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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 ID # AMS-NOP-19-0095

Re. LS: Sunset 603-604

These comments to the National Organic Standards Board (NOSB) on its Spring 2020 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.

Butorphanol

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(5) Butorphanol (CAS #-42408-82-2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the [Animal Medicinal Drug Use Clarification Act of 1994] **AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:**
(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

The TAP review was thorough with respect to the use of butorphanol as a drug, but information about impacts of butorphanol and its metabolites when excreted was missing. Since metabolites of the drug can cross the placenta and pass into the mammary gland and into milk, more information about the metabolites would be helpful. When petitioned, it was considered a safe and necessary option.

The TAP review said that butorphanol may interact with other medications, including tranquilizers, barbiturates, and antihistamines. If used with other central nervous system

depressants, butorphanol may increase the central nervous system or respiratory depression of those drugs.[1] Butorphanol and its metabolites are not considered toxic, but there are withdrawal periods to observe before using meat or milk.[2]

The use of butorphanol is an extra-label use, and is not labeled for use in food animals. 21 CFR §522.246 addresses the use of butorphanol in dogs, cats, and horses. Under horses, the following restriction is listed:
(iii) *Limitations.* Do not use in horses intended for human consumption.

Therefore, we ask that the LS do two things with respect to butorphanol:

1. Find and present information about impacts of butorphanol and its metabolites when excreted; and
2. Get a written determination from FDA regarding the legal use of butorphanol in food animals.

Supporters of relisting of butorphanol in the past have raised the following points:

- Butorphanol is a short acting opiate that is useful for its analgesic and sedative properties. Opioids are very effective and have a wider safety margin than other classes of analgesics. It is considered the most effective analgesic's available for the systemic treatment of mild-moderate pain in many species. It is commonly used by veterinarians for pain control during surgical procedures.
- This product is important to the humane treatment of organic animals. Butorphanol is a true anesthetic only used during surgery. Times of use include procedures such as stitching a milk vein or teat, surgery for a twisted stomach or a nictitans eye flap suture for pinkeye. Without the systemic anesthetic effect of Butorphanol such procedures would be painful for the animal and dangerous to the veterinarian.
- Anesthetic in veterinary medicine and should be available for veterinary practitioners to utilize in cases such as stitching a milk vein or teat, where the likelihood of getting severely kicked by the cow is high. Butorphanol helps to keep animals' feet "planted" on the ground during potentially otherwise painful necessary procedures to help restore them to health.
- The notion that the metabolites of this particular compound need to be somehow be under closer scrutiny is bewildering. If the question is posed for this material, it should be posed for all materials on the livestock list and probably any materials coming into contact with people on the processing list.

With regard to the extralabel use (ELU) in food animals under AMDUCA, we understand that butorphanol is allowed because the use is not prohibited. USDA did determine that

[1] TAP, p. 18
[2] TAP pp. 18, 25.

butorphanol is listed in the Food Animal Residue Avoidance Databank (FARAD), and the listed meat withdrawal and milk discard times are twice those listed in FARAD (2007 FR Notice).[3]

Since the public expects that organic production requirements are more stringent than FDA's, and reliance on AMDUCA's exemption of ELUs can be problematic,[4] we encourage the LS to address AMDUCA and ELUs in a discussion document that proposes policy to clarify the allowance of animal drugs for food animals as extra-label uses under AMDUCA.

With regard to the above comment concerning metabolites, we propose that all metabolites of materials on the National List be examined.

Flunixin

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(9) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

In the past, some have supported relisting because it is a strong NSAID (non-steroidal anti-inflammatory drug) related to aspirin, but about 100 times as strong, that when injected can bring pain relief, fever reduction and keep inflammation in check within a very short time and allowing animals to eat within a short period of time. They say that flunixin is far superior to aspirin in relieving abdominal pain due to colic and other digestive disturbances.

A TAP review was produced in 2007. The decision of the NOSB during the sunset review of 2015 does not reference the materials in the TAP review. All three TAP reviewers in 2007 opposed the listing of flunixin. Their reasons included:

- The database does not provide information as to how flunixin functions differently from aspirin or other similar drugs already approved in the list and why it is needed since flunixin is also an analgesic like aspirin.
- The potential side effects of residual flunixin in livestock to humans are not provided.
- It is not clear whether the use of flunixin would have harmful side effects to livestock beside its anti-inflammatory action.
- Flunixin is prohibited for use in horses intended for food (Title 21 - Food and Drugs, sec. 520.970a), therefore it poses potential safety concerns to other livestock intended for human consumption.
- If aspirin can perform similar function as flunixin but just slower, it is safer to use aspirin.
- The fact that flunixin can persist in inflammatory tissues is worrisome (ref. #12). No data are provided on the concentration of flunixin in muscles and milk, and its elimination rate from those compartments.

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[3] USDA, 2007. National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Livestock). Federal Register Vol. 72, No. 238, Wednesday, December 12, 2007, pp.70479- 70486.
[4] Geni Wren, 2008. Options for Pain Management. Bovine Veterinarian. https://ahdc.vet.cornell.edu/Sects/NYSCHAP/docs/BovineVetpain01-08.pdf.

- Information is also not provided on the biotransformation of flunixin and the activity and toxicity of its metabolites.
- The information provided is inadequate to judge the effect of flunixin on human health. The information in the criteria evaluation pertains to NSAID as a class, and is not specific for flunixin. Of particular concern is the probability of hypersensitivity reaction to flunixin in the general human population.
- Based on the doses used, flunixin is more potent than aspirin, but there is no information on comparing the efficacy between the two drugs, which is a more important consideration.
- For inclusion on the National Organic List of pharmaceuticals allowable for use in livestock products labelled as "organic" or "made from organic" the trifluoromethyl group is especially troublesome. If the label of "organic" is to have any meaning and TAP process is to have any credibility in the eyes of the skeptical public, pharmaceuticals such as this must not be allowed. Clear natural product alternatives are available and mentioned in NOSP documents: aspirin and related hydroxyphenyl compounds are effective and naturally occuring and can be given to livestock as willow bark or water extracts.
- If organic cattlemen wish to limit susceptibility of their herds to inflammation in a totally organic way, let them limit the omega-6-fatty acid content of the feeds and assure a trace source of omega-3 fatty acids in the appropriate ratio.
- At the very least, the source, manufacture, by-products and post-use breakdown products of the trifluoromethyl group should be outlined as exhaustively as for any halogenated hydrocarbon. Likewise, the discussion of point 7 on p. 18 about "sustainable agriculture", to be convincing, would have to outline how some future organic farmer might set up, with the help of her neighbors, a manufacturing operation to produce flunixin meglumine using only things found around the farm.

Although the above reasons for not listing flunixin are not new, they have not been considered by the LS during the previous reviews. Any proposal for relisting flunixin should address these issues.

Magnesium hydroxide

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(15) Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

In 2015, the NOSB did not address issues raised in the TAP review –specifically, that magnesium hydroxide is nonsynthetic (which would eliminate the need to list on §205.603) and the vagueness of the uses. These should be clarified.

Regarding the classification, in 2007, the NOSB stated that magnesium hydroxide could be either synthetic or nonsynthetic, but that it would be difficult for the producer to determine which is being used. Is this still the case?

Poloxalene

205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(21) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

> It is worthwhile reviewing the conclusion of the 2001 TAP review:
> Poloxalene is clearly synthetic and prohibited unless added to the National List for medical use. The TAP reviewers are divided and do not have a consensus recommendation. Two of the reviewers favor its allowance for emergency use only based on a need to prevent suffering and promote animal welfare. The third reviewer finds the rare emergency use not to be a compelling reason for considering as a permitted synthetic and does not see it as indispensable given that other treatments are available for cases of mild bloat, and other emergency treatments are called for in life threatening circumstances. This is supported by the lack of historic allowance, or demonstrated need by existing certification agencies. The two reviewers who favor limited allowance also suggested either an extended withdrawal time, or a limited allowance for a permitted number of emergency treatments per year for organic animals. No data to support an extended withdrawal time has been presented, but the NOSB may want to consider an overall policy for frequency of emergency treatment or develop criteria for emergency use medication in general.
>
> One reviewer made a strong statement about compatibility with organic:
> This material is not compatible with a system of organic, sustainable agriculture. It is synthetic and is derived from chemicals that are significant environmental contaminants, and thus the use of poloxalene in organic farming would be contributing (in principle, if not in quantity) to their continued manufacture and dispersal in the environment. There are acceptable methods for the prevention of this disorder and while allowing the emergency use of this chemical for unforeseen incidence of pasture bloat may seem reasonable, it is "enabling" lax pasture management and animal husbandry practices contrary to the principles of organic, sustainable agriculture.

In view of these conclusions and the existence of preventive measures and more compatible treatments, the NOSB should not relist unless there is strong evidence of need.

Formic Acid

§205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(2) Formic acid (CAS # 64-18-6) —for use as a pesticide solely within honeybee hives.

Formic acid is used to control varroa and tracheal mites in honeybees. It is less toxic and less hazardous than conventional miticides, but it is a synthetic that poses some hazards to beekeepers. Available alternatives include management practices, nonsynthetic materials, and a synthetic soap on the National List. When the NOSB approved formic acid, a technical review was not available, and the Livestock Subcommittee evaluated the petition based on information in the petition, but said it "will reevaluate the recommendation when the TR becomes available."

Formic acid poses health and environmental hazards.

Formic acid is toxic to plants.[5]

There is a potential for ill effects on workers. The technical review (TR) cites adverse effects of formic acid exposure on workers.[6] Beekeepers are required to use personal protective equipment when handling fumigants.[7] "Acute overexposure to formic acid causes irritation to the eyes, skin, and mucous membrane of the mouth, throat, and esophagus. Acute formic acid exposure also may be associated with complications such as cardiovascular collapse and ischemic damage to the heart, liver and kidneys, swelling of the airway, and respiratory distress. Because of the irritating and corrosive properties of the substance, ingestion of formic acid may cause ulceration of the gastrointestinal tract, which results in perforation and scarring of the gastrointestinal tract."[8] "Laboratory studies cited by EPA report negative results for mutagenic potential. Chronic exposure to formic acid may damage the kidneys."[9]

There are alternative materials and practices to the use of formic acid.

Natural substitutes include *Metarhizium anisopilae*, wintergreen salt-grease patties, neem oil, and dusts of powdered sugar or pollen substitutes.[10] In addition to the natural alternatives, sucrose octanoate ester is on the NL.[11] The TR mentions several mechanical means of controlling mites: use of a screened bottom board, drone-brood trapping, and resistant honey bees.[12]

In 2015, the LS was able to incorporate some input from a beekeeper in addition to the information in the TR. Honeybees are under attack from many fronts—including parasitic varroa and tracheal mites. Beyond Pesticides supports the relisting of formic acid as an aid to protecting honey bees from parasitic mites. Although it is a synthetic that poses some hazard to beekeepers, varroa and tracheal mites are a contributing factor to honey bee declines that threaten many agricultural crops, as well as bees and beekeepers, and the annotation will prevent most nontarget effects.

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[5] TR lines 327-333.
[6] TR lines 382-393.
[7] TR lines 261-262.
[8] TR lines 372-377.
[9] TR lines 364-367.
[10] TR lines 399-455.
[11] TR lines 457-458.
[12] TR lines 470-515.

Excipients

205.603(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

As defined in:

§205.2 *Excipients.* Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

Like "inert" ingredients in pesticide products, excipients in animal medications are not necessarily biologically or chemically inactive, and are not always listed on the label. If the Board is to do its job in reviewing excipients in accordance with OFPA, it must have adequate information about the identity and function of excipients. Therefore, it must seek information from materials review organizations and animal drug manufacturers to identify the excipients that are present in products used in organic livestock production so that they can be evaluated by the Board.

Just as the Inerts Working Group found that the number of "inert ingredients" present in pesticide products used in organic production is much smaller than the universe of chemicals that could be in those products, the LS will likely discover that the number of excipients actually present in products used in organic production is a fraction of those actually available for use.

In 2015, CCOF said that the present annotation is not clear. It allows for almost anything to be allowed as an excipient, but materials reviewers have to research using multiple databases (CFR title 21, GRAS database, EAFUS database, etc.) to gather that information. A clear annotation should state which specific excipients, if any, would not be allowed. Synthetic excipients are in almost every livestock healthcare product. Information on them is very difficult to obtain from manufacturers in certain cases.

The LS should make a commitment to identify and review the excipients used in organic production. A process for doing so is laid out in two NOSB recommendations on "inert" ingredients from April 2010 and October 2012.

EPA List 4 - Inerts of Minimal Concern

205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. (1) EPA List 4 – Inerts of Minimal Concern.

We support annotating the listings for List 4 "inerts" (on both §§601 and 603) to eliminate the use of nonylphenol ethoxylates (more properly termed alkylphenol ethoxylates). The CS raised this issue in a short discussion document in Spring 2016, but it has been subsequently dropped.

Nonylphenol ethoxylates (NPEs) are toxic environmental pollutants with safer alternatives.

Because the major use of NPEs is as a surfactant, most studies have concentrated on impacts on aquatic and semi-aquatic species. NPEs are highly acutely toxic to aquatic organisms, medium to high in chronic toxicity, medium to high in persistence, and exert estrogenic effects on a wide range of organisms. Breakdown products, especially nonylphenols (NPs), are much more toxic than NPEs;[13,14] and are also estrogenic.[15] EPA rates persistence medium to high; degradation products are persistent and toxic.[16] Nonylphenol ethoxylates (NPEs) can react with chlorine to form chlorinated nonylphenols that are mutagenic.[17] In aerobic systems, additional carboxylic acid compounds, that are also toxic, are produced.[18] NPEs inhibit the growth of young terrestrial and aquatic plants or trees at 10 ug/L, which is the contamination level frequently found in streams as a result of contamination from sewage sources. Concentrations of 20-500 mg/L inhibited or restricted growth of soil bacteria. [19] NPs and NPEs act as xenoestrogens in human cells.[20]

Because of concerns about the adverse health and environmental effects of NPEs, EPA's Design for the Environment (DfE) completed an alternatives assessment for synthetic surfactants, like NPEs, that are endocrine disrupting chemicals. DfE's goal is to assist in the voluntary phase-out of NPEs used in industrial detergents. The DfE assessment for NPEs reviewed several

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[13] EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

[14] Andrea Lani, 2010. Basis Statement for Chapter 883, Designation of the Chemical Class Nonylphenol and Nonylphenol Ethoxylates as a Priority Chemical and Safer Chemicals Program Support Document for the Designation as a Priority Chemical of Nonylphenol and Nonylphenol Ethoxylates, Bureau of Remediation and Waste Management, Maine Department of Environmental Protection.

[15] Mark R. Servos, 1999. Review of the Aquatic Toxicity, Estrogenic Responses and Bioaccumulation of Alkylphenols and Alkylphenol Polyethoxylates, Water Qual. Res. I. Canada,Volume 34, No. 1, 123-177. A support document for Environment Canada's environmental assessment under the Canadian Environmental Protection Act.

[16] EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

[17] A. Michael Warhurst, 1995. An Environmental Assessment of Alkylphenol Ethoxylates and Alkylphenols, Friends of the Earth, UK.

[18] P. Whitehouse, 2002. Environmental Impacts of Alkylphenol Ethoxylates and Carboxylates. Part 1: Proposals for the Development of Environmental Quality Standards. R&D Technical Report P2-115/TR3. Environment Agency, Rio House, Waterside Drive, Aztec West, Almondsbury, Bristol BS32 4UD.

[19] Sylvia S. Talmage, 1994. Environmental And Human Safety Of Major Surfactants: Alcohol Ethoxylates and Alkylphenol Ethoxylates, A report to The Soap and Detergent Association, Lewis Publishers: Boca Raton, Ann Arbor, London, Tokyo. Pp. 288-289.

[20] Mark R. Servos, 1999. Review of the Aquatic Toxicity, Estrogenic Responses and Bioaccumulation of Alkylphenols and Alkylphenol Polyethoxylates, Water Qual. Res. I. Canada,Volume 34, No. 1, 123-177. A support document for Environment Canada's environmental assessment under the Canadian Environmental Protection Act.

alternatives to NPE surfactants that are comparable in cost, readily available, and rapidly biodegrade to non-polluting, lower hazard compounds in aquatic environments.[21]

The NOSB must not allow the process unanimously supported by the NOSB to be stalled.

We applaud the CS for taking the action–to review and propose removal of NPEs as so-called "inert" ingredients in pesticides. So-called "inert" ingredients in pesticide products may not be chemically or biologically inert. They are designed to enhance the pesticidal activity of pesticide products and can have toxic properties that do not meet the standards of the Organic Foods Production Act (OFPA). They serve as a good example of why the NOSB, as it previously determined, cannot accept the previously EPA-classified List 4 materials as acceptable for listing under OFPA without scrutinizing the individual materials, either individually or in groups with chemicals of common mechanisms of toxicity and chemical composition. In other words, these potentially toxic inert ingredients may be of "toxicological concern," which require NOSB review under OFPA, which requires a broad cradle-to-grave assessment of all ingredients in allowed synthetic inputs. The NOSB must move forward with its review of inerts to ensure that materials in use in organic production comply with the standards of OFPA. Staring with NPEs is an important first step.

Active ingredients in pesticide products have been carefully screened to ensure that they meet the requirements of OFPA. Because of the thorough investigation by the NOSB and the additional scrutiny given by the public in written and oral comments, the active ingredients that are allowed in organic agriculture present little hazard to people and ecosystems, from their manufacture through their use and disposal.

So-called "inert" ingredients, on the other hand, have not received the same level of scrutiny to ensure that they meet OFPA standards. Reliance on the registration of pesticide products with "inert" ingredients by the U.S. Environmental Protection Agency does not ensure that the standards of OFPA are met, given that the reviews and use allowances under the agency's authorizing legislation (the Federal Insecticide, Fungicide and Rodenticide Act) are based on different, and often incompatible, standards. In addition, "inert" ingredients make of the largest part of many pesticide product formulations. As a result, the most hazardous part of pesticide products used in organic production is often these ingredients.

The NOSB recognizes these facts and has sought to address them. A short history was presented in the Fall 2012 Crops Subcommittee proposal:

> In 2006, EPA reassessed all inert ingredients used in pesticide formulations allowed on food crops, including former Lists 3, 4A, and 4B inerts, to ensure that they met the tolerance reassessment requirements of the Food Quality Protection Act. Inerts allowed for use in EPA registered pesticides applied to food now must either have a residue tolerance level or an exemption from tolerance level codified at 40 CFR Part 180. As a

[21] EPA, 2011. DfE Alternatives Assessment for Nonylphenol Ethoxylates.

result of this reclassification, NOP regulations concerning allowed inert ingredients are out-of-date when compared with current EPA regulations, since EPA eliminated its list categories when it completed its tolerance reassessment. The NOSB recommended in April 2010 that NOP establish a task force in collaboration with EPA and the NOSB to examine this problem and provide a recommendation to the Board for re-evaluation of former List 3 and List 4 inerts. In October 2010, the NOSB recommended the renewal until October 21, 2017 of the current exemption on the National List permitting former List 4 inerts "pending review by the program of inerts individually and as a class of materials." In May 2012, the NOSB recommended an expiration date of October 21, 2017 for the current exemption that permits former List 3 inerts in passive pheromone dispensers, to coincide with the sunset date for List 4 inerts.

The NOSB-NOP-EPA working group was established in June 2010, known as the Inerts Working Group (IWG). Current members include: Jay Feldman (NOSB), Zea Sonnabend (NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), and Lisa Brines (NOP). The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting.

At the fall 2012 NOSB meeting, following up on the NOSB recommendation of spring 2010, the Board unanimously passed a recommendation that was to put in motion the long-anticipated review of "inert" or "other" ingredients in pesticide products used in organic production:

The NOSB proposes this language to replace the current listing at section 205.601(m) and 205.603(e). The NOSB recommends that this change, including the listing of any approved (inert) ingredients, be completed prior to the October 21, 2017 sunset date for List 4 inerts:

<u>Current language at sections 205.601(m) and 205.603(e):</u> As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

<u>Replace the language at sections 205.601(m) and 205.603(e) with:</u>
As synthetic other ("inert") ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
(ii) Reserved (for list of approved other ("inert") ingredients)

And now, as "List 4 inerts" are up for sunset review, <u>the only progress that has been made is this proposal concerning nonylphenol ethoxylates, which has languished for the past four years.</u> The National Organic Program (NOP) has still not issued a notification to manufacturers and

users of products with a request for information on current inert ingredients in use. This 'data call-in notice' was intended to capture "inert" ingredients that may not be on the comprehensive list of 126 priority "inert" ingredients and 87 "minimal risk" substances eligible for registration under FIFRA section 25(b) used in formulations allowed in organic production, which was generated by the Inerts Working Group based on data from Material Review Organizations and provided to the public as categories at the Fall 2012 meeting of the NOSB. **The notice is overdue and should be issued without further delay.**

Since, as stated above, so-called "inert" ingredients likely pose more hazards than other materials used in organic production, their review deserves a higher priority than it is being given by NOP. These comments urge that the NOSB raise the priority level of "inerts" review to ensure compliance with the law.

All so-called "inerts"—especially those not on EPA's 25(b) list– are desperately in need of review for compliance with OFPA criteria. This is a relatively simple task since all 25(b) products require a full listing of all formulation ingredients. We support the proposed action on the first group. In spite of our support for this proposal, it would violate the intention of the Board to allow the indefinite extension of the listing for <u>any</u> of the so-called "inerts." Therefore, we request that all other substances falling under these listings be annotated with expiration dates.

We request that the NOSB and NOP implement the change in the listing as recommended unanimously by the National Organic Standards Board in its recommendations of April 2010 and October 2012:

Replace the language at sections 205.601(m) and 205.603(e) with:

> As synthetic other ("inert") ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
> (i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
> (ii) Reserved (for list of approved other ("inert") ingredients, with expiration dates until reviewed individually.)

The above process may be modified according to the NOSB recommendation of October 2015.

The recommendation of October 2015 makes three changes. First, it incorporates those "inerts" formerly on List 3:

> (iii) "Inert" ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.
>
> Second, it provides for petitioning new "inert" ingredients:
> (iv) [Reserved] (for any other inerts individually petitioned and reviewed).
>
> Finally, it provides for a method of evaluating other currently used "inerts":

(ii) Substances included on the EPA's Safer Chemical Ingredient List [SCIL].

Unfortunately, the last requires clarification, since materials can be included on the SCIL regardless of hazard. The SCIL is categorized by function, and individual materials are coded by acceptability according to the Safer Choice standards. Furthermore, any material exception from the general prohibition against the use of synthetics in organic production must be subject to sunset review.

The NOSB and NOP may, in collaboration with EPA, designate a sublist of the SCIL as "nonactive ingredients allowed in organic production" and solicit the assistance of the Safer Choice program in evaluating those materials to OFPA criteria. However, **all such materials—as well as those provided for under (i) (substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b)) —must ultimately be subject to sunset review according to OFPA criteria by the NOSB.**

Conclusion

Replace the language at sections 205.601(m) and 205.603(e) with:
As synthetic other ("inert") ingredients in pesticide formulations as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section that are used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);
(ii) "Inert" ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers;
(iii) [List of all "inerts," except the "minimum risk" 25(b) substances, known to be used in organic production, as determined by the Inerts Working Group, each annotated with an expiration date between June 27, 2021 and June 27, 2026.
(ii) Reserved (for list of approved other ("inert") ingredients, with expiration dates until reviewed individually.)

The APEs/NPEs should be removed from the list, as discussed by the Crops Subcommittee. This approach will allow the board to systematically review the "inerts" in groups over a five-year period, an approach the board has previously adopted unanimously.

Strychnine

Reference: §205.604 Nonsynthetic substances prohibited for use in organic livestock production. The following nonsynthetic substances may not be used in organic livestock production: (a) Strychnine

Strychnine is highly acutely toxic and has been found to be responsible for secondary poisonings. People affected by strychnine poisoning are not likely to survive. There are numerous alternative materials and practices.

Strychnine causes harm to humans and the environment.

Since strychnine baits are inserted underground, the ability to collect unused bait is small, increasing the likelihood of nontarget poisoning. Strychnine has resulted in secondary poisoning in pets that ate poisoned rodents.[22] Although all animals are susceptible, birds are more often affected. For example, species poisoned by strychnine in Michigan are rock dove, cardinal, Canada goose, dark-eyed junco, mallard duck, common grackle, blue jay and house sparrow.[23] People who are severely affected by strychnine poisoning are not likely to survive.[24]

Strychnine is not necessary.

There are many less dangerous materials and methods. They include: trapping, supporting predator habitat, flooding, ecologically-based rodent management,[25] habitat modification,[26] and encouraging predators.[27]

Strychnine is incompatible with organic practices.

Strychnine is highly toxic to humans and other species, causes secondary poisoning, and has many nontarget effects. It does not "promote plant and animal health by enhancing soil physical, chemical, or biological properties."

Conclusion

Strychnine should remain on §205.604.

Thank you for your consideration of these comments.

Sincerely,

Teresa Ann Shistar

Terry Shistar, Ph.D.
Board of Directors

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[22] National Pesticide Information Center, Rodenticides Topic Fact Sheet. http://npic.orst.edu/factsheets/rodenticides.pdf Accessed 6/23/2014.

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