

Rules and Regulations

Federal Register

Vol. 75, No. 128

Tuesday, July 6, 2010

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–09–0081; TM–09–04 FR]

RIN 0581–AC93

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

AGENCY: Agricultural Marketing Service, USDA.

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 November 19, 2008, and May 6, 2009. This final rule revises the annotation for tetracycline to eliminate the parenthetical reference and add an expiration date, and adds sulfurous acid, along with a restrictive annotation, to the National List for use in organic crop production.

DATES: *Effective Date:* This final rule becomes effective July 7, 2010.

FOR FURTHER INFORMATION CONTACT: Shannon Nally, Acting 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 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*), 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 must also be 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 National List has been amended eleven times: 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). Additionally, amendments to the National List, proposed on June 3, 2009 (74 FR 26591), are currently pending.

This final rule amends the National List to enact two recommendations submitted to the Secretary by the NOSB on November 19, 2008, and May 6, 2009.

II. Overview of Amendments

The following provides an overview of the amendments to § 205.601 of the National List regulations:

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This final rule amends § 205.601(i)(11) of the National List regulations by eliminating the parenthetical reference and adding an expiration date to read as follows:

Tetracycline, for fire blight control only and for use only until October 21, 2012.

This final rule amends § 205.601 of the National List regulations by adding a new paragraph (j)(9) to read as follows:

Sulfurous acid (CAS # 7782–99–2) for on-farm generation of substance utilizing 99% purity elemental sulfur per § 205.601(j)(2).

III. Related Documents

Three notices have been published announcing the meetings of the NOSB and its planned deliberations on recommendations involving the use of tetracycline in organic crop production. The two notices were published in the **Federal Register** as follows: (1) 73 FR 18491, April 4, 2008 (to consider a recommendation to add oxytetracycline hydrochloride as plant disease control for all diseases on the crops registered by EPA), (2) 73 FR 54781, September 23, 2008 (to consider a recommendation to add oxytetracycline hydrochloride for fire blight control), and (3) 71 FR 14493, March 22, 2006 (to consider the sunset recommendation for the continued listing of oxytetracycline calcium complex for fire blight control). Tetracycline (oxytetracycline calcium complex for fire blight control) was added to the National List by final rule in the **Federal Register** on December 21, 2000 (65 FR 80548). The listing of tetracycline (oxytetracycline calcium complex for fire blight control) was due to sunset on October 21, 2007. In 2006, during the sunset review process, the NOSB reviewed the listing of tetracycline and streptomycin for fire blight control and recommended the renewal of tetracycline and streptomycin on April 20, 2006, by a vote of 7 in favor and 4 against. Tetracycline (oxytetracycline calcium complex), for fire blight control was renewed by final rule in the **Federal Register** on October 16, 2007 (72 FR 58469). A proposal to amend the annotation for tetracycline was published in the **Federal Register** on January 12, 2010 (74 FR 1555). One notice has been published announcing the meeting of the NOSB and its planned deliberations on a recommendation involving sulfurous acid in organic crop production. The notice was published in the **Federal Register** on March 20, 2009 (74 FR 11904). Sulfurous acid was first proposed for addition to the National List on January 12, 2010 (74 FR 1555).

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List

based on proposed amendments developed by the NOSB. Sections 6518(k)(2) 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/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 (OMB).

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 § 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 final 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 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. The impact on entities affected by this final rule would not be significant. The effect of this final rule would be to allow the use of additional substances in agricultural production and handling. This action would modify 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.

According to the USDA, Economic Research Service, U.S. sales of organic food and beverages grew from \$3.6 billion in 1997 to \$21.1 billion in 2008.^{1 2} Fresh produce remains the most popular organic category for retail sales, accounting for 37% of U.S. organic food sales and averaging 15% growth per year between 1997 and 2007. The percentage of U.S. farmland in fruit production that was certified organic in 2008 reached nearly 3%. The Organic Trade Association's "2010 Organic Industry Survey" reports that sales of organic fruits and vegetables reached \$9.5 billion in 2009 and comprise 11.4% of all U.S. fruit and vegetable sales.

According to ERS data based on information from USDA-accredited certifying agents, the U.S. organic industry included approximately 14,540 certified organic crop and livestock operations in 2008, comprising almost 4.0 million acres. There were 2,790 organic handlers (brokers, distributors, wholesalers, and manufacturers) in 2005; in an ERS survey in 2005, just three (3) percent reported over \$100 million in sales, and 48 percent reported \$1 million or less in total gross sales (both organic and conventional products).³ AMS believes that most of these entities would be considered

¹ 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>.

² According to the Organic Trade Association's 2010 Organic Industry Survey, organic food sales reached \$24.8 billion in 2009, <http://www.ota.com>.

³ Greene, C., C. Dimitri, B. Lin, W. McBride, L. Oberholtzer and T. Smith. 2009. *Emerging issues in the U.S. Organic Industry*, Economic Information Bulletin No. 55, U.S. Department of Agriculture, Economic Research Service, <http://www.ers.usda.gov/Publications/EIB55>.

small entities under the criteria established by the SBA.

In addition, USDA has accredited 97 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

Under the OFPA, no additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by § 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.

AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

E. Received Comments on Proposed Rule TM-09-04

AMS received 35 comments on proposed rule TM-09-04. Comments were received from organic crop producers, consumers, an accredited certifying agent, a foreign government, a trade association, state extension personnel, a state advisory board, consultants and a manufacturer of crop protection products. A number of the comments opposed any use of tetracycline or sulfurous acid in organic crop production, and asserted that such amendments weakened the NOP regulations and compromised the integrity of organic foods. Other comments conveyed support for either or both of the proposed amendments; however, a few of those supportive comments suggested modifications to the wording of the proposed amendments.

Twenty-two of the comments submitted addressed tetracycline. Nearly all of the comments which opposed the proposed amendment for the tetracycline listing were directed at any use of tetracycline in organic production; the comments did not specifically address the proposed action to remove the identification of oxytetracycline calcium complex from the annotation for tetracycline, thereby permitting an equivalent form,

oxytetracycline hydrochloride to also be available for controlling fire blight. Most of the comments that were supportive of the proposed action to remove the specification on the form of tetracycline expressed opposition to the proposed expiration date of October 21, 2012.

Eighteen of the 35 comments addressed sulfurous acid. Comments in support of the proposed amendment to add sulfurous acid were primarily submitted by producers or persons who advise growers, such as, state extension specialists or consultants. They asserted that sulfurous acid is an important tool for organic growers enabling the use of water containing bicarbonates or having a high pH without degrading the soil as a result of that use. Comments that were opposed to the addition of sulfurous acid were primarily from consumers and did not offer specific reasons for their position. One commenter asserted that only large corporate farms would be able to afford the costs of specialized employees to manufacture the sulfurous acid.

Changes Requested But Not Made

Several comments expressed total opposition to the use of tetracycline and/or sulfurous acid in organic production asserting that these substances weaken the NOP regulations and undermine the integrity of organic foods; some of these comments opposed the use of pesticides in organic production altogether. A number of the comments in opposition did not include any evidence that would support the position stated.

Some of the reasons cited by comments in opposition to tetracycline included: The substance is harmful to human health and the environment; the diminished host resistance to fire blight; resistance to tetracycline; and alternative practices, such as, moving the crop to another location. One comment advised that the addition of tetracycline be postponed pending completion of EPA's registration review of tetracycline in 2014. We considered these comments, but have determined that the record supports the need for the continued availability of tetracycline for restricted use.

With regard to sulfurous acid, one comment threatened that organic products exported from the U.S. to the nation submitting the comment, could require certification as having been produced without use of sulfurous acid unless the need for sulfurous acid is clarified. The commenter also stated that elemental sulfur, already allowed for use in organic crop production, would be sufficient as an acidifying agent of the soil. The record indicates

that the use of sulfurous acid to lower the pH of irrigation water is preferable, from an environmental standpoint, to spreading elemental sulfur on the soil to address alkaline conditions that develop due to the alkalinity of the irrigation water. The later practice is currently allowed per § 205.601(j)(2). According to the record, the application of sulfurous acid in comparison to elemental sulfur, is better controlled, in terms of the quantity applied, and more benign to soil organisms.

The comment which stated that the use of sulfurous acid would be affordable to only large corporate farms did not present evidence to support that assertion. Furthermore, that stance was refuted by other comments submitted on the proposed rule which stated that the addition of sulfurous acid would benefit many stakeholders and is more cost effective than citric acid that is currently used for pH adjustment.

Expiration Date for Tetracycline

A number of comments, particularly from tree fruit growers and associations in the Pacific Northwest, argued for the continued use of tetracycline after the expiration date of October 21, 2012. Those who argue for the continued use of tetracycline after October 21, 2012, stated that there was no other effective alternative treatment available for fire blight and that the expiration for the use of tetracycline for organic apple and pear production would force them to exit the organic production industry. One comment informed that newer reigning varieties, such as Gala, Fuji, Jonagold, Pink Lady and Honeycrisp apples and Bartlett, Bosc and Asian pear varieties are highly susceptible to the disease and tetracycline is the most effective tool for controlling moderate to severe fire blight particularly after bloom period. These commenters also conveyed that the Pacific Northwest, Washington, Oregon and Idaho, produce 66% and 86% of all U.S. apples and pears and 14,000 tons of organic pears in Washington and Oregon.

According to the NOSB discussion at the November 2008 meeting, tetracycline was originally exempted for use in 2000, with the anticipation that alternative treatments for fire blight would be developed, or that new cultivars not susceptible to fire blight would become available for organic production. October 21, 2012, was selected as the expiration because the exemption for oxytetracycline calcium chloride was due to sunset on that date. It was determined that the effect of amending the annotation to delete the specification for oxytetracycline calcium chloride would reset the sunset

date to 5 years from the date of this final rule. As conveyed in the discussion at the NOSB meeting, the exemption for tetracycline has remained divisive and the NOSB did not want to extend the listing for another 5 years. Peracetic acid and copper fungicides were specifically mentioned as alternative substances for fire blight control, although these were noted as only partially or marginally effective. This is consistent with a comment to the proposed rule which acknowledged that Bordeaux mix (copper sulfate and lime) and other copper formulations sprayed at green-tip stage provide some protection, but can cause fruit scarring and are phytotoxic to some cultivars. It was noted anecdotally at the NOSB meeting that there are apple and pear varieties with limited resistance to fire blight and that some producers are growing pears without the use of tetracycline for the organic market in the European Union, where the use of antibiotics for organic crop production is not permitted.

Based on all public comment and documentation received, the NOP believes that issues regarding the availability and viability of alternatives to tetracycline for fire blight control remain outstanding. At the same time, we note the NOSB's recommendation to only allow the continued use of tetracycline for fire blight control until October 21, 2012. Though some commenters have requested the removal of the expiration date from use of tetracycline, the NOP recommends that such interested parties petition the NOSB, using the petition process outlined in 72 FR 2167 (January 18, 2007), to have the expiration date removed from the authorized use of the substance.

Classification of Tetracycline as a Bactericide

One comment asserted that oxytetracycline calcium complex was naturally produced in the soil by bacterial fermentation and therefore it is not an antibiotic, but a bactericide. This comment argued for the approval of the use of "natural" oxytetracycline to be extended indefinitely for organic production so that the organic apple and pear industry would not be lost to fire blight. The comment did not provide evidence to affirm that the entire production of oxytetracycline to its commercial form would qualify as nonsynthetic (natural) in accordance with the NOP regulations. Tetracycline, in technical literature and common use, is universally identified as an antibiotic. While tetracycline is derived from bacteria and has bactericidal properties,

we believe that "antibiotic" is the proper and accurate classification.

On-Site Rather Than On-Farm Generation of Sulfurous Acid

One of the comments expressed support for the addition of sulfurous acid, but requested that the annotation to refer to on-site generation instead of on-farm, because "farm" is not defined in the NOP regulation or in the Organic Food Production Act (OFPA), and use of that word could cause confusion in the organic industry. We recognize that there was considerable discussion over the precise wording to use in the annotation to capture the intent that it be produced at the location where the sulfurous acid would be used to prevent the use of sulfurous acid in forms that would be synthetically stabilized or preserved for shipping. Both terms, "farm" and "site", appear in the NOP regulations. However, we believe these are distinct, as farm refers specifically to land area in crop production, while "site" can refer to production or handling areas. We believe that "farm" is readily understood by the organic industry and is the more appropriate, specific term in this annotation.

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB. The revisions being made in the listing of one exempted substance and the substance being added to the National List were based on petitions from the industry and evaluated by the NOSB using criteria in the Act and the regulations. Because these revisions and the exemption have been subject to extensive discussion and comments and are considered vital to the most efficient organic crop production, NOP believes that producers should be able to use them in their operations as soon as possible. In crop production, the effective period for use of any practice or crop input may be limited by the progress of the growing season, and the utility of an exempted substance for organic production in any one year is dependent upon that substance being available when it is needed for use, as its use may be quite ineffective at any other time in the growing season. 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 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. § 205.601 is amended by:

■ A. Revising paragraph (i)(11).

■ B. Adding new paragraph (j)(9).

The addition and revision read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(i) * * *

(11) Tetracycline, for fire blight control only and for use only until October 21, 2012.

(j) * * *

(9) Sulfurous acid (CAS # 7782–99–2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

* * * * *

Dated: June 29, 2010.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. 2010–16335 Filed 7–2–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 916 and 917

[Doc. No. AMS–FV–09–0090; FV10–916/917–1 FIR]

Nectarines and Peaches Grown in California; Changes in Handling Requirements for Fresh Nectarines and Peaches

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule that changed the handling requirements applicable to well matured fruit covered under the nectarine and peach marketing orders (orders). The interim rule updated the lists of commercially significant varieties