Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–10–0078; NOP–09–03]

RIN 0581–AD05

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on June 20, 2008, and May 30, 2004. The recommendations addressed in this proposed rule pertain to establishing exemptions (uses) for two substances, fenbendazole and moxidectin, on the National List as parasiticides in organic livestock production. Consistent with the recommendations from the NOSB, this proposed rule would amend the National List to add these two substances, along with their restrictive annotations.

DATES: Comments must be received by July 5, 2011.

ADDRESSES: Interested persons may submit written comments on this proposed rule using one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave., SW., Room 2646–So., Ag Stop 0268, Washington, DC 20250–0268.

Instructions: All submissions received must include the docket number AMS–NOP–10–0078; NOP–09–03, and/or Regulatory Information Number (RIN) 0581–AD05 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for either or both of the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (*e.g.* scientific, environmental, manufacturing, industry, impact information, *etc.*). Only relevant material supporting your position should be submitted. All comments received will be posted without change to *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Comments submitted in response to this proposed rule will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2646–South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, PhD, Director, Standards Division, Telephone: (202) 720–3252; Fax: (202) 205–7808.

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 §§ 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 *et seq.*), (OFPA), and NOP regulations, in § 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 fourteen 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 70479); December 12, 2007, (72 FR 70479); September 18, 2008, (73 FR 59479); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR 51919); and December 13, 2010 (75 FR 77521). Additionally, proposed amendments to the National List published on November 8, 2010, (75 FR 68505) are currently pending.

This proposed rule would amend the National List to reflect two recommendations submitted to the Secretary by the NOSB on June 20, 2008, and May 30, 2004. Based upon their evaluation of petitions submitted by industry participants and reviews prepared by Technical Advisory Panels, the NOSB recommended that the Secretary amend § 205.603 of the National List to add two substances (fenbendazole and moxidectin) for use as parasiticides in organic livestock production under the conditions specified in their respective annotations. The exemption for use of each substance in organic production was evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517–6518).

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to

designated sections of the National List regulations:

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This proposed rule would amend § 205.603 of the National List Regulations by amending paragraph (a)(18) to move the name of the one listed substance (ivermectin) to a newly designated section (ii) and adding two new sections (i) and (iii) for the purpose of allowing the restricted use of the following substances in organic livestock production:

Fenbendazole (CAS #43210–67–9). Fenbendazole was petitioned for use in March 2007, as a parasiticide for the management of specific gastrointestinal worms and lungworms in organic livestock production.[1] Fenbendazole is a light brownish-gray, odorless crystalline powder which is insoluble in water and soluble in dimethyl sulfoxide. Fenbendazole is a member of the benzimidazole family of anthelmintics. It functions by blocking the polymerization of tubulin into microtubules in gastrointestinal worms and lungworms thereby disrupting the integrity and transport functions of the parasites' cells. Fenbendazole is most effective in ruminant animals because the rate of passage through the digestive system is slowed by the rumen or cecum.

When administered to livestock, fenbendazole and its metabolites can be released into the environment through the excretions of treated animals. Benzimidazole compounds demonstrate high chemical stability in the environment and fenbendazole binds tightly to soil particles, but rapidly degrades in sunlight.

In 1995, the Food and Drug Administration (FDA) issued a Finding of No Significant Impact (FONSI) based upon an environmental assessment of the use of fenbendazole suspension in dairy cattle.[2] The environmental assessment included studies on environmental fate of fenbendazole (*e.g.,* migration/adsorption in soil, photolysis, water solubility, biodegradation) and its potential toxicity in aquatic and terrestrial environments including toxicity to earthworms and dung beetles. In the FONSI, the FDA concluded that the introduction of fenbendazole as suspension, paste or premixes for treatment of dairy cattle, would not have a significant effect on the quality of the human environment. According to the Technical Advisory Panel (TAP) review prepared for the NOSB, there was no convincing evidence associating fenbendazole with serious chronic or acute effects upon human health.[3]

The FDA has approved forms of fenbendazole to treat parasites in cattle (including dairy cattle), goats, sheep, and swine (including pregnant swine), and turkeys. The FDA has approved four oral dosage forms of fenbendazole: suspension, powder, paste, and blocks, for various species of food animals, per 21 CFR 520.905(a)–(e). The FDA has also approved the use of fenbendazole in animal feeds for beef and dairy cattle, swine and turkeys, per 21 CFR 558.258. Table 1 shows the different forms of fenbendazole and the animals for which FDA has approved its use.[4]

TABLE 1—FDA APPROVED FENBENDAZOLE ORAL DOSAGE FORMS AND USES [4]

Fenbendazole dosage form	Suspension	Paste	Powder	Blocks	Animal feed
21 CFR reference	21 CFR 520.905(a)	21 CFR 520.905(c)	21 CFR 520.905(d)	21 CFR 520.905(e)	21 CFR 558.258
Animal species for which use is approved.	* Cattle—including dairy cattle of breeding age. * Beef cattle. * Non-lactating goats.	* Cattle	* Swine	* Cattle—excluding dairy cattle of breeding age.	* Turkeys. * Swine. * Dairy and beef cattle—not for use in veal calves.

Per the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), the FDA established specific tolerances at 21 CFR 556.275 for residues of fenbendazole in animal tissues to be used as food. The acceptable daily intake (ADI) and tolerances are listed for liver, muscle and milk among the livestock species for which FDA has approved its use.

The NOP regulations at § 205.238(b)(1) permit the use of synthetic parasiticides if included on § 205.603 of the National List in breeder stock, excluding the last third of gestation and during lactation for progeny that will be sold, labeled or represented as organic. Section 205.2 of the NOP regulations defines breeder stock as "female livestock whose offspring may be incorporated into an organic operation at the time of their birth." Neither the NOP regulations nor the NOSB recommendation restrict the use of parasiticides to ruminant animals. In effect, this proposed action would allow the use of the applicable form of fenbendazole among breeder stock for beef and dairy cattle, goats, and swine, provided it is not administered during the last third of gestation and lactation for progeny that will be sold as organic. The action would also allow the use of the applicable form of fenbendzole for turkeys.

At its May 20–22, 2008, meeting in Washington, DC, the NOSB recommended revising the National List at § 205.603(a)(18) to permit the use of fenbendazole under the following conditions: "Only to be used upon written diagnosis of clinical infestation by a veterinarian; prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved

[1] The petition was submitted by Intervet Inc., and is retrievable from the NOP Web site in the Petitioned Substances Database, *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[2] Hoechst-Roussel Agri-Vet Company. May 1995. Environmental Assessment NADA 128–620 Fenbendazole Suspension 10% in Dairy Cattle of Breeding Age. Retrieved from FDA's Animal and Veterinary area via NADA number (the FONSI is also available via the link to the Environmental Assessment): *http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm072419.htm.*

[3] Technical Advisory Panel Review on Parasiticides (Fenbendazole, Ivermectin and Levamisole). November 25,1999. Retrieved from National Organic Program Petitioned Substances Database: *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[4] This table does not include the FDA mandated limitations and restrictions on use. That information can be found in the referenced section of the CFR. This table only includes livestock applicable to organic production and does not list other types of animals, such as horses not intended for food, dogs and zoo animals, for which certain forms of oral fenbendazole are 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." Except for the provision, "only to be used upon written diagnosis of clinical infestation by a veterinarian," the recommended annotation is identical to the National List annotation for the parasiticide ivermectin at § 205.603. These common components reiterate the restrictions on the use of parasiticides in general, as set forth in §§ 205.238(b) and (c)(4)–(5).

During this open meeting, the NOSB evaluated the use of fenbendazole against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA and received public comment. The record contains acknowledgement of the risks associated with chemical treatment of parasites, particularly to non-target organisms, human health and the food chain, residue accumulation and target organism resistance. However, the NOSB has considered the role of fenbendazole as part of an integrated system of animal health care, which includes the relief of pain and suffering that can be caused by parasitic infestation. The NOP regulations prohibit the routine use of synthetic parasiticides, per § 205.238(c)(4), and the infrequent use of fenbendazole in organic production is expected to mitigate its introduction to and persistence in the environment. The NOSB emphasized that the allowance of additional parasiticides should not be viewed as an indication that parasiticides will be approved with greater facility. The NOSB reiterated that organic livestock producers are first and foremost responsible for managing parasites through practices specified in their organic system plans, including selection of disease resistant breeds, rotational grazing and culling of susceptible animals. The NOSB concluded that fenbendazole had clear advantages over ivermectin which is the only parasiticide currently approved for use in organic production. In its discussion, the NOSB noted these comparative advantages of fenbendazole over ivermectin: (1) More targeted spectrum of activity; (2) notably benign to earthworms, plant life, microorganisms and particularly dung beetles, all of which are important in sustainable systems; (3) very few reports of anthelmintic resistance even in conventional livestock production; and, (4) very low toxicity.[5]

For the purpose of clarity, the Secretary is proposing that the shared elements of the annotation for ivermectin and proposed annotation for fenbendazole be placed as a separate paragraph at § 205.603(a)(18). The contents of that paragraph, which restate the requirements provided in §§ 205.238(b) and (c)(4)–(5), would apply to each parasiticide listed beneath including ivermectin and the new listings for fenbendazole and moxidectin as proposed below. The repetition of these requirements in § 205.603 of the National List ensures that the provisions which appear in another section of the regulations will not be overlooked.

The NOP engaged in consultations with the EPA and FDA. Concerning the use of fenbendazole, the EPA deferred to FDA as the appropriate regulatory body. The FDA informed the NOP that the proposed amendment to exempt fenbendazole for use in organic livestock is consistent with FDA regulations. The requirement that fenbendazole may only be used upon written diagnosis of clinical infestation by a veterinarian exceeds FDA requirements and is only applicable to the use of fenbendazole in organic livestock production.[6]

Therefore, after consultation with the EPA and FDA regarding the NOSB recommendation, the Secretary is proposing to accept the NOSB's recommendation and amend § 205.603(a) of the National List by removing ivermectin from (18) and placing ivermectin in new section (ii) and adding fenbendazole at new section (i) 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).

Moxidectin was petitioned in March 2003, for use as a topical medical treatment for controlling internal and external parasites in organic cattle production.[7] It is a white to pale yellow powder that is slightly soluble in water and is readily soluble in various organic solvents. Moxidectin belongs to the milbemycin group of macrolides. It is chemically synthesized from nemadectin, a fermentation product of *Streptomyces cyaneogriseus* subsp. *Noncyanogenus.* Moxidectin functions as an endectocide (a drug effective against both internal and external parasites) and activates glutamate-gated chloride channels and GABA-gated chloride channels, causing paralysis of certain arthropods and nematodes. Moxidectin is effective against a wide range of adult and larval internal and external parasites including gastrointestinal roundworms, lungworms, cattle grubs, mites, lice and horn flies.

Moxidectin and its active metabolites are primarily introduced into the environment through excretion of feces. In addition, a minute amount of topically applied moxidectin may wash off treated cattle when rainfall follows treatment.[8] Moxidectin is a lipophilic material that breaks down under sunlight and binds tightly to the soil, which mitigates the potential for contamination of water sources and effects on aquatic organisms. Under aerobic conditions, the half-life of moxidectin in the environment was found to be about two months. In water, moxidectin breaks down fairly rapidly through photodegradation, and has a half-life of 6.8 hours. Various studies on the effect of moxidectin and its metabolites upon non-target soil organisms have been equivocal. Some studies have shown adverse effects

[5] NOSB Recommendation on Fenbendazole. June 20, 2008. Retrieved from National Organic Program Petitioned Substances Database. Transcripts from the NOSB May 20–22, 2008 meeting can be retrieved from the NOP webpage in the NOSB section: *http://bit.ly/iemAwC.*

[6] The FDA regulations at 21 FR 520.905a state that the 10 mg fenbendazole suspension for beef cattle is restricted to use by or on the order of a licensed veterinarian. The FDA regulations do not stipulate that requirement for other dosage forms. The NOP requirement for a 90-day withdrawal period for milk or milk products from an animal treated with an allowed parasiticide also exceeds FDA requirements for use among nonorganic livestock. The 90-day milk withdrawal period was set based upon consumer expectations for organically raised animals and is only applicable to the use of this substance under the NOP regulations (65 FR 80573).

[7] The petition was submitted by Fort Dodge Animal Health and is retrievable from the NOP Web site in the Petitioned Substances Database, *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[8] According to the 2003 Technical Advisory Panel review, in a study submitted to the FDA by the manufacturer, less than 1% of the applied dose of moxidectin was found to wash off treated cattle when rainfall occurred within 30 minutes of product application.

upon non-target organisms, while others showed moxidectin to be comparatively less harmful to arthropods than other parasiticides, notably ivermectin, and to have no adverse impact on earthworms, dung fauna, plant germination or leaves of growing plants.

The FDA considered the environmental effects of the pour-on form of moxidectin for cattle and in 1997, issued a finding of no significant impact (FONSI) declaring that use of the drug would not have a significant effect on the human environment. The FONSI noted that based upon its similarities to avermectins, moxidectin is not expected to have a significant effect on dung-dependent insects as toxicity is mitigated by temporal and spatial distribution.[9] The TAP review prepared for the NOSB stated that some parasites which are resistant to ivermectin have been effectively reduced by moxidectin treatment.[10]

At its May 28–30, 2004, meeting in Chicago, IL, the NOSB recommended adding moxidectin to the National List, with the annotation that it be used only for internal control of parasites. In this open meeting, the NOSB evaluated moxidectin against the criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

In a proposed rule published in the **Federal Register** on July 17, 2006, (71 FR 40624), the USDA indicated that moxidectin would not be added to the National List as recommended by the NOSB because moxidectin is classified as a macrolide antibiotic. Moxidectin is a derivative of the antibiotic nemadectin, which is produced during the fermentation of *Streptomyces cyaneogriseus* sp. *noncyanogenus.* This decision was based upon the rationale that, although moxidectin was approved by FDA for use as a parasiticide in conventional livestock production, the substance is classified as an antibiotic due to its origin as a derivative of the antibiotic nemadectin, and, therefore, its use in organic livestock would be inconsistent with the prohibition of antibiotics at § 205.238(c)(1).

In response to the July 17, 2006, proposed rule (71 FR 40624), a number of comments were submitted in support of the NOSB recommendation that moxidectin be included on the National List for internal control of parasites.[11] The comments characterized USDA's decision not to add moxidectin to the list as arbitrary and without scientific or regulatory basis. The commenters argued that moxidectin is a parasiticide, and does not act as an antibiotic when used as a medical treatment to eliminate parasites from livestock. One comment stated that a defining feature of an antibiotic is its ability to inhibit the growth of microorganisms or kill them outright. The commenter further stated that moxidectin does not exhibit this capacity when used for parasites because it eliminates the parasitic organisms, rather than bacterial infections.

Based upon the evidence received through public comments on the July 17, 2006, proposed rule, the NOP verified the information supplied by commenters and, subsequently, concurred that moxidectin, though categorized as a macrolide antibiotic, does not function as such when used as a parasiticide. In a final rule (72 FR 70479) published in the **Federal Register** on December 12, 2007, USDA announced that moxidectin would be added to the National List through a future rulemaking action.

The FDA has approved oral, injectable and topical dosage forms of moxidectin for treatment in beef and dairy cattle, and sheep. The various approved dosage forms of moxidectin are summarized in Table 2.

TABLE 2—FDA APPROVED MOXIDECTIN FORMS AND USES [12]

Moxidectin dosage form	Oral—solution	Injectable—solution	Topical
21 CFR reference	21 CFR 520.1454	21 CFR 522.1450	21 CFR 524.1451
Animal species for which use is approved.	Sheep—excluding female sheep providing milk for human consumption.	Beef and non-lactating dairy cattle; no use in veal calves.	Beef and dairy cattle; no use in veal calves.

Per the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), the FDA established tolerances for moxidectin in animal products to be used as food at 21 CFR 556.426. The acceptable daily intake (ADI) and residue tolerances are listed for liver, milk and meat of cattle and sheep.

The NOSB recommended the use of moxidectin for control of internal parasites only. The FDA approved indications for use of the topical and injectable solutions include internal and external parasites, therefore, this recommended limitation is only for the purposes of organic livestock production. Organic producers using moxidectin to treat infection would need to demonstrate that any use of moxidectin is for control of internal parasites only. Such information should be available as part of their animal health records.

In considering the NOSB deliberations on moxidectin and the TAP review, the NOP identified an inconsistency between the TAP review's data on persistence of moxidectin in the environment and the data reported as part of the recommendation from the NOSB Livestock Committee. The TAP review stated that moxidectin has a half-life of two months in aerobic soil conditions, but the NOSB Livestock Committee inadvertently recorded the half-life of moxidectin as six months in the soil on the committee recommendation submitted to the NOSB. Based upon the six month half-life, the Livestock Committee proposed an annotation restricting use of moxidectin to control for internal parasites as an effort to minimize the environmental impact of its use. While

[9] Retrieved from FDA's Animal and Veterinary area via NADA number for 141–099 CYDECTIN® 0.5% Pour-On for Cattle (Moxidectin): *http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm072419.htm.*

[10] Technical Advisory Panel review on Moxidectin. April 2003. Retrieved from National Organic Program Petitioned Substances Database: *http://www.ams.usda/nop;* Transcripts from the NOSB May 28–30, 2004 meeting can be retrieved from the NOSB section of the NOP webpage.

[11] The public comments to proposed rule, TM–03–04, can be retrieved from the NOP Web site in the public comments area: *http://www.ams.usda.gov/AMSv1.0/NOPPublicComments.*

[12] The table does not include the FDA mandated limitations and restrictions on use. That information can be found in the referenced section of the CFR. This table only includes livestock applicable to organic production and does not include dogs for which certain injectable and oral forms of moxidectin are approved or horses and ponies not intended for food for which the moxidectin oral gel form is approved.

the discrepancy between the TAP review and the Livestock Committee recommendation was discussed at their May 28–30, 2004, meeting, the NOSB opted to recommended moxidectin with an annotation to limit its use for the treatment of internal parasites.[13]

The NOP regulations permit the use of synthetic parasiticides in breeder stock, excluding the last third of gestation and during lactation for progeny that will be sold, labeled or represented as organic, § 205.238(b)(1). The NOP regulations, at § 205.2, define breeder stock as "female livestock whose offspring may be incorporated into an organic operation at the time of their birth." In effect, this proposed action would allow the use of the applicable form of moxidectin among breeder stock for beef and dairy cattle, and sheep, provided it is not administered during the last third of gestation and during lactation for progeny that will be sold as organic. In accordance with the portions of the NOP regulations which pertain to the use of any approved parasiticide, §§ 205.238(b) and (c)(4)–(5), moxidectin must not be administered on a routine basis and must not be administered to slaughter stock. Per § 205.238(b), moxidectin may only be administered to dairy stock, a minimum of 90 days prior to the production of milk or milk products that are to be labeled as organic when preventive practices and veterinary biologics have failed.

The NOP engaged in consultations with the FDA and EPA concerning the approved use of the substance. The EPA deferred to FDA as the appropriate regulatory body. Based upon consultations with the FDA, the NOP was informed that moxidectin is approved for use by the FDA for treatment and control of internal and external parasites in beef and dairy cattle (21 CFR 524.1452). Further, the FDA regulations do not require a withdrawal time following the application of topical moxidectin to nonorganic beef and dairy cattle.[14] Therefore, the limitation on the use of moxidectin for control of internal parasites only, and the 90-day withdrawal period for organic milk/milk products following treatment with moxidectin are only applicable to the use of moxidectin among livestock under organic management.

After consulting with EPA and FDA and assessing public comments on the proposed rule (71 FR 40624), the Secretary proposes to accept NOSB's recommendation to amend § 205.603(a)(18) of the National List by adding newly designated section (iii), under the existing restrictions at § 205.603(a)(18) as follows: (iii) Moxidectin (CAS #113507–06–5)—for control of internal parasites only. Because of the discrepancy between the TAP review and the NOSB recommendation on the issue of persistence of the substance in the environment, the AMS invites specific comments on the need for the proposed annotation to limit the use of the moxidectin as an internal parasiticide 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 proposed 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 July 17, 2006, proposed rule (71 FR 40624), the 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. On December 12, 2007, in a final rule (72 FR 70479), the USDA responded to comments from the proposed rule (71 FR 40624) and affirmed that the NOSB recommended use of moxidectin is as a parasiticide, not as an antibiotic.

IV. Statutory and Regulatory Authority

The OFPA, as amended [7 U.S.C. 6501 *et seq.*], 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 § 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/AMSv1.0/nop.*

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 proposed 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 § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of 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 § 2108(b)(2) of 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 § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug

[13] Technical Advisory Report on Moxidectin. April 2003. Retrieved from National Organic Program Petitioned Substances Database: *http://www.ams.usda/nop;* Transcripts from the NOSB May 28–30, 2004, meeting can be retrieved from the NOSB section of the NOP webpage.

[14] The FDA regulations, at 21 CFR 522.1450, require that cattle not be slaughtered within 21 days of treatment with the injectable form of moxidectin solution.

and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of 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 *et seq.*) 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, the 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). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the use of additional substances in agricultural production and handling. This action would relax the regulations published in the final rule and would provide small entities with more tools to use in day-to-day operations. The 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, USDA 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.

Based on USDA data from the Economic Research Service (ERS), the U.S. organic sector included nearly 13,000 certified organic crop and livestock operations at the end of 2008. These operations contained more than 4.8 million certified acres consisting of 2,665,382 acres of cropland and 2,160,577 acres of pasture and rangeland. The total acreage under organic management represents a twelve percent increase from 2007.[15] AMS believes that most of the certified production and handling operations would be classified as small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages have grown from $3.6 billion in 1997 to nearly $21.1 billion in 2008.[16] Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2009, organic food sales grew 5.1 percent.[17]

In addition, USDA has accredited 94 certifying agents who provide certification services to producers and handlers. 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 proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.,* or OMB's implementing regulation at 5 CFR part 1320.

The AMS is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

E. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to list two parasiticides on the National List. A 60-day period for interested persons to comment on this rule is provided and is deemed appropriate.

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 proposed to be 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: April 29, 2011.

David R. Shipman,

Associate Administrator, Agricultural Marketing Service.

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[15] 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/.*

[16] Dimitri, C., and L. Oberholtzer. 2009. *Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers,* Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, *http://www.ers.usda.gov/Publications/EIB58.*

[17] Organic Trade Association's *2010 Organic Industry Survey, http://www.ota.com.*