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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-TM-07-0136; TM-07-14FR]

RIN 0581-AC77

National Organic Program (NOP); Sunset Review (2011)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule addresses recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on November 5, 2009, and April 29, 2010. The recommendations addressed in this final rule pertain to the continued exemption (use) of 12 substances in organic production and handling. Consistent with the recommendations from the NOSB, this final rule continues the exemption (use) of 12 substances (along with any restrictive annotations) on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List).

DATES: *Effective Date:* This final rule becomes effective September 12, 2011.

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

SUPPLEMENTARY INFORMATION:

I. Background

The Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. 6501 *et seq.*, authorizes the establishment of the National List of Allowed and Prohibited Substances (National List). The National List identifies synthetic substances that may be used in organic production and nonsynthetic (natural) substances that

are prohibited in organic crop and livestock production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic and nonorganic agricultural substances that may be used in organic handling.

The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If they are not reviewed by the NOSB within 5 years of their inclusion on the National List and renewed by the Secretary, their authorized use or prohibition expires. This means that synthetic substances Hydrogen chloride (CAS # 7647-01-0) and Ferric phosphate (CAS # 10045-86-0), currently allowed for use in organic crop production, will no longer be allowed for use after the sunset date, September 12, 2011. This also means that Egg white lysozyme (CAS # 9001-63-2), L-Malic acid (CAS # 97-67-6), Microorganisms, Activated charcoal (CAS #s 7440-44-0; 64365-11-3), Cyclohexylamine (CAS # 108-91-8), Diethylaminoethanol (CAS # 100-37-8), Octadecylamine (CAS # 124-30-1), Peracetic acid/Peroxyacetic acid (CAS # 79-21-0), Sodium acid pyrophosphate (CAS # 7758-16-9), and Tetrasodium pyrophosphate (CAS # 7722-88-5), currently allowed for use in organic handling, will no longer be allowed for use after the sunset date, September 12, 2011.

This final rule reflects recommendations submitted to the Secretary by the NOSB concerning the continued use of 12 substances on the National List in organic production and handling. Consistent with the recommendations from the NOSB, this final rule renews 12 exemptions on the National List (along with any restrictive annotations).

Under the authority of the OFPA, as amended (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on recommendations 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 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); and December 13, 2010 (75 FR 77521). Additionally, proposed amendments to the National List were published on November 8, 2010 (75 FR 68505), and a final rule affirming a previous amendment was published on March 14, 2011 (76 FR 13504).

II. Overview of Renewals

The following provides an overview of the renewals for designated sections of the National List regulations:

Renewals

This final rule continues the exemptions at § 205.601, along with any restrictive annotations for the following synthetic substances allowed for use in organic crop production: Ferric phosphate (CAS # 10045-86-0); and Hydrogen chloride (CAS # 7647-01-0). This final rule continues the exemptions at § 205.605(a), along with any restrictive annotations, for the following nonsynthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))": Egg white lysozyme (CAS # 9001-63-2); L-Malic acid (CAS # 97-67-6); and Microorganisms. This final rule continues the exemptions at § 205.605(b), along with any restrictive annotations, for the following synthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food groups(s))": Activated charcoal (CAS #s 7440-44-0; 64365-11-3); Cyclohexylamine (CAS # 108-91-8); Diethylaminoethanol (CAS # 100-37-8); Octadecylamine (CAS # 124-30-1); Peracetic acid/Peroxyacetic acid (CAS # 79-21-0); Sodium acid pyrophosphate (CAS # 7758-16-9); and Tetrasodium pyrophosphate (CAS # 7722-88-5).

Nonrenewals

The NOSB determined that a continuing need was demonstrated for the authorization of the 12 exemptions. In addition, most comments received on the proposed rule (76 FR 2880)

supported renewal of all 12 exemptions. Accordingly, there are no nonrenewals.

III. Related Documents

One advanced notice of proposed rulemaking with request for comments was published in the **Federal Register** on March 14, 2008 (73 FR 13795), to make the public aware that the allowance for 12 synthetic and nonsynthetic substances in organic production and handling will expire, if not reviewed by the NOSB and renewed by the Secretary. The proposed rule for this final rule was published in the **Federal Register** on January 4, 2011 (76 FR 288).

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)(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 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/>.

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 § 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 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. 601–612) 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 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 continued use of additional substances in agricultural production and handling. 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 USDA, Economic Research Service (ERS) data based on information from USDA-accredited certifying agents, the number of certified U.S. organic crop and livestock operations totaled nearly 13,000 and certified organic acreage exceeded 4.8 million acres in 2008.¹ ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in 2007.² AMS believes that most of these entities would be considered 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 2008.³ The organic industry is viewed as the fastest growing sector of agriculture, representing over 3 percent of overall

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

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

³ 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>.

food sales in 2009. Between 1990 and 2008, organic food sales historically demonstrated a growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.⁴

In addition, USDA has 94 accredited 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 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 regulations at 5 CFR part 1320.

E. Comments Received on Proposed Rule AMS-TM-07-0136

AMS received nine comments on proposed rule AMS-TM-07-0136. Comments were received from an organic producer, trade associations, handlers, and private citizens. Most comments expressed positions in support of the 12 substances considered under this sunset review. One individual did not refer to subjects within the scope of this rulemaking.

Some commenters specifically supported substances that they promote, represent, or rely on. A comment submitted in support of Ferric phosphate emphasized the importance of the substance to reduce snail damage on organic crops. A comment received on Hydrogen chloride voiced that there are no good alternatives to the use of the substance for removal of residual lint from ginned cottonseed, a process necessary to facilitate mechanical planting. A comment received on Egg white lysozyme stated that the substance is essential for organic wine production. A comment submitted in support of L-Malic acid underscored that no alternatives exist for this substance and stated its importance as a processing aid for pH adjustment in organic products. Multiple comments received on Microorganisms emphasized the critical need for microorganisms in organic food processing for production of dairy, bread, fruit, vegetable, and meat products. Comments received in

support of the allowance for Activated charcoal confirmed the necessity of this substance as a filtering aid in organic processing. Comments submitted supporting the allowance for the substances Cyclohexylamine, Diethylaminoethanol, and Octadecylamine, all boiler water additives, stated that these substances are important for packaging sterilization. Comments supporting the use of Peracetic acid/Peroxyacetic acid for sanitizing food contact surfaces indicated that there are no alternative materials with equivalent functionality. One comment submitted in support of Sodium acid pyrophosphate stated that without the allowance for this substance as a leavening agent, many organic baked goods would no longer be available because a satisfactory alternative does not exist. The same commenter also emphasized the necessity of Tetrasodium pyrophosphate in the manufacturing of meat analog products to facilitate proper flow in the extrusion process and ensure the development of suitable product texture. Overall, at least one comment was received in favor of renewal for all 12 substances considered under this sunset review.

Changes Requested But Not Made

One commenter opposed the continued use of six of the 12 substances: Cyclohexylamine, Diethylaminoethanol, Octadecylamine, Peracetic acid/Peroxyacetic acid, Sodium acid pyrophosphate, and Tetrasodium pyrophosphate. The commenter based their objection on the safety of the substances as described in the material safety data sheets (MSDS) for each substance and recommended removal of these substances from the National List. However, the NOSB reviewed these substances against the evaluation criteria in 7 U.S.C. 6517 and 6518 of the OFPA, and found that when these substances are used as limited by the annotations for each substance, they do not pose any danger to the environment or to manufacturing personnel or consumers. The NOSB concluded that these substances remain essential to organic production since no organic alternatives exist and recommended that the exemption for these substances on the National List continue. The NOP concurs with the NOSB's evaluation and recommendation of these substances and, therefore, does not find that sufficient information was provided by the commenter to justify the removal of these substances from the National List.

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB for the purpose of fulfilling the requirements of 7 U.S.C. 6517(e) of the OFPA. Section 7 U.S.C. 6517(e) requires the NOSB to review each substance on the National List within 5 years of its publication. The substances being reauthorized for use on the National List were initially authorized for use in organic agriculture on September 12, 2006. Because these substances are critical to organic production and handling operations, producers and handlers should be able to continue to use these substances for a full 5-year period beyond their expiration date of September 12, 2011.

Accordingly, pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register**. This rule shall be effective on September 12, 2011.

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.

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

Authority: 7 U.S.C. 6501-6522.

Dated: July 28, 2011.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2011-19659 Filed 8-2-11; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2010-1307; Directorate Identifier 2010-NM-049-AD; Amendment 39-16671; AD 2011-09-09]

RIN 2120-AA64

Airworthiness Directives; Bombardier, Inc. Model CL-600-2A12 (CL-601) and CL-600-2B16 (CL-601-3A, CL-601-3R, and CL-604 Variants) Airplanes

Correction

In rule document 2011-17402 appearing on page 41653-41657, in the issue of Friday, July 15, 2011, make the following correction:

⁴Organic Trade Association's 2011 Organic Industry Survey, <http://www.ota.com>.