This final rule amends the USDA’s National organic regulations (7 CFR part 205) to renew exemptions and prohibitions for the following synthetic substances in organic agricultural production and handling (use categories and any restrictive annotations remain unchanged, but have been omitted from this overview):

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

1. Ethanol.
2. Isopropanol.
3. Calcium hypochlorite.
5. Sodium hypochlorite.
7. Soap-based algicide/demossers.
8. Herbicides, soap-based.
9. Newspaper or other recycled paper, without glossy or colored inks.
11. Herbicides, soap-based paper, without glossy or colored inks.
12. Soaps, ammonium.
14. Boric acid.
15. Elemental sulfur.
16. Lime sulfur-including calcium polysulfide.
17. Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils.
18. Soaps, insecticidal.
20. Pheromones.
22. Vitamin D₃.
23. Copper hydroxide.
24. Copper oxide.
25. Copper oxychloride.
27. Hydrated lime.
29. Lime sulfur.
30. Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
31. Potassium bicarbonate.
32. Elemental sulfur.
33. Streptomycin.
34. Tetracycline (oxytetracycline calcium complex).
35. Aquatic plant extracts (other than hydrolyzed).
36. Elemental sulfur.
37. Humic acids.
38. Lignin sulfonate.
Organic Livestock Production

Substances Prohibited for Use in

Section 205.604 Nonsynthetic Substances Prohibited for Use in Organic Livestock Production

1. Strychnine.

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))”

(a) Nonsynthetics allowed:

1. Alginic acid.
2. Citric acid.
3. Lactic acid.
5. Calcium carbonate.
6. Calcium chloride.
7. Dairy cultures.
8. Diatomaceous earth.
9. Enzymes.
10. Flavors.
11. Kaolin.
12. Magnesium sulfate.
15. Perlite.
17. Potassium iodide.
18. Sodium bicarbonate.
19. Sodium carbonate.
20. Carnauba wax.
21. Wood resin wax.
22. Autolysate yeast.
23. Bakers yeast.
24. Brewers yeast.

(b) Synthetics allowed:

1. Alginites.
2. Ammonium bicarbonate.
3. Ammonium carbonate.
4. Ascorbic acid.
5. Calcium carbonate.
6. Calcium hydroxide.
7. Calcium hypochlorite.
10. Tribasic calcium phosphates.
11. Calcium hypochlorite.
13. Sodium hypochlorite.
14. Ethylene.
15. Ferrous sulfate.
17. Diglycerides.
18. Glycerin.
20. Lecithin—bleached.
22. Magnesium chloride.
23. Magnesium stearate.
26. Ozone.
27. Pectin (low-methoxy).
28. Phosphoric acid.
29. Potassium acid tartrate.
30. Potassium carbonate.
31. Potassium citrate.
32. Potassium hydroxide.
33. Potassium iodide.
34. Silicon dioxide.
35. Sodium citrate.
36. Sodium hydroxide.
37. Sodium phosphates.
38. Sulfur dioxide.
39. Tocopherols.
40. Xanthan gum.

Section 205.606 Nonagricultural Produced Agricultural Products Allowed as Ingredients in or on Processed Products Labeled as “Organic”

1. Cornstarch (native).
2. Gums—water extracted only (arabic, guar, locust bean, carob bean).
3. Kelp—for use only as a thickener and dietary supplement.
4. Lechitin—unbleached.
5. Pectin (high-methoxy).

Nonrenewals

This final rule amends the USDA’s National List by removing exemptions (and any restrictive annotations) for the following substances in organic agricultural production and handling:

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

Milk replacers without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

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))”

Colors—nonsynthetic sources only. Potassium tartrate made from tartaric acid.

Error in Proposed Rule

In review of the proposed rule, the Secretary identified that carrageenan was included in the proposal as an exemption set to expire on October 21, 2007. This is not correct. Carrageenan was amended to the National List on October 31, 2003 (68 FR 61987) and has an expiration date of October 31, 2008, not October 31, 2007. As a result, the renewal of carrageenan will not be carried out through this rulemaking. The exemption will remain in effect on the National List until October 31, 2008. Continued use of the exemption after such date will be contingent upon future rulemaking.

III. Related documents

One advanced notice of proposed rulemaking with request for comments was published in Federal Register Notice 70 FR 35177, June 17, 2005, to make the public aware that the...
allowance of 169 synthetic and non-synthetic substances in organic production and handling will expire, if not reviewed by the NOSB and renewed by the Secretary. On March 6, 2007, a proposed rule with request for comments was published in Federal Register Notice 72 FR 9872.

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 final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 6514(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 6503 through 6507 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 6507(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 6519(f) of the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspections Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.). Section 6520 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). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this final rule would not be significant. This action would reauthorize certain provisions of the National List to provide small entities continued access to tools that they can use in day-to-day operations. The AMS concludes that the economic impact of this final rule, 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.

Based upon USDA’s Economic Research Service and AMS data compiled from 2001 to 2005, the U.S. organic industry at the end of 2005 included nearly 8,500 certified organic crop and livestock operations, plus more than 2,900 handling operations. Organic crop and livestock operations reported certified acreage totaling more than 4.05 million acres of organic farm production. Total organic crop and livestock operations increased by more than 18 percent from 2001 to 2005, while total certified acreage more than doubled during this time period. AMS estimates that these trends continued through 2006 and will be higher in 2007.

U.S. sales of organic food and beverages have grown from $1 billion in 1990 to nearly $17 billion in 2006. Organic food sales are projected to reach $23.8 billion for 2010. The organic industry is viewed as the fastest growing sector of agriculture, currently representing nearly 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 accredited 99 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 address 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

Under the OPA, no additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, et seq., or OMB’s implementing regulation at 5 CFR part 1320.

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. Received Comments on Proposed Rule AMS–TM–06–0222

AMS received 11 comments on proposed rule AMS–TM–06–0222. Comments were received from organic consumers, trade associations, organic handlers, ingredient manufacturers, and one foreign government. In general, comments were in support of the proposed rule. One commenter questioned whether AMS had made errors in listing certain proposed substances under § 205.601 by duplicating entries. Specifically, the commenter questioned whether hydrogen peroxide, newspaper or other recycled paper, elemental sulfur, horticultural oils, and lignin sulfonate were duplicates and entered in error. In response to the concern expressed by the commenter, AMS did not list the aforementioned substances in error. The substances appear twice under § 205.601 of the National List because they have multiple uses. For example, hydrogen peroxide is authorized and listed for use under § 205.601(a) as an algicide, disinfectant, and sanitizer. It is also authorized and listed for use under § 205.601(i) as a plant disease control.

A few commenters requested that certain proposed exemptions be discontinued due to the assertions that the substances were either (1) nonsynthetic and did not require identification on the National List or (2) were no longer necessary for organic production due to the presence of an alternative. USDA believes that these comments did not provide sufficient information/documentation to support the arguments; therefore, we recommend that the commenters submit petitions to the NOSB and have the substances of interest reviewed through the National List review process.

A foreign government requested that the Secretary provide scientific justification for the use of Potassium bicarbonate, Humic acids, Lignin sulfonate, and liquid fish products in organic production. The comment noted that such substances are not included in Annex 2 of the Codex Guidelines for Organically Produced Foods or do not meet Section 5 of the Codex Guidelines. The foreign government also requested the Secretary to explain why the NOSB did not consider removing the prohibition on the use of “Ash from manure burning” as they believe its use complies with the principles of organic production. Lastly, they requested an explanation as to why the exemption for nonsynthetic colors was proposed for removal from the National List whereas the exemption for nonsynthetic flavors was proposed for retention.

In response to the comments regarding Potassium bicarbonate, Humic acids, Lignin sulfonate, and liquid fish products, these substances have been determined by the NOSB and the Secretary to meet national statutory and regulatory provisions regarding the use of substances in organic agriculture (the OPA). In addition, the USDA does not believe that such substances are inconsistent with the Codex Guidelines. The Guidelines provide that national governments take the following criteria into consideration when making determinations on the addition of substances to their National Lists: (1) Substances are consistent with principles of organic production as outlined in these Guidelines; (2) use of the substance is necessary/essential for its intended use; (3) manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment; (4) they have the lowest negative impact on human or animal health and quality of life; and (5) approved alternatives are not available in sufficient quantity and/or quality. All of these have been criteria have been taken into consideration for determining the whether Potassium bicarbonate, Humic acids, Lignin sulfonate, and liquid fish products are compatible with organic systems of agriculture.

In addition, the foreword to Annex 2 of the Codex Guidelines provides that “The following lists (Annex 2; Tables 1, 2, 3, and 4) do not attempt to be all inclusive or exclusive, or a finite regulatory tool, but rather provide advice to governments on internationaly agreed inputs.” Therefore, we believe that the absence of a substance from Annex 2 of the Codex Guidelines does not mean that the substance is inconsistent with the Codex Guidelines. Instead, we believe that the Codex Guidelines are more focused on the system of review and criteria utilized by national governments to accept or reject the use of substances in organic agriculture. Our National List review system embodies the criteria of the Codex Guidelines; it also engages science, public interests/comments, and federal agency consultations that help contribute to well-informed decision-making.

In response to the foreign government’s comment on why the NOSB did not consider removing the prohibition on the use of “Ash from manure burning,” the NOSB, based on input from the public, did not believe the prohibition on the use of “Ash from manure burning” should be lifted. Manure ash was originally prohibited due to the environmental impact of its manufacture and its adverse impact on soil quality when compared with compost and raw manure.

Lastly, with respect to the foreign government’s question as to why the exemption for nonsynthetic colors was proposed for removal from the National List whereas the exemption for nonsynthetic flavors was proposed for retention, the NOSB voted not to renew the exemption to permit the use of nonsynthetic colors in organic handling because the substance category (nonsynthetic colors) had never received a formal recommendation from the NOSB to be included on the National List during the regulation of the NOP regulations. Nonsynthetic colors were erroneously included in the final rule. As a result, the NOSB received several comments to remove the category of nonsynthetic colors from the National List, as nonsynthetic colors should be evaluated by the NOSB through the petition process.

The NOSB took comments into account that raised concern about how the broad category of “nonsynthetic colors” produces difficulty in determining and verifying what colors are truly nonsynthetic versus synthetic and how such ambiguity could give rise to the use of inappropriate substances in organically handled products. In addition, the NOSB also deliberated on the historical fact that nonsynthetic colors had been permitted for use by the organic industry for over five years. As a result, commenters raised a general concern that removing nonsynthetic colors from the National List could cause a disruption in the manufacture of organic products in the handling sector. Taking all of these concerns into consideration, the NOSB...
considered that in the absence of an initial recommendation from the NOSB to permit the addition of nonsynthetic colors as a broad category that they could not continue to permit the exemption of nonsynthetic colors on § 205.605(a). As a result, the NOSB voted not to renew the exemption of nonsynthetic colors on § 205.605(a).

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB for the purpose of fulfilling the requirements of 7 U.S.C. 6517(o) of the OFPA. 7 U.S.C. 6517(e) requires the NOSB to review each substance on the National List within 5 years of its publication. The substances being reauthorized for use on the National List were initially authorized for use or prohibition in organic agriculture on October 21, 2002. Because these substances are critical to organic production and handling operations, producers and handlers should be able to continue to use them beyond their 5-year expiration date of October 21, 2007. Accordingly, this rule shall be effective on October 21, 2007.

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:


2. Section 205.603 is revised to read as follows:

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

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

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

(1) Alcohols.

(2) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

(3) Iodine—used for enrichment or fortification when FDA approved.

(4) Hydrogen peroxide.

(5) Copper sulfate.

(6) Magnesium sulfate.

(7) Water.

(b) As topical treatment, external parasiteic or local anesthetic as applicable.

(1) Copper sulfate.

(2) Iodine.

(3) Lidoacaine—as a local anesthetic.

(c) For use in postparturition therapeutic applications.

(1) Chlortetracycline—used as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(2) Hydrogen peroxide.

(3) Iodine.

(4) Magnesium sulfate.

(5) Water.

(d) As a lubricant.

(1) DL-Methionine.


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

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(2) [Reserved]

§ 205.605 [Amended]

3. In § 205.605, substances “colors, nonsynthetic sources only” is removed from paragraph (a) and the substance “Potassium tartrate made from tartaric acid” is removed from paragraph (b).


Lloyd C. Day,
Administrator, Agricultural Marketing Service.

[FR Doc. E7–20326 Filed 10–15–07; 8:45 am]
BILLING CODE 4410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, and 150

RIN 3150–AH41

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending several regulations governing the distribution of byproduct material. The reporting requirements for licensees distributing byproduct material to persons exempt from licensing are being changed, obsolete provisions are being deleted, certain regulatory provisions are being clarified, and smoke detector distribution regulations are being simplified. In addition, this final rule modifies the process for transferring a generally licensed device for use under a specific license. Aspects of this rule will affect distributors of exempt byproduct material, some general licensees, and some users of exempt products. These actions are intended to