

**National Organic Standards Board  
Livestock Subcommittee Proposal  
Clarifying “emergency” for use of synthetic parasiticides in organic livestock production  
August 29, 2017**

## **I. INTRODUCTION**

The use of parasiticides in organic production is strictly confined to emergencies under the current regulation. Parasiticides cannot be used routinely, but animals in need of medical attention cannot be ignored in favor of retaining organic status. Typically farmers perform preventative practices such as introducing clean animals into their herds or flocks, selecting breeds which have high resistance to parasites, and managing their land, especially 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.

A discussion document was circulated in Spring 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 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. These recommendations are presently pending rulemaking by the USDA.

During the two years 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 the term emergency was not sufficiently well defined and 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”.

This proposal addresses the concerns of NOSB members and the organic stakeholder community to clarify when approved synthetic parasiticide use is performed as an emergency treatment. This proposal describes when the use of the synthetics to treat parasites would be seen as an emergency treatment. Included in the proposal is the monitoring of parasite threshold levels and examples of various organic production practices that would have been ineffective in controlling the parasite problems. Having this clarity on what circumstances constitute an emergency treatment provides operators and certifiers a consistent and clear standard. Organic stakeholders including livestock producers, certifiers consumers, handlers and others expect use of synthetics are overseen as part of a comprehensive organic system plan. The NOSB recommended 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.

### III. RELEVANT AREAS OF THE RULE

The language below reflects the recommendations unanimously approved by the NOSB and presently in Rulemaking.

§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)—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.
  - (ii) Ivermectin (CAS #70288-86-7)—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.
  - (iii) Moxidectin (CAS #113507-06-5)—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 our discussion document for the April 2017 meeting:

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 stated they 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.

Below is a sampling of responses to our questions:

*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 and 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).*

*The proposal should include specific methods and practices as well as define "emergency" use to ensure consistency among producers and certifiers. "Emergency" should be defined as a situation that significantly jeopardizes the well-being of the animal treated and/or threatens to undermine the overall preventative practices protecting the rest of the herd or operation. An emergency should be demonstrated by a recommendation from a veterinarian, fecal tests, or other specific, measurable methods to ensure consistent enforcement.*

*"Emergency" with respect to the use of synthetic parasiticides is defined as a serious parasite load that effects the immediate welfare of an individual animal, where the use of parasiticides is the only way to protect that animal's welfare after other documented methods of treatment have failed.*

*The term "emergency" should mean the animal is infested and sick. If the health of the animal is compromised, the animal needs to be tested to validate the emergency. If validated, then it should be prescribed treatment. All of this should be done by a licensed veterinarian. Parasiticides shouldn't be used as a preventative method or as a regular routine to maintain a healthy animal. The veterinarian should approve any prescribed parasiticides before the farmer administers any medicine to the animal. There should also be specific preventative practices implemented to minimize the use of parasiticides. These include such things as not overgrazing the pastures; placing the feed in troughs instead of on the ground; and not overstocking the pastures with too many animals.*

*A definition of "emergency"- A sudden, irregular or unexpected situation that requires urgent attention."*

*Clarifying the hierarchy defined at §205.238(a-b), perhaps drawing from the structure of the Facility pest management standard at §205.271.*

*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 and 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). For further clarification, the organic system plan's preventive measures should be defined through a hierarchy of management practices first, natural materials second, and approved synthetics third.*

*Further clarification will assist certifiers in enforcing these regulations consistently.*

*We support a definition of emergency that clarifies the following:*

- *That the procedure is not routine.*
- *That preventative measures have failed.*
- *That identifies testing or procuring the recommendation of a veterinarian to determine infestation and whether the animal's life is at risk.*
- *Steps are taken to prevent a reoccurrence.*

*This clarification will help certifiers with enforcement by having a specific area of the rule to cite that prevents routine use and requires a plan to prevent a similar issue from reoccurring.*

*Certifiers need to ensure that producers engage in a number of preventive measures, such as rotational grazing, providing healthy herd rations, and keeping susceptible animals on clean pastures, to manage parasites in their livestock herds.... Certifiers should enforce the use of parasiticides for emergency use only and ensure that the organic system plan is changed to prevent further use in future years. NODPA asks the NOSB livestock subcommittee to develop an "emergency use" definition as it relates to a livestock operation in the final regulation. It is essential for operators and certifiers to have clarification of this "emergency" term..... Certifiers interpret the current regulations differently with some producers using a more routine use of these materials as a preventative when there is an historical problem with parasites. Different cultures and communities have different standards for emergency use and as the NOP organic standards are used internationally, definitions within regulation are increasingly important. Providing a hierarchy of activities, similar to what is used in crop production when approaching pest management, is one way to provide direction, and we believe with input from the organic community, the development of this definition need not be an onerous task..... the term "emergency use" must be clearly defined through regulation as soon as possible to balance the lowering of the withdrawal time, provide clear standards for use internationally and retain the integrity of the organic seal."*

The Organic Livestock and Poultry Practices (OLPP) Final Rule (82 FR 7042, December 19, 2017) addresses in a general way how internal parasite problems should be addressed on an organic livestock operation. Public commenters asked the NOSB to consider the OLPP requirements and the NOSB livestock subcommittee believes this proposal further enhances the requirements of the OLPP.

*Organic livestock operations must have comprehensive plans to minimize internal parasite problems in livestock. The plan will include preventive measures such as pasture management, fecal monitoring, and emergency measures in the event of a parasite outbreak. Parasite control plans shall be approved by the certifying agent."*

## V. Discussion

Public commenters and the NOSB agree that clarification is needed, both for what constitutes an emergency, and what should be required of an operator to lessen reliance on routine use of approved synthetic parasiticides. The Livestock Subcommittee recommends additional rulemaking at §205.238. Both the crops and handling sections of the final rule contain a pest management hierarchy requiring methods of control first, use of natural materials second and use of approved synthetics as a last resort. This proposal follows a similar hierarchy, offering a clear and verifiable system for both operators and certifiers.

Each age and type of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. These 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 the synthetic parasiticides is a last resort after other activities have been shown to be ineffective in parasite control. The short wait time proposed by the NOSB between use of these synthetic parasiticides and the sale of organic livestock products, should only be performed 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 information that will result in consistency between certifiers when implementing this rule.

Examples of practices and monitoring are listed in the proposed rule below. Rather than providing a list that states the only methods of parasite monitoring and management, the proposal below provides examples which can allow producers and certifiers the flexibility to develop and approve other methods that perform the same function.

The proposal below would be sufficient in providing the needed clarification, and would not require a further definition of the term "emergency" in §205.200 Terms Defined. Since the word "emergency" is used in numerous places throughout the final rule, adding a definition that mostly relates to synthetic parasiticide use could result in unintended effects on other areas of the organic regulation.

This proposal strengthens the language within the Organic Livestock and Poultry Practices rule, and does not contradict it.

## VI. PROPOSAL

**Below is the current standard:**

### **§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;
- (4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;
- (5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and
- (6) Administration of vaccines and other veterinary biologics.

(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 to be sold, labeled, or represented as organically produced; and
- (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

- (1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under §205.603, or any substance that contains a nonsynthetic substance prohibited in §205.604.
- (2) Administer any animal drug, other than vaccinations, in the absence of illness;
- (3) Administer hormones for growth promotion;
- (4) Administer synthetic parasiticides on a routine basis

**This is the additional language to be added to §205.238(c)(4) [new text *in italics*]:**

(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.*
- (5) Administer synthetic parasiticides to slaughter stock;
- (6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or
- (7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

**Subcommittee vote:**

Motion to approve the proposal on clarifying “emergency” for use of synthetic parasiticides in organic livestock production.

Motion by: Harriet Behar

Seconded by: Dan Seitz

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB August 29, 2017**