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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 205

[Document Number AMS–NOP–11–0058; NOP–11–09FR]

RIN 0581–AD15

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

**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 recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on October 28, 2010, and April 29, 2011. This final rule amends the annotation for tetracycline for use in organic crop production and adds two substances: formic acid and attapulgit, along with any restrictive annotations, for use in organic livestock production and organic processing, respectively.

**DATES:** *Effective Date:* This final rule is effective August 3, 2012.

**FOR FURTHER INFORMATION CONTACT:** Melissa Bailey, Ph.D., 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 synthetic substances that may be used and nonsynthetic (natural) substances that may not be used in

organic production. The National List also identifies nonagricultural 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 the 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, as amended (7 U.S.C. 6501–6522), the National List can be amended by the Secretary based on recommendations 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 13504); August 3, 2011 (76 FR 46595); February 14, 2012 (77 FR 8089); May 15, 2012 (77 FR 28472); and June 6, 2012 (77 FR 33290). Additionally, proposed amendments to the National List were published on January 12, 2012 (77 FR 1980), and on February 6, 2012 (77 FR 5717).

This final rule amends the National List to enact three recommendations submitted to the Secretary by the NOSB on October 28, 2010, and April 29, 2011. One recommendation addressed the annotation for tetracycline in organic crop production. The other recommendations pertained to the addition of two substances, formic acid for use in organic livestock production and attapulgit for use in organic handling.

##### *Tetracycline*

Tetracycline is a broad-spectrum antibiotic for control of bacteria, fungi and mycoplasma-like organisms which

functions by inhibiting protein synthesis in bacteria and altering bacterial membranes so that vital genetic material is leaked. For regulatory purposes, Environmental Protection Agency (EPA) uses the term oxytetracycline to refer to pesticides containing either calcium oxytetracycline or hydroxytetracycline monohydrochloride (oxytetracycline hydrochloride). Oxytetracycline is registered with the EPA for the following agronomic uses: fire blight of apples, pears, peaches and nectarines; pear decline; bacterial spot on peaches and nectarines; lethal yellowing of coconut palm; and lethal decline of pritchardia palm.

The current listing for tetracycline on the National List at § 205.601(i)(12) is as follows:

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

Tetracycline (oxytetracycline calcium complex) was added to the National List by a final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). Since 2000, four notices have been published announcing the meetings of the NOSB and its planned deliberations involving the use of tetracycline in organic crop production. The four notices were published in the **Federal Register** as follows: (1) 71 FR 14493, March 22, 2006 (to consider the sunset recommendation for the continued listing of oxytetracycline calcium complex for fire blight control); (2) 73 FR 18491, April 4, 2008 (to consider a recommendation to add a second form of tetracycline, oxytetracycline hydrochloride, as plant disease control for all diseases on the crops registered by EPA); (3) 73 FR 54781, September 23, 2008 (to consider a recommendation to add a second form of tetracycline, oxytetracycline hydrochloride, for fire blight control and to place an expiration date on the use of all forms); and (4) 76 FR 12013, March 4, 2011 (to consider removal of the expiration date of tetracycline for fire blight control). The most recent final rule pertaining to tetracycline added an allowance for the use of oxytetracycline hydrochloride, and added an expiration date of October 21, 2012. This rule was published in the **Federal Register** on July 6, 2010 (75 FR 38693).

In October 2010, a petition was submitted to the NOSB to remove the expiration date for tetracycline. In effect, the petitioner requested an allowance for the use of tetracycline to control fire blight in organic apples and pears beyond the substance's current expiration date of October 21, 2012. On April 29, 2011, the NOSB issued a recommendation to extend the use of tetracycline to control fire blight in apples and pears only until October 21, 2014, by a vote of 13 in favor and 1 against. Consistent with this NOSB recommendation, AMS published a proposal on November 8, 2011 to amend the annotation for tetracycline by extending its use for fire blight control in apples and pears only until October 21, 2014 (76 FR 61941).

#### *Formic Acid*

Formic acid was petitioned for use in May 2010, as a pesticide for suppression of *Varroa* mites.<sup>1</sup> The Environmental Protection Agency (EPA) has exempted synthetic formic acid from the requirement of a tolerance in or on honey and honeycomb when used to control tracheal mites and suppress *Varroa* mites in bee colonies, and applied in accordance with label use directions (40 CFR 180.1178).<sup>2</sup>

At its October 25–28, 2010, meeting, the NOSB recommended adding formic acid to the National List for use in organic livestock production solely as a pesticide within honeybee hives. Consistent with this NOSB recommendation, AMS published a proposal on November 8, 2011 to amend § 205.603(b) of the National List by adding formic acid, with a restrictive annotation (76 FR 61941).

#### *Attapulgit*

Attapulgit was petitioned in May 2009 for two uses: (1) as a nonsynthetic processing aid in organic handling for purifying vegetable and animal oils; and (2) as a livestock feed additive.<sup>3</sup> The FDA has listed this substance in the database, “Everything Added to Food in the United States (EAFUS) (Doc. No. 1943)” and references this substance among those generally regarded as safe in 21 CFR Part 582.99 when used as an adjuvant for pesticide chemicals. The EPA permits attapulgit as an inert

ingredient eligible in minimum risk pesticides applied for food and non-food uses which are exempt from federal registration under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA has determined that attapulgit is exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied pre- and post-harvest per 40 CFR 180.910.<sup>4</sup>

At its April 26–29, 2011, meeting, the NOSB recommended adding attapulgit to the National List for use as a processing aid in organic handling of plant and animal oils. Consistent with this NOSB recommendation, AMS published a proposal on November 8, 2011, to amend § 205.605(b) the National List by adding attapulgit, with a restrictive annotation (76 FR 61941).

## II. Overview of Amendments

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

#### *Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production*

This final rule amends § 205.601(i)(12) of the National List regulations by: (1) Inserting the qualifying words “in apples and pears”; between the words “control” and “only,” in the current annotation and (2) replacing the current expiration date of “October 21, 2012” with the new expiration date, “October 21, 2014”, after which tetracycline may not be used in organic crop production.

#### *Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production*

This final rule amends § 205.603 of the National List regulations by redesignating current paragraphs (b)(2) through (b)(7) as paragraphs (b)(3) through (b)(8) for the purpose of adding the following substance as an external parasiticide at (b)(2):

Formic acid (CAS #64–18–6)—for use as a pesticide solely within honeybee hives.

#### *Section 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as “Organic” or “Made With Organic (Specified Ingredients or Food Group(s))”*

This final rule amends § 205.605(a) of the National List by adding attapulgit as follows:

Attapulgit—as a processing aid in the handling of plant and animal oils.

## III. 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)(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.

#### *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 section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA 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 section 6507(b)(2) of the OFPA, a State organic certification program may contain additional

<sup>1</sup> The petition was submitted by the Hawaii Department of Agriculture, and is retrievable from the NOP Web site in the Petitioned Substances Database: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>.

<sup>2</sup> Tracheal mites lay eggs inside bees' tracheal tubes, and their larvae feed on the bee after the eggs hatch.

<sup>3</sup> Due to the nonsynthetic classification of this substance, a petition for use as an additive for organic livestock feed is not required.

<sup>4</sup> Technical Report on Attapulgit. February 1, 2010. A copy of this report is available in the petitioned substances database, <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>.

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)).

Section 6520 of the OFPA 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, 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). 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. 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 NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 17,000 in 2010. According to USDA, Economic Research Service (ERS) data based on information from USDA-accredited certifying agents, certified organic acreage exceeded 4.8 million acres in 2008.<sup>5</sup> In 2009, U.S. certified organic apple acreage exceeded 21,000 acres, primarily concentrated in Washington and California.<sup>6</sup> ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in 2007.<sup>7</sup> AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

U.S. sales of organic food and beverages have grown from \$1 billion in 1990 to \$26.7 billion in 2010. Sales in 2010 represented 7.7 percent growth over 2009 sales.<sup>8</sup> The USDA has 93 accredited certifying agents who

<sup>5</sup> 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/>.

<sup>6</sup> Kirby, Elizabeth, and David Granatstein. *Status of Organic Tree Fruit in Washington State—2009*, Washington State University, March 2010.

<sup>7</sup> U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation*. <http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm>.

<sup>8</sup> Organic Trade Association. 2011. *Organic Industry Survey*. [www.ota.com](http://www.ota.com).

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 proposed 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–11–09

AMS received 25 comments on proposed rule AMS–11–0058; NOP–11–09PR. Comments were received from organic crop producers, crop distributors, consumers, accredited certifying agents, trade associations, non-profit organizations, growers associations, advocacy groups and an industry working group.

Twenty one of the comments submitted addressed tetracycline. Seventeen comments supported a continued allowance for tetracycline in organic crop production after its current expiration date of October 21, 2012. Two commenters opposed any use of tetracycline in organic crop production, and asserted that antibiotic use is contrary to organic principles. These two comments concurred with the NOSB's concerns over engendering antibiotic resistance and supported the eventual prohibition of all antibiotic use, including that for tetracycline, in organic crop production. One commenter specifically supported the 2014 expiration date on the grounds that current research efforts are too heavily focused on antibiotic product replacement instead of on the NOSB's principle of achieving agro-ecosystems that are ecologically, socially, and economically sustainable.<sup>9</sup> The same

<sup>9</sup> NOSB's Principles of Organic Production and Handling, Adopted October 17, 2001. <http://>

commenter stated that, in the absence of alternative materials that could meet organic standards, organic consumers would support the planting of existing varieties that are more resistant to fire blight than those varieties favored by the conventional market.

One commenter expressed support for the use of formic acid as a pesticide in bee hives, stating that the substance is a safe and effective treatment that is easy to apply. The commenter also conveyed that an allowance for this use of formic acid under the NOP regulations would be consistent with other international organic standards. In the proposed rule on November 8, 2011 (76 FR 61941), AMS specifically sought comments on the appropriate placement of formic acid on § 205.603 of the National List. No comments were received addressing this topic, therefore the proposal to list formic acid at § 205.603(b) of the National List is retained in this final rule. No comments were received regarding attapulgit.

Two comments stated their general opposition to the allowance of synthetics in organic production and handling, and two comments submitted statements unrelated to the proposed rulemaking action.

#### Changes Requested But Not Made

Many comments supportive of continuing the allowance for tetracycline recommended that the substance be listed without an expiration date. Such an action would, in effect, extend the allowance for the substance until October 2017 under the five year sunset review process for the National List. These commenters believe that more alternatives to tetracycline could be available to organic producers by 2017. These comments further stated that an October 21, 2014 expiration date for tetracycline will not provide a sufficient timeframe for development and implementation of suitable alternatives. These commenters described the following as specific concerns with the expiration of tetracycline from the National List: (1) An increase in streptomycin resistance by the pathogen, which will further limit the ability of producers to control fire blight;<sup>10</sup> (2) consumer preference for apple and pear varieties which are more susceptible to fire blight; and (3) the lack of fire blight resistant root stocks and effective biological controls. Many of these comments stated that the

expiration of tetracycline in 2014 could result in a reduced volume of U.S. organic apples and pears. Some commenters cited the potential costs to organic apple and pear growers (e.g. cost to replant trees, reduced productivity in existing trees) and organic handlers (e.g. constrained domestic supply of organic apples and pears) following the expiration of tetracycline from the National List in 2014. The commenters suggested that the slow development and limited availability of alternatives to control fire blight control in organic orchards could also trigger conversion to conventional production.

Several commenters expressed their preference that tetracycline be allowed beyond 2014 (e.g. until 2015, 2016, or 2017) to allow the industry time to develop more alternatives to this substance. Listing tetracycline with a later date or without an expiration date would not meet the intent of the NOSB to phase out the use of this substance in organic apple and pear production over time. Therefore, consistent with the NOSB recommendation, AMS is codifying the October 21, 2014 expiration date to the listing for tetracycline through this final rule. AMS notes that extending the allowance for the use of tetracycline after the October 21, 2014, expiration date would require a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Some commenters also stated that allowing the substance to expire on October 21, 2014 would have a negative economic impact on small businesses and that this rulemaking action should therefore be classified as "significant". AMS disagrees. This action does not further restrict the use of this substance. This action extends the allowance for the substance in organic crop production for an additional two years after its current expiration date of October 21, 2012. Parties interested in requesting an extension for the authorized use of tetracycline in organic crop production after October 21, 2014 may submit a petition to the NOSB. The petition process is outlined in 72 FR 2167 (January 18, 2007).

Based on the public comments received, commenters remain concerned regarding the availability and efficacy of alternatives to tetracycline for fire blight control. Several commenters specifically requested that the NOSB reconsider the October 21, 2014 expiration date for tetracycline. Further, commenters asked that the NOP and the NOSB develop a phase-out plan for the use of antibiotics in fruit trees that has benchmarks and

timelines based on consultations with appropriate stakeholders to ensure that the methods proposed to reach them are feasible. The NOSB recommended that tetracycline is allowed for fire blight control in apples and pears through October 21, 2014. Parties interested in requesting an extension for the authorized use of tetracycline in organic crop production after October 21, 2014 may submit a petition to the NOSB. Parties interested in having the NOSB develop a phase-out plan for the use of antibiotics in tree fruit production may submit public comments to the NOSB at any of their public meetings. The public comment process is outlined on the NOP Web site.

Commenters also requested that the NOP establish a Fire Blight Task Force to assist in development of alternatives. After the NOSB issued their recommendation on tetracycline in April 2011, stakeholders from the research community and organic tree fruit industry established a working group to consolidate efforts and develop alternatives to tetracycline for fire blight control. This working group is expected to provide updates to the public on their progress at future NOSB meetings. Furthermore, in response to the requests by the NOSB and to comments from the public for additional resources to support research on alternatives to tetracycline in organic production, AMS submitted requests to the USDA Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA) in May 2011 for assistance in prioritizing research in the following areas: (1) The efficacy of combinations of substances for fire blight management; (2) breeding, production, and propagation of resistant cultivars and rootstocks that are commercially viable; and (3) cultural practices, crop management, disease forecasting and other production practices that can optimize control of this disease.<sup>11</sup> In fiscal year 2011, NIFA funded a project through the Organic Agriculture Research and Extension Initiative (OREI) for research on the development of non-antibiotic treatments for the control of fire blight in organic apple and pear crops. In January 2012, NIFA included a targeted request for additional research proposals on alternatives to the use of tetracycline for fire blight control in organic production as part of their solicitation for proposals under OREI.<sup>12</sup>

[www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3013893](http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3013893).

<sup>10</sup> Streptomycin is currently listed at § 205.601 of the National List for fire blight control in organic apple and pear production. This allowance on the National List expires on October 21, 2014.

<sup>11</sup> May 2011 Letters submitted by NOP to USDA ARS and NIFA on fire blight research. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5091325>.

<sup>12</sup> January 2012 OREI Request for Proposals. National Institute of Food and Agriculture.

AMS will continue to seek assistance across USDA as appropriate on this issue.

A few commenters requested that the NOP address concerns with the current use of antibiotics in organic tree fruit production through ensuring compliance with § 205.206(a)(3). Section 205.206(a) requires producers to use management practices to prevent disease through crop rotation, sanitation measures and cultural practices. Section 205.206(a)(3) lists specific cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Certifying agents are responsible for ensuring that all organic producers use management practices to prevent disease. Certifying agents verify that organic producers are meeting all USDA organic requirements including utilizing preventative management practices to prevent disease.

These same commenters also stated that, as part of a strategy for addressing fire blight in organic apple and pear production, the NOP should consider variances under § 205.290 to allow antibiotic use in instances when fire blight disease puts orchards at risk. Temporary variances for the use of a synthetic substance that is not on the National List (i.e. use of tetracycline after October 21, 2014) cannot be granted per the current requirements at § 205.290(e).

#### *F. Effective Date*

This final rule reflects recommendations submitted to the Secretary by the NOSB. The amendment to the listing of one exempted substance and the addition of two substances to the National List were based on petitions from the industry and evaluated by the NOSB using criteria in OFPA and the NOP regulations. Because the amendments have been subject to extensive discussion and public comment and are considered vital to organic crops, processing and livestock production, AMS believes that producers and handlers should be able to use them on their operations as soon as possible. Furthermore, tetracycline is due to expire from the National List on October 21, 2012; this action must be finalized by October 21, 2012, to ensure that organic apple and pear producers have access to this substance for two additional years beyond its current expiration date. 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. Section 205.601 paragraph (i)(12) is revised to read as follows:

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

\* \* \* \* \*

(i) \* \* \*

(12) Tetracycline, for fire blight control in apples and pears only until October 21, 2014.

\* \* \* \* \*

■ 3. Section 205.603 is amended by:

■ A. Redesignating paragraphs (b)(2) through (b)(7) as paragraphs (b)(3) through (b)(8); and

■ B. Adding paragraph (b)(2) to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(2) Formic acid (CAS # 64–18–6)—for use as a pesticide solely within honeybee hives.

\* \* \* \* \*

■ 4. In § 205.605(a), the substance “Attapulgit” is added in alphabetical order to read as follows:

#### **§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”**

\* \* \* \* \*

(a) \* \* \*

Attapulgit—as a processing aid in the handling of plant and animal oils.

\* \* \* \* \*

Dated: July 27, 2012.

**David R. Shipman,**  
*Administrator, Agricultural Marketing Service.*

[FR Doc. 2012–18819 Filed 8–1–12; 8:45 am]

**BILLING CODE 3410–02–P**

## **FEDERAL RESERVE SYSTEM**

### **12 CFR Part 234**

**[Regulation HH; Docket No. R–1412]**

**RIN 7100–AD 71**

#### **Financial Market Utilities**

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Final rule.

**SUMMARY:** The Board is publishing a final rule, Regulation HH, Designated Financial Market Utilities. This rule implements provisions of sections 805(a) and 806(e) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act” or “Act”), including risk-management standards for financial market utilities (“FMUs”) that are designated as systemically important by the Financial Stability Oversight Council (the “Council”) and standards for determining when a designated FMU is required to provide advance notice of proposed changes to its rules, procedures, or operations that could materially affect the nature or level of risks presented by the designated FMU.

**DATES:** This final rule is effective September 14, 2012.

**FOR FURTHER INFORMATION CONTACT:** Jennifer A. Lucier, Assistant Director (202) 872–7581 or Kathy C. Wang, Senior Financial Services Analyst (202) 872–4991, Division of Reserve Bank Operations and Payment Systems; Christopher W. Clubb, Senior Counsel (202) 452–3904 or Kara L. Handzlik, Senior Attorney (202) 452–3852, Legal Division; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Title VIII of the Dodd-Frank Act, titled the “Payment, Clearing, and Settlement Supervision Act of 2010,” was enacted to mitigate systemic risk in the financial system and to promote financial stability, in part, through enhanced supervision of designated FMUs.<sup>1</sup> Section 803 of the Dodd-Frank

<sup>1</sup> The Dodd-Frank Act, Public Law 111–203, 124 Stat. 1376, was signed into law on July 21, 2010.