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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number TM-02-03]

RIN 0581-AC19

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances

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 reflect recommendations submitted to the Secretary by the National Organic Standards Board (NOSB). Technical corrections have also been included in this final rule to clarify specific sections of the National List and adequately reflect previous NOSB recommendations. Consistent with recommendations from the NOSB, this final rule would: add ten substances, along with any restrictive annotations, to the National List, revise the annotations of two substances, and make eight technical revisions.

EFFECTIVE DATE: This rule becomes effective November 3, 2003.

FOR FURTHER INFORMATION CONTACT: Richard H. Mathews, Program Manager, National Organic Program, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Standards (NOS) (7 CFR part 205), the National List (§§ 205.600 through 205.607). The National List is the Federal list that identifies synthetic substances and ingredients that are

allowed and nonsynthetic (natural) substances and ingredients that are prohibited for use in organic production and handling. Since established, the National List has not been amended. However, 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.

This final rule amends the National List to reflect recommendations submitted to the Secretary by the NOSB from June 6, 2000 through October 20, 2002. Between the specified time period, the NOSB has recommended that the Secretary add ten substances to §§ 205.601 through 205.603 of the National List based on petitions received from industry participants. These substances were evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517 and 6518) and the NOS. The NOSB also recommended that the Secretary revise the annotations of two substances included within sections 205.602 and 205.605.

The NOSB has recommended that the Secretary add additional substances to sections 205.603 and 205.605 which have not been included in this final rule but are under review and, as appropriate, will be included in future rulemaking.

In addition to the amendments made based on June 6, 2000 through October 20, 2002, NOSB recommendations, this final rule also makes technical revisions to specific sections of the National List that provide clarity and adequately reflect the intent of the paragraphs identified within those sections.

II. Overview of Amendments

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

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This final rule amends the introductory paragraph of § 205.601 by adding language to clarify that synthetic substances used in crop production must be used in a manner which does not contribute to contamination of crops, soil, or water. The amendment further clarifies that synthetic substances, except those in paragraphs (c), (j), (k), and (l), may only be used when the provisions of § 205.206(a)

through (d) prove insufficient to prevent or control the target pest.

This final rule amends paragraph (a) of § 205.601 (as algicide, disinfectants and sanitizers, including irrigation cleaning systems) by adding the following materials:

Copper Sulfate, for use as an algicide, is limited to one application per field during any 24-month period.

Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Ozone Gas, for use as an irrigation system cleaner only; and

Peracetic acid, for use in disinfecting equipment, seed, and asexually propagated planting material.

Paragraph (a) is further amended by correcting the spelling of the word "demisters" contained in subparagraph (a)(4) to "demossers."

This final rule amends paragraph (e) of § 205.601 by adding the following material:

Copper Sulfate, for use as tadpole shrimp control in rice production, is limited to one application per field during any 24-month period.

Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

This final rule amends paragraph (f) by changing "As insect attractants" to "As insect management."

This final rule amends paragraph (i) of § 205.601 (as plant disease control) by adding the following substance:

Peracetic acid, for use to control fire blight bacteria.

Paragraph (i) is further amended by removing the annotation contained in subparagraph (i)(3).

This final rule revises paragraph (k) of § 205.601 (as plant growth regulators) by inserting the word "gas" behind "ethylene" to be consistent with the June 2000 NOSB recommendation for the substance. Section 205.601(k) now reads "As plant growth regulators—Ethylene gas, for regulation of pineapple flowering."

This final rule revises paragraph (m) of § 205.601 by inserting a new subpart (2) as follows:

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

Section 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

This final rule amends § 205.602 by adding the following substance:

Calcium chloride, except as a brine-sourced foliar spray to treat physiological disorders associated with calcium uptake.

This final rule revises current paragraph (h) of § 205.602 by amending its annotation to read as follows:

Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This final rule revises current subparagraph (4) of § 205.603(a) by correcting the spelling of the word "chlorohexidine" to "chlorhexidine."

This final rule revises paragraph (b)(4) by replacing "Bordeaux mixes" with "as external pest control."

This final rule amends paragraph (d) of § 205.603 (as feed additives) by adding the following three substances:

DL—Methionine, DL—Methionine—Hydroxy Analog, and DL—Methionine—Hydroxy Analog Calcium—for use only in organic poultry production until October 21, 2005.

This final rule revises current subparagraph (1) of § 205.603(d) by removing examples (i) and (ii) copper sulfate and magnesium sulfate, as they are both approved for use by FDA and do not need to be listed individually as examples. As currently published, subparagraphs § 205.603(d)(1)(i) and (ii) may have misled some readers to believe that the use of trace minerals are limited only to copper sulfate and magnesium sulfate. Therefore, the revision made in this final rule for current subparagraph (1) of § 205.603(d) reads "Trace minerals, used for enrichment or fortification when FDA approved."

This final rule amends current paragraph (e) of § 205.603 (as synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as active pesticide ingredients in accordance with any limitations on the use of such substances) by redesignating current paragraph (f) of § 205.603 as subparagraph (1) under § 205.603(e). While drafting § 205.603 for final publication in the **Federal Register**,

current paragraph (f) was intended to be designated as § 205.603(e)(1), however, its designation was not properly assigned. Therefore, this final rule redesignates current paragraph (f) of § 205.603 as subparagraph (e)(1) of the same section.

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 current paragraph (a) of § 205.605 by adding agar-agar, carageenan and tartaric acid as technical corrections. These substances were included on the National List proposed in the **Federal Register** on December 16, 1997, but were inadvertently omitted from the National List published in the **Federal Register** on March 13, 2000, and the final rule published on December 21, 2000, Final Rule (7 CFR part 205).

This final rule revises current paragraph (b)(10) of § 205.605 by amending its annotation to read as follows:

Ethylene, allowed for postharvest ripening of tropical fruit and degreening of citrus.

Paragraph (b) is further amended by adding tartaric acid as a technical correction.

Ethylene, for organic crop production, was a substance that was petitioned and reviewed for inclusion onto the National List after promulgation of the proposed rule published in the **Federal Register** on March 13, 2000. The NOSB approved and recommended that ethylene gas be included on the National List with the annotation "for regulation of pineapple flowering." After receiving the NOSB recommendation for the material, the NOP, while finalizing the NOS, included the material on the National List without receiving public comment on the material through the Federal rulemaking process. As a result, the proposed rule requested public comment on the use of ethylene gas and this final rule addresses comments that were received on the use of ethylene gas for regulation of pineapple flowering.

III. Related Documents

Eight 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) 64 FR 54858, October 8, 1999, (Ethylene); (2) 65 FR

33802, May 25, 2000, (Ethylene gas); (3) 65 FR 64657, October 30, 2000, (Calcium borogluconate and Peracetic acid); (4) 66 FR 10873, February 20, 2001, (Poloxalene); (5) 66 FR 48654, September 21, 2001, (Calcium chloride, Copper sulfate, Methionine); (6) 67 FR 19375, April 19, 2002, (Potassium sorbate and Sodium propionate); (7) 67 FR 54784, August 26, 2002, (Ozone gas, Pheromones, Sodium (Chilean) nitrate, Propylene glycol, Magnesium hydroxide/Magnesium oxide, Kaolin pectin, Bismuth subsalicylate, Flunixin, Xylazine, Tolazoline, Butorphanol, Mineral oil, Activated charcoal, Epinephrine); and (8) 67 FR 62950, October 9, 2002, (Potassium sulfate and Calcium propionate).

IV. Statutory and Regulatory Authority

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary, at § 6517(d)(1), 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 onto or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOS. 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 to be non-significant for purposes of Executive Order 12866, and therefore, does not have to be 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. The final rule was reviewed under this Executive Order and no additional related information has been obtained since then. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under section 2115 of the Organic Foods Production Act (OFPA) (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 OFPA (7 U.S.C. 6514(b)). States are also preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 7 U.S.C. 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 regulation 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 (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. AMS has also considered the economic impact of this action on small entities and has determined that this final rule will have an impact on a substantial number of small entities. However, AMS has determined that the impact on entities affected by this rule will not be significant. The effect of this rule will be to allow the use of additional substances in agricultural production and handling. This action relaxes the regulations published in the final rule and provides 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, will be minimal and entirely beneficial to small agricultural service firms. Accordingly, the Administrator of the AMS hereby 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 \$750,000 and small agricultural producers are defined as those having annual receipts of less than \$5,000,000.

The U.S. organic industry at the end of 2001 included nearly 6,600 certified crop and livestock operations, including organic production and handling operations, producers, and handlers. These operations reported certified acreage totaling more than 2.34 million acres, 72,209 certified livestock, and 5.01 million certified poultry. Data on the numbers of certified handling operations are not yet available, but likely number in the thousands, as they would include any operation that transforms raw product into processed products using organic ingredients. Growth in the U.S. organic industry has been significant at all levels. From 1997 to 2001, the total organic acreage grew by 74 percent; livestock numbers

certified organic grew by almost 300 percent over the same period, and poultry certified organic increased by 2,118 percent over this time. Sales growth of organic products has been equally significant, growing on average around 20 percent per year. Sales of organic products were approximately \$1 billion in 1993, but are estimated to reach \$13 billion this year, according to the Organic Trade Association (the association that represents the U.S. organic industry). In addition, USDA has accredited 85 certifying agents who have applied to USDA to be accredited in order to 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 entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995, the existing information collection requirements for the NOP are approved under OMB number 0581-0181. 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, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

E. Comments Received

Altogether, 23 comments were received on these proposed revisions and amendments. Commenters included consumers, producers, processors, the National Organic Standards Board (NOSB), certifying agents, food industry organizations, State governments, and trade organizations.

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

No comments were opposed to the revision of the introductory text concerning use of materials as required in 205.203(c) and 205.206(a)-(d). One commenter, however, questioned whether every substance in 205.601 has to be measured against the criteria in 205.206(a)-(d). The commenter pointed out that algicides should be measured against these criteria in paragraphs 205.206(a)-(d), but that disinfectants, sanitizers, and cleaning materials in irrigation systems should not have to meet the criteria in (a)-(d). The commenter suggests revising paragraph 205.601(b) to include algicides and

removing the term algicides from 205.601(a). We agree that the use of disinfectants and sanitizers listed in § 205.601(a) should not be measured against the criteria in paragraphs 205.206 (a)–(d). Accordingly, we have amended the introductory text to exclude disinfectants and sanitizers. We disagree, however, with removing algicides from § 205.601(a). We recognize that there may be similar types of changes that could be made to improve the organization of the National List and the categories of materials and substances. Therefore, we will request that the NOSB begin work on addressing such organizational issues for inclusion in future rulemaking. One commenter asked that the final rule be written in plain English so that an average person will understand what is being said. We have made considerable efforts to write these regulations in plain English, but note that the regulations dealing with the National List are inherently difficult to understand because of their technical nature.

(a) As algicides, disinfectants and sanitizers, including irrigation cleaning systems—(3) Copper Sulfate. Two commenters opposed the addition of copper sulfate to the National List when it was published in December, 2000 and restated their opposition; one commenter cited problems with harmonization with European standards which do not allow the use of copper sulfate. USDA is currently engaged in discussions with the European Union (EU) concerning harmonization and mutual recognition of our respective standards for organic production and processing, and we believe these issues will be addressed in those discussions. Copper sulfate has been the subject of considerable debate and review at more than one NOSB public meeting, and the annotations restricting its use reflect an attempt by the NOSB to address all of the concerns raised regarding the use of copper sulfate in organic systems. Two commenters requested that the phrase “in aquatic rice systems” be added as it was stated in the NOSB recommendation. These two comments have merit and we have made the requested change.

(5) Ozone gas. No commenters opposed the addition of ozone gas.

(6) Peracetic acid. One commenter noted that many peracetic acid formulations contain small amounts of toxic stabilizer compounds, and that the National List should only be for formulations of this material that do not have synthetic stabilizers in them. However, we believe the NOSB understands the full nature of peracetic acid and its uses and made its

recommendation accordingly. The public is invited to petition the NOSB to reconsider any material at any time that new information becomes available. Such information should also be forwarded to the NOSB prior to its re-review of any materials on the National List before the sunset date of five years after being added to the List. One commenter asked that this paragraph be further amended to require that documentation be shown that alternatives including biocontrols have been tried. However, with the revision to the introductory text in this subsection, we believe the additional annotation is not necessary and the final rule remains as proposed.

(e) As insecticides (including acaricides or mite control)—(3) Copper Sulfate. The word “aquatic” will be added before the words “rice production” to be consistent with the revised wording in paragraph (a) (3).

(f) As insect attractants—Pheromones. Commenters pointed out that the word “attractants” may be somewhat inaccurate. Pheromones may also include mating disruption or other general confusion, not necessarily synonymous with attraction. We have amended the paragraph to state “as insect management.” We also received two comments urging a policy guidance statement be issued to clarify types of pheromones permitted as those that are EPA-exempt or EPA-registered without additional synthetic toxicants (unless those are also on the List) or those containing no List 1 or List 2 inerts. We will publish on our Web site such policy guidance.

(i) As plant disease control—(3) Hydrated lime. Numerous commenters pointed out that the annotation is incorrectly written in the current regulations. As currently written, the annotation reads “must be used in a manner that minimizes copper accumulation in the soil.” However, there is no copper in hydrated lime. The annotation referred to an earlier reference to “Bordeaux mixes” that are a combination of copper sulfate plus hydrated lime. Accordingly, we have deleted the annotation altogether as suggested by the commenters.

(7) Peracetic acid. Commenters pointed out that the proposed annotation referring to EPA approval is unnecessary, as the material is currently regulated by EPA and it is unnecessary to restate EPA’s status in the NOP regulation. These comments have merit and we have amended the annotation to read “for use to control fire blight bacteria.” And one comment opposed the addition of additional synthetic materials to the National List,

specifically, the addition of paracetic acid to section 205.601. The commenter raised concerns that the addition of synthetic materials to the National List could continue a disturbing trend of moving organic systems away from the basic principles of minimizing use and dependence on purchased inputs, especially synthetic substances. Congress recognized that synthetic materials might be necessary for organic production to develop and that is why the National List was created in the first place. Moreover, the process of adding a material to the National List is sufficiently rigorous that by itself, the process will provide a natural limit to the number of materials that may be added to the List.

(k) As plant growth regulators. No commenters opposed to the addition of “gas” behind “ethylene.”

(m) As synthetic inert ingredients as classified by the EPA, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances—(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers. One commenter objected to the addition of any List 3 Inert unless a Technical Advisory Panel (TAP) review is conducted and the NOSB approved the substance for addition to the National List. However, we believe the annotation accurately reflects the NOSB’s understanding that in passive pheromone dispensers, the allowance of List 3 Inerts poses no significant harm to sustainable systems, including crops, soil, and water. Accordingly, no change is made to this provision.

Section 205.602 Nonsynthetic Substances Prohibited for Use in Organic Crop Production

No comments were opposed to the addition of calcium chloride.

The language in the proposed rule on sodium nitrate differs in two places, and may be misleading. The amendment to paragraph (g) should read: Sodium nitrate—unless use is restricted to no more than 20 percent of the crop’s total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.” Two commenters opposed the use of sodium nitrate in any amount, or for any crop production, and one of those commenters cited problems with harmonization with European standards for organic crop production. USDA is currently engaged in discussions with the European Union (EU) concerning harmonization and mutual recognition of our respective standards for organic production and processing, and we

believe these issues will be addressed in those discussions. Sodium nitrate was a subject of considerable debate and review at more than one NOSB public meeting, and the annotation restricting its use reflects an attempt by the NOSB to address all of the concerns that were raised regarding the use of sodium nitrate in organic systems.

The NOSB also commented that the natural substance sodium chloride (also known as salt) should be prohibited and added to 205.602, with the annotation that it be permitted in organic cotton production to comply with emergency spray programs or to prevent immediate loss of crop. The NOSB pointed out that failure to add this material to 205.602 means that it may be used without restriction, when the NOSB recommended its addition to the list of prohibited natural materials in 1995. However, we did not include this material for comment in the proposed rule that was issued in April 2003. Therefore, we believe it is inappropriate to add this material to this final rule without offering the public a chance to comment on the NOSB's recommendation. This material can be included in subsequent rulemaking so that the public can comment on its proposed addition to 205.602, with the annotation recommended by the NOSB.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

(b) As topical treatment, external parasiticide or local anesthetic as applicable—(4) hydrated lime. The annotation following hydrated lime refers to Bordeaux mixes, which the NOSB correctly points out is a crop protection material, not a livestock material. The NOSB recommended changing the annotation to replace "Bordeaux mixes" with "as external pest control." We agree and have revised the annotation accordingly.

(d) As feed additives—(1) DL-Methionine; DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—for use only in organic poultry production until October 21, 2005. We received two comments in opposition to the addition of these three methionine materials as a feed additive for organic poultry feed; one comment cited problems with EU harmonization, which we have addressed above. Methionine has been the subject of considerable debate and review at more than one NOSB meeting, and the annotation restricting its use reflects an attempt by the NOSB to address all of the concerns raised regarding the use of methionine in organic systems.

(2) Trace minerals, used for enrichment or fortification when FDA approved. We received two comments raising concerns on this proposed change. One commenter seemed to think that we were eliminating trace minerals from allowed synthetic materials for use in livestock production. We are not eliminating their use; rather we eliminated the references to copper sulfate and magnesium sulfate to eliminate the perception that only those two trace minerals could be used since they were the only two examples listed. As long as the trace mineral is approved by FDA for use in feed supplements for the purpose of enrichment or fortification, the trace mineral is allowed under these regulations. Notwithstanding their allowed use in paragraph (d)(2), producers are also bound to comply with paragraphs (a) and (b) of § 205.237 dealing with livestock feed, including paragraph (b)(2) and (b)(6), which prohibit a producer from providing feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life or use feed additives and supplements in violation of the Federal Food, Drug, and Cosmetic Act. These livestock feed standards are also why we did not take the recommended changes of the second commenter that wanted a two-year period of use for minerals approved by the NOSB after a TAP review is conducted, and questioned NOP's policy with respect to trace minerals for animal feeds. This commenter cited an NOSB statement in 1995 that nutrients should come from organic sources, followed by non-synthetic sources if organic is unavailable, and only allowing synthetic sources of minerals if natural sources are unavailable. We believe that the regulations as written, especially § 205.237(a) addresses this concern by requiring feed to be 100 percent organic, with exceptions for nonsynthetic substances and synthetic substances as allowed under § 205.603(d).

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))"

The proposed rule contained a typographical error, listing both nonsynthetic and synthetic lists as § 205.605(a). The synthetic nonagricultural substance list should be denoted as § 205.605(b).

(b) Synthetics allowed—Tartaric acid. As noted in the proposed rule, tartaric

acid was one of three materials that were inadvertently omitted from publication on the National List in the final regulations that were published on December 21, 2000, and the proposed rule would amend the National List to include tartaric acid in § 205.605(a). However, the NOSB pointed out in their comments that the NOSB had approved both synthetic and nonsynthetic forms of tartaric acid. Accordingly, § 205.605(a) and (b) are amended to include tartaric acid.

Ethylene—we received one comment asking why this is not in the list of synthetic materials approved for crop production, since it deals with ripening for fruit. However, its use is clearly intended for fruit that has left the farm and is enroute to final consumers and is more appropriately considered part of a processing function to prepare the fruit for final purchase. Three commenters opposed its addition to the National List, citing general concerns about adding more synthetic materials to the National List and degrading the status of organic products and one of those comments cited problems with European harmonization.

Congress recognized that synthetic materials might be necessary for organic production to develop and that is why the National List was created in the first place. Moreover, the process of adding a material to the National List is sufficiently rigorous that by itself, the process will provide a natural limit to the number of materials that may be added to the List.

The USDA is currently engaged in discussions with the European Union (EU) concerning harmonization and mutual recognition of our respective standards for organic production and processing, and we believe these issues will be addressed in those discussions.

Pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register**.

This rule reflects recommendations submitted to the Secretary by the NOSB. The ten substances proposed to be 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 critical to organic production and handling operations, the National List should be amended as soon as possible.

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. Revising the introductory text.
 - b. Redesignating paragraphs (a)(3) and (a)(4) as paragraphs (a)(4) and (a)(7), respectively.
 - c. Adding new paragraphs (a)(3), (a)(5), and (a)(6).
 - d. Revising the word “demisters” in newly redesignated paragraph (a)(7) to read “demossers.”
 - e. Redesignating paragraphs (e)(3) through (e)(7) as paragraphs (e)(4) through (e)(8).
 - f. Adding a new paragraph (e)(3).
 - g. Revising paragraph (f).
 - h. Revising paragraph (i)(3).
 - i. Redesignating paragraphs (i)(7) through (i)(10) as paragraphs (i)(8) through (i)(11), respectively.
 - j. Adding a new paragraph (i)(7).
 - k. Revising paragraph (k).
 - l. Adding new paragraph (m)(2).
- The revisions read as follows:

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

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

(a) * * *

(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

* * * * *

(5) Ozone gas—for use as an irrigation system cleaner only.

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.

* * * * *

(e) * * *

(3) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

* * * * *

(f) As insect management.

Pheromones.

* * * * *

(i) * * *

(3) Hydrated lime.

(7) Peracetic acid—for use to control fire blight bacteria.

* * * * *

(k) As plant growth regulators.

Ethylene gas—for regulation of pineapple flowering.

* * * * *

(m) * * *

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

* * * * *

■ 3. Section 205.602 is revised to read as follows:

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

- (a) Ash from manure burning.
- (b) Arsenic.
- (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
- (d) Lead salts.
- (e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
- (f) Sodium fluoaluminat (mined).
- (g) Sodium nitrate—unless use is restricted to no more than 20% of the crop’s total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.
- (h) Strychnine.
- (i) Tobacco dust (nicotine sulfate).
- (j)–(z) [Reserved]

■ 4. Section 205.603 is amended by:

- a. Revising paragraph (a).
- b. Revising the word “chlorohexidine” in paragraph (a)(4) to read “chlorhexidine”.

■ c. Redesignating paragraphs (b)(1) through (b)(5) as (b)(2) through (b)(6), respectively and redesignating paragraph (b)(6) as paragraph (b)(1).

■ d. Revising newly redesignated paragraph (b)(4).

■ e. Redesignating paragraphs (d)(1) and (d)(2) as paragraphs (d)(2) and (d)(3), respectively.

■ f. Adding a new paragraph (d)(1).

■ g. Revising newly redesignated paragraph (d)(2).

■ h. Revising the designation for paragraph (f) to read “(e)(1)”.

■ i. Reserving paragraphs (f)–(z).

The revisions and addition read as follows:

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

* * * * *

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol—disinfectant only.

(2) Aspirin—approved for health care use to reduce inflammation.

(3) Biologics—Vaccines.

(4) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(5) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(6) Electrolytes—without antibiotics.

(7) Glucose.

(8) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(9) Hydrogen peroxide.

(10) Iodine.

(11) Magnesium sulfate.

(12) Oxytocin—use in postparturition therapeutic applications.

(13) Parasiticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

(14) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

(b) * * *

(4) Lime, hydrated—as external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

* * * * *

(d) * * *

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—for use only in organic poultry production until October 21, 2005.

(2) Trace minerals, used for enrichment or fortification when FDA approved.

* * * * *

■ 5. Section 205.605 is revised 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)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

(a) *Nonsynthetics allowed:*

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

Agar-agar.

Bentonite.

Calcium carbonate.

Calcium chloride.

Carageenan.

Colors, nonsynthetic sources only.

Dairy cultures.

Diatomaceous earth—food filtering aid only.

Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Kaolin.

Magnesium sulfate, nonsynthetic sources only.

Nitrogen—oil-free grades.

Oxygen—oil-free grades.

Perlite—for use only as a filter aid in food processing.

Potassium chloride.

Potassium iodide.

Sodium bicarbonate.

Sodium carbonate.

Tartaric acid.

Waxes—nonsynthetic (Carnauba wax; and Wood resin).

Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked—nonsynthetic smoke flavoring process must be documented).

(b) *Synthetics allowed:*

Alginates.

Ammonium bicarbonate—for use only as a leavening agent.

Ammonium carbonate—for use only as a leavening agent.

Ascorbic acid.

Calcium citrate.

Calcium hydroxide.

Calcium phosphates (monobasic, dibasic, and tribasic).

Carbon dioxide.

Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Glycerides (mono and di)—for use only in drum drying of food.

Glycerin—produced by hydrolysis of fats and oils.

Hydrogen peroxide.

Lecithin—bleached.

Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Magnesium chloride—derived from sea water.

Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Ozone.

Pectin (low-methoxy).

Phosphoric acid—cleaning of food-contact surfaces and equipment only.

Potassium acid tartrate.

Potassium tartrate made from tartaric acid.

Potassium carbonate.

Potassium citrate.

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Potassium iodide—for use only in agricultural products labeled “made

with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Silicon dioxide.

Sodium citrate.

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Sodium phosphates—for use only in dairy foods.

Sulfur dioxide—for use only in wine labeled “made with organic grapes,” *Provided*, That, total sulfite concentration does not exceed 100 ppm.

Tartaric acid.

Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

Xanthan gum.

(c)–(z) [Reserved]

■ 6. In § 205.607, paragraph (c) is revised to read as follows:

§ 205.607 Amending the National List.

* * * * *

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, 1400 Independence Ave., SW., Room 4008–So., Ag Stop 0268, Washington, DC 20250.

* * * * *

Dated: October 27, 2003.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 03–27415 Filed 10–30–03; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 101, 141, 201, 260, 352, and 357

[Docket Nos. RM02–14–000 and RM02–14–001; Order No. 634–A]

Regulation of Cash Management Practices

October 23, 2003.

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is amending its regulations to implement reporting requirements for FERC-regulated entities that participant in cash