



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

September 18, 2023

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

Docket # AMS-NOP-23-0026

Re. LS: 2025 Sunset

These comments to the National Organic Standards Board (NOSB) on its Fall 2023 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.

The Organic Foods Production Act requires that substances be listed on the National List “by specific use or application.” Some of these listings in §603 do not meet this requirement. We request that all listings be annotated with the specific use or application.

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.

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

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

Organic livestock producers have a limited number of treatments for disease available, so it is important to have vaccines available for disease prevention. However, organic regulations at 205.105(e) prohibit the use of genetically engineered (made with excluded

methods) vaccines unless they are on the National List,¹ and, as has been noted by the LS, there is a great deal of inconsistency in enforcing this prohibition. No genetically engineered vaccines have been petitioned or approved. Inconsistency in enforcement of organic regulations is of great concern to organic consumers, and was recognized by the NOSB in 2019, in recommending a change to § 205.105(e), to read: “Excluded methods, except for vaccines: Provided, That, ***vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.***” In doing so, the NOSB gave this rationale:

The definition of “commercially available” is part of the regulation and a description of how this would be applied to a vaccine is in the attached recommendation. The current regulation allows vaccines from excluded methods to be used, provided they have been individually reviewed and approved for listing as a synthetic on the National List. The current listing has proven to be cumbersome. The long timespan between the petitioning of a material and its eventual placement on the National List does not provide organic livestock producers the vaccines they need now, or what they might need in the future, in a timely manner. This recommendation only allows vaccines from excluded methods if there are no vaccines available that have not been produced through use of excluded methods. This would provide vaccines needed by producers whether the need was caused by an emergency, was required by governmental agencies, or just as a way to prevent a disease from occurring in their livestock. New methods of genetic engineering continue to be introduced. However, the numerous NOSB recommendations since 2016 on excluded methods and the ongoing dialog and recommendations detailing which types of methods should be considered excluded, and which ones should not, informs the organic community and the National Organic Program if the method used to make the vaccine is to be considered excluded or not.

Conclusion

Beyond Pesticides supports the relisting of vaccines as listed. NOP must implement the NOSB recommendation of 2019 to change the restriction of excluded methods in §205.105(e).

Electrolytes

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

¹ §205.105 *Allowed and prohibited substances, methods, and ingredients in organic production and handling.* To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:
(e) Excluded methods, except for vaccines: *Provided, That, the vaccines are approved in accordance with §205.600(a);*
§205.600 *Evaluation criteria for allowed and prohibited substances, methods, and ingredients.*
(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(8) Electrolytes—without antibiotics

The Organic Foods Production Act requires that substances be listed on the National List “by specific use or application.” This listing does not meet this requirement. We request that all listings be annotated with the specific use or application.

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 types of conditions or illnesses. They may not be used in the absence of an illness.

Conclusion

Beyond Pesticides supports the relisting of electrolytes, with an annotation giving the specific use, 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 believes that the issues raised by glycerin 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.

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, and that the NOSB give more attention to the classification and acceptability of materials made by fermentation.

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). 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.²

We have concerns regarding phosphoric acid and the lack of clear and consistent standards across all certifiers. It is our understanding that a water rinse is not required after use, and that, in fact, the Pasteurized Milk Ordinance (PMO) requires this product not be rinsed. It appears that some certifiers require a water rinse due to the way products are being reviewed. For example, if it is the policy of the certifier that all ingredients in cleaner/sanitizer products must be allowed on the National List for the product to be allowed without a rinse, the vast majority of phosphoric acid products will require a rinse because they contain other (“inert”) ingredients not on the National List. Should the material contain only phosphoric acid and water, according to these certifiers, it would be allowed without a rinse.

² See “descalers” at <http://www2.epa.gov/saferchoice/products>.

Consistency is required in the way that certifiers apply the standards. We urge the LS to add to its work agenda the development of an annotation that clarifies when a rinse or purge is or is not required.

Conclusion

While we support relisting of phosphoric acid, we encourage the LS to add to its work agenda an annotation regarding rinse after use, as well as consideration of possible 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. The annotation should list specific use(s).

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.

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.” [Emphasis added.] However, a proposed rule published by NOP on January 17, 2018³ would add mineral oil to the National List for relief of intestinal impaction (as recommended by the NOSB in 2002). The contradictions between the FDA statements and proposed rule need to be clarified.

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

³ 83 FR 2498.

Conclusion

Beyond Pesticides supports the relisting of mineral oil but asks that the LS clarify the potential conflict with FDA concerning the internal use.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.
Board of Directors