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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-20-0089

Re. CS: Sunsets

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

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.

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? 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**

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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.

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.

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.[5]

Rice accumulates arsenic[6] and is the largest non-seafood source of arsenic in the American diet.[7] 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.[8] Although the principal source of the arsenic has been identified as arsenic pesticides formerly used in areas now used for rice production,[9] 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 TR or TAP review to address these

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

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

[7] 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.

[8] 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.

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

systems. This would be a good use of a Technical Advisory Panel –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?

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."[10] *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. Those test results should be 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 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 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 phase out 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

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

have deleterious effects on the lungs and cause respiratory disease.[11] 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.[12]

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, the Crops Subcommittee should ask:

1. **Does the use of ozone in organic crop production pose a hazard for workers?**
2. **Would restrictions on the use of ozone (annotation) help protect workers?**

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."[13] The process is described in Appendix B or the EPA Draft Health and Environmental Risk Assessment for Peroxy Compounds.[14]

EPA has efficacy data for peracetic acid products that indicate strong effectiveness on hard surfaces.[15] 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.

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[11] Ozone TAP, lines 296-299. August 14, 2002.
[12] Ozone TAP, lines 695-697.
[13] https://beta.regulations.gov/document/EPA-HQ-OPP-2009-0546-0017.
[14] https://beta.regulations.gov/document/EPA-HQ-OPP-2009-0546-0017.
[15] http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:7:::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:2278.

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.[16]

> 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.[17]

In March 2020, EPA issued a human health and environmental risk assessment for peroxy compounds.[18] Previously, the American Conference of Governmental Industrial Hygienists (ACGIH) set new occupational exposure limits for peracetic acid,[19] the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) established even more stringent limits,[20] and a review by scientists from Ecolab, a member of the PCTF and manufacturer of peracetic acid products, has come up with similar limits.[21] 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.[22]

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

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[16] http://www.epa.gov/sites/production/files/2014-04/documents/pr2013-2.pdf.
[17] 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.
[18] https://beta.regulations.gov/document/EPA-HQ-OPP-2009-0546-0017.
[19] http://potentcompoundsafety.com/2014/02/acgih-occupational-exposure-limit-peracetic-acid.html.
[20] 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/.
[21] 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.
[22] 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.

peracetic acid.[23] The TR reveals that there are several distinct substances called "peracetic acid," and that not all are permitted under NOP regulations.[24]

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?**

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 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 demanding 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.

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[23] 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*.
[24] 2016 Peracetic Acid TR Crops. Lines 236-260 and Table 5.

NOP refused to codify this recommendation. In doing so, NOP has violated 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 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 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 submit the following information to help the CS begin its review.

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).[25]

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

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).[26] Little toxicological information is available concerning octyl bromide, but it is harmful if inhaled and causes eye, skin, and respiratory tract irritation.[27] 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.[28]

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).

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

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[26] 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.

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

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

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.

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.

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."

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.[29]

2-Hydroxy-4-n-octyloxybenzophenone

Ciba submitted 3 adverse effects reports under TSCA for sensitization. It is not readily biodegradable.[30]

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."

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[29] 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.

[30] 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.

Environmental impacts from its use or manufacture

BHT

An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.[31] Another review cites classifications as hazardous.[32]

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.[33]

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

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)."[34]

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[31] 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.

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

[33] 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.

[34] 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

"[R]elated compounds in the benzophenone family have been shown to form estrogenic photoproducts, upon exposure to UV or sunlight (Hayashi et al. 2006)." [35]

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.[36]

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."

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) 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

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

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

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.[37]

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.[38] 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.[39]

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[37] 2011 Crops TR.

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

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

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.[40]

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.

Questions to address

1. **Are there (crop-related) uses of chlorine materials that are required by other laws?**
2. **Are there uses of chlorine materials that are essential in organic crop production?**
3. **Are there uses of chlorine materials in organic crop production for which other materials must be approved?**
4. **What happens to the sodium hydroxide produced when hypochlorous acid is made by electrolysis?**

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.[41]

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:

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[40] 2011 Crops TR and 2006 Livestock TR.

[41] 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;

> 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.

We opposed the petition in spite of the recognition of some need. Beyond Pesticides board member Chip Osborne of Osborne Organics is a nationally recognized expert on organic land care. Here are his comments on the importance of liquid humates in organic and transitional land care:

> Many of the programs that I am developing involve the use of liquid humate, such as my work with municipalities, school districts, and the National Park Service. It is my experience that when I am trying to develop programs to reduce and eliminate pesticide use, it is important that we also eliminate synthetic fertilizer use. It is my opinion and observation that the repeated use of synthetic fertilizers ultimately creates a dependence upon the synthetic control products.
>
> So, in order for me to be successful from the pesticide aspect, I need to move nutrition to the organic perspective. A combination of no pesticides while using synthetic fertilizers usually meets with less than satisfactory outcomes. As we all know in organics of any kind, we are talking about creating and building a system as opposed to arbitrarily putting down a series of product inputs. We are trying to be proactive as opposed to being reactive.

The nutritional programs that I have been working with the last couple of years are all programs that focus on low dose applications of nitrogen and phosphorus. I am working on the principle that "less is more." I find that I can use an organic source of nitrogen, either liquid or granular and use it at low dose as long as I have other inputs that address other aspects of that system. Traditionally, nitrogen has been used as the direct stimulus for growth. From the organic perspective, we certainly need to address the needs of the plant, but we also need to address soils and soil health. This is where the humate comes in.

I have had great success by combining low dose applications of nitrogen, kelp, humates, reconstituted sea minerals, and molasses. This combination has allowed me to meet nutritional requirements because I am influencing aspects of the system without using nitrogen in large amounts. I am using soluble humate to address the health of soils and improve interactions within the organic matter fraction. This fraction ultimately supports much of the biological life in the soil, which in turn is fundamental for success in mineralizing an organic source of nitrogen to the inorganic (ammonium or nitrate).
I have multiple projects and trials underway in various regions of the country that involve liquid programs similar to what I have outlined here. They range in scale from small to large. All of these, for the most part, rely on a formulation of humic acid as part of that liquid application. In my programs it is no one input that creates success, but rather a combination of low dose inputs that all work together to assist in the creation of a healthy system.

We create healthy, vigorously growing plants in order to outcompete pest pressures--insects, weeds, and disease. Building a healthy system is much more than just applying a bag of fertilizer. It is critical that the needs of the plants and the needs of the soil both be met upfront. It is in this framework that liquid humate is important to me. I would love to be able to design organic nutritional programs where I could say that all inputs are OMRI approved.

Questions to address

1. **Are liquid humates (and hence magnesium oxide) still needed?**
2. **Is it possible to obtain magnesium oxide whose manufacture does not use sulfuric or hydrochloric acid?**

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?

Questions:

1. **Is there any evidence that the prohibition is inappropriate?**
2. **What are the alternatives to the use "as a foliar spray to treat a physiological disorder associated with calcium uptake"?**

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 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, we support it for its clarifying effect.

Thank you for your consideration of these comments.

Sincerely,

Teresa Ann Shistar

Terry Shistar, Ph.D.
Board of Directors