Call-in, which was withdrawn and reissued in February 2012, imposing new data requirements for human toxicity, ecotoxicity, environmental fate, and occupational exposure. In November 2013, EPA recognized the Peroxy Compounds Task Force (PCTF), composed of registrants and potential registrants of peroxy compound products, as a data submitter for these materials.[25]

> In its summary of human health effects data for the peroxy compounds EPA finds: High concentrations of peroxy compounds [including peracetic acid and hydrogen peroxide] are … corrosive and can be acutely toxic and/or extremely irritating to the lungs and skin.[26]

In March 2020, EPA issued a human health and environmental risk assessment for peroxy compounds.[27] Previously, the American Conference of Governmental Industrial Hygienists (ACGIH) set new occupational exposure limits for peracetic acid,[28] the National

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[22] https://beta.regulations.gov/document/EPA-HQ-OPP-2009-0546-0017.

[23] https://beta.regulations.gov/document/EPA-HQ-OPP-2009-0546-0017.

[24] http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:7:::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:2278.

[25] http://www.epa.gov/sites/production/files/2014-04/documents/pr2013-2.pdf.

[26] Summary of Human Health Effects Data for the Peroxy Compounds Registration Review Decision Document. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0546-0003.

[27] https://beta.regulations.gov/document/EPA-HQ-OPP-2009-0546-0017.

[28] http://potentcompoundsafety.com/2014/02/acgih-occupational-exposure-limit-peracetic-acid.html.

Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) established even more stringent limits,[29] and a review by scientists from Ecolab, a member of the PCTF and manufacturer of peracetic acid products, has come up with similar limits.[30] The review also stated:

> Overall, there are notable deficiencies in the PAA toxicological dataset, particularly in regards to information gaps concerning chronic toxicity (e.g., carcinogenicity, mutagenicity/genotoxicity, reproductive/developmental toxicity, repeat-dose toxicity) and the fact that a large number of toxicity studies did not follow conventional testing methodology. However, the available in vivo and human experience data indicate that sensory irritation appears to be the most sensitive health endpoint and protecting against this endpoint should adequately mitigate risk from other potential effects.[31]

In addition to the new Technical Review (TR), published after the CS completed its preliminary review in 2016, several recent journal articles have examined health effects of peracetic acid.[32] The TR reveals that there are several distinct substances called "peracetic acid," and that not all are permitted under NOP regulations.[33]

The NOSB needs to take a comprehensive look at all sanitizers, their needs, and evaluate whether all needs can be met with materials that have low impacts on human health and the environment.

Questions regarding peracetic acid:

1. **Does the annotation need to be changed to reflect the TR findings that not all substances identified as "peracetic acid" are permitted under NOP regulations—to, for example, limit the use to certain forms?**
2. **Is there new information about occupational hazards that should be taken into account in the sunset decision and/or in formulating an additional annotation?**
3. **Can peracetic acid be used for fireblight without harm to soil and workers?**
4. **Is peracetic acid effective for all uses of chlorine? If peracetic acid remains on the National List, can chlorine be eliminated from use in organic production?**

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[29] National Research Council (US) Committee on Acute Exposure Guideline Levels. Acute Exposure Guideline Levels for Selected Airborne Chemicals: Volume 8. Washington (DC): National Academies Press (US); 2010. 7, Peracetic Acid Acute Exposure Guideline Levels. Available from: http://www.ncbi.nlm.nih.gov/books/NBK220001/.

[30] Pechacek, N., Osorio, M., Caudill, J., & Peterson, B. (2015). Evaluation of the toxicity data for peracetic acid in deriving occupational exposure limits: A minireview. *Toxicology letters*, *233*(1), 45-57.

[31] Pechacek, N., Osorio, M., Caudill, J., & Peterson, B. (2015). Evaluation of the toxicity data for peracetic acid in deriving occupational exposure limits: A minireview. *Toxicology letters*, *233*(1), 45-57.

[32] Dugheri, S., Bonari, A., Pompilio, I., Colpo, M., Montalti, M., Mucci, N. and Arcangeli, G., 2018. Assessment of occupational exposure to gaseous peracetic acid. *Int. J. Occ. Med. Environ. Health*, *31*, pp.527-535. Hawley, B., Casey, M., Virji, M.A., Cummings, K.J., Johnson, A. and Cox-Ganser, J., 2018. Respiratory symptoms in hospital cleaning staff exposed to a product containing hydrogen peroxide, peracetic acid, and acetic acid. *Annals of work exposures and health*, *62*(1), pp.28-40. Weber, D.J., Consoli, S.A. and Rutala, W.A., 2016. Occupational health risks associated with the use of germicides in health care. *American journal of infection control*, *44*(5), pp.e85-e89. Kim, J. and Huang, C.H., 2020. Reactivity of Peracetic Acid with Organic Compounds: A Critical Review. *ACS ES&T Water*.

[33] 2016 Peracetic Acid TR Crops. Lines 236-260 and Table 5.

EPA List 3 - Inerts of Unknown Toxicity

205.601(m) (2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

One of the most egregious failures of NOP has been its repeated lack of action on so-called "inert" ingredients. Because of that failure, every sunset brings to a new NOSB a listing that has not been changed in response to over a decade of NOSB recommendations. EPA has long since (2006) stopped updating the "inerts" lists. The NOSB, which has been recommending since 2007 to review individual "inert" ingredients, has instead been given the option of relisting the outdated lists.

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. In doing so, NOP has violated the Organic Foods Production Act (OFPA) §6517(d) (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 identities of the former list 3 "inerts" are known, and they should be examined in accordance with OFPA criteria.

The CS proposal of spring 2012 identified the "inerts" formerly on List 3 that were 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 that at least some will be found to be acceptable when reviewed by the NOSB, but the existence of such an exceptional listing undermines the integrity of the organic label.

In addition to the three List 3 "inerts" identified in 2012, a fourth chemical formerly on List 3 has been identified as being in use in passive pheromone dispensers in organic production—benzaldehyde, CAS #100-52-7. Benzaldehyde is not approved for food use. It is approved for nonfood use and as a fragrance in nonfood uses.[34] The addition of another chemical to the known List 3 “inerts” used in organic production shows a hazard of delaying the review of these chemicals as recommended by the NOSB.

We submit the following information to help the CS begin its review of these chemicals.

The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.

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).[35]

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).[36] Little toxicological information is available concerning octyl bromide, but it is harmful if inhaled and causes eye, skin, and respiratory tract irritation.[37] 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.[38]

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[34] https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:3:::::P3_ID:9369.

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

[36] 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.

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

[38] 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-(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 U.S. 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).

Benzaldehyde (CAS # 100-52-7)

According to PubChem, benzaldehyde is produced principally by the hydrolysis of benzal chloride or the partial oxidation of toluene.[39] PubChem lists the following sources for a description of the manufacture of benzaldehyde:

> Opgrande Jl et al; Benzaldehyde. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2016). John Wiley & Sons, Inc. Online Posting Date: May 16, 2003.
> Bruhne F, Wright E; Benzaldehyde. Ullmann's Encyclopedia of Industrial Chemistry 7th ed. (1999-2016). NY, NY: John Wiley & Sons. Online Posting Date: October 15, 2011.O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 186.

A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.

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

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.

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[39] https://pubchem.ncbi.nlm.nih.gov/compound/Benzaldehyde#section=Methods-of-Manufacturing.

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

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

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.

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

"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.

Benzaldehyde (CAS # 100-52-7)

Cameo Chemicals is a database designed for hazardous materials response and planning. Its review of benzaldehyde finds, "Inhalation of concentrated vapor may irritate eyes, nose and throat. Liquid is irritating to the eyes. Prolonged contact with the skin may cause irritation."[40]

A number of EPA programs track or regulate benzaldehyde.[41] EPA has reviewed benzaldehyde as an "inert" ingredient and approved it for nonfood and fragrance uses.[42]

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[40] https://cameochemicals.noaa.gov/chemical/216.

[41] https://sor.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=CASNO&p_value=100-52-7#.

[42] https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:2.

Benzaldehyde is reviewed in EPA's Integrated Risk Information System (IRIS).[43] EPA has reviewed potentially relevant carcinogenicity and non-cancer data for benzaldehyde for the Superfund program.[44]

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 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."

Benzaldehyde (CAS # 100-52-7)

Benzaldehyde is "a nontoxic, combustible liquid that reacts with oxidizing reagents. Benzaldehyde must be blanketed with an inert gas at all times since it is oxidized readily by air to benzoic acid. In contact with strong acids or bases it will undergo an exothermic condensation reaction. A violent reaction was observed on contact with peroxyacids (peroxyformic acid). An explosion occurred when pyrrolidine, benzaldehyde, and propionic acid were heated to form porphyrins."[45] Incompatible materials include strong oxidizing agents, strong reducing agents, strong bases, alkali metals, aluminum, iron, phenols, oxygen.[46]

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

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[43] https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=332.

[44] https://cfpub.epa.gov/ncea/pprtv/documents/Benzaldehyde.pdf.

[45] https://cameochemicals.noaa.gov/chemical/216.

[46] Sigma-Aldrich; Safety Data Sheet for Benzaldehyde. Product Number: 418099, Version 5.3 (Revision Date 02/26/2015). Available from, as of April 21, 2016: https://www.sigmaaldrich.com/safety-center.html.

(Mikami et al., 1979a)." An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.[47]

2-Hydroxy-4-n-octyloxybenzophenone

Ciba submitted 3 adverse effects reports under TSCA for sensitization. It is not readily biodegradable.[48]

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 than 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."

Benzaldehyde (CAS # 100-52-7)

Along with more detailed reports, PubChem[49] gives the following summary of toxicity, from the Hazardous Substances Data Bank (HSDB):[50]

> HUMAN EXPOSURE AND TOXICITY: It may cause contact dermatitis. It was positive in sister chromatid exchange assay with human lymphocytes from healthy non-smoking donors. Benzaldehyde was found to induce formation of stable DNA-protein cross-links in cultured human lymphoma cells. Benzaldehyde was found to lack significant activity against most human tumor cells tested. ANIMAL STUDIES: It was was slightly irritating to the rabbit eye. Histological examination of the trachea and lungs showed a slight irritation of respiratory epithelium for nonsensitized guinea pigs. In the acute studies, benzaldehyde induced deaths and decreased body-weight gain in both sexes of rats given 800 or 1600 mg/kg/day and caused deaths in both sexes of mice given 1600 or 3200 mg/kg/day. In the 90-day studies, deaths occurred in both sexes of rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Body-weight gain was depressed in male rats on 800 mg/kg/day, in male mice on 600 mg/kg/day and in female mice on 1200 mg/kg/day. Necrotic and degenerative lesions were seen in the cerebellar and hippocampal regions of the brain in both sexes of rats given 800 mg/kg/day, but not in mice. Renal tubular necrosis occurred in male and female rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Mild epithelial hyperplasia or hyperkeratosis of the

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[47] 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.

[48] 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.

[49] https://pubchem.ncbi.nlm.nih.gov/compound/Benzaldehyde#section=Toxicity.

[50] https://pubchem.ncbi.nlm.nih.gov/source/hsdb/388.

> forestomach was seen in male and female rats on 800 mg/kg/day. In an inhalation study performed with rats, it was found that the principal histopathological change was the development of goblet cell metaplasia in the respiratory epithelium lining of the nasal septum. In 2 year studies, there was no evidence of carcinogenic activity of benzaldehyde for male or female rats receiving 200 or 400 mg/kg per day. There was some evidence of carcinogenic activity of benzaldehyde for male or female mice, as indicated by increased incidences of squamous cell papillomas and hyperplasia of the forestomach. Benzaldehyde was studied for mutagenicity using Salmonella typhimurium tester strains TA100, TA102 and TA104, with or without metabolic activation. It was non-mutagenic under all test conditions with dose ranges from 33 to 3333 ug/plate. No induction of chromosomal aberrations was observed in CHO cells treated with up to 500 ug/mL benzaldehyde without metabolic activation or with up to 1600 ug/mL with metabolic activation.

Along with more detailed reports, PubChem[51] gives the following summary of environmental fate, from the Hazardous Substances Data Bank (HSDB):[52]

> Benzaldehyde's production and use as a food additive, as a fragrance in cosmetics, perfumes, and detergents, as a chemical intermediate and as a solvent may result in its release to the environment through various waste streams. Benzaldehyde is also released to the environment in emissions from combustion processes such as gasoline and diesel engines, incinerators and wood burning. It is formed in the atmosphere through photochemical oxidation of toluene and other aromatic hydrocarbons. It occurs naturally in many plant species and has been identified in volcanic emissions. If released to air, a vapor pressure of 1.27 mm Hg at 25 °C indicates benzaldehyde will exist solely as a vapor in the atmosphere. Vapor-phase benzaldehyde will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 30 hours. Small quantities of benzaldehyde have been detected in atmospheric aerosol particulates that can be physically removed from air via dry and wet deposition. Benzaldehyde has been detected in rain, snow, fog, and cloud water. Benzaldehyde absorbs UV radiation between 300 and 380 nm and, therefore, may be susceptible to direct photolysis by sunlight. If released to soil, benzaldehyde is expected to have very high mobility based upon an estimated Koc of 11. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 2.67X10-5 atm-cu m/mole. Benzaldehyde may volatilize from dry soil surfaces based upon its vapor pressure. A number of biological screening studies have demonstrated that benzaldehyde is readily biodegradable. If released into water, benzaldehyde is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Utilizing the Japanese MITI test, 66% of the Theoretical BOD was reached in 2 weeks indicating that biodegradation is an important environmental fate process. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 1.5 and 14 days,

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[51] https://pubchem.ncbi.nlm.nih.gov/compound/Benzaldehyde#section=Environmental-Fate-Exposure-Summary.

[52] https://pubchem.ncbi.nlm.nih.gov/source/hsdb/388.

> respectively. An estimated BCF of 4.4 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions. Occupational exposure to benzaldehyde may occur through inhalation and dermal contact with this compound at workplaces where benzaldehyde is produced or used. Monitoring data indicate that the general population may be exposed to benzaldehyde via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with consumer products containing benzaldehyde. (SRC)

Environmental impacts from its use or manufacture

BHT

An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.[53] Another review cites classifications as hazardous.[54]

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.[55]

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)."

Benzaldehyde (CAS # 100-52-7)

Benzadehyde is harmful to aquatic organisms with long-lasting effects.[56,57]

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[53] 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.

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

[55] 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.

[56] http://www.ilo.org/dyn/icsc/showcard.display?p_lang=en&p_card_id=0102&p_version=2.

[57] https%3A%2F%2Fwww.vigon.com%2Fproduct%2Fbenzaldehyde-natural%2F%3Fdoc%3DMSDS%2F500026_vigon_sds_us_english.pdf%26namee%3DBenzaldehydeNaturalSDS&usg=AOvVaw3cAR40ulXUZp7ILUGc9Uh6.

Effects on human health

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 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)."[58]

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)." [59]

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.[60]

Benzaldehyde (CAS # 100-52-7)

> PubChem[61] gives the following summary from HSDB:[62]
> HUMAN EXPOSURE AND TOXICITY: It may cause contact dermatitis. It was positive in sister chromatid exchange assay with human lymphocytes from healthy non-smoking donors. Benzaldehyde was found to induce formation of stable DNA-protein cross-links in cultured human lymphoma cells. Benzaldehyde was found to lack significant activity against most human tumor cells tested. ANIMAL STUDIES: It was was slightly irritating to the rabbit eye. Histological examination of the trachea and lungs showed a slight irritation of respiratory epithelium for nonsensitized guinea pigs. In the acute studies, benzaldehyde induced deaths and decreased body-weight gain in both sexes of rats given 800 or 1600 mg/kg/day and caused deaths in both sexes of mice given 1600 or 3200 mg/kg/day. In the 90-day studies, deaths occurred in both sexes of rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Body-weight gain was depressed in male rats on 800 mg/kg/day, in male mice on 600 mg/kg/day and in female mice on 1200 mg/kg/day. Necrotic and degenerative lesions were seen in the cerebellar and hippocampal regions of the brain in both sexes of rats given 800 mg/kg/day, but not in

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

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

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

[61] https://pubchem.ncbi.nlm.nih.gov/compound/Benzaldehyde#section=Toxicity-Summary.

[62] https://pubchem.ncbi.nlm.nih.gov/source/hsdb/388.

mice. Renal tubular necrosis occurred in male and female rats on 800 mg/kg/day and in male mice on 1200 mg/kg/day. Mild epithelial hyperplasia or hyperkeratosis of the forestomach was seen in male and female rats on 800 mg/kg/day. In an inhalation study performed with rats, it was found that the principal histopathological change was the development of goblet cell metaplasia in the respiratory epithelium lining of the nasal septum. In 2 year studies, there was no evidence of carcinogenic activity of benzaldehyde for male or female rats receiving 200 or 400 mg/kg per day. There was some evidence of carcinogenic activity of benzaldehyde for male or female mice, as indicated by increased incidences of squamous cell papillomas and hyperplasia of the forestomach. Benzaldehyde was studied for mutagenicity using Salmonella typhimurium tester strains TA100, TA102 and TA104, with or without metabolic activation. It was non-mutagenic under all test conditions with dose ranges from 33 to 3333 ug/plate. No induction of chromosomal aberrations was observed in CHO cells treated with up to 500 ug/mL benzaldehyde without metabolic activation or with up to 1600 ug/mL with metabolic activation.

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."

Benzaldehyde (CAS # 100-52-7)

Benzaldehyde is toxic to nematodes[63] and soil microorganisms[64] and has been suggested as a soil fumigant. It may be toxic to crops.[65]

Conclusion

The NOSB should sunset List 3 "inerts" and refer the NOP to the 2012 NOSB recommendation. We understand the importance of pheromones to organic production, and it

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[63] Chavarria-Carvajal, J.A., Rodriguez-Kabana, R., Kloepper, J.W. and Morgan-Jones, G., 2001. Changes in populations of microorganisms associated with organic amendments and benzaldehyde to control plant-parasitic nematodes. *Nematropica*, pp.165-180.

[64] Wilson, C.L., Solar, J.M., El Ghaouth, A. and Fravel, D.R., 1999. Benzaldehyde as a soil fumigant, and an apparatus for rapid fumigant evaluation. *HortScience*, *34*(4), pp.681-685.

[65] Skinner, J.J., 1918. Soil aldehydes: A scientific study of a new class of soil constituents unfavorable to crops, their occurrence, properties and elimination in practical agriculture. *Journal of the Franklin Institute*, *186*(6), pp.723-741.

is not our intention to remove pheromones through this action (though further investigation of specific pheromones may be necessary). Rather, we want to ensure that the materials used in organic production are consistent with all OFPA criteria.

Chlorine Materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite

205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
(i) Calcium hypochlorite
(ii) Chlorine dioxide
(iii) Hypochlorouse acid
(iv) Sodium hypochlorite

We have previously included some general remarks about when the use of sanitizers and disinfectants is appropriate. We began with defining some terms, discussing what we believe to be mistaken translations of NOSB recommendations into regulation, discussing some relevant issues of microbial ecology, looking at chlorine-based chemicals, and finally concluding that the NOSB must undertake a much deeper investigation before allowing the use of chlorine-based materials for another five years. Please refer to our Spring 2017 comments for the general frame of reference for these comments. Here we will hit the highlights.

Before an adequate sunset review can be performed, the NOSB and NOP need to clarify whether chlorine is required by other statutes. Some have said that other laws require the use of chlorine in higher concentrations than those listed on the National List. If other laws specifically require the use of chlorine, then it must be allowed under the organic program. If it is required, the use should be included on the National List with specific citations for the requirements.

In comparison to use in handling, the use of chlorine materials allowed under §205.601 is relatively limited. The regulation allows drinking water that meets the criteria of the Safe Drinking Water Act to be used in contact with food and crops –which may thus be irrigated and washed with tap water. Higher concentrations may be used for disinfecting equipment, but it must not result in concentrations higher than those in tap water contacting the soil or crops. The exception is sprouts, and the NOSB should determine whether that exception is necessary.

Chlorine materials are hazardous to humans and the environment during manufacture and use.

Chlorine is a strong oxidizer and hence does not occur naturally in its pure (gaseous) form. The high oxidizing potential of chlorine leads to its use for bleaching, biocides, and as a chemical reagent in manufacturing processes. Because of its reactivity, chlorine and many of its compounds bind with organic matter. When used as a disinfectant, chlorine reacts with microorganisms and other organic matter. Similarly, the toxicity of chlorine to other organisms comes from its power to oxidize cells. Chlorine has toxic effects on beneficial soil organisms.[66]

In addition to the purposeful production of toxic chlorine compounds, the manufacture and use of chlorine compounds results in the unintended production of other toxic chemicals. Disinfection with chlorine, hypochlorite, or chloramines results in the formation of carcinogenic trihalomethanes, haloacetic acids, and other toxic byproducts.[67] Disinfection with chlorine dioxide produces undesirable inorganic byproducts, chlorite and chlorate. Industrial production of chlorine compounds, use of chlorine bleach in paper production, and burning of chlorine compounds releases dioxins and other persistent toxic chemicals into the environment.[68]

There are alternatives to chlorine materials.

Again, the uses of chlorine materials allowed under §205.601 are quite limited. The use of chlorinated tap water for irrigation should be avoided when possible, but often no alternative source may be available. For cleaning equipment and irrigation systems, technical reviews on chlorine have identified the following alternative materials: ethanol and isopropanol; copper sulfate; hydrogen peroxide; peracetic acid –for use in disinfecting equipment, seed, and asexually propagated planting material; soap-based algaecide/demossers; phosphoric acid, and ozone. The TRs also identified some alternative practices –steam sterilization and UV radiation.[69]

Chlorine materials are not compatible with organic production.

The fact that use of chlorine is so universally associated with the production of persistent toxic chemicals has led some environmental groups to seek a ban on chlorine-based chemicals. We believe that organic production should, for the same reasons, avoid the use of chlorine as much as possible. The allowance of chlorine in the rule reflects the fact that many organic growers—like most of the rest of us— depend on water sources that have been treated with chlorine.

Conclusion

We do not believe that organic producers should have to filter chlorine out of the tap water they use for irrigating, cleaning equipment, washing vegetables, or cleaning food-contact surfaces. But they should not be adding more chlorine. Organic production and handling should be, to the extent possible, chlorine-free.[70]

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[66] 2011 Crops TR.

[67] Alexander G. Schauss, 1996. Chloride – Chlorine, What's the difference? P. 4. http://www.mineralresourcesint.com/docs/research/chlorine-chloride.pdf.

[68] ATSDR, 1998. Toxicological Profile for Chlorinated Dibenzo-p-Dioxins. Pp. 369 ff. http://www.atsdr.cdc.gov/toxprofiles/tp104.pdf.

[69] 2011 Crops TR and 2006 Livestock TR.

[70] The Organic Foods Production Act, §6518(m), lists three criteria that directly pertain to chlorine: (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems; (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance [. . .]

Magnesium oxide

§205.601(j)(5) Magnesium oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.

In voting to list magnesium oxide in 2014, a minority opinion supported adding an expiration date, with the following justification:

> A synthetic material used in organic production, even if used in small quantities, must meet all of the OFPA criteria. Current consideration of the material has raised issues relating to environmental impacts and alternatives. (1) The review in 5 years must be performed with the same standard for allowing continued use as is used to approve use in the first place; (2) the need for liquid humates and hence MgO should be re-evaluated; (3) the possibility of using nonsynthetic acids in place of synthetic sulfuric acid must be re-evaluated.

Beyond Pesticides supported the minority position to list with a 5-year expiration date annotation.

Magnesium oxide is a relatively benign substance that has a wide range of uses. In this use, a small addition of magnesium oxide to a clay suspension agent prevents the settling of finely ground humates in liquid. The approval of magnesium oxide permits the use of natural humates in a liquid formulation, but it is still preferable to add humates through soil-building practices (including composting), and we urge that the certification of organic system plans recognize that tools like this should not become a crutch on which there is continuous reliance.

Moreover, although magnesium oxide is relatively benign, its manufacture creates pollution or depends on polluting industries. The process of using salt brine depends on additions of sulfuric or hydrochloric acids, which relies on industries creating sulfuric acid pollution or the chlorine industry, and organic production should not be reliant on those industries, which do not embrace the core values and principles of organics. On the other hand, the process using dolomite limestone requires high inputs of fossil fuel energy and results in releases of carbon dioxide into the atmosphere both from combustion and from the gas driven off from the limestone.

The need for magnesium oxide is tied to the need for liquid humates. Liquid humates are a substitute for the humates that are naturally produced by organic practices. While we do not oppose relisting of magnesium oxide for this use, we encourage the CS to explore ways to limit the use of liquid humates and magnesium oxide after a transition to organic.

Calcium chloride

205.602(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

The sunset is for prohibition as a nonsynthetic, but it is still relevant that the rule states in section 205.601(j):

> “(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.”
>
> The TAP review was done in 2001. Summary (lines 14-17):
> All the reviewers concluded that the material is inappropriate for soil application given the high chloride content and high solubility. Two of the three reviewers would prohibit all production uses except for foliar applications to correct nutritional deficiencies. All three reviewers agree that natural sources of food-grade calcium chloride should be allowed as a postharvest dip. One would support adding synthetic food-grade sources to the National List for postharvest treatment.
>
> TAP reviewer 2 (lines 423-425):
> I don’t see supporting evidence that this is entirely compatible. It appears that one of the reasons that Ca is deficient in the organs of certain fruits is that breeds of crops have been introduce to maximize fruit yield. If the deficiency is dependent on variety of fruit, would it behoove us to promote the use of varieties that do not exhibit the deficiencies?

The 2021 TR does not seem to add information that would contribute to the issue of whether to allow calcium chloride to be used with the existing annotation. It is still not clear that the conditions exist—“a physiological disorder associated with calcium uptake”—that <u>require</u> the use of soluble calcium.

Rotenone

We support the relisting of rotenone on §205.602, prohibited nonsynthetic materials. Even though the Environmental Protection Agency’s registration for rotenone was voluntarily cancelled for all uses except as a piscicide in 2006—and thus rotenone is not allowed in organic production in the U.S.—one only needs to search the web to find that there is a widespread misconception that organic farmers still use it. Organic agriculture is widely, but falsely, criticized for still using rotenone, which is associated with Parkinson’s disease and other central nervous system damage. Products grown outside the U.S. and sold here, which would not be affected by EPA’s registration decisions now must be grown without rotenone.

So, even though the listing of rotenone on §205.602 will not make a difference legally on use in the U.S., we support it for its clarifying effect, especially related to imports.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors