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National Organic Standards Board
USDA-AMS-NOP
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Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. LS: Sunset 2019 materials on §205.603 and §205.604

These comments to the National Organic Standards Board (NOSB) on its Spring 2017 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.

§205.603

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

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

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]

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.' (US EPA, 1996) 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' (US EPA, 2011a). 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]

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[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.

[4] Technical Review of Chlorhexidine, 2015. Lines 304-309.

[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.

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 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. If the NOSB chooses this option, we suggest that the LS develop an annotation that could be considered with the sunset proposal.

Chlorine Compounds

See separate comments.

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

[8] Technical Review of Chlorhexidine, 2015. Lines 509-521.
[9] Technical Review of Chlorhexidine, 2015. Lines 554-561.
[10] Technical Review of Chlorhexidine, 2015. Lines 534-542.
[11] Organic Foods Production Act §6517.

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]

The technical review (TR) says there are no natural (non-synthetic) products available that can be used as a management strategy to treat hoof relate 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. If the NOSB chooses this option, we suggest that the LS develop an annotation that could be considered with the sunset proposal.

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." 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.

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[12] TR lines 119-127.
[13] The TR includes sheep, though the petition for zinc sulfate says sheep do not tolerate copper.
[14] TR lines 578-579.

(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.

In 2015, the NOSB voted to reduce the withdrawal period for slaughter livestock from 90 days to 8 days, but this change has not been made in the regulations yet. Procaine is similar to lidocaine, but less widely used now. Both were supported by animal livestock producers and Dr. Hubert Karreman in 2015 because they are true local anesthetics numbing only the area to be worked on, safe, and there are no alternatives.

Conclusion

Beyond Pesticides supports the relisting of lidocaine and procaine (with the new annotation) because they facilitate the humane treatment of animals in minor surgery and are rapidly cleared from the body.

Oxytocin

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

In 2015, the relisting of oxytocin was supported, limiting its use to "emergency post-partum therapeutic application of an animal with a prolapsed uterus which has been replaced and needs rapid contraction so as to not re-prolapse." Dr. Hubert Karreman said, "Oxytocin, however, may be being used incorrectly in helping animals with mastitis to let their milk down better. This was not one of the annotations that it was granted." OTA reported one comment from a producer, "To help fresh cows give their milk down so they have complete milk out to prevent illness. Used on a selective basis but vital when we need it." This indicates that some producers do use it in a way that is not intended by the annotation.

Conclusion

While Beyond Pesticides is supportive of relisting, we are concerned that comments reported by OTA conflict with the allowed use of oxytocin and wonder whether the annotation could be clarified –or at least, the NOSB could clarify it in the written record of the recommendation.

Tolazoline

See xylazine and tolazoline below.

(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. 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]

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 transcripts[22] 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

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[15] http://www.ccac.ca/en_/training/niaut/vivaria/analgesia/xylazine.
[16] Wlaź, 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.
[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.

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." 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.

In 2015, livestock producers and Dr. Hubert Karreman supported the relisting of xylazine and tolazoline 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.

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."

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

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.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors