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USDA-AMS-NOP
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Washington, DC 20250-0268

Docket ID # AMS-NOP-21-0038

Re. LS: Sunsets

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.

Activated charcoal

§205.603(a) (6) Activated charcoal (CAS # 7440-44-0)—must be from vegetative sources.

This is one of several materials recommended by the NOSB for addition to the National List in 2002 and added by the National Organic Program (NOP) in 2018. We—and the NOSB—have been at a disadvantage in evaluating this material because the Technical Review (TR) that was due in late January or early February was not available. A TR review is now available, in addition to the TAP review from 2002.

> In response to
> “Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers?”

the TR states,[1] “Activated charcoal does not contain any active ingredients listed in part (A) of this question.” If this were true, then activated charcoal would not be eligible for listing on §603. However, activated charcoal as listed on §603 is a livestock medicine. This is important not only in determining eligibility for listing, but also because, as a synthetic material, activated charcoal is not an allowable feed ingredient and must be used under the terms constraining the use of medicines in organic livestock production. These include OFPA §6509 (d)(1), “For a farm to be certified under this chapter as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not—. . .(C) administer medication, other than vaccinations, in the absence of illness.” Thus, some of the uses reported in the TR—such as a routine food additive—are not allowed.

Activated charcoal is used as the preferred therapeutic treatment as needed for treatment of suspected poisoning by plants or moldy silage. Activated charcoal removes toxic chemicals by adsorption. It is then excreted. The 2002 TAP review expressed concern about manure from treated animals: “The purpose of activated carbon is to absorb toxins accidentally ingested by livestock, allowing these toxins to safely pass through the GI track of the animal without being absorbed by the body. These toxins would be then be deposited in the animal’s manure. Animal manure cannot contaminate crops, soil or water with pathogenic organisms, heavy metals or residues of prohibited substances (7 CFR 205.203(c)). If the toxins can be broken down by composting without harming the composting organisms, the contaminated manure can be composted (and documented in the organic management plan). If the toxins are heavy metals, the manure must be disposed of without contaminating organic crop lands or water.”[2] In view of this concern, the NOSB should consider annotating the listing for activated charcoal to include proper handling of manure after treatment.

Calcium borogluconate

§205.603 (a)(7) Calcium borogluconate (CAS # 5743-34-0) - for treatment of milk fever only.

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were acted upon in a final rule published in December 2018.

The listing allows calcium borogluconate for treatment of milk fever. We—and the NOSB—are at a disadvantage in evaluating this material because a recent Technical Review is not available.

In the TAP review prepared in 2000, several issues were raised:

- No LD_{50} was found for calcium borogluconate.
- No information about the metabolism and fate of the boron portion was available.
- The calcium gluconate portion may be produced by fermentation of a genetically engineered form of *Aspergillus niger*.

[1] Activated charcoal TR, 2021. Line 270.
[2] Activated charcoal technical advisory panel report, 2002. Lines 432-438.

Calcium borogluconate was used in organic cows for milk fever before 2018 by virtue of its inclusion as an electrolyte. There is a 2015 technical review of electrolytes, which has this to say about calcium borogluconate:

- All of these materials except magnesium citrate, calcium borogluconate, magnesium hypophosphite and magnesium borogluconate are FDA permitted feed additives. All of these materials except glycine, calcium borogluconate, magnesium borogluconate, and calcium sulfate are Generally Recognized as Safe (GRAS). Those not GRAS or approved food additives are considered slightly toxic."[3]
- "The average dose of boric acid that produces toxic effects in humans is 3.2 g. In sensitive individuals, the dose that produces toxic effects is 0.1 g (Harper et al. 2012). The maximum dose of calcium borogluconate for milk fever is 125 grams, and this contains 32 g of boric acid (Bayer 2013b). From mouse data, at least 90% would be excreted in urine over 96 hrs (Harper, et al. 2012). Assuming the remaining (3.2 g), went into the milk, it would be diluted when the dairy pooled the milk with that from other cows…. If the milk from a treated cow was not pooled about 3.2 g would be excreted over a 96 hr period into about 22 gallons of milk. The average concentration in the milk would be about 145 mg/gallon. The amount in one gallon would be about 22 times lower than the average toxic threshold. In the rare case of individuals sensitive to boric acid acid, the amount would be about 1.5 times lower than the toxic threshold."[4]

These very helpful calculations in the TR suggest that a withdrawal period should be established. In addition, boron, boric acid, and borates have recently been classified as reproductive and developmental toxicants.[5]

The TR's calculations of boron excreted suggest that the resulting environmental boron would not exceed normal levels after cows are treated—assuming that cows are not treated on a routine basis.[6]

Veterinarians believe that calcium borogluconate is an essential emergency treatment for milk fever.[7] In view of the concerns expressed above, we hope that the LS will examine the need for an annotation establishing a withdrawal period.

A Note on Off-Label Uses of Livestock Drugs

The standards of the Food and Drug Administration are different from organic standards. However, OFPA §6519(c)(6) does require compliance with Federal Food, Drug, and Cosmetic Act (FFDCA). The requirements of OFPA and the organic regulations can only go

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[3] Lines 888-894.
[4] Lines 983-999.
[5] Agency for Toxic Substances and Disease Registry, 2010. Toxicological Profile for Boron. https://www.atsdr.cdc.gov/ToxProfiles/tp26.pdf.
[6] Lines 897-910.
[7] TAP review, personal communications between Christie Badger and Dr. Hue Karreman and Dr. Dayna Locitzer.

beyond what is required by the FFDCA, so the NOSB must be able to get a clear sense of what FDA requires. The electrolytes technical report states,[8]

> The FDA considers electrolyte formulations to be animal drugs, but many of the formulations have not been formally approved by the FDA. Often this is because they are non-proprietary, general use materials, and no company has applied for a New Animal Drug Approval (NADA) (OMRI 2013; USDA 2005b).
>
> Over 3,000 animal drugs currently being marketed have not been formally approved by the FDA. Many are benign, and have a long history of safe use. For instance, calcium borogluconate formulations have been in use since 1935. FDA enforcement and regulation of these unapproved drugs has a low priority. They are generally marketed without FDA interference (USDA 2005b) via FDA's use of regulatory discretion with illegally marketed drugs (US FDA 2011).

We come back to this periodically with animal drugs. For example, use of xylazine and tolazoline that is allowed by the organic regulations appears to be contrary to FDA regulations. How can NOP depend on FDA assessments of "illegally marketed drugs" sold "without FDA interference"? It puts organic producers, the NOSB, certifiers, and inspectors in a difficult position if we are relying on an agency that's not doing anything.

It is not clear what the NOSB can do about this situation besides recommending that NOP request a written clarification from FDA.

Calcium propionate

§205.603(a) (8) Calcium propionate (CAS # 4075-81-4)—for treatment of milk fever only.

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were listed in a final rule published in December 2018.

The listing allows calcium propionate for treatment of milk fever. We—and the NOSB—are at a disadvantage in evaluating this material because a recent technical review is not available. The TAP review from 2002 raised the following issues and concerns:

- The level of concern is different for the routine use as a mold inhibitor than for the therapeutic use for milk fever.
- Most of the TAP review was concerned with the use as a mold inhibitor, and the therapeutic use was not examined as closely.
- It is not clear how calcium propionate compares with other materials in treating milk fever.
- The use as a mold inhibitor (i.e., a synthetic preservative) does not appear to be compatible with organic production.

[8] Lines 375-383.

Calcium propionate was used in organic cows for milk fever before 2018 by virtue of its inclusion as an electrolyte. There is a 2015 technical review of electrolytes, which has little to say about calcium propionate. While we have found reports of illness when calcium propionate is used as a preservative in food,[9] we cannot determine the relevance of these reports to the use for treatment of milk fever, and encourage the LS to seek a TR on calcium propionate.

In view of the lack of information, the NOSB should not relist calcium propionate.

Chlorine materials (Calcium hypochlorite, Chlorine dioxide, hypochlorous acid, sodium hypochlorite)

§205.603(a)(7) Chlorine materials -—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
(i) Calcium hypochlorite.
(ii) Chlorine dioxide.
(iii) Hypochlorous acid.
(iv) Sodium hypochlorite.

Basic chlorine chemistry

Chlorine is the second most reactive element (after fluorine) in the halogen series. Halogens bond with hydrogen to form acids, are typically produced from minerals or salts, and are generally toxic. The middle halogens –chlorine, bromine, and iodine—are often used as disinfectants.

Chlorine is a strong oxidizer and hence does not occur naturally in its pure (gaseous) form. Nearly all naturally occurring chlorine occurs as chloride, the ionic form found in salts such as sodium chloride. Gaseous chlorine is formed by running an electric current through salt brine.

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. In the case of bleaches, the reaction with chlorine destroys chemicals responsible for color. 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.

The difference between chlorine and chloride

Chloride, the ionic form of chlorine, occurs naturally and is necessary for life. Synthetic chlorine compounds may be inert –in which case the chlorine is responsible for a lack of biodegradability—or its toxic effects. Chlorinated organic compounds include pesticides ranging

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[9] For example, Dengate, S. and Ruben, A., 2002. Controlled trial of cumulative behavioural effects of a common bread preservative. *Journal of Paediatrics and Child Health*, *38*(4), pp.373-376.

from DDT to 2,4-D, as well as contaminants like dioxins. Chlorine gas was the first poison gas used in warfare. The largest use of chlorine is in the manufacture of polyvinyl chloride (PVC).

Chlorine gas reacts with water to produce hydrochloric acid (HCl), hypochlorous acid (HOCl), and hypochlorite (OCl^-). When hypochlorous acid reacts with ammonia, it forms chloramines, which are reactive enough to be used as disinfectants, but are more stable than hypochlorous acid and hypochlorite.

Another series of reactions creates chlorine dioxide, an extremely toxic and potentially explosive gas that dissolves in water, rather than reacting with it. Sodium chlorate is produced by electrolysis of hot salt water. Chlorine dioxide is produced by reacting sodium chlorate with a suitable reducing agent in a strongly acidic solution. Sodium chlorite may be produced from the chlorine dioxide solution under alkaline conditions using hydrogen peroxide. Acidifying the sodium chlorite solution produces chlorine dioxide for disinfection.

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.[10] 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.[11]

The essential difference, then, is between chloride compounds and the toxic products and by-products of the chlorine chemical industry. Almost all of the former are naturally-occurring materials that do not share the characteristics of toxicity and undesired persistence of the latter. The fact that use of chlorine —as opposed to chloride— 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. We don't 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.[12]

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

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

[12] 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 [. . .]

Disinfection

Terminology relating to chlorine-based disinfection

In the past, we have seen some confusion over the terminology used to describe chlorine in treated water. This description may help:

> Reactive chlorine (RC) is the combined concentration of various chlorine species able to react and interconvert in a given system. It is essentially synonymous with total residual chlorine (TRC), combined residual chlorine (CRC), and total available chlorine (TAC). It includes free available chlorine (FAC; hypochlorous acid [HOCl] and the hypochlorite ion [OCl]; also referred to as free residual chlorine [FRC]) and combined available chlorine (CAC; organic and inorganic chloramines [NH_2Cl, $NHCl_2$, and NCl_3] or *N*-chloramides).[13]

Chlorine disinfection in organic regulations

There is a history[14] of misunderstanding and misinterpretation of the original November 1995 NOSB recommendation on chlorine materials that has led to confusion and the allowance of uses of chlorine by NOP that were not permitted by the NOSB recommendation. In 1995, the NOSB intended to distinguish chlorine used to disinfect tools, equipment, and other hard surfaces from chlorine used in direct contact with food and crops.

In November, 1995, the NOSB approved the following recommendation concerning the use of chlorine:

> Chlorine Bleach (Calcium hypochlorite, sodium hypochlorite, chlorine dioxide) - Determined to be synthetic; Vote - Unanimous (2 absent).
>
> The NOSB's decision is to allow this material for use for organic crop production, organic food processing, and organic livestock production.
> Vote: 9 aye / 2 opposed / 2 absent.
>
> Annotation: Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L expressed as Cl2). This substance is to be reviewed again in two years.

With respect to the use in contact with food and crops, no direct use of chlorine is allowed by the 1995 recommendation, but use of tap water is allowed if the level of residual chlorine –the chlorine available for disinfection after the <u>water</u> has been disinfected—is less

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[13] Canadian Environmental Quality Guidelines Canadian Council of Ministers of the Environment, 1999. Canadian Water Quality Guidelines for the Protection of Aquatic Life: Reactive Chlorine Species, p. 1. http://ceqg-rcqe.ccme.ca/download/en/208.

[14] The early history can be found in the 2003 NOSB recommendation "Measuring Effluent: Clarification of Chlorine Contact with Organic Food." https://www.ams.usda.gov/sites/default/files/media/Rec%20Regulation%20Change%20on%20Chlorine%20Contacting%20Org%20Food.pdf.

than the limit in the Safe Drinking Water Act (SDWA). So, tap water can be used to wash produce and irrigate crops, but more chlorine cannot be added for those purposes (with the exception of sprouts.)

With respect to the disinfection of tools, equipment, and hard surfaces, the NOSB simply allowed the use, taking the position that it is not appropriate for the NOP to prescribe the manner of use of these materials. However, the NOSB did state that any residues from such actions should not contact food or crops unless they also meet the SDWA standards.

The first confusion resulted when NOP, in translating the recommendation into regulations, omitted a portion in the recommendation in the listings on §603 and §605.

Chlorine materials used for disinfection are listed in three places on the National List, all of which are subject to 2017 sunset:

> [Crops] §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.
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> [Livestock] §205.603 (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
> (i) Calcium hypochlorite.
> (ii) Chlorine dioxide.
> (iii) Sodium hypochlorite.
>
> [Handling] §205.605(b) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Since "residual chlorine" means (as defined above) the total active chlorine that is available during the use of the water, a straightforward reading would be that that organic producers and processors may use water that is allowable as tap water under the Safe Drinking Water Act –with the exception of cleaning crop production tools and irrigation systems (as long as the concentrated solution does not contact crops) and the use on sprouts.

The NOP guidance on use of chlorine materials,[15] in attempting to clarify the meaning of the regulations, creates greater confusion and permits far more chlorine than is allowed under the regulations and the recommendations on which they are based. NOP correctly states, "This annotation [in §205.605(b)] was originally crafted to acknowledge that levels of chlorine permitted in municipal drinking water were considered acceptable for organic food production and handling." NOP then cites the spring 2003 recommendation by the NOSB on the definition of "residual chlorine" under the Safe Drinking Water Act. It continues,

"The Organic Foods Production Act is not designed to function as a waste water regulation. Instead, it is a regulation designed to protect organic integrity. As such, processing operations must demonstrate compliance with the chlorine annotation by monitoring the chlorine content of the water which is in direct contact with organic products, not the wash water which is discharged from the facility."

However, NOP goes on to explain what this means in practice:

4.1 Crop operations:

1. Residual chlorine levels in the water in direct crop contact (when used pre-harvest) or as water from cleaning irrigation systems applied to soil should not exceed the maximum residual disinfectant limit under the SDWA.

2. Chlorine products may be used up to maximum labeled rates for disinfecting and sanitizing equipment or tools. No intervening event is necessary before equipment is used in contact with organic crops.

4.2 Livestock operations:

1. Residual chlorine levels in the water in direct food or animal contact (for example, drinking water) should not exceed the maximum residual disinfectant limit under the SDWA.

2. Chlorine products may be used up to maximum labeled rates for sanitizing equipment or tools (including dairy pipelines and tanks). Label instructions should be followed regarding requirements for rinsing or not rinsing prior to the equipment's next use.

4.3 Handling operations (includes on-farm post-harvest handling)**:**

1. For food handling facilities and equipment, chlorine materials may be used up to maximum-labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label use directions.

2. Water used in direct post-harvest crop or food contact (including flume water to transport fruits or vegetables, wash water in produce lines, egg or carcass washing) is

[15] NOP 5026. Guidance: The Use of Chlorine Materials in Organic Production and Handling. https://www.ams.usda.gov/rules-regulations/organic/handbook/5026.

permitted to contain chlorine materials at levels approved by the Food and Drug Administration or the Environmental Protection Agency for such purpose.
a. Rinsing with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA must immediately follow this permitted use.
b. Certified operators should monitor the chlorine level of the final rinse water, the point at which the water last contacts the organic product. The level of chlorine in the final rinse water must meet limits as set forth by the SDWA.
c. Water used as an ingredient in organic food handling should not exceed the maximum residual disinfectant limit for the chlorine material under the SDWA, as required by the Organic Food Production Act (7 U.S.C. 6510(a)(7)).

The explanation for crop operations is an acceptable translation of the NOSB recommendation and the listing on §205.601, where the annotation refers only to water in contact with soil or water. However, the guidance for livestock—even though it is consistent with the NOSB recommendation—is inconsistent with the listing on §205.603, which does not refer to a use of a chlorine product outside the use of treated water, and states that the residual chlorine content in the water must not exceed the SDWA limit. Furthermore, the guidance for handling is inconsistent with both the NOSB recommendation and the regulations at §205.605(b)—because it allows use of chlorine for purposes not allowed by the recommendations and food contact with chlorine above the SDWA limits.

We are thus starting from a point at which NOP—through both rulemaking and "guidance"has allowed the use of synthetic substances beyond the uses allowed by NOSB recommendations. We have further recommendations, but first we will suggest corrected language that correctly translates the NOSB recommendation:

> [Livestock, corrected] §205.603 (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water for wash water in direct crop or food contact and in flush water from cleaning equipment and surfaces that is applied to crops or fields shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
> (i) Calcium hypochlorite.
> (ii) Chlorine dioxide.
> (iii) Sodium hypochlorite.

Alternatives to chlorine disinfection

To the extent that organic production requires a disinfectant other than the level of residual in finished drinking water, the NOSB should be looking at non-chlorine alternatives. The above-cited 2003 NOSB recommendation stated:

> The TAP reviews pointed out many ways in which chlorine is unsatisfactory for organic handling. Chlorine compounds and other halogens have been shown to produce trihalomethanes. It was the NOSB's opinion that while chlorine needs to be allowed in

the handling of organic food out of concern for public health and safety, its use needs to be minimized and operators need incentives and clear guidance to develop viable alternatives that protect the public as effectively as chlorine, but are less harmful to food handlers and the environment.

Toward that end, the NOSB has recommended other methods for disinfecting water in crop contact, including ozone, hydrogen peroxide, and periacetic acid. The review of chlorine should be prioritized in the re-review process in light of new information about alternatives, food safety, health effects, and application procedures. To the extent possible, the NOSB encourages the adoption of non-chemical and less toxic methods of disinfection of wash and chill water. This should be done with the full support and cooperation of the Food and Drug Administration's Center for Food Safety and Nutrition, and the Food Safety Inspection Service.

EPA's Design for the Environment (DfE) program has been investigating alternative disinfectants.[16] A DfE label on a disinfectant means that the product meets the following criteria:

1. It is in the least-hazardous classes (i.e. III and IV) of EPA's acute toxicity category hierarchy;
2. It is unlikely to have carcinogenic or endocrine disruptor properties;
3. It is unlikely to cause developmental, reproductive, mutagenic, or neurotoxicity issues;
4. It has no outstanding "conditional registration" data issues;
5. EPA has reviewed and accepted mixtures, including inert ingredients;
6. It does not require the use of Agency-mandated personal protective equipment;
7. It has no unresolved or unreasonable adverse effects reported;
8. It has no unresolved efficacy failures (associated with the Antimicrobial Testing Program or otherwise);

- It has no unresolved compliance or enforcement actions associated with it; and
- It has the identical formulation as the one identified in the DfE application reviewed by EPA.[17]

EPA has approved the following for use in DfE disinfectant products: citric acid, hydrogen peroxide, l-lactic acid, ethanol, isopropanol, peracetic acid, sodium bisulfite, and chitosan.[18] DfE disinfectant product formulations and "inert" ingredients must also meet the DfE standard for safer cleaning products.[19] All of the approved DfE disinfectant active ingredients, except sodium bisulfite and chitosan, are on the National List. Citric and lactic acids are considered nonsynthetic, are listed on §205.605(a), and do not need to be listed in order to be used in crop

[16] http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html.
[17] http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html.
[18] http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html.
[19] http://www.epa.gov/dfe/pubs/projects/formulat/dfe_criteria_for_cleaning_products_10_09.pdf.

or livestock production. In addition, the need for equipment to be clean must be distinguished from a need for disinfection, and disinfection is difficult to accomplish if a surface is not clean.[20]

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, ozone. The TRs also identify some alternative practices – steam sterilization and UV radiation.[21]

Technical reviews for the above sanitizers and EPA's Design for the Environment (DfE) program have identified alternatives, including essential oils and natural acids.

Essential oils are often cited as a class of natural disinfectants. The TR for hydrogen peroxide refers to the following essential oils and extracts: clove oil, melaleuca (tea tree) oil, and oregano oil, pine oil, basil oil, cinnamon oil, eucalyptus oil, helichrysum oil, lemon and lime oils, peppermint oil, tea tree oil, and thyme oil. Aloe vera contains six antiseptic agents active against fungi, bacteria and viruses. There is considerable research on essential oils as disinfectants that could be useful to organic producers. For example, an early review by Janssen et al described methods for screening.[22] A more recent review by Kalemba and Kunicka provides an updated review of screening methods and an overview of the susceptibility of human and food-borne bacteria and fungi towards different essential oils and their constituents.[23] Deans and Ritchie compare the potency of 50 different essential oils and the range of their antibacterial action against 25 genera of bacteria.[24] Based on a review of the literature, the NOSB should encourage the use of safer materials more compatible with organic principles.

Practices that eliminate the need for disinfectants

Technical reviews have mentioned practices that eliminate the need for disinfectant materials. They include: hot water, steam, UV radiation, slow filtration for cleaning water. As pointed out at the beginning of these comments, "cleaning" is not synonymous with disinfection, and it is possible that in some cases, disinfection is not necessary at all.

Conclusion

While the uses of disinfectants vary so that no one method or material is likely to be effective in all cases, there are numerous alternative methods and materials that should allow organic producers and handlers to avoid the use of the most toxic materials—in particular,

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[20] Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf.

[21] 2011 Crops TR and 2006 Livestock TR.

[22] Janssen, A. M., Scheffer, J. J. C., & Svendsen, A. B. (1987). Antimicrobial activities of essential oils. *Pharmaceutisch Weekblad*, *9*(4), 193-197.

[23] Kalemba, D., & Kunicka, A. (2003). Antibacterial and antifungal properties of essential oils. *Current medicinal chemistry*, *10*(10), 813-829.

[24] Deans, S. G., & Ritchie, G. (1987). Antibacterial properties of plant essential oils. *International journal of food microbiology*, *5*(2), 165-180.

those containing chlorine. Regarding alternative materials for teat dips, the iodine TR says, "The available information suggests that commercial antimicrobial products containing oxidizing chemicals (e.g., sodium chlorite, hypochlorite, iodophor), natural products composed of organic acids (e.g., lactic acid), and homemade products using vinegar (i.e., acetic acid) as the active ingredient may all be equally effective teat dip treatments." The active ingredients identified by the DfE are safer and effective alternatives.

We have discussed many alternatives that are available for use by organic producers and handlers. Rather than simply proposing another renewal of the use of chlorine-based materials, the NOSB subcommittees should commission a TR that (1) determines which disinfectant/sanitizer uses are required by law, and (2) comprehensively examines more organically-compatible methods and materials to determine whether chlorine-based materials are actually needed for any uses. If there are uses for which chlorine is necessary, then the NOSB should review them for inclusion on the National List and, assuming compliance, annotate the uses to those allowed.

Kaolin pectin

§205.603(a) Kaolin pectin—for use as an adsorbent, antidiarrheal, and gut protectant.

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were acted upon in a final rule published in December 2018. We—and the NOSB—are at a disadvantage in evaluating this material because the requested technical review is not available.

Kaolin pectin is used as an adsorbent, antidiarrheal, and gut protectant in organic livestock production. There has been recent discussion of pectin by the NOSB as it is used in organic food processing, particularly relating to its classification. If pectin is non-amidated, then kaolin pectin is nonsynthetic and should not be listed on §205.603. In fact, the 2002 NOSB recommendation stated, "It is probably not necessary to list kaolin pectin since in one form it is a natural." In view of these issues, kaolin pectin should not be renewed. We recommend that the NOSB specifically address the issue of whether kaolin pectin containing amidated forms of pectin should be allowed (since non-amidated forms are already allowed.)

In reviewing the impact of the manufacture of kaolin pectin, the LS must consider the impacts of raising the non-organic crops used to produce pectin.

Oranges

California Farmworker Poisonings, 1992–2010: 508 reported (CA acreage: 180,000). These poisoning incidents only represent the tip of the iceberg because it only reflects reported incidents in one state that requires poisoning reports from health care professionals. It is widely recognized that pesticide incidents are underreported and often misdiagnosed.

Pesticide Tolerances —Health and Environmental Effects: The database shows that while oranges grown with toxic chemicals show low pesticide residues on the finished commodity, there are 73 pesticides with established tolerance for oranges, 31 are acutely toxic creating a hazardous environment for farmworkers, 65 are linked to chronic health problems (such as cancer), 21 contaminate streams or groundwater, and 61 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 25 pesticides used on oranges that are considered toxic to honey bees and other insect pollinators. For more information on how to protect pollinators from pesticides, see Beyond Pesticides' BEE Protective webpage.

- This crop is dependent on pollinators.
- This crop is foraged by pollinators.

Apples

California Farmworker Poisonings, 1992–2010: 104 reported (CA acreage: 17,500). These poisoning incidents only represent the tip of the iceberg because it only reflects reported incidents in one state that requires poisoning reports from health care professionals. It is widely recognized that pesticide incidents are underreported and often misdiagnosed.

Pesticide Tolerances —Health and Environmental Effects: The database shows that while apples grown with toxic chemicals show low pesticide residues on the finished commodity, there are 109 pesticides with established tolerance for apples, 39 are acutely toxic creating a hazardous environment for farmworkers, 92 are linked to chronic health problems (such as cancer), 21 contaminate streams or groundwater, and 92 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 41 pesticides used on apples that are considered toxic to honey bees and other insect pollinators. For more information on how to protect pollinators from pesticides, see Beyond Pesticides' BEE Protective webpage.

- This crop is dependent on pollinators.
- This crop is foraged by pollinators.

Mineral Oil

§205.603(a)(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were listed in a final rule published in December 2018. There is a new limited-scope technical review available.

The 2015 TR says, "[B]ased on consultations with the US Food and Drug Administration (FDA), the NOP was informed that mineral oil has not received approval through the FDA drug approval process to be authorized as a medical treatment in cattle, and the substance would not qualify for extra-label use by a licensed veterinarian. . . . Accordingly, the NOP was unable to accept the NOSB recommendation to allow the use of mineral oil as a livestock medication under 7 CFR 205.603. Mineral oil remains prohibited for use in organic livestock production as an orally administered treatment of constipation in cattle and other ruminants." The contradictions between the FDA statements the listing need to be clarified. This is yet another example of the difficulty of depending on FDA, when that agency's actions are not clear about how they should impact NOSB actions.

Conclusion

The 2021 TR lists a number of non-synthetic alternatives to mineral oil, some which share the same mode of action, and some which include intestinal stimulation in their mode of action. In addition, mineral oil varies in its degree of purity and may include toxic and carcinogenic components. We suggest that the NOSB either annotate the listing of mineral oil to ensure a high degree of purity or remove it from the National List, which would require the substitution of natural alternatives.

Nutritive supplements

(21) Nutritive supplements—injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

These substances were among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that listed in a final rule published in December 2018. We—and the NOSB—are at a disadvantage in evaluating this material because the requested technical review is not available.

This listing makes available injectable vitamins, minerals, and electrolytes in addition to use orally as feed additives (vitamins and minerals per §205.603(d)) or medical treatments (electrolytes without antibiotics per §205.603(a)). The listing of injectable vitamins, minerals, and electrolytes makes sense if it is clear that they may be used therapeutically, but not on an ongoing basis. Just as with orally-supplied vitamins and minerals, synthetic inputs may be needed to respond to unusual conditions or fine tune the system, but in organic production, they cannot be routine. The blanket listing of all synthetic vitamins as feed additives (205.603(d)) is not justified. Nor should the listing of injectable vitamins and minerals refer to the use as feed additives. The 1995 NOSB recommendation on vitamins saw a limited use of synthetic vitamins, to be reviewed within two years. Livestock producers were to "to decrease or eliminate use of feed additives when possible." From the table in the 2015 technical review, we conclude that livestock feed should rarely need supplementation with synthetic vitamins, so it should be made clear that all synthetic vitamins, minerals, and electrolytes may be provided only as medical treatments.[25]

Propylene glycol

§205.603(a) (27) Propylene glycol (CAS #57-55-6)—only for treatment of ketosis in ruminants.

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[25] 2015 Technical Review of Vitamins for Livestock, lines 1142-1201.

This substance was among 35 NOSB recommendations on amendments to the National List, made between November 2000 and November 2016, that were published in a final rule in December 2018. The requested technical review is only now available.

The proposed rule would add propylene glycol to §205.603 of the National List for use in organic livestock production with the annotation, "only for treatment of ketosis in ruminants." Although the TR identifies only minor adverse environmental and health impacts associated with the use of propylene glycol, norms for treatment of organic livestock, as cited by the LS, require that health issues be addressed preventively. The TR identifies feeding high levels of concentrates as a risk factor, while grazing and high-forage diets lead to a lower rate of ketosis.[26]

Nonetheless, it is important to be able to respond in the case that preventive practices are not effective. In view of this, it is important to review the recommendations for treating ketosis of Dr. Paul Dettloff.[27] Dr. Dettloff does not mention propylene glycol, but gives a number of suggestions for prevention (maintaining a high-energy diet before calving, including dry long-stemmed hay) and treatment (glucose IV, homeopathic lycopodium, molasses, and Wellness Tonic containing apple cider vinegar and aloe vera, with tinctures of rose hips, dandelion root and plantain.)[28] The TR identifies molasses, glycerin, glucose, choline, and B vitamins as alternative treatments.[29]

In view of these considerations, propylene glycol should be sunsetted.

Sodium chlorite, acidified

§205.603(a) (28) Sodium chlorite, acidified—allowed for use on organic livestock as a teat dip treatment only.
§205.603(b) (9) Sodium chlorite, acidified—allowed for use on organic livestock as teat dip treatment only.

Acidified Sodium Chlorite (ASC) is 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 early 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. We don't 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

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[26] Propylene glycol TR, 2021. Lines 727-743.
[27] Paul Dettloff, 2009. *Alternative Treatments for Ruminant Animals*, revised and expanded edition. Acres U.S.A. Austin, TX.
[28] Details at http://drpaulslab.net/dairy-treatment/ and http://drpaulslab.net/products/.
[29] TR, lines 653-718.

they should not be adding more chlorine. Organic production and handling should be, to the extent possible, chlorine-free.

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.

ASC and chlorine chemistry is harmful to humans and the environment. We addressed this issue in more detail in our comments on chlorine materials (above), but here we will address ASC in particular. "Acidified sodium chlorite" refers to a solution containing several active chlorine species that is formed when acid is added to sodium chlorite. The chlorine compounds contained in ASC include chlorite, chlorate, chlorous acid, and chlorine dioxide gas. The main active ingredient is considered to be chlorous acid, which is a strong oxidizing agent.

Chlorine dioxide is very toxic. It is a severe respiratory and eye irritant. Chronic exposure to animals and workers has resulted in death. Repeated acute exposure to workers has caused eye and throat irritation, nasal discharge, cough, wheezing, bronchitis, and pulmonary edema. Repeated exposure may lead to chronic bronchitis.[30] "In addition, exposure to high levels of chlorine dioxide and chlorite in animals both before birth and during early development after birth may cause delays in brain development."[31]

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.[32] 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 release dioxins and other persistent toxic chemicals into the environment.[33]

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.

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[30] CDC, Occupational health guideline for chlorine dioxide. http://www.cdc.gov/niosh/docs/81-123/pdfs/0116.pdf.
[31] ATSDR, Public Health Statement for Chlorine Dioxide and Chlorite. http://www.atsdr.cdc.gov/phs/phs.asp?id=580&tid=108.
[32] Alexander G. Schauss, 1996. Chloride –Chlorine, What's the difference? P. 4. http://www.mineralresourcesint.com/docs/research/chlorine-chloride.pdf.
[33] ATSDR, 1998. Toxicological Profile for Chlorinated Dibenzo-p-Dioxins. Pp. 369 ff. http://www.atsdr.cdc.gov/toxprofiles/tp104.pdf.

ASC is not necessary. In its listing proposal, the LS said, "There are several teat dips available on the market, but some may be more irritating to the animal than others, and some bacteria may become resistant, and thus a broader array of teat dip ingredient choices for organic farmers seems essential." Beyond Pesticides cannot accept a rationale of resistance management based on providing more toxic chemicals. This approach is responsible for the proliferation of toxic chemicals in the environment and the ineffectiveness of disease and pest management. The best way to preserve the effectiveness of materials is to save their use for limited occasions when nontoxic control measures are inadequate. Routine use creates strong selection pressure for resistance. Rotating use of several toxic chemicals eventually leads to multiple chemical resistance.

Again in the listing proposal, the LS said, "Research indicates that alternative practices to teat dipping/spraying or udder washing are not advised, as the exclusion of a disinfecting step from a mastitis control program would significantly increase the likelihood of infection." Yet, according to the technical review, "The available information suggests that commercial antimicrobial products containing oxidizing chemicals (e.g., sodium chlorite, hypochlorite, iodophor), natural products composed of organic acids (e.g., lactic acid), and homemade products using vinegar (i.e., acetic acid) as the active ingredient may all be equally effective teat dip treatments."[34]

Conclusion

We urge the NOSB to make a commitment to make organic chlorine-free to the extent possible by sunsetting ASC.

Zinc sulfate

§205.603(b) (11) Zinc sulfate—for use in hoof and foot treatments only.

Zinc sulfate poses environmental and health risks.

According to the technical review, emissions from zinc and zinc sulfate production include sulfur dioxide and other gases (sulfur oxides (SOx), nitrogen oxides (NOx), volatile organic gaseous compounds (non-methane volatile organic compounds and methane (CH4)), carbon monoxide (CO), carbon dioxide (CO2), nitrous oxide (N2O), and ammonia (NH3), particulate matter, and heavy metals such as cadmium and zinc. Other chemicals released include lead, cadmium, mercury, zinc, polychlorinated biphenyls (PCBs), and polychlorinated dibenzodioxins.

The disposal method for spent foot bath solutions is mixing the solution with manure, and eventually spreading it on fields. There is concern about buildup of copper and zinc from the disposal of this solution. A study cited by the TR found, "[F]arms regularly using $CuSO_4$ could be applying as much as 4 to 6 kg of Cu/ha annually from the disposal of footbath solutions,

[34] ASC TR, 2013. Lines 540-543.

which is considered as much as 45 to 50 times the annual Cu needed for most crops."[35] This article recommends steps to lower the impacts of copper sulfate from footbaths on soils: test for copper regularly; spread the copper solutions across a large area; reduce the concentration of copper in and frequency of footbath use; use a clean water footbath preceding the copper sulfate footbath in order to improve efficacy; and finally, "The best long-term solution is to find new ways of preventing or treating hoof problems besides using CuSO4."

With regard to zinc sulfate, however, the situation is less clear. Zinc can have severe impacts on soil microbial life. However, according to the TR, "Zinc sulfate interacts with the soil to which it is added. Its toxicity is dependent on its bioavailability. Bioavailability depends on soil type and aging, which further depend on pH, cation exchange capacity and leaching. Soil biochemistry influences the predicted no effect concentration (PNEC) and ecological soil screening level (Eco-SSL) for zinc sulfate, however; zinc soil concentrations protective of wildlife and the environment have not entirely been resolved."[36]

Therefore, it is not easy to point to a threshold above which soil zinc concentrations should not raise. The best practice might be to ensure that zinc levels in the soil do not increase –unless the zinc is added to correct a deficiency.

There are alternatives to zinc sulfate.

The TR lists ethanol, pine tar, peracetic acid, and hydrogen peroxide, in addition to copper sulfate as alternative materials. The TR also lists aspirin and a combination of tea tree oil, jojoba oil, benzathonium chloride, water, propylene glycol, and emulsifiers. Not all of the ingredients of the last are on the National List. Alternative control methods listed in the TR include isolation of affected individuals, application of topically applied agents to hooves that have been pared to expose lesions, full access to pasture, housing with dry floors when indoors, and a good diet rich in zinc.

Routine use of zinc sulfate is not compatible with organic production.

The Livestock Health Care Standard requires:

> §205.238 (a) The producer must establish and maintain preventive livestock health care practices, including:
> (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

Thus, if zinc sulfate is used, it should not be the first recourse, but the alternative that is used when the other management practices mentioned above have been shown to be insufficient.

[35] Downing, T. W., Stiglbauer, K., Gamroth, M. J., & Hart, J. (2010). Case study: Use of copper sulfate and zinc sulfate in footbaths on Oregon dairies. *The Professional Animal Scientist*, *26*(3), 332-334. http://pas.fass.org/content/26/3/332.full.pdf.

[36] Zinc sulfate TR, 2015. Lines 518-522.

Conclusion

If the NOSB decides to relist zinc sulfate, it should recommend an additional annotation comparable to the annotation for coppers in crops, as well as an expiration date to ensure that zinc sulfate receives rigorous review and that soil problems that arise may be addressed:

§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable

Zinc sulfate for use as a footbath only, *provided,* that zinc sulfate must be used and disposed of in a manner that minimizes accumulation in the soil, as shown by routine soil testing. Until [5 years from publication in the *Federal Register*].

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors