

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

[Doc. No. TM-05-02]

National Organic Program; Proposed Amendment 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 one recommendation submitted to the Secretary by the National Organic Standards Board (NOSB). Consistent with the recommendation from the NOSB, this proposed rule would revise the annotation of one substance on the National List, Methionine, to extend its use in organic poultry production until October 21, 2008.

DATES: Comments must be received by August 15, 2005.

ADDRESSES: Interested persons may comment on this proposed rule using the following procedures:

- Mail: Comments may be submitted by mail to: Arthur Neal, Director of Program Administration, National Organic Program, USDA-AMS-TMP-NOP, 1400 Independence Ave., SW., Room 4008-So., Ag Stop 0268, Washington, DC 20250.
- E-mail: Comments may be submitted via the Internet to: National.List@usda.gov. or to <http://www.regulations.gov>.

- Fax: Comments may be submitted by fax to: (202) 205-7808.

- Written comments on this proposed rule should be identified with the docket number TM-05-02. Commenters should identify the topic and section number of this proposed rule to which the comment refers.

- Clearly indicate if you are for or against the proposed rule or some portion of it and your reason for it. Include recommended language changes as appropriate.

- Include a copy of articles or other references that support your comments. Only relevant material should be submitted.

It is our intention to have all comments to this proposed rule, whether submitted by mail, E-mail, or fax, available for viewing on the National Organic Program (NOP) homepage. Comments submitted in response to this proposed rule will be available for viewing in person at USDA-AMS, Transportation and Marketing, Room 4008-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:

Arthur Neal, Director of Program Administration, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000 the Secretary established, within the NOP regulations [7 CFR part 205], the National List regulations (National List) (§§ 205.600 through 205.607). The National List identifies synthetic substances that are allowed and nonsynthetic substances that are prohibited in organic crop and livestock production. The National List also identifies nonsynthetic and synthetic substances that are allowed for use in certified handling operations. Under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the National List has been amended twice, October 31, 2003 (68 FR 61987), and November 3, 2003 (68 FR 62215).

This proposed rule would amend the National List to reflect one recommendation submitted to the Secretary by the NOSB on March 3,

2005. Based on their evaluation of a petition submitted by industry participants, the NOSB recommended that the Secretary amend § 205.603(d)(1) of the National List by revising the annotation of Methionine, a feed additive, to extend its use in organic poultry production until October 21, 2008. The use of Methionine in organic production was evaluated by the NOSB using the evaluation criteria specified in OFPA (7 U.S.C. 6517-6518).

A 15-day comment period has been deemed appropriate to allow interested persons to respond to this proposed rule. Fifteen days is deemed appropriate because, under the NOP regulations (7 CFR part 205.603(d)), the authorized use of Methionine will expire for organic poultry operations on October 21, 2005. Final rulemaking to extend the use of Methionine in organic poultry production, if adopted, should be completed before October 21, 2005. Any comments that are received timely will be considered before a final determination is made in this matter.

II. Overview of Proposed Amendment

The following provides an overview of the proposed amendment made to § 205.603 of the National List:

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This proposed rule would revise current paragraph (d)(1) of § 205.603 as follows:

DL-Methionine, DL-Methionine-hydroxyl analog, and DL-Methionine-hydroxyl analog calcium (CAS #—59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2008.

Methionine was petitioned for its continued use as a synthetic feed additive in organic poultry operations. Methionine is a colorless or white crystalline powder that is soluble in water. It is classified as an amino acid and considered to be an essential amino acid that is regulated as an animal feed nutritional supplement by the Food and Drug Administration (21 CFR 582.5475).

Methionine was originally included on the National List on October 31, 2003 with an early expiration date of October 21, 2005, (the normal time period for the use of a substance contained in the National List is five years, beginning with the date the substance appears on the National List regulations).

Methionine was petitioned by organic livestock producers as a part of the NOSB's 1995 initial review of synthetic amino acids considered for use in organic livestock production. The petitioners asserted that Methionine was a necessary dietary supplement for organic poultry, due to an inadequate supply of organic feeds containing sufficient concentrations of naturally-occurring Methionine. Petitioners suggested synthetic Methionine would be fed as a dietary supplement to organic poultry at levels ranging from 0.3 to 0.5 percent of the animal's total diet. The petitioners also asserted that a prohibition on the use of synthetic Methionine would contribute to nutritional deficiencies in organic poultry thereby jeopardizing the animal's health. After consideration of the justification provided for the inclusion of Methionine and an assessment under the evaluation criteria provided in OFPA (7 U.S.C. 6517–6518), the NOSB considered the use of synthetic Methionine to be consistent with OFPA and recommended its inclusion onto the National List for use in organic poultry production with an early expiration on its use (October 21, 2005). The NOSB recommended an early expiration on the use of Methionine to encourage the organic poultry industry to phase out the use of synthetic Methionine in poultry diets and develop non-synthetic alternatives to its use as a feed additive.

Since the inclusion of Methionine on § 205.603(d)(1) of the National List on October 31, 2003, the organic poultry industry has been unable to develop suitable non-synthetic alternatives for the substitution of synthetic Methionine in organic poultry diets. As a result, on January 10, 2005, the two organic poultry producers petitioned the NOSB to extend the use of Methionine in organic poultry production beyond October 21, 2005, to provide additional time for development of non-synthetic alternatives. Preliminary research results on nonsynthetic alternatives to synthetic Methionine was provided to the NOSB. Although considered inconclusive, the preliminary results have demonstrated that research trials were underway to identify non-synthetic alternatives for phasing out synthetic Methionine in organic poultry diets.

The NOSB, at its February 28–March 3, 2005, meeting in Washington, DC, received and evaluated public comment on the petition to extend the use of Methionine in organic poultry production beyond October 21, 2005. The NOSB concluded that Methionine is consistent with the evaluation criteria

of 7 U.S.C. 6517 and 6518 of the OFPA; however, the NOSB maintained that non-synthetic alternatives must be developed during the additional extension on the use of synthetic Methionine in organic poultry diets. Therefore, the NOSB recommended Methionine be added to the National List for use only in organic poultry production until October 1, 2008, so that the organic poultry industry could continue its research to develop non-synthetic alternatives for the use of synthetic Methionine.

In response to the NOSB recommendation regarding the use of DL-Methionine in organic livestock production, this action proposes to amend § 205.603(d)(1) of the National List regulation as follows:

DL-Methionine, DL-Methionine-hydroxyl analog, and DL-Methioninehydroxyl analog calcium (CAS #–59–51–8; 63–68–3; 348–67–4)—for use in organic poultry production until October 1, 2008.

III. Related Documents

Two notices were published regarding the meeting of the NOSB and its deliberations on the recommendation and substance petitioned for amending the National List. The substance and recommendation included in this proposed rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 66 FR 48654, September 21, 2001, and (2) 70 FR 7224, February 11, 2005, (Methionine). The substance and recommendation in this proposed rule was initially submitted for proposed rulemaking in the **Federal Register** Notice, FR 68 18556, April 16, 2003, and added to the National List as final rule in the **Federal Register** Notice, FR 68 61987, October 31, 2003.

IV. Statutory and Regulatory Authority

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary, at § 6517(d)(1), to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of 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 onto or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (65 FR 43259, July 13, 2000) can be accessed through the NOP

Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined to be non-significant for purposes of Executive Order 12866, and therefore, does not have to be 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. The final rule adding Methionine to the National List was reviewed under this Executive Order and no additional related information has been obtained since then. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under § 2115 of the OFPA (7 U.S.C. 6514) 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 regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection 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 and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (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 Agricultural Marketing Service (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 and has determined that this proposed rule would have an impact on a substantial number of small entities. However, AMS has determined that 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 entirely beneficial to small agricultural service

firms. Accordingly, the Administrator of the AMS hereby 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 \$6,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

The U.S. organic industry at the end of 2001 included nearly 6,600 certified crop and livestock operations, including organic production and handling operations, producers, and handlers. These operations reported certified acreage totaling more than 2.34 million acres, 72,209 certified livestock, and 5.01 million certified poultry. Data on the numbers of certified handling operations are not yet available, but likely number in the thousands, as they would include any operation that transforms raw product into processed products using organic ingredients. Growth in the U.S. organic industry has been significant at all levels. From 1997 to 2001, the total organic acreage grew by 74 percent, livestock numbers certified organic grew by almost 300 percent over the same period, and poultry certified organic increased by 2,118 percent over this time. Sales growth of organic products has been equally significant, growing on average around 20 percent per year. Sales of organic products were approximately \$1 billion in 1993, but reached \$15 billion in 2004. In addition, since the implementation of OPFA on October 21, 2002, USDA has accredited 97 certifying agents who have applied to USDA to be accredited in order to 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 believe that most of these entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, the existing information collection requirements for the NOP are approved under OMB number 0581-0181. 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, or OMB's implementing regulation at 5 CFR part 1320.

E. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted to the Secretary by the NOSB for extending the use of Methionine, a synthetic substance, in organic poultry production until October 21, 2008. The NOSB evaluated this substance using criteria in the OFPA. The substance's evaluation was initiated by a petition from two organic poultry producers. The NOSB has determined that no wholly natural substitute product is presently available. Loss of the use of this substance would disrupt many well-established and accepted organic poultry operations. Therefore, this substance is presently a necessary component of a nutritionally adequate diet for organic poultry. Accordingly, AMS believes that a 15-day period for interested persons to comment on this rule is 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. Section 205.603, paragraph (d)(1) is revised to read as follows:

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

* * * * *

(d) * * *

(1) DL-Methionine, DL-Methionine-hydroxyl analog, and DL-Methionine-hydroxyl analog calcium (CAS #—59-51-8; 63-68-3; 348-67-4)—for use in organic poultry production until October 1, 2008.

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Dated: July 25, 2005.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

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