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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 # AMS-NOP-21-0087

Re. LS: 2024 Sunsets on §205.603

These comments to the National Organic Standards Board (NOSB) on its Spring 2022 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 following comments address livestock materials on §205.603 due to sunset in 2024.

Chlorhexidine

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

(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

Chlorhexidine poses environmental and health hazards.

Exposure to chlorhexidine can result in skin irritation, serious eye damage, sensitization causing asthma or breathing difficulties, and respiratory irritation. Environmental effects include high toxicity to aquatic life with long-lasting effects.¹ Use in a human medical/dental setting has resulted in a high rate of certain side effects, including headache, upper respiratory infection, toothache, sinusitis, and influenza-like symptoms.² In a subchronic dermal rabbit toxicity study systemic effects included degenerative changes in the livers of females.³

¹ PubChem: Chlorhexidine. <https://pubchem.ncbi.nlm.nih.gov/compound/chlorhexidine>. Accessed 1/24/2017.

² Side Effect Resource. <http://sideeffects.embl.de/drugs/2713/>. Accessed 1/24/2017.

³ EPA, 1996. R.E.D. Facts: Chlorhexidine diacetate.
<https://archive.epa.gov/pesticides/reregistration/web/pdf/3038fact.pdf>.

The 2015 Technical Review (TR) of chlorhexidine states, “It should be noted that US EPA did not conduct an environmental fate assessment during the 1996 reregistration process because “it is unlikely for the environment to be exposed to the pesticide when it is used as labeled. More recently, the Agency determined that an environmental fate assessment was necessary for chlorhexidine as an example of ‘disinfectant/sanitizers used in animal premises that may potentially pass through wastewater treatment plants (WWPTs) and may be discharged into terrestrial and aquatic environments.’ This assessment is not currently available.”⁴

Chlorhexidine teat dips are unnecessary.

Teat dips are used pre-milking and post-milking. The efficacy of post-milking teat dips is well-established, while the efficacy of pre-milking teat dips is questionable, especially in pasture-grazed herds.⁵ In addition, milk may be contaminated by pre-milking teat dips.⁶ The use of teat dips should therefore be restricted to post-milking.

The TR identifies a number of alternative teat dips:

Small-scale milk producers use homemade udder washes containing lavender essential oil, water, and apple cider vinegar (i.e., acetic acid) as the active antimicrobial agent. Other procedures for pre- and post-milking treatments include an udder wash (warm water or warm water with a splash of vinegar) in combination with a teat dip (1 part vinegar, 1 part water, plus 3–4 drops Tea Tree oil per ounce). Naturally derived acids (e.g., lactic acid) may be used as standalone germicides or further activated through the synergistic interaction with hydrogen peroxide to provide a bactericidal teat cleansing treatment. In addition to the natural substances mentioned above, a small number of synthetic substances are currently allowed as disinfectants, topical treatments, and external parasiticides in organic livestock production.⁷

The synthetics identified by the TR are iodine, ethanol, isopropanol, sodium hypochlorite, and hydrogen peroxide.⁸ Significantly, the TR states,

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. For

⁴ Technical Review of Chlorhexidine, 2015. Lines 304-309. Internal citations omitted.

⁵ Morton, J.M., Penry, J.F., Malmo, J. and Mein, G.A., 2014. Premilking teat disinfection: Is it worthwhile in pasture-grazed dairy herds?. *Journal of dairy science*, 97(12), pp.7525-7537. Williamson, J.H. and Lacy-Hulbert, S.J., 2013. Effect of disinfecting teats post-milking or pre-and post-milking on intramammary infection and somatic cell count. *New Zealand veterinary journal*, 61(5), pp.262-268. Gleeson, D., Edwards, P. and O’Brien, B., 2016. Effect of omitting teat preparation on bacterial levels in bulk tank milk. *Irish Journal of Agricultural and Food Research*, 55(2), pp.169-175.

⁶ French, E.A., Mukai, M., Zurakowski, M., Rauch, B., Gioia, G., Hillebrandt, J.R., Henderson, M., Schukken, Y.H. and Hemling, T.C., 2016. Iodide Residues in Milk Vary between Iodine-Based Teat Disinfectants. *Journal of food science*, 81(7), pp.T1864-T1870.

⁷ Technical Review of Chlorhexidine, 2015. Lines 500-508.

⁸ Technical Review of Chlorhexidine, 2015. Lines 509-521.

example, commercially available post-milking teat germicides containing Lauricidin[®] (glyceryl monolaurate), saturated fatty acids (caprylic and capric acids), lactic acid and lauric acid reduced new intramammary infections (IMI) in cows inoculated with *Staphylococcus aureus* and *Streptococcus agalactiae* at levels approaching those achieved using iodophor products.⁹

Furthermore, *Serratia* species, common causative agents of mastitis, are often resistant to chlorhexidine.¹⁰

Use of chlorhexidine teat dips is not compatible with organic production.

The use of chlorhexidine teat dips is limited to “when alternative germicidal agents and/or physical barriers have lost their effectiveness.” Since bacterial resistance to other germicidal agents indicates a reliance on materials whose use in organic production should be by definition exceptional,¹¹ it should not provide the pretext for use of another synthetic material.

Conclusion

Organic producers should not be countering resistance to medications (or pesticides) through introduction of another toxic chemical, particularly one that depends on chlorine chemistry. Beyond Pesticides does not object to the use of chlorhexidine “for surgical procedures conducted by a veterinarian.” However, the annotation, “Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness” should be removed. Since the LS has not proposed an annotation at this meeting, we urge that consideration of an annotation to the listing be placed on the LS work agenda.

Copper sulfate

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

Walk-through footbaths containing copper sulfate solution are used to help control and prevent hoof-related diseases in dairy cattle. One solution is considered effective for 150 to 300 animal passes. Spent solution is mixed with manure waste and ultimately disposed by land application.

Copper sulfate footbaths have a relatively low cost per footbath and appear to effectively control the infectious hoof diseases. The major concern is disposal of the copper sulfate solution, which is ultimately spread on the land with manure. It is possible that maximum soil copper loading rates may be exceeded in a relatively short time.¹²

⁹ Technical Review of Chlorhexidine, 2015. Lines 554-561.

¹⁰ Technical Review of Chlorhexidine, 2015. Lines 534-542.

¹¹ Organic Foods Production Act §6517.

¹² TR lines 119-127.

The TR says there are no natural (non-synthetic) products available that can be used as a management strategy to treat hoof related diseases and lameness in dairy cattle and sheep operations.¹³ Several management tools available can help reduce the cost of treatment and prevent hoof related diseases. These include the use additional dietary supplements (i.e., feeding of iodine, feeding of zinc methionine), free stall (cubicle) design, limiting contact with gravel or rocky surfaces, and hoof trimming practices.¹⁴ Zinc sulfate has been petitioned and approved for the use.

Conclusion

We suggest an annotation, “Substance must be used and disposed of in a manner that minimizes accumulation of copper in the soil, as shown by routine soil testing.” This is comparable to the annotation for copper sulfate in crops. We urge that consideration of an annotation to the listing be placed on the LS work agenda.

Glucose

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

(11) Glucose

In 2015, the relisting of glucose was supported by organic livestock producers and veterinarians because of its importance in treating ketosis, and “IV dextrose/glucose is required in such cases in order to rapidly replenish the blood supply’s sugar so the brain can function normally.” In 2017, the LS noted, “On an organic dairy farm, glucose is an essential animal health tool. It is used typically to treat ketosis, and there was universal approval for keeping this material on the National List. Since glucose is an ingredient in calcium gluconate used to treat milk fever, retaining glucose on the National List of approved synthetics also maintains this important tool for treatment of this ailment as well.”

No adverse impacts have been identified.

Conclusion

Beyond Pesticides supports the relisting of glucose because of its importance in treatment and the absence of adverse effects.

Lidocaine and Procaine

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

(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

¹³ The TR includes sheep, though the petition for zinc sulfate says sheep do not tolerate copper.

¹⁴ TR lines 578-579.

In 2017, the NOSB voted to remove procaine from the National List, but the National Organic Program (NOP) has failed thus far to make the change, which was the subject of a proposed rule August 24, 2021. If it remains on the list at the time of the NOSB meeting, the NOSB should vote to reaffirm the removal.

Livestock producers and Dr. Hubert Karreman in state the need for a true local anesthetic such as lidocaine, which numbs only the area to be worked on, is safe, and without alternatives.

Conclusion

Beyond Pesticides supports the relisting of lidocaine because it facilitates the humane treatment of animals in minor surgery and is rapidly cleared from the body. We support the removal of procaine for the reasons given by the LS in 2017.

Oxytocin

**205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(17) Oxytocin -use in post parturition therapeutic applications.**

In 2017, the NOSB voted to remove oxytocin from the National List, but NOP has failed thus far to make the change, which was the subject of a proposed rule August 24, 2021. If it remains on the list at the time of the NOSB meeting, the NOSB should vote to reaffirm the removal.

Oxytocin is a hormone and, even if rarely used, it leaves organic dairy farmers open to valid criticism that they can still use hormones. Oxytocin may be a good treatment for prolapsed uterus, but alternative treatments are also available. Paul Dettloff's *Alternative Treatments for Ruminant Animals* lays out a procedure that uses some organically approved treatments, and does not require oxytocin for a successful outcome. He uses a mixture of warm water and aloe vera with a tincture to induce uterine contractions. He says, "They usually breed back and won't prolapse the next time."

Prolapse should be a rare occurrence. Past comments have shown the annotation to be vague and that oxytocin was misused, to help cows let down their milk. Cows can become dependent on it for let-down. It is a hormone, and even though its use is intended to be limited, allows a use of hormone in organic dairy, which is contrary to consumer expectations.

Conclusion

Oxytocin should be removed from the National List based on the NOSB's 2017 recommendation. If it remains on the list at the time of the NOSB meeting, the NOSB should vote to reaffirm the removal. Past comments have shown the annotation to be vague and that it was misused, to help cows let down their milk. Cows can become dependent on it for let-down. There are alternatives. It is a hormone, and even though its use is intended to be limited, allows a use of hormone in organic dairy, which is contrary to consumer expectations.

(Xylazine and) Tolazoline

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

(22) Tolazoline (CAS #-59-98-3)—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:

- (i) Use by or on the lawful written order of a licensed veterinarian;**
- (ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and**
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.**

(23) Xylazine (CAS #-7361-61-7)—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:

- (i) Use by or on the lawful written order of a licensed veterinarian;**
- (ii) The existence of an emergency; and**
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.**

Tolazoline is used in conjunction with xylazine, and thus both should be reviewed together. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of xylazine. During the 2015 review, the lead reviewers suggested that the materials be reviewed together, but the sunset reorganization has resulted in their being given different sunset dates.

Xylazine interacts with other tranquilizers, analgesics, and anesthetics.¹⁵ It impairs the effectiveness of anticonvulsants.¹⁶ Tolazoline has a number of interactions with other drugs.¹⁷ A metabolite of xylazine, 2,6-xylidine, is genotoxic and carcinogenic.¹⁸ “Numerous pharmacological side-effects of xylazine have been observed in treated animals, including mydriasis, impairment of thermo-regulatory control, various effects on the cardiovascular system, acid-base balance and respiration, hyperglycaemia, and haematological and gastrointestinal effects. Cattle and sheep are approximately 10 times more sensitive to xylazine than horses, dogs and cats.”¹⁹

According to the TAP review, “There are, in fact, many alternative *practices* available for many uses of xylazine.”²⁰

¹⁵ http://www.ccac.ca/en/_training/niat/vivaria/analgesia/xylazine.

¹⁶ Wlaż, P., & Roliński, Z. (1996). Xylazine impairs the anticonvulsant activity of conventional antiepileptic drugs in mice. *Journal of Veterinary Medicine Series A*, 43(1-10), 495-500.

¹⁷ TAP, p.36.

¹⁸ TAP, p. 12.

¹⁹ TAP, p. 25.

²⁰ TAP, p. 42.

It appears that FDA does not permit the use of xylazine in food-producing animals, and the NOP cannot overrule FDA's ruling.²¹ The transcripts²² indicate that the NOSB was under the impression that xylazine could be used as an "off-label use." FDA says, "The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) permits veterinarians to prescribe extralabel uses of certain approved new animal drugs and approved human drugs for animals under certain conditions."²³ However, in this case, the FDA specifically said it is not to be used in food-producing animals.

FDA regulations state:

21 CFR §530.21 Prohibitions for food-producing animals.

(a) FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in food-producing animals if FDA determines that:

(1) An acceptable analytical method needs to be established and such method has not been established or cannot be established; or

(2) The extralabel use of the drug or class of drugs presents a risk to the public health.

(b) A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.

According to the TAP review, "The FDA has approved xylazine hydrochloride for use as a veterinary anesthetic, and tolazoline hydrochloride as a reverser of xylazine, but in both cases, use of these medications in 'food-producing animals' is specifically unapproved." The FDA regulations state,

21 CFR §522.2662 (iii) *Limitations*. Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.

An off-label use may be allowable in the absence of a specific prohibition, but since FDA does explicitly prohibit the use of xylazine in food-producing animals, it should be delisted. Since tolazoline is listed as an antidote to xylazine, it should also be removed from the National List.

Xylazine and tolazoline have been supported as critically-needed materials for the humane restraint and sedation of large animals for farmers and veterinarians to do commonly carried out surgical procedures. The function is mainly sedative but also has some anesthetic properties. Its use by livestock veterinarians is widespread for many procedures so that animals will not inflict injury to the humans working with them.

²¹ FDA regulations at 21 CFR 522.2662(d)(2)(iii) and 21 CFR 522.2662(d)(3)(iii). OFPA §6519(c)(6)(B)

²² Transcript of September 2002 meeting, pages 568-578.

²³ http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm085377.htm#Extra-Label_Use.

Conclusion

The FDA's regulations are confusing, given the fact that in spite of what appears to be explicit language in FDA regulations prohibiting the use of xylazine in food animals, it nevertheless appears to be in common use in certain situations, with FDA's blessing. In conversations with livestock producers and veterinarians, we have heard comments ranging from, "Its use is solely for the convenience of the human treating the animal," to "I don't like using it, but there have been cases –like sewing up a gash in a bull's face– that I wouldn't have been able to treat without it."

AMDUCA puts much responsibility on the shoulders of the veterinarian, even with the Food Animal Residue Avoidance and Database (FARAD) database as support. In this case, it also puts that responsibility on the shoulders of the NOSB. And it raises more general issues for the NOSB and NOP. Should off-label uses –that are not supported by regulation based on accepted scientific research– be allowed in organic production? If they are allowed, how is the public supposed to interpret that allowance as protecting organic integrity? If such uses are not allowed, does it put animals at risk? Since FDA does not force testing as entry to the marketplace, how can the NOSB and NOP ensure that animal drugs allowed under AMDUCA meet safety standards for drug use and the more stringent standards of OFPA? These questions do not necessarily need to be answered during this sunset review, but they should be acknowledged by the LS as valid concerns and put on the subcommittee's agenda as a discussion document.

Elemental Sulfur

205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(2) Elemental sulfur—for treatment of livestock and livestock housing.

Sulfur was added to the National List for control of ectoparasites –fleas, ticks, and mites. It is allowed for use in crop production. It has low human toxicity. The main environmental impacts come from manufacture (fossil fuel production), transportation (pipeline leaks), and storage (blowing dust.) In case of contamination arising from transportation or storage, it can have significant impacts on plants and soil life. Although the impacts of its use are minor, it does not appear to be necessary.

Sulfur may have significant impacts.

Sulfur is of generally low toxicity to humans. Its acute toxicity is low, as shown by its LD₅₀ of more than 5 g/kg body weight. It is an eye and skin irritant, but not a sensitizer. However, the hydrogen sulfide (H₂S) gas produced during the anaerobic degradation of liquid manure is highly toxic. The technical review (TR) cites EPA's judgment that elemental sulfur is a negligible contributor to the H₂S livestock production hazard.²⁴ It is not clear whether the use of sulfur as petitioned would "cause polio encephalomalacia in ruminants and ... inhibit arachidonic acid metabolism and platelet plasma membrane function in rabbits," hazards identified by the TR.²⁵

²⁴ TR lines 301-319.

²⁵ TR lines 215-216.

Overuse in crop production can lead to soil acidification.²⁶ The main environmental threat from its use on animals is from manufacture, storage, and transportation, where toxic H₂S gas may be emitted from molten sulfur and blowing sulfur dust can acidify soil.

Sulfur is not essential for organic livestock production.

The TR identifies natural alternative materials for parasite control, including neem, kaolin, diatomaceous earth, and several essential oils.²⁷ It also identifies practices that would make ectoparasiticides unnecessary, including vector exclusion, sanitation, baits, traps, monitoring, biological control.²⁸

Sulfur's compatibility with organic practices is debatable.

Elemental sulfur has been used as an ectoparasiticide (as well as for other uses) since it was available as a mined material and therefore would have been classified as natural. Sulfur is now available only as a synthetic material, as a byproduct of fossil fuel production. The hazards associated with its use are no greater –and may actually be less (taking into account the reduction in sulfur emissions from those fossil fuels) – than those associated with mined sulfur. On the other hand, its manufacture is currently dependent on the manufacture of fossil fuels.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in dark ink, appearing to read "Terry Shistar".

Terry Shistar, Ph.D.
Board of Directors

²⁶ TR line 294.

²⁷ TR lines 323-328.

²⁸ TR lines 332-347.