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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number AMS–TM–07–0112; TM–06–04FR]

RIN 0581–AC61

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

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) regulations to reflect recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on August 17, 2005. Consistent with the recommendations from the NOSB, this final rule adds one substance, along with any restrictive annotations, to two sections of the National List. This final rule also clarifies the use and prohibition of chitosan.

DATES: This rule becomes effective December 11, 2007.

FOR FURTHER INFORMATION CONTACT: Bob Pooler, Agricultural Marketing Specialist, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background.

On December 21, 2000, the Secretary established, within the NOP (7 CFR part 205), the National List regulations (§§ 205.600 through 205.607). The National List regulations identify synthetic substances and ingredients that are allowed and nonsynthetic (natural) substances and ingredients that are prohibited for use in organic production and handling. Under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the National List has been amended five times, October 31, 2003 (68 FR 61987), November 3, 2003 (68 FR 62215), October 21, 2005 (70 FR 61217), September 11, 2006 (71 FR 53299), and June 27, 2007 (72 FR 35137). Additionally, an amendment to the National List, proposed on July 17, 2006 (71 FR 40624), is currently pending.

This final rule amends the National List to reflect recommendations submitted to the Secretary by the NOSB on August 17, 2005. On that date the NOSB recommended that the Secretary add one substance to § 205.601 and § 205.603 of the National List regulations.

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 (e) of § 205.601 of the National List regulations by adding Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This final rule amends paragraph (b) of § 205.603 of the National List regulations by adding Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.

III. Related Documents

One notice was published regarding the meeting 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 **Federal Register** Notice 70 FR 43116, July 26, 2005, and published as a proposed rule on July 3, 2006 (71 FR 37854).

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/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 proposed 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 section 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 section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed 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 (FIFRA) (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). 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 relax 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 entirely 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 $6,500,000 and small agricultural producers are defined as those having annual receipts of less than $750,000. This final rule would have an impact on a substantial number of small entities.

The U.S. organic industry at the end of 2001 included nearly 6,949 certified organic crop and livestock operations. Data on the numbers of certified organic handling operations (any operation that transforms raw product into processed products using organic ingredients) were not available at the time of survey in 2001; but they were estimated to be in the thousands. By the end of 2006, the number of certified organic crop, livestock, and handling operations totaled over 14,800 operations based on reports by certifying agents to the NOP as part of their annual reporting requirements. 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 an estimated $12.2 billion in 2004, $13.8 billion in 2005, and nearly $17 billion in 2006. The organic industry is viewed as the fasting growing sector of agriculture, representing almost 3 percent of overall food and beverage sales. Since 1990, organic retail sales have historically demonstrated a growth rate between 20 to 24 percent each year including a 22 percent increase in 2006.

In addition, USDA has 98 accredited certifying agents (ACAs) who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the NOP Web site, at *http://www.ams.usda.gov/nop.* AMS believes that most of these entities 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 regulations 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. Discussion of Comments Received

Eleven (11) comments were received on proposed rule TM–06–04. Comments were submitted by two (2) non-profit organizations, one (1) state department of agriculture, one (1) private certifying agent, and seven (7) consumers. One additional consumer comment was received but because it addresses grass fed beef it was not considered in this rulemaking. The comments can be viewed at *http://www.ams.usda.gov/nop/PublicComments/NLAmendmentsCrops&LSTM=06=04/PublicCommentsCrops&Livestock TM=06=04.html*.

Sucrose Octanoate Esters

The seven (7) consumer comments opposed adding sucrose octanoate esters (SOE) to §§ 205.601 and 205.603 on the grounds that they oppose the use of pesticides. Two other commenters favored the addition of SOE to §§ 205.601 and 205.603. The remaining two (2) commenters did not address the addition of SOE and were assumed to take no position regarding its addition to §§ 205.601 and 205.603.

The seven (7) consumer comments provided brief statements of opposition, to adding sucrose octanoate esters, expressed as one or more of the following reasons: (1) Organic implies that no pesticides were used, (2) the evidence cited is not convincing that sucrose is safe, (3) organic does and should indicate that the substance is unaltered, (4) no pesticides should be allowed in food labeled certified organic, (5) do not favor pollution of

organic standards, (6) if special warnings come with the synthetic how can it be used in organic production, and (7) people who buy organic foods do so because they want food that is free of substances they would not normally ingest.

We have considered these comments. The OFPA and NOP regulations allow for the use of certain pesticides that have been reviewed and evaluated for inclusion on the National List by the NOSB.

In organic crop and livestock production, insect pests are controlled primarily through management practices including physical, mechanical, and biological controls. When these practices are not sufficient, a biological, botanical, or synthetic substance approved for use on the National List may be used. To be added to the National List the OFPA requires that the NOSB review the substance against the criteria established under 7 U.S.C. 6517 and 6518. At its August 17, 2005, meeting in Washington, DC, the NOSB evaluated SOE against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that SOE is consistent with the OFPA evaluation criteria. Accordingly, the NOSB recommended adding SOE to the National List for use in organic crop and livestock production as an insecticide/miticide.

SOE was petitioned for use in organic crop and livestock production as an insecticide/miticide. SOE exists as an amber-colored liquid. The mixture of esters is manufactured from two biochemicals—sucrose (table sugar) and an octanoic acid ester (commonly found in plants and animals). The active ingredient acts by dissolving the waxy protective coating (cuticle) of target pests, causing the insect or mite to dry out and die.

Under FIFRA, the EPA has registered SOE as a biochemical that targets mites and certain soft-bodied insects (e.g., aphids) at three distinct commercial sites: Food and non-food crops, including certain ornamentals; media for growing mushrooms; and adult honey bees (*http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_035300.htm*). In assessing risks to human health, the EPA has concluded that no risks to humans are expected from the use of SOE as a pesticide active ingredient. SOE are not toxic to mammals, but in high concentrations, they are corrosive to the eye. To avoid irreversible eye damage, exposed workers are required to wear appropriate protective clothing. In assessing risks to the environment, the EPA determined that no risks to the environment are expected from the use of SOE in pesticide products because: (a) The esters biodegrade rapidly and therefore do not persist in the environment, (b) the esters are not toxic to mammals or other non-target organisms, (c) organisms are already exposed because these sucrose esters are found in plants, and (d) the tiny amounts used in pesticide products are not expected to substantially increase the amount of these esters in the environment.

The NOP consulted with the EPA and Food and Drug Administration (FDA) to ensure that the NOSB recommendation for the use of SOE in organic crop and livestock production would be consistent with Federal regulations governing the use of the substance. The EPA informed the NOP that the recommended use of SOE in organic crop and livestock production is consistent with EPA regulations. The FDA likewise confirmed that the referenced sucrose octanoate ester product is appropriately licensed by the EPA for its use.

In consideration of the preceding information the NOP has decided to add SOE to §§ 205.601 and 205.603.

Chitosan

In the July 3, 2006, proposed rule (71 FR 37854), the NOP stated it ''will not propose to specifically add chitosan to the National List as an adjuvant, it is already permitted for use at § 205.601(m) of the National List regulations.'' Comments were received regarding this statement and, as a result, the NOP is clarifying the use and prohibition of chitosan in organic agriculture.

Chitosan (Poly-D Glucosamine) (CAS #–9012–76–04) was petitioned for use in organic crop production as an adhesive adjuvant to be used with fungicides approved for use under the NOP regulations. At its August 17, 2005, meeting in Washington, DC, the NOSB recommended adding chitosan to the National List for use in organic crop production as an insecticide, with the restriction that it only be used as an adjuvant. In this open meeting, the NOSB evaluated chitosan against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that chitosan is consistent with the OFPA evaluation criteria. The NOSB recommended restricting the use of chitosan to an adjuvant only, due to the fact that chitosan could also be used as a plant defense booster and plant growth enhancer.

The NOP consulted with the EPA concerning the NOSB's recommendation to include chitosan on the National List for use as an adjuvant. The EPA stated that, in addition to chitosan being registered as an active ingredient, it is also approved as an EPA List 4B inert ingredient. The EPA further informed the NOP that chitosan, used as an adjuvant, would be considered an inert ingredient. The NOP regulations, at § 205.601(m), permits the use of EPA List 4 inert ingredients with nonsynthetic substances or synthetic substances approved for use under the NOP regulations as an active pesticide ingredient. As a result, the NOP stated ''it will not propose to specifically add chitosan to the National List as an adjuvant; it is already permitted for use at § 205.601(m) of the National List regulations.''

The two (2) non-profit organizations, one (1) state department of agriculture, and one (1) private certifying agent commented on the decision not to add chitosan for use in organic crop production as an adhesive adjuvant to be used with fungicides approved for use under the NOP regulations. The commenters did not oppose NOP's decision but requested further explanation and elaboration on the factors that led to that determination.

One commenter agreed that chitosan should be considered approved for use as a List 4 inert ingredient under 205.601(m)(l). The commenter believed that such an interpretation would allow for the use of chitosan as an inert ingredient when it is a component of a final product, e.g. listed as an inert ingredient in a Brand Name material and functions as an adjuvant. However, the same commenter noted that the NOP proposal to not specifically add chitosan to the National List may pose challenges for some organic operators in some states because a spray ''adjuvant'' (inert ingredient) may be regulated as a ''pesticide'' (active ingredient) in varying states. As a result, the commenter suggested that the NOP modify language in 205.601 (m) to explicitly recognize that ''adjuvants classified by the EPA,'' along with inerts, are allowed to be combined with nonysnthetic or synthetic substances approved for use in organic production.

We considered all of the comments. In addition to the comments, we consulted further with the EPA concerning the use of chitosan as an adjuvant. The EPA confirmed, as they had before, that chitosan, in addition to its approved use as an active ingredient and plant defense booster/plant growth regulator (enhancer), is also approved as an EPA List 4B inert ingredient. It also reiterated

that chitosan could be used as an adjuvant and that adjuvants are considered inert ingredients under the EPA. However, in cases where chitosan would be combined with a fungicide, chitosan could not be considered an inert ingredient or adjuvant, because chitosan has active fungicidal properties and is labeled for use against fungal diseases such as blight. The EPA also commented that for chitosan to be considered an inert or adjuvant in a formulation, it could not exhibit pesticidal activity. In that regard, the EPA determined that it could not verify that chitosan does not have any fungicidal activity for the intended use and at the proposed levels mentioned in the petition; data does not support its non-fungicidal activity in such a use.

In addition to the concerns raised about chitosan's use as an adjuvant in combination with another fungicide, the issue of whether chitosan should be considered an insecticide (as recommended by the NOSB) or a plant disease control was mentioned. The EPA informed the NOP that data does not reveal chitosan having insecticidal properties. Instead, chitosan is considered more of a systemic acquired response inducer and demonstrates fungicidal activity. As a result, for the purpose of the NOP regulations, chitosan would be better characterized as a plant disease control.

Based on the information submitted through public comment and gathered in further consultation with the EPA, we have determined that chitosan, when used in combination with another fungicide, cannot be considered an inert or adjuvant. It is considered an active ingredient in such cases. However, in cases where chitosan is used in combination with an approved active ingredient on the National List and does not demonstrate any pesticidal/fungicidal activity, it could be considered an inert ingredient or adjuvant.

The preceding chitosan discussion is summarized as follows:

Chitosan was petitioned for use in organic crop production as an adhesive ''adjuvant'' to be used with fungicides approved for use under the NOP regulations. The NOSB recommended adding chitosan to the National List for use in organic crop production as an ''insecticide,'' with the restriction that it only be used as an ''adjuvant.'' The EPA informed the NOP that data does not reveal chitosan having insecticidal properties. Because the NOSB recommended the use of chitosan as an adjuvant, the recommendation restricts the use of the substance to the capacity of an inert ingredient. AMS, in consultation with EPA, has determined that chitosan, when used as an ''adjuvant'' (not demonstrating any pesticidal activity), is already allowed under the existing inert ingredient provisions of § 205.601(m) of the NOP regulations. However, chitosan, when used in combination with a fungicide, cannot be considered an inert or adjuvant, because chitosan has fungicidal properties and is considered an active ingredient in such cases. Accordingly, unless specifically added to § 205.601 of the National List as an active ingredient, chitosan cannot be used with a fungicide.

Therefore, AMS has decided to refer the chitosan recommendation back to the NOSB so that it can reconsider the intended use of the substance and its inclusion on the National List (i.e., should it be considered a plant disease control; and should it be included on the National List as an approved active ingredient?). In the meantime, chitosan, under the inert ingredient provisions of § 205.601(m) of the NOP regulations, can be used as an ''adjuvant'' (not demonstrating any pesticidal activity) in combination with approved active ingredients on the National List, provided the approved active ingredient is not a registered fungicide. Chitosan, when used in combination with a fungicide, is an active ingredient and remains a prohibited substance that shall not be used in organic agriculture. Further, chitosan remains prohibited for use as a plant defense booster, a plant growth enhancer, and as an active ingredient in any other capacity. If readers have questions concerning when a substance qualifies to be an active or inert ingredient, they should contact the EPA for further information and guidance.

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB. The substance being added to the National List was based on a petition from the industry and evaluated by the NOSB using criteria in the Act and the regulations. Because this substance is crucial to organic crop and livestock production 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 adding new paragraph (e)(9) to read as follows:

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

* * * * *

(e) * * *

(9) Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.

* * * * *

■ 3. Section 205.603 is amended by adding new paragraph (b)(7) to read as follows:

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

* * * * *

(b) * * *

(7) Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.

* * * * *

Dated: December 5, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–23880 Filed 12–7–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE277, Special Condition 23–217–SC]

Special Conditions; Honda Aircraft Company Model HA–420 Hondajet; Protection of Systems for High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued to Honda Aircraft Company, for a Type Certificate for the HA–420