

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket No. AMS-TM-07-0062; TM-07-061F]

RIN 0581-AC71

National Organic Program (NOP) – Amendments to the National List of Allowed and Prohibited Substances (Processing)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with requests for comments.

SUMMARY: This Interim final rule amends the Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) regulations to enact 38 recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) during public meetings held May 6 – 8, 2002, in Austin, Texas, and March 27 – 29, 2007, in Washington, DC. This action is also being taken to provide an additional 60 days for the public to comment on these 38 amendments to the National List.

EFFECTIVE DATES: This interim final rule becomes effective June 21, 2007. All comments received by (60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER) will be considered prior to the issuance of the final rule.

ADDRESSES: Interested persons may comment on this interim final rule using any of the following procedures:

- Mail: Comments may be submitted by mail to Robert Pooler, Agricultural Marketing Specialist, National Organic Program, USDA/AMS/TMP/NOP, 1400 Independence Ave., SW, Room 4008-So., Ag Stop 0268, Washington, DC 20250.

- Internet: www.regulations.gov.
- Written comments on this interim final rule should be identified with the docket number AMS- TM-07-0062. Commenters should identify the topic and section number of this interim final rule to which the comment refers.
- Clearly indicate if you are for or against the interim final rule or some portion of it and your reason for it. Include recommendation changes as appropriate.
- Include a copy of articles or other references that support your comments. Only relevant material should be submitted.

All comments to this interim final rule, submitted by the above procedures, will be available for viewing at: www.regulations.gov. Comments submitted in response to this interim final rule will also be available for viewing in person at USDA-AMS, Transportation and Marketing, National Organic Program, 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 on official Federal holidays). Persons wanting to view comments received in response to this interim final rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Agricultural Marketing Specialist, National Organic Program, USDA/AMS/TM/NOP, Room 4008-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250. Phone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

The Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 et seq.),

authorizes the establishment of the NOP regulations. On December 21, 2000, the Secretary established, within the NOP (7 CFR part 205), the National List regulations §§ 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the non-synthetic substances that may not be used in organic production. The National List also identifies synthetic, non-synthetic non-agricultural and non-organic agricultural substances that may be used in organic handling. The OFPA and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance for organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any non-organic agricultural, non-synthetic non-agricultural substance used in organic handling must also be on the National List.

Until recently, some producers, handlers and certifying agents have misinterpreted National List regulations § 205.606 to mean that any non-organic agricultural product which was determined by an accredited certifying agent to be not commercially available in organic form could be used in organic products, without being individually listed pursuant to the National List procedures. In January 2005, the First Circuit Court of Appeal's decision in Harvey v. Johanns found that such an interpretation is contrary to the plain meaning of the OFPA and held that 7 CFR § 205.606 shall not be interpreted to create a blanket exemption to the National List requirements specified in §§ 6517 and 6518 of the OFPA (7 U.S.C. §§ 6517-6518). Therefore, consistent with the district court's final judgment and order, dated June 9, 2005, on July 1, 2005, the NOP published a notice regarding § 205.606 (70 FR 38090), and on June 7, 2006, published a final rule (71 FR 32803) revising § 205.606 to clarify that the section shall be interpreted to permit the use of a non-organically produced agricultural product only when the product has

been listed in § 205.606, and when an accredited certifying agent has determined that the organic form of the agricultural product is not commercially available. In order to enable an orderly transition, the district court's final judgment and order allowed for products produced in conformance with the misinterpretation of § 205.606 to be produced and sold until June 9, 2007, after which point no non-conforming products may enter the stream of commerce. As a result, since June 9, 2007, any certified products that have been produced and entered into the stream of commerce using non-organic agricultural ingredients that are not listed in § 205.606 are in non-compliance with the district court's final order and judgment on Harvey v. Johanns.

Concerning organic products that contain no more than 5% non-organic agricultural ingredients that do not appear on the National List, such products that have been produced and labeled as organic prior to June 9, 2007, are considered to be in the stream of commerce. "Organic" products that meet this description may remain in the market place as organically produced until the existing supply is exhausted.

On May 15, 2007, USDA published a proposed rule (72 FR 27252) to amend the National List regulations to enact recommendations submitted to the Secretary by the NOSB as a result of public meetings held on May 6-8, 2002, in Austin, TX, and March 27-29, 2007, in Washington, DC. This proposed rule suggested the addition of 38 non-organic agricultural ingredients, along with any restrictive annotations, to the National List regulations. The 38 ingredients proposed for addition to the National List were based on petitions from the industry, in response to the potential impact of the district court's final order and judgment concerning changes to § 205.606 of the NOP regulations.

NOP and NOSB received approximately 99 petitions to add more than 600 non-organic

agricultural ingredients and substances to § 205.606 of the National List regulations. After Program review for adequate petition information, 79 petitions to add 52 substances to the National List were forwarded through the petition review process to the NOSB Materials and Handling Committees for review and evaluation against the OFPA criteria and NOP regulations. Prior to the respective public NOSB meetings, 52 draft recommendations from the NOSB committees were posted on the NOP website for review and public comment. Of the 52 petitioned ingredients, the NOSB, for their March 2007 meeting, requested, received, and reviewed public comments on the petitioned ingredients and voted to add 38 ingredients to § 205.606 of the National List.

Under the authority of OFPA and the NOP regulations, the National List can be amended by the Secretary based upon recommendations by the NOSB.

II Overview of Amendments.

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

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

This interim final rule amends § 205.606 of the National List regulations by adding the following substances:

Color Ingredients from Agricultural Products.

Annatto extract color (pigment CAS # 1393-63-1) – water and oil soluble.

Beet juice extract color (pigment CAS # 7659-95-2).

Beta-Carotene extract color from carrots (CAS # 1393-63-1).

Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Carrot juice color (pigment CAS # 1393-63-1).

Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Chokeberry – Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Paprika color - dried powder and vegetable oil extract (CAS # 68917-78-2).

Pumpkin juice color (pigment CAS # 127-40-2).

Purple potato juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0,

1429-30-7, and 134-04-3).

Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

Saffron extract color (pigment CAS # 1393-63-1).

Turmeric extract color (CAS # 458-37-7).

Ingredients or Processing Aids from Agricultural Products

Casings, from processed intestines (no CAS #)

Celery powder (No CAS #).

Chia (Salvia hispanica L.) (no CAS #).

Dillweed oil (CAS # 8006-75-5).

Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8).

Fructooligosaccharides (CAS # 308066-66-2).

Galangal, frozen (no CAS #).

Gelatin (CAS # 9000-70-8).

Hops (Humulus lupulus) (no CAS #).

Inulin, oligofructose enriched (CAS # 9005-80-5).

Konjac flour (CAS # 37220-17-0).

Lemongrass, frozen (no CAS #).

Orange shellac, unbleached (CAS # 9000-59-3).

Pepper, chipotle chile (no CAS #).

Rice starch, unmodified (CAS # 977000-08-0) – for use in organic handling until [two years from date of publication].

Sweet potato starch, for bean thread production only (no CAS #).

Turkish bay leaves (no CAS #).

Wakame seaweed (Undaria pinnatifida) (no CAS #).

Whey protein concentrate (no CAS #).

III. Related Documents – Federal Register Notices

Two notices and one proposed rule (72 FR 27252) 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 interim final rule were announced for NOSB deliberation in the following Federal Register Notices: (1) 67 FR 19375, April 19, 2002, (Gelatin, Konjac flour, Orange shellac); (2) 72 FR 10971, March 12, 2007, (Casings, Celery powder, Chia (Salvia hispanica L.), Colors - from agricultural products: Annatto extract; Beet juice; Beta-carotene extract; Purple carrot juice; Black currant juice; Blueberry juice; Carrot juice; Cherry juice; Chokeberry/Aronia juice; Elderberry juice; Grape juice; Grape skin extract; Paprika; Pumpkin juice; Purple potato juice; Red cabbage extract; Red radish extract; Saffron; Turmeric; Dillweed oil, Fish oil, Fructooligosaccharides, Galangal - frozen, Hops, Inulin - oligofructose enriched, Lemongrass - frozen, Pepper - chipotle chile, Rice starch, Sweet potato starch, Turkish bay leaves, Wakame seaweed (Undaria pinnatifida), and Whey protein concentrate).

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 recommendations by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to recommend changes 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 website 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 interim 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 § 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 § 6519(f) of the OFPA (7 U.S.C. 6519(f)), this interim 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 interim final rule would not be significant. The effect of this interim final rule would be to allow the use of additional substances in agricultural production and handling. This action would modify the regulations to provide both large and 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 both large and small agricultural service firms. Accordingly, AMS certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities. AMS invites comments on the economic impact on small entities of this interim final rule.

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 interim 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 number of 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 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

Under the OFPA, no additional collection or recordkeeping requirements are imposed on the public by this interim 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-07-0062.

AMS received approximately 1,250 comments on proposed rule AMS-TM-07-0062. Comments were received from organic producers and handlers, accredited certifying agents, consumers, retailers, food service establishments and public interest groups. In general, comments were opposed to the abbreviated comment period for proposed rule AMS-TM-07-0062 and requested an extended comment period. There were comments that supported the addition of all 38 non-organic agricultural ingredients to the National List; while other comments opposed the addition of all non-organic agricultural ingredients to § 205.606 of the National List.

Many comments either supported or opposed the specific National List amendments of the following non-organic agricultural ingredients: casings from processed intestines; gelatin; colors from agricultural products; konjac flour; hops; lemongrass; Turkish bay leaves; turmeric; and whey protein concentrate. Some comments addressed the inclusion of CAS numbers or the use of scientific names to identify the non-organic ingredients.

Though a significant number of comments were received, very few comments submitted were from processors or handlers. Comments from this segment of the industry would be helpful in developing a final rule. A number of comments expressed concern regarding the information and criteria used for determining the fragility of the organic ingredient supply or organic availability of the proposed 38 non-organic agricultural ingredients.

As a result of the district court's final order and judgment in Harvey v. Johanns and requests for an extension of the public comment period on AMS-TM-07-0062, AMS is issuing this interim final rule to (1) permit the use of the 38 ingredients during the extended comment and final rulemaking periods to minimize the impact to the organic industry and (2) extend the comment period (60 days) to receive additional comments regarding the addition of the 38 non-organic agricultural ingredients to § 205.606.

F. Effective Date

Effective June 9, 2007, these 38 substances were prohibited for use in processed products labeled as "organic." Continued loss of the use of these products would disrupt the trade of food products currently being labeled as "organic". Therefore, the continued use of these products as ingredients in foods labeled as "organic" is necessary to prevent possible significant business disruption for organic producers and handlers. Accordingly, pursuant to 5 U.S.C. 553, it is found, and determined, upon good cause, that it is impracticable, unnecessary, and contrary to the public interest to give further notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this interim final 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 205.606 is revised to read as follows:

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

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

(a) Casings, from processed intestines.

(b) Celery powder.

(c) Chia (Salvia hispanica L.).

(d) Colors derived from agricultural products.

(1) Annatto extract color (pigment CAS # 1393-63-1) - water and oil soluble.

(2) Beet juice extract color (pigment CAS # 7659-95-2).

(3) Beta-carotene extract color, derived from carrots (CAS # 1393-63-1).

(4) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

(5) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).

- (6) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (7) Carrot juice color (pigment CAS # 1393-63-1).
- (8) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (9) Chokeberry - Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (10) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (11) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (12) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (13) Paprika color (CAS # 68917-78-2) - dried, and oil extracted.
- (14) Pumpkin juice color (pigment CAS # 127-40-2).
- (15) Purple potato juice (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (16) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (17) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3).
- (18) Saffron extract color (pigment CAS # 1393-63-1).

- (19) Turmeric extract color (CAS # 458-37-7).
- (e) Dillweed oil (CAS # 8006-75-5).
- (f) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606.
- (g) Fructooligosaccharides (CAS # 308066-66-2).
- (h) Galangal, frozen.
- (i) Gelatin (CAS # 9000-70-8).
- (j) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean).
- (k) Hops (Humulus lupulus).
- (l) Inulin-oligofructose enriched (CAS # 9005-80-5).
- (m) Kelp - for use only as a thickener and dietary supplement.
- (n) Konjac flour (CAS # 37220-17-0).
- (o) Lecithin - unbleached.
- (p) Lemongrass – frozen.
- (q) Orange shellac-unbleached (CAS # 9000-59-3).
- (r) Pectin (high-methoxy).
- (s) Peppers (Chipotle chile).
- (t) Starches.
- (1) Cornstarch (native).
- (2) Rice starch, unmodified (CAS # 977000-08-0) - for use in organic handling until [Insert date two years after effective date of final rule].
- (3) Sweet potato starch – for bean thread production only.

(u) Turkish bay leaves.

(v) Wakame seaweed (Undaria pinnatifida).

(w) Whey protein concentrate.

Dated:

Lloyd C. Day, Administrator
Agricultural Marketing Service