National Organic Standards Board Livestock Subcommittee Discussion Document Clarifying "emergency" for use of synthetic parasiticides in organic livestock production

December 20, 2016

I INTRODUCTION

The use of parasiticides in organic production is strictly confined to emergencies. Parasiticides cannot be used routinely, but sick animals must be treated. Typically farmers bring clean animals into their herds or flocks, select breeds which have high resistance to parasites, and manage their land, especially pastures, in a manner which reduces the likelihood of parasite infection. If an increased parasite load 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, the farmer, working with the veterinarian, may need to use one of the synthetic parasiticides on the National List.

This discussion document is intended to seek public comment from a broad cross section of stakeholders to determine if any changes should be made to Section 205.238, Livestock Healthcare Practice Standard as it pertains to parasite prevention plans and use of approved synthetic parasiticides, and if clarification of the term "emergency" is needed

II BACKGROUND

In October 2015 the NOSB recommended continued listing of three parasiticides; Ivermectin, Moxidectin and Fenbenzadole, as part of its Sunset Review. In April 2016 the NOSB unanimously approved annotations amending the use of Fenbenzadole 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.

During the two years during which these changes were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information some sectors of stakeholder suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused. Some stakeholders approved removal of Ivermectin and annotations to the other two parasiticides but urged clarification of what constitutes an "emergency".

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 DISCUSSION

The following quotes are examples from public commenters concerning the term "emergency" as used in practice prior to use of approved synthetic parasiticides:

Certifier: "We believe that further transparency on the meaning of the term "emergency use" is imperative.it has been difficult to explain "emergency" to (recent) transitioning producers (who are) proposing a more routine use of these materials as a preventative when there is an historical problem with parasites. The annotation changes, which allow a much shorter withdrawal time between use and sale of organic products from these treated animals, will most certainly result in greater use of these synthetics." Another accredited organic certification agency also "believes that the term "emergency use" must be clearly defined through regulation as soon as possible."

A dairy producer association stated: "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."

Another producer association commented: "The NOSB has an opportunity to strengthen the standards and improve compliance, while also retaining the parasiticides needed in an emergency...... Creating a definition for 'emergency.'"

Industry comment: "We encourage NOSB to consider additional guidelines they can provide to operators and ACAs to properly identify and document emergency situations, so that the changes to annotations and use of parasiticides proposed by the Livestock Subcommittee do not result in routine use of these substances."

The IOIA: "our greater concern is the unequal application of emergency treatment. As inspectors, we see considerable difference in how emergency is determined. We are opposed to any changes that make it too easy for parasiticide use to become routine in an organic system. Perhaps there's a need to define emergency use better or to describe the need to follow a decision making hierarchy as currently exists in the regulation for 3 both crop and handling standards."

V REQUEST FOR PUBLIC COMMENT

- 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?

VI MOTION TO APPROVE THIS DISCUSSION DOCUMENT.

Motion by: Jean Richardson Seconded by: Harriet Behar Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Ashley Swaffar, Subcommittee Chair, to transmit to NOSB December 20, 2016