

March 23, 2018

Ms. Michelle Arsenault National Organic Standards Board USDA-AMS-NOP 1400 Independence Ave. SW., Room 2648-S, Mail Stop 0268 Washington, DC 20250-0268

#### Re. LS: 2020 Sunset

These comments to the National Organic Standards Board (NOSB) on its Spring 2018 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.

### **Alcohols: Ethanol, Isopropanol**

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (1)(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive (1)(ii) Isopropanol-disinfectant only

#### Ethanol

Ethanol may be manufactured from ethylene or by fermentation. The usual feedstock for fermentation is corn, so the use of genetic engineering is an issue. Ethylene is a hazardous gas. Hazards from the use of ethanol are low. Nonsynthetic ethanol, essential oils, and heat treatment are alternatives, as well as preventive management.

Ethanol is approved for use of EPA's Design for the Environment label for sanitizers.

#### Isopropanol

Isopropanol is volatile and likely to escape to the environment, but its toxicity is low, and it is readily biodegradable. Nonsynthetic ethanol, essential oils, and heat treatment are alternatives, as well as preventive management. Isopropyl alcohol can also be produced by fermentation.

Past supporters of the alcohols have cited use as an antiseptic in organic animal health care, cleanser for the teat end prior to taking a milk sample for bacterial culture, and a substrate to make tinctures of plants.

### Conclusion

The NOSB should investigate the availability organic and/or nonsynthetic alcohols from non-GMO fermentation organisms and feedstock. Findings on this issue are necessary to support a proposal to relist, and Beyond Pesticides supports the LS proposal to relist ethanol and isopropanol if that evidence is presented.

# Aspirin

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (2) Aspirin-approved for health care use to reduce inflammation

In the past, supporters of listing aspirin said it is a widely available medication used for the treatment of pain, inflammation, and pyrexia (fever). It has a wide safety margin with low risk of side effects associated with related nonsteroidal anti-inflammatory drugs (NSAID) drugs. Common conditions in which farmers employ aspirin include mastitis, soft tissue injuries, arthritis, pain control when cows have foot rot, and fever. It also has the benefit of usually being given orally.

While agreeing with the above benefits of aspirin, Hubert Karreman, VMD also points out alternatives:

Homeopathic belladonna, pyrogen and aconite all often used by those who prefer to use homeopathic remedies; however, homeopathy is not a preferred mode of treatment by many individuals since its mode of action is not so easily understandable. There are botanical tinctures such as feverfew and white willow which would have pharmacologic amounts of compounds which reduce fever but may not reduce pain and inflammation. Additionally, these tinctures are not so widely available as is aspirin and aspirin is useful for three indications (fever, pain, inflammation) and not just one.

#### Conclusion

Beyond Pesticides supports the relisting of aspirin because of its importance in treating pain and inflammation.

### **Biologics, Vaccines** 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (4) Biologics - Vaccines

Supporters of the listing of vaccines, note their importance in preventing disease. Dr. Karreman distinguished the role of vaccines from that of nosodes, which are made from actual disease materials and used in disease outbreaks. He also supported allowing all vaccines, including those produced by genetic engineering (GE) because GE vaccines can be generated more quickly when needed.

### Conclusion

Beyond Pesticides supports the relisting of vaccines as listed. No vaccines based on genetically engineered organisms have been or should be approved.

## **Electrolytes**

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (8) Electrolytes—without antibiotics

Supporters of listing of electrolytes say they are indispensable for correcting metabolic disturbances due to dehydration, and they are basic to proper care for animals in various conditions arising from many different causes.

### Conclusion

The LS explained in 2015,

Electrolytes are important in the care of animals to prevent dehydration and animals suffering from diarrhea, anorexia or the inability to absorb fluids from the digestive tract (OMRI 2010). In essence, electrolytes are only to be used when preventive practices and veterinary biologics are inadequate these type of conditions or illnesses. They may not be used in the absence of an illness.

Beyond Pesticides supports the relisting of electrolytes in order to provide support to the animals in times of illness.

# Glycerine

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (12) Glycerine - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

For the purposes of processing and handling, the NOSB recommended in Spring 2015 to list glycerin only on §205.606 –apparently accepting the argument of the petitioner that it should be so listed in order to impose the commercial availability restriction. Beyond Pesticides agrees with the Handling Subcommittee (HS) that the issues raised by the glycerin petition are complex. We believe that the approach to listing glycerin needs to recognize this complexity.

As shown by the HS in Spring 2015, glycerin is made by a number of processes. Currently, the product of one process, hydrolysis of fats and oils, is listed on the National List (§205.603 and §205.605(b)) as a synthetic. The petition approved in the spring to delist synthetic glycerin on 605(b) was based on the production of "organic" glycerin through fermentation of organic cornstarch. This glycerin is considered "organic" because it is considered a processed form of organic cornstarch, and because "fermentation" is an allowed form of processing.

### **Fermentation Processes**

This material raises issues that should be addressed by the NOSB: What criteria must be applied to determine whether fermentation products are acceptable as inputs in organic production and processing? What criteria must be applied in classifying the products of fermentation as

agricultural/nonagricultural or synthetic/nonsynthetic? The materials classification guidance treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural or from nonsynthetic to synthetic. Yet fermentation processes vary widely from pickling, wine-making, and cheese-making to manufacture of substances that have no apparent relationship to the substrate. Glycerin made by fermentation of cornstarch is an example of the latter. The processes vary in nutrients added, physical methods of isolating the product, solvents used, and ancillary substances added. The fact that all of these processes involve the growth of microorganisms does not seem to be sufficient to treat them the same. Therefore, we request that the NOSB add to its workplan the development of criteria for evaluating products of fermentation processes.

Some supporters of the listing of glycerin say it is needed as an oral supplement to follow-up dextrose/glucose IV for ketosis. Glycerin is closely related to propylene glycol (prohibited in organics) in its gluconeogenic action (creates new sugars in vivo) in the rumen. This use is not permitted by the annotation. If this use is important, it should be petitioned for inclusion on the National List.

### Conclusion

The NOSB needs more clarity around the classification of products of fermentation. The NOSB needs to decide whether the action on glycerin as a material used in processing and handling applies to livestock uses.

We suggest that glycerin be relisted on §205.603, that the NOSB give more attention to the classification and acceptability of materials made by fermentation, and that the use as an oral supplement to follow-up dextrose/glucose IV for ketosis be petitioned and examined by the NOSB.

# **Phosphoric acid**

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (20) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs

Phosphoric acid is synthetic. It is used to remove deposits on equipment, so its use is slightly different from the other materials on 205.603 (a) As disinfectants, sanitizer, and medical treatments as applicable. Among the acids used for the purpose, phosphoric acid is considered less corrosive than most. The production of phosphoric acid is dependent on phosphate mining and processing, which are polluting and produce hazardous and radioactive waste products. Contact of phosphoric acid with skin and eyes should be avoided because of its corrosivity. Phosphate pollution contributing to eutrophication of waterbodies receiving treated wastewater is a possible consequence of the use of phosphoric acid cleaners.

Phosphoric acid poses environmental hazards in manufacture and disposal, and health risks during use. Because its use is slightly different from the other materials on 205.603(a), there

may not be a more compatible substance in this list. We encourage the NOSB to continue to seek safer alternatives.<sup>1</sup>

## Conclusion

While we support relisting of phosphoric acid, we encourage the LS to look at alternatives in EPA's Safer Choice program.

# Lime, hydrated

§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

In the past, supporters of listing hydrated lime said it is much needed compound for its listed uses. They cite its use in a walk-through box, which can reduce the use of copper sulfate and its importance in controlling flies and fly larvae in straw bedding. It is not clear that the latter use is compatible with the annotation.

## Conclusion

Beyond Pesticides supports the use of hydrated lime when it can replace more toxic inputs. If, as indicated in past comments, the use of hydrated lime as a walk-through can reduce the use of copper sulfate for that purpose, then that use should be encouraged.

# **Mineral oil**

§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable (6) Mineral oil - for topical use and as a lubricant

Notable information provided by the 2015 TR includes:

- "[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. <u>Mineral oil remains prohibited for use in organic livestock production as an orally administered treatment of constipation in cattle and other ruminants.</u>" Emphasis added.
- Information concerning alternatives was provided. Many alternatives –management and nonsynthetic materials—were identified for both uses.
- Hazards associated with the manufacture of mineral oil were documented.

# **Other Spring Comments**

Supporters of mineral oil say it is important for its listed uses, including fly control.

<sup>&</sup>lt;sup>1</sup> See "descalers" at <u>http://www2.epa.gov/saferchoice/products</u>.

#### Conclusion

Beyond Pesticides supports the delisting of mineral oil. There are alternatives to both use as an external parasiticide and as a lubricant that are more compatible with organic production. If the NOSB decides to keep mineral oil on the National List, the prohibited internal use should be eliminated by a change of annotation –for instance, "Use as an orally administered treatment of constipation in cattle and other ruminants is not allowed"– or by noting the exception in the NOSB recommendation.

### Sucrose octanoate esters

§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.

Sucrose Octanoate Esters (SOEs) are surfactants –closely related to soaps– that have a mode of action similar to insecticidal soaps. However, a limited number of experiments have shown SOEs not to affect a range of predators and parasitoids that are killed by insecticidal soaps. Impacts on soil fauna have not been established. They have low toxicity to humans and are produced in a closed system. The Technical Reviews (TRs), which rely heavily on EPA's Biopesticides Registration Action Document, provide insufficient information to evaluate SOEs relative to OFPA criteria.

Supporters of SOEs say it is a biochemical insecticide/miticide manufactured from sugar and vegetable oil-derived fatty acids important in pest control.

#### Conclusion

SOEs were originally petitioned as a control for varroa mites on honey bees –and that remains the only supported livestock use. We are disappointed that we have not seen comments from beekeepers concerning the relative efficacy and hazard of SOEs in controlling varroa mites, and we hope that the LS seeks input from beekeepers. The generic annotation "in accordance with approved labeling," which always applies as a matter of law, should be replaced with one that describes the use –such as "for control of varroa mites in honey bees."

Nevertheless, in view of the restrictive use of SOEs, and the difficulty that beekeepers are experiencing in maintaining the health of honey bee colonies in recent times, we support keeping SOEs on the National List.

Thank you for your consideration of these comments.

Sincerely,

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Terry Shistar, Ph.D. Board of Directors