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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-10-0078; NOP-09-03FR]

RIN 0581-AD05

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (Livestock)

AGENCY: Agricultural Marketing Service

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA's) National List of Allowed and Prohibited Substances (National List) to enact two recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on June 20, 2008, and May 30, 2004. This final rule establishes exemptions (uses) for two substances, fenbendazole and moxidectin, along with any restrictive annotations, as parasiticides in organic livestock production.

EFFECTIVE DATE: This rule becomes effective [INSERT DATE 1 DAY AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Program (NOP) (7 CFR part 205), the National List regulations sections 205.600 through

205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501-6522), (OFPA), and NOP regulations, in section 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the NOP has published multiple amendments to the National List: October 31, 2003 (68 FR 61987); November 3, 2003 (68 FR 62215); October 21, 2005 (70 FR 61217); June 7, 2006 (71 FR 32803); September 11, 2006 (71 FR 53299); June 27, 2007 (72 FR 35137); October 16, 2007 (72 FR 58469); December 10, 2007 (72 FR 69569); December 12, 2007 (72 FR 70479); September 18, 2008 (73 FR 54057); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR 51919); December 13, 2010 (75 FR 77521); March 14, 2011 (76 FR 13501); August 3, 2011 (76 FR 46595); and February 14, 2012 (77 FR 8089). Additionally, proposed amendments to the National List were published on November 8, 2011 (76 FR 69141); January 12, 2012 (77 FR 1980; 77 FR 1996); and February 6, 2012 (77 FR 5717).

This final rule amends the National List to enact two recommendations submitted to the Secretary by the NOSB on June 20, 2008, and May 30, 2004.

II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List regulations:

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This final rule amends § 205.603(a) of the National List regulations by revising paragraph (a)(18) to move ivermectin to a new section (ii), adding fenbendazole at new section (i), and adding moxidectin at new section (iii) as follows: (a)(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. 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.

- (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.

III. Related Documents.

Two notices were published regarding the meetings of the NOSB and deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this final rule were announced for NOSB deliberation in the following Federal Register notices: (1) 73 FR 18491, April 4, 2008, (Fenbendazole); (2) 69 FR 18036, April 6, 2004, (Moxidectin).

In a proposed rule published on July 17, 2006 (71 FR 40624), USDA announced its decision that moxidectin would not be proposed for inclusion on the National List because of its macrolide antibiotic classification, which was inconsistent with NOP policy prohibiting the use of antibiotics in organic livestock production. In a final rule published on December 12, 2007 (72 FR 70479), USDA responded to comments from the proposed rule and affirmed that the NOSB recommended use of moxidectin is as a parasiticide, not as an antibiotic.

The proposal to allow the emergency use of the two substances in this final rule was published as a proposed rule on May 5, 2011 (76 FR 25612).

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under section 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at <http://www.ams.usda.gov>.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted under the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the

authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 – 399), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 – 136(y)).

The OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this final rule would not

be significant. The effect of this final rule is to allow the use of additional substances in agricultural production and handling. This action would modify the regulations published in the final rule to provide small entities with more tools to use in day-to-day operations. AMS concludes that the economic impact of this addition of allowed substances, if any, would be minimal and beneficial to small agricultural service firms. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA Economic Research Service (ERS) data based upon information from USDA-accredited certifying agents, the number of certified U.S. organic crop and livestock operations totaled nearly 13,000 and certified organic acreage exceeded 4.8 million acres in 2008.¹ ERS, based upon the list of certified operations maintained by the National Organic Program, estimated the number of certified handling operations was 3,225 in 2007.² AMS believes that most of the certified production operations would be classified as small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages grew from \$3.6 billion in 1997 to nearly \$21.1 billion in 2008. Between 1990 and 2008, organic food sales demonstrated a

¹ U.S. Department of Agriculture, Economic Research Service. 2009. Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992-2008. <http://www.ers.usda.gov/Data/Organic/>.

² U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers*, <http://www.ers.usda.gov/Data/OrganicHandlers>

growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7 percent.³ Sales of organic dairy products, including milk, yogurt and cheese totaled approximately \$3.6 billion in 2010.⁴

In addition, USDA has accredited 93 certifying agents who provide certification services to producers and handlers under the NOP. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, Chapter 35).

E. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Comments Received on Proposed Rule NOP-09-03

AMS received 15 comments on the proposed rule AMS-NOP-10-0078; NOP-09-03. Comments were received from large animal veterinarians, organic dairy producers and handlers, a livestock parasitologist, agricultural consultants, a trade association, an accredited certifying agent, a nonorganic beef operation, and a private citizen. Some of

³ Organic Trade Association's *2010 Organic Industry Survey*, <http://www.ota.com>.

⁴ Ibid.

the comments supported the additions of fenbendazole and moxidectin to the National List as proposed. Many comments stated that fenbendazole and moxidectin were preferable to ivermectin, which is the only parasiticide currently approved for internal use in organic dairy or breeder livestock. Several comments supporting the use of fenbendazole and moxidectin asserted that under the access to pasture requirements for organic ruminants, which were fully implemented in June 2010, these livestock face an increased risk of parasite infestations which warrants greater access to synthetic parasiticides. Some comments emphasized that the restrictive annotations as proposed would ensure that use of fenbendazole and moxidectin would be used infrequently as a last resort emergency treatment when preventive practices and veterinary biologics are not effective. Two comments which opposed the use of both fenbendazole and moxidectin either disputed their necessity in organic livestock production or broadly opposed the use of animal drugs in organic production.

A number of comments expressed support for fenbendazole by comparing that substance to the parasiticide ivermectin, with respect to ecological impacts, effectiveness and parasite resistance. Some comments characterized fenbendazole as more benign towards earthworms and dung beetles than ivermectin. Commenters described ivermectin as harmful to aquatic and soil plants, micro-organisms, earthworms, and dung beetles. Several comments indicated that ivermectin has limited effectiveness. One comment specifically noted that this parasiticide does not cover all life stages of all gastro-intestinal parasites. Another comment remarked that the development of resistance to ivermectin can be attributed to the frequency of treatment in organic production due to the lack of other approved treatments for internal parasites. Finally, one comment noted

that there are no ivermectin products labeled for use in female cattle of breeding age, while fenbendazole is not subject to such restriction. Support for the use of moxidectin was also framed in comparison to ivermectin. Several comments stated that moxidectin is less toxic to important soil organisms and a more effective treatment for long-term control of certain fecal parasitic eggs.

The Food and Drug Administration (FDA) regulations permit the use of topical and injectable solutions of moxidectin for both internal and external parasites, however, only the topical form is permitted in dairy cattle. In the proposed rule, AMS specifically requested comments on the moxidectin annotation which limits use for internal parasites only. One comment stated that moxidectin could be useful to treat external parasiticides, but the availability of fenbendazole would make moxidectin unnecessary for internal parasites. Some comments, however, suggested that a producer's ability to alternate parasiticides would help prevent resistance. As comments did not substantively object to the proposed use of moxidectin, the listing of moxidectin for internal parasites only has not been altered. As of this final rule, three parasiticides will be permitted for internal parasites in organic livestock production: ivermectin, fenbendazole, and moxidectin.

Changes Requested But Not Made.

Reduce the Length of the Milk Withdrawal Period. A number of comments which supported the use of fenbendazole objected to the proposed 90-day milk withholding period following treatment with fenbendazole. They indicated that the use of fenbendazole would not be feasible in organic production if milk cannot be marketed as organic for 90 days following treatment. The alternatives suggested by commenters were a 30-day withholding period or no withholding period. The commenters proposed that a

30-day withholding period would be a disincentive to routine use, but would not be excessively punitive. Other commenters argued for no withholding period to be consistent with FDA approved fenbendazole labels for use in dairy cattle.

Several commenters who supported the use of fenbendazole cited economic factors for opposing the 90-day withholding period for milk. They explained that recent amendments to the NOP regulations at section 205.239, which requires pasturing of ruminants during the grazing season, will increase livestock exposure to parasites.⁵ The comments also explained that cows are at the greatest risk of parasite infection during the first 100 days of lactation which can decrease milk production, and consequently, financial returns. Other commenters argued that the risk of parasite infestation is greatest during the first year of any animal's life, when the animal is not sufficiently mature to have developed the immune responses that protect mature animals from parasites. One of these comments explained that lactating mature animals do not normally need parasiticides due to fully developed immune mechanisms, and that administration of parasiticides in early lactation could be used to increase milk production.

A number of comments cited research to assert that fenbendazole is rapidly metabolized and does not leave residues in milk. The studies cited indicated that fenbendazole degrades quickly after 48 hours and residues were undetectable after 72 hours to six days.

Under the existing NOP regulations at § 205.238(b), a 90-day milk withholding period is required after use of any synthetic parasiticide treatment approved for organic dairy animals. This has been a requirement since the NOP regulations were established

⁵ Commenters were referencing amendments codified through the NOP Access to Pasture final rule. This rule was published in the Federal Register on February 17, 2010 (75 FR 7154).

in 2000. Despite objections at that time, which asserted that the provision ignored animal welfare and farm economics, the 90-day withholding period was retained in the NOP final rule. The preamble to the NOP final rule explained that the 90-day timeframe was based on a NOSB recommendation and the NOSB has the authority to reconsider this requirement (65 FR 80573).

The NOSB has the authority to recommend a change to the 90-day milk withholding period. The OFPA restricts the Secretary from adding an exemption for the use of a synthetic substance unless this has been proposed by the NOSB. A reduction in the withholding period would relax the use restrictions on a synthetic substance and would, therefore, require NOSB consideration. Any NOSB recommendation to change a withholding period for parasiticides would need to address section 205.238(b) in the Livestock Health Care practice standards as well as the listing for parasiticides at section 205.603(a)(18). AMS understands that producers may occasionally need to withhold milk from the organic market when fenbendazole is administered to lactating dairy animals that are suffering from parasite infestation. However, the routine use of parasiticides is prohibited under the NOP regulations and therefore AMS does not expect that use of fenbendazole will be widespread or frequent. Furthermore, rotating pastures and maintaining suitable stocking rates are preventative practices that can interrupt the host-parasite cycle and reduce susceptibility of livestock to infection.

Requirement for the Written Order from a Veterinarian for Fenbendazole. A comment speculated that the requirement to obtain a written veterinarian's order to administer fenbendazole may encourage the use of ivermectin and moxidectin because these do not require a veterinarian's written order in organic production. FDA requires the order of a

licensed veterinarian only for the administration of 10 mg. fenbendazole suspension to beef cattle, per 21 CFR Section 520.905(2)(iii). FDA regulations do not stipulate that requirement for other fenbendazole dosage forms. The annotation requiring a veterinarian's written order for any administration of fenbendazole was recommended by NOSB to prevent non-emergency use and is only applicable to the use of the fenbendazole in organic production. AMS concurs with the NOSB's intent that organic producers have limitations on access to a synthetic parasiticide to discourage routine or indiscriminate use.

Removing the Prohibition of Parasiticide Use in Slaughter Stock. Several comments urged that parasiticides on the National List be permitted for use in both dairy and beef animals during the first year of life when an animal's immune system is more susceptible to parasites. The existing NOP regulations at section 205.238(c)(5) prohibit the administration of synthetic parasiticides to slaughter stock. A comment characterized the prohibition on parasites in meat producing animals (i.e. slaughter stock) as irrational since both meat and dairy animals can suffer from parasite infections. In addition, one comment noted that several years may pass from parasiticide treatment until slaughter.

Expanding the use of parasiticides to organic slaughter stock is broader than the scope of proposed actions considered in this rulemaking. Lifting the prohibition on the use of parasiticides in slaughter stock would merit full consideration by the NOSB since such a change would establish new uses for synthetic substances in organic livestock production.

G. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB. The substances being added to the National List were based upon petitions from the industry and were evaluated by the NOSB using criteria in the Act and the regulations. One of these recommendations was first made by the NOSB in 2004, and the substance was discussed in two subsequent Federal Register publications (71 FR 40624 and 72 FR 70479) prior to the recent proposed rule (76 FR 25612). Because these substances have been subject to such extensive discussion and comment and these parasiticides are considered vital as an emergency treatment in organic livestock production, AMS believes that livestock producers should be able to use them on their operations as soon as possible. Accordingly, AMS finds that good cause exists under 5 U.S.C. 553(d)(3) for not postponing the effective date of this rule until 30 days after publication in the Federal Register.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501 – 6522.

2. In § 205.603, paragraph (a)(18) is revised to read as follows:

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

* * * * *

(a) * * *

(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. 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.

(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.

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Dated: May 10, 2012

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