

**National Organic Standards Board
Livestock Subcommittee Proposal
Clarifying “emergency” for use of synthetic parasiticides in organic livestock production
February 20, 2018**

I. INTRODUCTION

Organic farmers rely upon their management skills and knowledge to implement preventative practices such as sourcing disease-free animals into their herds or flocks, monitoring their herds for vigor and selecting breeds which have high resistance to parasites. All organic livestock must have access to the outdoors when appropriate for the region and animal’s stage of life. Organic farmers manage their land, especially ruminant pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List.

The use of approved synthetic parasiticides in organic livestock production under the current regulation is confined to “emergency use”. Use of these synthetic parasiticides in an emergency situation does not result in the livestock’s products being removed from the organic marketplace. These approved synthetic parasiticides cannot be used routinely. The organic status of animals must not result in the farmer withholding medical treatment. If there is no organically approved material or activity to solve the problem, the farmer must use a nonapproved material and then remove the products from this animal from sale into the organic marketplace (7 CFR 205.238(c)(7)).

A discussion document was circulated in Spring 2017 and a proposal circulated in Fall 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to §205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if a definition or clarification of the term “emergency” was needed.

II. BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides, ivermectin, moxidectin and fenbendazole, as part of its sunset review. In April 2016 the NOSB unanimously approved annotations amending the use of fenbendazole and moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of ivermectin from the National List. On January 19, 2018, a proposed rule to implement the NOSB recommendations from April 2016 was printed in the Federal Register for public comment ([83 FR 2498](#)).

During the two year period in which these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an “emergency”.

Two documents were presented to the public for comment specifically addressing the term “emergency” when considering the use of approved synthetic parasiticides for organic livestock. Organic producers, organic certifiers and nonprofits that aid transitioning producers commented that there must be a consistently implemented standard across all regions, sizes of farms, and types of farms. The organic standard should not encourage “certifier shopping” to seek out those that interpret the regulations in a looser manner than others, which could be encouraged by gray areas in the rule.

Organic farmers consistently ask the NOSB for strict standards with clear meanings, so they are confident all organic products in the marketplace meet the same standard. Producers also want to know there is an economic and production “level playing field” between themselves and their competition. Consistent implementation of the National Organic Program regulations, based upon clear and precise definitions contribute to both producer and consumer trust in the organic label. Clarification on emergency treatment when using parasiticides for organic livestock will contribute to lessening the gray area on this specific subject.

Providing this clarification also provides a better understanding of what organic certification agencies should look for in an organic system plan and operators should use as preventative management practices. The NOP proposed rule change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics. Clarification of when an emergency would allow use of synthetic parasiticides on organic livestock is a necessity to provide consistency, trust, and integrity.

III. RELEVANT AREAS OF THE RULE

Current regulation addressing livestock health care

§205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
 - (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
 - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
 - (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
 - (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
 - (2) Dairy animals as allowed under §205.603.
 - (3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
- (18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and

breeder stock, when organic system plan-approved preventive management does not prevent infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—For control of internal parasites only

Proposed rule - January 17, 2018 (83 FR 2498)

Changes in bold for ease of identification.

Parasiticides § 205.603(a)(23)

Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. ~~Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.~~ **Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.** In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. **Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.**

Fenbendazole § 205.603 (a)(23)(i)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

Ivermectin

Removed from the list of approved synthetics

Moxidectin § 205.603(a)(23)(ii)

Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.

IV. Public comment

The NOSB asked the following questions in the April 2017 discussion document:

1. Does the term “emergency” need to be defined?
2. If so, how should the term “emergency” be defined?
3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer’s parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?
4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

Numerous certifiers and organic stakeholders agreed with the necessity of providing further clarification for the term “emergency” when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk. Some stated that describing expectations of what constitutes an “emergency” provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

Additional language to be added to §205.238(c)(4) [new text *in italics*] was proposed in our October 2017 proposal document.

(4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*

- i) *Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.*
- ii) *Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.*
- iii) *Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.*
- iv) *Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.*
- v) *When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National*

List of synthetic substances allowed for use in organic livestock production may be used as an emergency treatment. Provided, That, the conditions for using the substance are documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.

Numerous commenters stated this proposal was too prescriptive. While the NOSB was seeking to provide voluntary examples for preventative and monitoring activities similar to the pest management hierarchies found in the crops and handling sections of the rule, there was concern that having them listed in regulatory language resulted in these activities being mandated and not voluntary. There was comment that listing various activities in an NOP guidance document would be more useful for both producers and certifiers.

Many commenters preferred that a definition of emergency be placed in 205.2, with some suggesting this would be sufficient to address this issue. Others suggested a more general statement be added to the body of the regulation.

Numerous commenters suggested this definition:

A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Many commenters suggested improvements to 205.238 (b) - suggestion in bold

When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

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- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy animals as allowed under §205.603.
- (3) Fiber bearing animals, as allowed under §205.603.
- (4) ***Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and reinfestation, forage height diversity, use of allowed nonsynthetic botanicals, biologics and minerals to maintain parasite levels below treatment***

thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.

V. Discussion

The two items above, improvement to 205.238 (b) and a definition of emergency treatment of livestock for parasiticide use, when presented together, address both emergency assessment, and Organic System Plan practices. The wording in 205.238 (b) is not a mandate, but instead forms a strong foundation for operators and certifiers to use when reviewing and verifying an organic system that protects the health of the animals and meets the organic regulations.

Each region and operation has their own challenges. New-to-organic producers who may be accustomed to relying on synthetic parasiticides, could benefit from this language to help them understand what is required. Having these two descriptions in the rule could also provide the consistency between certifiers in the implementation of the rule, while giving flexibility to allow for operator response to their site-specific needs.

Each age and species of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. Scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency.

Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of synthetic parasiticides is a last resort after other activities have been exhausted.

The short wait time as indicated in the January 2018 NOP proposed rule, between use of synthetic parasiticides and the sale of organic livestock products, should only be allowed when there is a documented need for an emergency treatment. This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as what type of documentation needs to be provided to certifiers in their review.

VI. Subcommittee Discussion

The proposed addition to the regulation provides a clear path for operators and certifiers to promote consistency within the certification process. Monitoring, management, and natural products must be used before a synthetic is allowed. The wording above is practical for the operators and provides the verification tools needed by the certifiers, without being too prescriptive or adding excessive paperwork. The wording above meets the concerns of the vast majority of the public commenters, providing both a workable solution and the clarity requested. The definition as presented above, includes many requirements and is better placed within the regulation, rather than in the definition section of the rule.

VII. MOTION TO APPROVE THIS PROPOSAL

Add to § 205.2 Definitions

Emergency (treatment for parasite control in breeding, dairy and fiber bearing animals). An urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering.

Add to § 205.238 (b)

[Note: assumes adoption of changes in NOP proposed rule (83 FR 2498, January 17, 2018)]

(4) Organic breeding, dairy and fiber bearing animals when meeting the following conditions:

(i) Organic livestock has been managed according to 238(b) and 238(c)(2), 238(c)(4), and 603(a)(23) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, forage height and plant diversity to maintain parasite levels below treatment thresholds and monitoring with documentation of parasites through use of methods such as fecal monitoring and FAMACHA (FAffa Malan Chart—used for tracking anemia in goats and sheep).

(ii) The organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years.

Motion by: Harriet Behar

Seconded by: Jesse Buie

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair to transmit to NOSB February 28, 2018