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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-TM-09-0003; TM-08-06FR]

RIN 0581-AC91

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to enact six recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) from November 30, 2007, and May 22, 2008. This final rule adds aqueous potassium silicate and sodium carbonate peroxyhydrate, along with any restrictive annotations, for use in organic crop production, and adds gellan gum, fortified cooking wine—Marsala, fortified cooking wine—sherry, and tragacanth gum, along with any restrictive annotations, for use in organic handling. This final rule also removes the listing for glycerine oleate (glycerol monooleate) as the use exemption for this substance as a synthetic inert ingredient in organic crop production expired on December 31, 2006.

DATES: *Effective Date:* This rule becomes effective December 14, 2010.

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

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Program (NOP) [7 CFR part 205], the National List regulations §§ 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501 *et seq.*), (OFPA), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling 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 thirteen 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 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), and August 24, 2010 (75 FR 51919). Additionally, a proposed amendment to the National List was published on November 8, 2010 (75 FR 68505).

This final rule amends the National List to enact six recommendations submitted to the Secretary by the NOSB on November 30, 2007, and May 22, 2008, and removes the listing of one substance, as its use exemption has expired.

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 paragraph (a) of § 205.601 of the National List regulations by adding new paragraph (a)(8) for the addition of one substance as follows: Sodium carbonate peroxyhydrate (CAS #—15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

This final rule amends paragraphs (e) and (i) of § 205.601 by: (1) Redesignating paragraphs (e)(2) through (e)(9), and paragraphs (i)(1) through (i)(11), as paragraphs (e)(3) through (e)(10) and (i)(2) through (i)(12), respectively; and (2) adding new paragraphs (e)(2) and (i)(1) to add one substance as follows: aqueous potassium silicate (CAS #—1312-76-1)—the silica used in the manufacture of potassium silicate must be sourced from naturally occurring sand.

This final rule amends paragraph (m)(2) of § 205.601 of the National List regulations by: (1) Removing the expired exemption for glycerine oleate (glycerol monooleate) (CAS #—37220-82-9)—for use only until December 31, 2006; and (2) redesignating paragraph (m)(2)(ii) as new paragraph (m)(2).

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 regulations by adding one substance in alphabetical order as follows: Gellan gum (CAS #—71010-52-1)—high-acyl form only.

Section 205.606 Nonorganically Produced Agricultural Products Allowed as Ingredients in or on Processed Products Labeled as "Organic."

This final rule amends § 205.606 of the National List regulations by: (1) Redesignating paragraphs (g) through (t) and (u) through (w) as paragraphs (h) through (u) and (w) through (y); and (2) adding new paragraph (g) for the addition of two substances as follows: Fortified cooking wines, (1) Marsala, (2) sherry; and (3) adding new paragraph (v) for the addition of one

substance as follows: Tragacanth gum (CAS #–9000–65–1).

III. Related Documents

Three notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this final rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 72 FR 10971, March 12, 2007, (Gellan gum); (2) 72 FR 58046, October 12, 2007, (Potassium silicate, Sodium carbonate peroxyhydrate, Gellan gum); and (3) 73 FR 18491, April 4, 2008, (Marsala cooking wine, Sherry cooking wine, Tragacanth gum). The recommendation to allow the use of the six substances in this final rule, and the removal of the expired substance, was published as a proposed rule on June 3, 2009 (74 FR 26591).

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 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 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 farming and handling 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 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 National Organic Program, estimated the number of certified handling operations was 3,225 in 2007.² AMS believes that most of these entities would be considered

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>.

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 food sales in 2009. Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2009, organic food sales grew 5.1%.⁴

In addition, USDA has 98 accredited certifying agents (ACAs) who provide certification services to producers and handlers under the NOP. A complete list of names and addresses of ACAs may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. The 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 section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

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

E. Received Comments on Proposed Rule

AMS received comments from 9 submitters on the proposed rule TM-08-06. Comments were received from handlers, a trade association, a non-profit organization, an accredited certifying agent, and an industry group. There was support among the comments for the allowance of each of the six proposed use exemptions. However, a few of those supporting comments suggested modifications to the proposed amendments. One comment also expressed support for the removal of the expired listing for glycerol monooleate. One additional commenter expressed blanket opposition to allowing these

substances in organic production and handling, but did not offer any specific objections. The comments can be viewed at: <http://www.regulations.gov/>.

One comment in favor of the addition of aqueous potassium silicate to § 205.601 requested that the NOP clarify what measures would be used to verify and enforce the source restriction, and what oversight and technical assistance the NOP will provide to certifying agents and their subcontractors. The comment refers to the annotation that the silica used in the manufacture of potassium silicate must be sourced from naturally occurring sand. The National List contains a number of substances which have annotations that specify source or processing restrictions, particularly for handling substances. The NOP has previously advised that ACAs obtain written documentation from the manufacturer(s) of the input product(s) to discern whether a substance/product conforms to restrictive annotations.

One comment in favor of adding tragacanth gum to § 205.606 requested that the NOSB further consider the impact of pesticides and fertilizers in the production of nonorganic ingredients, such as tragacanth gum and wine grapes (in reference to the cooking wines). The commenter cited the criteria established in 7 U.S.C. 6518(m), which includes the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance, effects of the substance on biological and chemical interactions in the agroecosystem, and its compatibility with a system of sustainable agriculture. During the May 2008 meeting, the Board discussed how to consider the impact of conventional production methods for substances petitioned for addition to § 205.606. In the context of wine grapes used to produce fortified cooking wines, the Board clarified that its evaluation covered the production and use of the finished wine product and not the production of the raw ingredients in the wine. Thus, in accordance with 7 U.S.C. 6518(m), the Board considered potential adverse effects upon the agroecosystem from the manufacture, use and disposal of the fortified cooking wine and not the individual ingredients in the wine. The Board determined that the fortified cooking wines, sherry and Marsala, satisfied the OFPA criteria in section 6518(m). In regards to tragacanth gum, the Board reviewed the production process for the gum and found it to be identical to a water extracted gum that is currently listed in § 205.606. At its May 20-22, 2008, meeting in Baltimore, MD, the NOSB evaluated tragacanth

gum against the criteria established under 7 U.S.C. 6517 and 6518, and concluded that tragacanth gum is consistent with the OFPA evaluation criteria. Members of the public are always invited to submit comments regarding specific production concerns of any particular substance that has been petitioned for addition to § 205.606. The NOP solicits such comments in notices of NOSB meetings and proposed rules, both of which are published in the **Federal Register** and on the NOP Web site.

Changes Based on Comments

Gellan Gum

Several comments addressed gellan gum. These comments favored the addition of gellan gum to § 205.605, and several specifically referenced support for the listing of gellan gum as nonsynthetic substance on § 205.605(a). One comment in support of the exemption for gellan gum, recommended an annotation to allow only the native form of gellan gum, *i.e.*, the high-acyl form. The comment stated that low-acyl gellan gum is chemically modified by alkali treatment prior to alcohol precipitation and is, therefore, synthetic. The comment indicated that a restriction of the exemption to the high-acyl form aligns with the intent of the NOSB as conveyed during the November 27-30, 2007 meeting discussion.

There are 2 forms of gellan gum: High- and low-acyl. To manufacture the low-acyl form, an alkali is added and the temperature is raised to remove acetyl groups. A strong acid is then used to lower the pH and the gum is recovered from solution by clarification and precipitation. The high-acyl form is not subject to deacetylation with an alkali salt. After fermentation, the high-acyl form is precipitated out of solution with isopropyl alcohol.

We believe the different manufacturing processes for high- and low-acyl gellan gum merits a revision to the proposed amendment to clarify that only the high-acyl form of gellan gum may be classified as nonsynthetic. Deacetylation, the removal of acetyl group(s) from molecules, results in chemical change. Thus, in accordance with the NOP definition of synthetic, the resulting substance would be synthetic. Based upon this reasoning, we agree with the comment that the recommendation to add gellan gum as a nonsynthetic substance pertains only to the high-acyl form. Therefore, we have amended the listing by adding the annotation "high-acyl form only."

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>.

⁴ Organic Trade Association's 2010 Organic Industry Survey, <http://www.ota.com>.

Changes Requested But Not Made*Fortified Cooking Wines—Marsala and Sherry*

Two comments addressed Marsala and sherry fortified cooking wines. One comment did not support the listing on the basis that organic versions of these cooking wines are commercially available, but failed to provide documentation to support this claim. One comment requested an annotation to prohibit fortified wines that contain synthetic sulfites, such as sulfur dioxide or potassium metabisulfite. The comment referenced the restriction of sulfur dioxide to wines that are “made with organic grapes” in questioning the legal basis for allowing cooking wines containing sulfites to be listed on § 205.606 and, therefore, to be used to produce “organic” products.

In its discussion at the May 20–22, 2008 meeting, the NOSB acknowledged that the manufacturer cited in the fortified cooking wine petitions did not add sulfites to its sherry and Marsala cooking wines. However, the NOSB did not recommend prohibiting sherry or Marsala cooking wines which contain added sulfites. We believe the recommendation is consistent with OFPA, § 6510(a)(3), which prohibits the addition of sulfites except in the production of wine. Therefore, we are not adopting the proposed annotation to prohibit conventional forms of Marsala and sherry fortified cooking wines which contain added sulfites.

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB. The substances 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 substances are crucial to organic crop production and processing operations, producers should be able to use them in their operations as soon as possible. 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 is amended by:

- A. Adding new paragraph (a)(8);
 - B. Redesignating paragraphs (e)(2) through (e)(9) as (e)(3) through (e)(10) and adding new paragraph (e)(2);
 - C. Redesignating paragraphs (i)(1) through (i)(11) as (i)(2) through (i)(12) and adding new paragraph (i)(1); and
 - D. Revising paragraph (m)(2).
- The additions and revisions read as follows:

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

* * * * *

(a) * * *

(8) Sodium carbonate peroxyhydrate (CAS #–15630–89–4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

* * * * *

(e) * * *

(2) Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

* * * * *

(i) * * *

(1) Aqueous potassium silicate (CAS #–1312–76–1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

* * * * *

(m) * * *

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

* * * * *

■ 2. Section 205.605 is amended by adding one new substance in alphabetical order to paragraph (a) 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 group(s)).”

* * * * *

(a) * * *

* * * * *

Gellan gum (CAS # 71010–52–1)—high-acyl form only.

* * * * *

■ 3. Section 205.606 is amended by:

- A. Redesignating paragraphs (g) through (t) and (u) through (w) as paragraphs (h) through (u) and (w) through (y) respectively;
- B. Adding new paragraphs (g) and (v) to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

* * * * *

(g) Fortified cooking wines.

(1) Marsala.

(2) Sherry.

* * * * *

(v) Tragacanth gum (CAS #–9000–65–1).

* * * * *

Dated: December 7, 2010.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2010–31196 Filed 12–10–10; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 29**

[Docket No. SW023; Special Conditions No. 29–023–SC]

Special Conditions: Sikorsky Aircraft Corporation Model S–92A Helicopter; Installation of a Search and Rescue (SAR) Automatic Flight Control System (AFCS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Sikorsky Aircraft Corporation (Sikorsky) model S–92A helicopter. This helicopter, as modified by Sikorsky, will have novel or unusual design features associated with installing an optional SAR AFCS. The applicable airworthiness standards do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards the Administrator considers necessary to show a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is December 3, 2010. We must receive your comments by February 11, 2011.

ADDRESSES: You must mail or deliver two copies of your comments to: Federal