This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service

7 CFR Part 205
[Docket Number TM–06–04]

RIN 0581–AC61

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend 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 proposed rule would add two substances, along with any references that support your comments. Only relevant material should be submitted.

It is our intention to have all comments to this proposed rule, whether submitted by mail, e-mail, or fax, available for viewing on the NOP homepage. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA–AMS, Transportation and Marketing, Room 4008—South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Bob Pooler, Agricultural Marketing Specialist, Telephone: (202) 205–7808. 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 three times, October 31, 2003 (68 FR 61987), November 3, 2003 (68 FR 62215), and October 21, 2005 (70 FR 61217). Additionally, an amendment to the National List, proposed on September 16, 2005 (70 FR 54660), is currently pending.

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

II. Overview of Proposed Amendments

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

This proposed rule would amend paragraph (e) of § 205.601 of the National List regulations by adding the following substance:

Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4). Sucrose octanoate esters (SOE) were petitioned for use in organic crop production as an insecticide/miticide. SOE exist 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). Sucrose esters were isolated when researchers investigated the insecticidal properties of the leaf hairs on tobacco leaves. 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 the Federal Insecticide, Fungicide, and Rodenticide Act (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/biocides/ingredients/factsheets/factsheet_03500.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.

At its August 17, 2005, meeting in Washington, DC, the NOSB recommended adding SOE to the National List for use in organic crop production as an insecticide/miticide. In this open meeting, the NOP informed the NOSB that the recommended use of SOE in organic crop production is consistent with EPA regulations. The FDA confirmed that the referenced sucrose octanoate ester product is appropriately licensed by the EPA for its use.

Therefore, after consultation with the EPA and FDA concerning the NOSB’s recommendation to permit the use of SOE in organic crop production, the Secretary is proposing to accept the NOSB’s recommendation and amend § 205.601(e) of the National List by adding SOE as an insecticide/miticide as follows:

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

This proposed rule would amend paragraph (b) of § 205.603 of the National List regulations by adding the following substance:

Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4). Sucrose octanoate esters (SOE) were petitioned for use in organic livestock production as an insecticide/miticide for honeybees. Sucrose octanoate esters exist 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). Sucrose esters were isolated when researchers investigated the insecticidal properties of the leaf hairs on tobacco leaves. 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 chitosan as a biopesticide that is used primarily as a plant growth enhancer, and as a substance that boosts the ability of plants to defend against fungal infections, including early and late blight, downy and powdery mildew, and gray mold. The EPA has concluded that no risks to the environment are expected because chitosan has not shown toxicity in mammals, it is abundant in nature, and it is used in tiny amounts.

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 NOP evaluated chitosan against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OPF, received public comment, and concluded that chitosan is consistent with the OPFA evaluation criteria.
The NOSB restricted 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. As a plant growth enhancer, the mode of action is believed to be that chitosan is taken up by plant cells where it enters the cell nucleus and stimulates messenger ribonucleic acid and enzyme production. This action stimulates the plant to produce more lignin in the stems, resulting in stronger stems. However, as an adjuvant, the application rate of chitosan would be approximately 0.011 pounds per 20 gallons of water. At such a rate, chitosan would be unlikely to act as a defense booster and plant growth enhancer. It is also unlikely that it would create unacceptable changes in soil temperature, water availability, pH levels, nutrient availability, or salt concentration.

The NOP consulted with the EPA concerning the NOSB’s recommendation to include chitosan on the National List. The EPA informed the NOP that for a petitioned use of chitosan, as an adjuvant, the substance would not be considered an active ingredient, but an inert ingredient. The EPA further stated that, in addition to chitosan being registered as an active ingredient, it is also approved as an EPA List 4B 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 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.

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 proposed rule were announced for NOSB deliberation in Federal Register Notice 70 FR 43116, July 26, 2005.

IV. Statutory and Regulatory Authority

The OPF, 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 OPF 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 (65 FR 43259) 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 section 2115 of the OPF (7 U.S.C. 6514) 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 2115(b) of the OPF (7 U.S.C. 6514(b)). States are also preempted under sections 2104 through 2108 of the OPF (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations until the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OPF.

Pursuant to section 2108(b)(2) of the OPF (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 OPF, (b) not be inconsistent with the OPF, (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 OPF (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary to conduct 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 OPF (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 OPF 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 80148). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed 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. The 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 processors, 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 proposed 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. These operations reported certified acreage totaling more than 2.09 million acres of organic farm production. 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 2004, the number of certified organic crop, livestock, and handling operations totaled nearly 11,400 operations. Based on 2005 data, certified organic acreage increased to 2.2 million acres.

U.S. sales of organic food and beverages have grown from $1 billion in 1990 to an estimated $12.2 billion in 2004. Organic food sales are projected to reach $14.5 billion for 2005; total U.S. organic sales, including nonfood uses, are expected to reach $15 billion in 2005. The organic industry is viewed as the fastest growing sector of agriculture, representing 2 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. This growth rate is projected to decline and fall to a rate of 5 to 10 percent in the future.

In addition, USDA has accredited 94 certifying agents who have applied to USDA to be accredited in order to provide certification services to processors 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 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 proposed 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. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted to the Secretary by the NOSB. The 2 substances proposed to be added to the National List were based on petitions from the industry. The NOSB evaluated each petition using criteria in the OFPA. Because these substances are critical to organic production and handling operations, producers and handlers should be able to use them in their operations as soon as possible. A 30 day period for interested persons to comment on this rule is provided.

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 proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

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


2. In §205.601 a new paragraph (e)(9) is added 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. In §205.603 a new paragraph (b)(7) is added 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.
* * * * *