



BEYOND PESTICIDES

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

September 19, 2017

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

Re. LS: 2019 Sunsets on §205.603

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

The following comments address livestock materials on §205.603 due to sunset in 2019.

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.

Chlorine Materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite

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

(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

In our Spring 2017 comments, we included some general remarks about when the use of sanitizers and disinfectants is appropriate, and we ask that NOSB members review them. We began by defining some terms, discussing what we believe to be mistaken translations of NOSB recommendations into regulation, discussing some relevant issues of microbial ecology, looking at chlorine-based chemicals, and finally concluding that the NOSB must undertake a much

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

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

¹¹ Organic Foods Production Act §6517.

deeper investigation before allowing the use of chlorine-based materials for another five years. **We again request that the NOSB conduct such an investigation.**

The NOSB and NOP need to clarify whether chlorine is required by other statutes. Some have said that other laws require the use of chlorine in higher concentrations than those listed on the National List. If other laws specifically require the use of chlorine, then it must be allowed under the organic program. If it is required, the use should be included on the National List with specific citations for the requirements.

Chlorine disinfection in organic regulations

With respect to the use in contact with food and crops, no direct use of chlorine is allowed by the 1995 recommendation, but use of tap water is allowed if the level of residual chlorine –the chlorine available for disinfection after the water has been disinfected– is less than the limit in the Safe Drinking Water Act (SDWA). So, tap water can be used to wash produce and irrigate crops, but more chlorine cannot be added for those purposes (with the exception of sprouts.)

With respect to the disinfection of tools, equipment, and hard surfaces, the NOSB simply allowed the use, taking the position that it is not appropriate for the NOP to prescribe the manner of use of these materials. However, the NOSB did state that any residues from such actions should not contact food or crops unless they also meet the SDWA standards.

Since “residual chlorine” means the total active chlorine that is available during the use of the water, a straightforward reading of the regulation would be that organic livestock producers and processors may use water that is allowable as tap water under the Safe Drinking Water Act.

The NOP guidance on use of chlorine materials,¹² in attempting to clarify the meaning of the regulations, creates greater confusion and permits far more chlorine than is allowed under the regulations and the recommendations on which they are based. NOP correctly states, “This annotation [in §205.605(b)] was originally crafted to acknowledge that levels of chlorine permitted in municipal drinking water were considered acceptable for organic food production and handling.” NOP then cites the spring 2003 recommendation by the NOSB on the definition of “residual chlorine” under the Safe Drinking Water Act. It continues,

“The Organic Foods Production Act is not designed to function as a waste water regulation. Instead, it is a regulation designed to protect organic integrity. As such, processing operations must demonstrate compliance with the chlorine annotation by monitoring the chlorine content of the water which is in direct contact with organic products, not the wash water which is discharged from the facility.”

However, NOP goes on to explain what this means in practice (livestock portion):

¹² NOP 5026. Guidance: The Use of Chlorine Materials in Organic Production and Handling. <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5090760>.

4.2 Livestock operations:

1. Residual chlorine levels in the water in direct food or animal contact (for example, drinking water) should not exceed the maximum residual disinfectant limit under the SDWA.
2. Chlorine products may be used up to maximum labeled rates for sanitizing equipment or tools (including dairy pipelines and tanks). Label instructions should be followed regarding requirements for rinsing or not rinsing prior to the equipment's next use.

The explanation for livestock –even though it is consistent with the NOSB recommendation– is inconsistent with the listing on §205.603, which does not refer to a use of a chlorine product outside the use of treated water and states that the residual chlorine content in the water must not exceed the SDWA limit.

We are thus starting from a point at which NOP –through both rulemaking and “guidance”– has allowed the use of synthetic substances beyond the uses allowed by NOSB recommendations. We have further recommendations, but first we will suggest corrected language that correctly implements the NOSB recommendation:

[Livestock, corrected] §205.603 (a) As disinfectants, sanitizer, and medical treatments as applicable. (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water for wash water in direct crop or food contact and in flush water from cleaning equipment and surfaces that is applied to crops or fields shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.

Chlorine materials are hazardous to humans and the environment during manufacture and use.

Chlorine is a strong oxidizer and hence does not occur naturally in its pure (gaseous) form. The high oxidizing potential of chlorine leads to its use for bleaching, biocides, and as a chemical reagent in manufacturing processes. Because of its reactivity, chlorine and many of its compounds bind with organic matter. When used as a disinfectant, chlorine reacts with microorganisms and other organic matter. Similarly, the toxicity of chlorine to other organisms comes from its power to oxidize cells. Chlorine has toxic effects on beneficial soil organisms.¹³

There are alternatives to chlorine materials.

Again, the uses of chlorine materials allowed under §205.601 are quite limited. The use of chlorinated tap water for irrigation should be avoided when possible, but often no alternative source may be available. For cleaning equipment and irrigation systems, technical reviews on chlorine have identified the following alternative materials: ethanol and

¹³ 2011 Crops TR.

isopropanol; copper sulfate; hydrogen peroxide; peracetic acid –for use in disinfecting equipment, seed, and asexually propagated planting material; soap-based algaecide/demossers; phosphoric acid, ozone. The TRs also identified some alternative practices –steam sterilization and UV radiation.¹⁴ EPA’s Safer Choice (formerly Design for the Environment) program has been investigating alternative disinfectants and has approved the following for use in Safer Choice disinfectant products: citric acid, hydrogen peroxide, l-lactic acid, ethanol, isopropanol, peroxyacetic acid, and sodium bisulfate.¹⁵ Safer Choice disinfectant product formulations and “inert” ingredients must also meet the Safer Choice standard for safer cleaning products.¹⁶ All of the approved Safer Choice disinfectant active ingredients except sodium bisulfate are on the National List. Citric and lactic acids are considered nonsynthetic, are listed on §205.605(a), and do not need to be listed in order to be used in crop or livestock production.¹⁷

Essential oils are often cited as a class of natural disinfectants. The TR for hydrogen peroxide refers to the following essential oils and extracts: clove oil, melaleuca (tea tree) oil, and oregano oil, pine oil, basil oil, cinnamon oil, eucalyptus oil, helichrysum oil, lemon and lime oils, peppermint oil, tea tree oil, and thyme oil. Aloe vera contains six antiseptic agents active against fungi, bacteria, and viruses. There is considerable research on essential oils as disinfectants that could be useful to organic producers. For example, an early review by Janssen et al described methods for screening.¹⁸ A more recent review by Kalemba and Kunicka gave an updated review of screening methods and an overview of the susceptibility of human and food-borne bacteria and fungi towards different essential oils and their constituents.¹⁹ Deans and Ritchie compared the potency of 50 different essential oils and the range of their antibacterial action against 25 genera of bacteria.²⁰ A review of the literature should be encouraged by the NOSB to encourage the use of safer materials more compatible with organic principles.

Technical reviews have mentioned practices that eliminate the need for disinfectant materials. They include: hot water, steam, UV radiation, slow filtration for cleaning water. As pointed out earlier, “cleaning” is not synonymous with disinfection, and it is possible that in some cases, disinfection is not necessary at all. And, as indicated above, disinfection is sometimes unhealthy.

Chlorine materials are not compatible with organic production.

The fact that use of chlorine is so universally associated with the production of persistent toxic chemicals has led some environmental groups to seek a ban on chlorine-based

¹⁴ 2011 Crops TR and 2006 Livestock TR.

¹⁵ <http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html>.

¹⁶ http://www.epa.gov/dfe/pubs/projects/formulat/dfe_criteria_for_cleaning_products_10_09.pdf.

¹⁷ <http://www.epa.gov/pesticides/regulating/labels/design-dfe-pilot.html>.

¹⁸ Janssen, A. M., Scheffer, J. J. C., & Svendsen, A. B. (1987). Antimicrobial activities of essential oils. *Pharmaceutisch Weekblad*, 9(4), 193-197.

¹⁹ Kalemba, D., & Kunicka, A. (2003). Antibacterial and antifungal properties of essential oils. *Current medicinal chemistry*, 10(10), 813-829.

²⁰ Deans, S. G., & Ritchie, G. (1987). Antibacterial properties of plant essential oils. *International journal of food microbiology*, 5(2), 165-180.

chemicals. We believe that organic production should, for the same reasons, avoid the use of chlorine as much as possible. The allowance of chlorine in the rule reflects the fact that many organic growers—like most of the rest of us— depend on water sources that have been treated with chlorine.

Conclusion: Chlorine-based disinfectants

While the uses of disinfectants vary so that no one method or material is likely to be effective in all cases, there are numerous alternative methods and materials that should allow organic livestock producers to avoid the use of the most toxic materials—in particular, those containing chlorine. The active ingredients identified by the Safer Choice are safer and effective alternatives.

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.²¹

The technical review (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.²² 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.²³ 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. 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.

²¹ TR lines 119-127.

²² The TR includes sheep, though the petition for zinc sulfate says sheep do not tolerate copper.

²³ TR lines 578-579.

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.

(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.

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 allowed to sunset. 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.

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.²⁴ It impairs the effectiveness of anticonvulsants.²⁵ Tolazoline has a number of interactions with other drugs.²⁶ A metabolite of xylazine, 2,6-xylidine, is genotoxic and carcinogenic.²⁷ “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.”²⁸

According to the TAP review, “There are, in fact, many alternative *practices* available for many uses of xylazine.”²⁹

It appears that FDA does not permit the use of xylazine in food-producing animals, and the NOP cannot overrule FDA’s ruling.³⁰ The transcripts³¹ 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.”³² 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.

²⁴ http://www.ccac.ca/en/_training/niaut/vivaria/analgesia/xylazine.

²⁵ 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.

²⁶ TAP, p.36.

²⁷ TAP, p. 12.

²⁸ TAP, p. 25.

²⁹ TAP, p. 42.

³⁰ FDA regulations at 21 CFR 522.2662(d)(2)(iii) and 21 CFR 522.2662(d)(3)(iii). OFPA §6519(c)(6)(B)

³¹ Transcript of September 2002 meeting, pages 568-578.

³² http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm085377.htm#Extra-Label_Use.

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.

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.”

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.

We agree with the LS that xylazine and tolazoline should be considered together.

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