Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–11–0003; NOP–10–13PR]

RIN 0581–AD13

National Organic Program (NOP); Sunset Review (2013)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) following their November 2011 and May 2012 meetings. These recommendations pertain to the 2013 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the recommendations from the NOSB, this proposed rule would continue the allowed uses of multiple synthetic and nonsynthetic substances and the prohibition of one nonsynthetic substance on the National List (along with any restrictive annotations). This proposed rule would also remove one synthetic substance from the National List.

DATES: Comments must be received by June 3, 2013.

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA–AMS–NOP, 1400 Independence Ave. SW., Room 2646-So., Ag Stop 0268, Washington, DC 20250–0268.

Instructions: All submissions received must include the docket number AMS–NOP–11–0003; NOP–10–13PR, and/or Regulatory Information Number (RIN) 0581–AD13 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (e.g. scientific, environmental, manufacturing, industry, impact information, etc.). Only relevant material supporting your position should be submitted. All comments received and any relevant background documents will be posted without change to *http://www.regulations.gov.*

Document: For access to the document and to read background documents or comments received, go to *http://www.regulations.gov*. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA–AMS, National Organic Program, Room 2646-South Building, 1400 Independence Ave. SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6522) authorizes the establishment of the National List. The National List, codified within the USDA organic regulations at 7 CFR 205.600 through 205.607, identifies synthetic substances that may be used in organic production and nonsynthetic (natural) substances that are prohibited in organic crop and livestock production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic and nonorganic agricultural substances that may be used in organic handling.

The exemptions and prohibitions granted on the National List are required to be reviewed every 5 years under OFPA by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under OFPA to renew such exemptions and prohibitions. If they are not reviewed by the NOSB within 5 years of their inclusion on the National List and renewed by the Secretary, their authorized use or prohibition expires. The Secretary published an Advanced Notice of Proposed Rulemaking (ANPR) (76 FR 31495) in the **Federal Register** on June 1, 2011, to announce the review of 11 exempt substances and one prohibited nonsynthetic substance authorized under the USDA organic regulations. This ANPR established November 3, 2013, as the date by which the Sunset 2013 review and renewal process must be concluded. The ANPR explained that the exemptions and prohibitions not renewed by this date will be removed from the National List. This ANPR also requested public comment on the continued use or prohibition of these substances. The public comment period lasted 60 days. A list of these substances is provided as Table 1 in the Overview of Proposed Actions section. These substances were originally added to the National List on November 3, 2003 (68 FR 61987), and November 4, 2003 (68 FR 62215), and were previously renewed under the Sunset process on November 3, 2008 (73 FR 59479).

The Agricultural Marketing Service (AMS) received 25 comments on the substances in response to the ANPR. AMS received comments from producers, handlers, distributors, organic associations, a certifying agent, and various industry groups. Some of these comments addressed more than one substance. We received general comments stating that the listings should remain as they are currently codified. We received one general comment that did not address the substances under this Sunset review. Most comments indicated support for substances that the commenters' promoted, represented, or relied upon. Comments specifically supported a

continued allowance for the following substances: copper sulfate, ozone gas, peracetic acid, EPA List 3 Inerts,[1] agar-agar, animal enzymes, calcium sulfate, carrageenan, glucono delta-lactone, tartaric acid, and cellulose. Two comments specifically supported a continued prohibition on calcium chloride as annotated on the National List. One commenter requested that the annotations for two listings of copper sulfate, one at section 205.601(a)(3) and one at section 205.601(e)(4) for use in aquatic rice systems, be amended to remove the restriction based on the number of applications during a specified timeframe. The commenter requested that the restriction limiting application rates to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent be maintained, but the restriction on number of applications during any 24-month period be eliminated.

The NOSB reviewed the comments received from the ANPR and developed recommendations regarding the continued use and prohibition of the substances under review. The NOSB received additional public comments concerning the pending sunset of these substances in response to two **Federal Register** notices announcing meetings of the NOSB and its planned deliberations on Sunset 2013 recommendations. The notices were published in the **Federal Register** as follows: October 7, 2011 (76 FR 62336), and April 9, 2012 (77 FR 21067). The NOSB received further written and oral testimony at both of these public meetings which occurred in Savannah, GA on November 29–December 2, 2011, and Albuquerque, NM on May 22–25, 2012. The written comments can be retrieved via *http://www.regulations.gov* by searching for the document ID numbers: AMS–NOP–11–0081 (November 2011 meeting) and AMS–NOP–12–0017 (May 2012 meeting). The oral comments were recorded in the meeting transcripts which are available on the NOP Web site at *http://www.ams.usda.gov/nop.*

At its November 2011 and May 2012 meetings, the NOSB addressed multiple National List exemptions and a prohibition under the 2013 Sunset review. The NOSB recommended that the Secretary: (1) Renew multiple exemptions and one prohibition without change, (2) remove an exemption for one synthetic substance, tartaric acid, and (3) amend the exemptions for two synthetic substances, EPA List 3—Inerts of unknown toxicity and cellulose, and one nonsynthetic substance, carrageenan. In accordance with NOSB's published policies and procedures, it also issued a second round of recommendations to renew the existing listings for EPA List 3—Inerts of unknown toxicity, cellulose, and carrageenan without change.[2] These second recommendations authorize the Secretary to renew these three listings ''as is'' considering the expiration date of November 3, 2013.

Because the NOSB's sole justification for restricting the allowance of carrageenan was on the basis of food safety concerns, despite the fact that FDA regulations provide for its use as a safe food additive when used in accordance with 21 CFR 172.5, 21 CFR 172.620 and 21 CFR 172.626, AMS is renewing carrageenan as codified based on the NOSB's second recommendation. Based on concern over the impact of changing the annotation for cellulose, AMS is renewing the listing for cellulose as codified based on the NOSB's second recommendation. For EPA List 3—Inerts of unknown toxicity, AMS is concerned that including an expiration date as part of its annotation during the Sunset review would complicate the NOSB's established inerts review process. Therefore, AMS is renewing the listing for EPA List 3—Inerts of unknown toxicity as codified based on the NOSB's second recommendation. In summary, this rule proposes to renew multiple listings without change and remove one listing (tartaric acid—made from malic acid).

Under the authority of OFPA, the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, AMS has published multiple amendments to the National List beginning on October 31, 2003 (68 FR 61987). AMS published the most recent amendment to the National List on September 27, 2012 (77 FR 59287).

II. Overview of Proposed Actions

At its November 2011 and May 2012 meetings, the NOSB reviewed the listings set to sunset on November 3, 2013, for multiple exemptions and one prohibition that are authorized on the National List. On December 2, 2011, the NOSB finalized its recommendations on the following substances: animal enzymes, calcium chloride, copper sulfate (two uses), glucono delta-lactone, ozone gas, peracetic acid (two uses), and tartaric acid (two sources). On May 25, 2012, the NOSB finalized its recommendations on agar-agar, calcium sulfate, carrageenan, cellulose, and EPA List 3—Inerts of unknown toxicity.

The NOSB's recommendations to continue existing exemptions and prohibitions are based on consideration of public comments and applicable supporting evidence that express a continued need for the use or prohibition of the substance(s) as required by OFPA.

Concerning OFPA criteria used to make recommendations regarding the discontinuation of an authorized exempted synthetic substance (7 U.S.C. 6517(c)(1)), the NOSB's decision is based on consideration of public comments and applicable supporting evidence that demonstrates the currently authorized exempted substance is: (a) Harmful to human health or the environment; (b) no longer necessary for organic production due to the availability of alternative wholly nonsynthetic substitute products or practices; and (c) inconsistent with organic farming and handling practices.

Based on the NOSB recommendations, AMS' proposed actions for the Sunset 2013 proposed rule are outlined in Table 1.

[1] EPA refers to the Environmental Protection Agency.

[2] In October 2010, the NOSB changed its Sunset policy to enable the NOSB to make recommendations to add or change annotations (restrictions) on applicable National List substances under Sunset review. This change in policy ensures that the NOSB can address new use patterns and scientific information on substances allowed in organic production. This policy limits such annotations to those which clarify the existing annotation or make the annotation more restrictive. The policy does not provide for an annotation change that would result in expanded use of an exempted material. This is described starting on p. 56 of the NOSB Policies and Procedures Manual available on the NOP Web site at: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3013893.*

TABLE 1—OVERVIEW OF PROPOSED ACTIONS FOR SUNSET 2013

National List Section	Substance listing	Proposed action
Synthetic substances allowed for use in organic crop production.		
205.601(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.	Renew.
205.601(a)(5)	Ozone gas—for use as an irrigation system cleaner only	Renew.
205.601(a)(6)	Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material.	Addressed through separate rulemaking action; see February 5, 2013 proposed rule (78 FR 8040).
205.601(e)(4)	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.	Renew.
205.601(i)(8)	Peracetic acid—for use to control fire blight bacteria	Addressed through separate rulemaking action; see February 5, 2013 proposed rule (78 FR 8040).
205.601(m)(2)	EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.	Renew.
Nonsynthetic substances prohibited for use in organic crop production		
205.602(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.	Renew.
Nonsynthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).''		
205.605(a)	Agar-agar	Renew.
205.605(a)	Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).	Renew.
205.605(a)	Calcium sulfate—mined	Renew.
205.605(a)	Carrageenan	Renew.
205.605(a)	Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.	Renew.
205.605(a)	Tartaric acid—made from grape wine	Renew.
Synthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).''		
205.605(b)	Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.	Renew. NOSB recommendation for annotation change under consideration for a separate rulemaking action.
205.605(b)	Tartaric acid—made from malic acid	Remove.

The following *Renewals* and *Nonrenewals* sections provide explanations for AMS' proposed actions.

Renewals

AMS has reviewed and accepts the NOSB recommendations for the continued exemption or prohibition of certain substances. Accordingly, this proposed rule would:

1. Renew the exemptions at section 205.601, along with any restrictive annotations, for the following synthetic substances allowed for use in organic crop production as shown in Table 1: copper sulfate (2 uses), ozone gas, and EPA List 3 Inerts;

2. Renew the prohibition at section 205.602, along with its restrictive annotation, for the following nonsynthetic substance prohibited for use in organic crop production as shown in Table 1: calcium chloride; and

3. Renew the exemptions at section 205.605, along with any restrictive annotations, for the following nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' as shown in Table 1: agar-agar, animal enzymes, carrageenan, cellulose, calcium sulfate, glucono delta-lactone, and tartaric acid made from grape wine.

AMS is accepting NOSB's second recommendations rather than the NOSB's first recommendations to add or amend restrictive annotations for the following substances under Sunset review: EPA List 3 Inerts, carrageenan, and cellulose. The specific circumstances for implementing the NOSB's second recommendations for these substances are outlined below.

EPA List 3—Inerts of Unknown Toxicity

An inert ingredient is defined in section 205.2 the USDA organic

regulations as ''any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).'' There are currently two categories of inert ingredients allowed on the National List with restrictive annotations: EPA List 3—Inerts of unknown toxicity (section 205.601(m)), and EPA List 4—Inerts of minimal concern (sections 205.601(m) and 205.603(e)).

In 2006, EPA reassessed all inert ingredients used in pesticide formulations allowed on food crops. This reassessment resulted in a new classification system which made the EPA List system obsolete. This means that the National List references to EPA List 3 and EPA List 4 inerts are now out-of-date when compared with current EPA regulations.[3] In June 2010, NOP convened an NOSB–NOP–EPA inerts working group (IWG) for the purpose of addressing these obsolete references to EPA inert lists.

At the NOSB May 2012 meeting, the NOSB recommended several changes to the allowance for inerts as part of its Sunset review for EPA List 3 Inerts.[4] The changes included: (1) Modification to the introductory text at section 205.601(m); (2) amending the listing and annotation for EPA List 3 Inerts to read as follows: ''Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until October 21, 2017;'' and (3) amending section 205.2 to add a definition for ''passive polymeric dispenser products'' that is intended to be removed in coordination with the proposed expiration date of October 21, 2017, at section 205.601(m). Concurrent with Sunset Review policy, the NOSB also issued a second recommendation to renew the existing listing for EPA List 3 Inerts.

On October 16, 2012, the NOSB passed a recommendation which outlined the procedure by which the NOSB would review both EPA List 3 and EPA List 4 inerts over a four-year timespan, with the goal of completing the majority of the reviews by October 2017, the sunset date for EPA List 4 inerts. As of October 2012, the IWG had compiled a list of 16 classes or groups comprising 126 individual substances for review. In its recommendation, the NOSB acknowledged that, ''Given the scope of [technical evaluation reports] and NOSB evaluation of these materials, it is recognized that the completion of this process will take substantial resources and time . . . Because of the challenge that this represents, the NOSB will assess the viability of the timeline after it completes the recommendation on the first few groups of materials.'' AMS recognizes the recommendation's intent to address the complex challenges presented by the out-of-date listings in a timely manner. However, a rulemaking action to add an expiration date at this time may be problematic in the event that the timeline for inerts review takes longer than the projected four years; therefore, we are not proposing the addition of an expiration date to the exemption for EPA List 3 Inerts. This rule proposes to implement the NOSB's second recommendation to renew the exemption for EPA List 3—Inerts of unknown toxicity at section 205.601 as codified, along with its current restrictive annotation. This approach would meet the timeframe required by the sunset provision of OFPA and the listing for EPA List 3 Inerts would subsequently have a sunset date of November 3, 2018. Furthermore, the IWG's continuing review of inerts may result in additional outcomes beyond the NOSB's other recommendations to modify the introductory text for section 205.601(m) and add a definition in section 205.2 for passive polymeric dispenser products. This may in turn influence AMS' future considerations for a rulemaking on EPA List 3 Inerts.

Carrageenan

Carrageenan is currently permitted as a nonagricultural, nonsynthetic ingredient in organic handling in section 205.605(a) of the National List. Under U.S. Food and Drug Administration (FDA) regulations, carrageenan and its salts can be used as a food additive under the conditions specified at 21 CFR 172.5 (General Provisions for Direct Food Additives), and at 21 CFR 172.620 and 21 CFR 172.626 (Specific Provisions for Carrageenan and Its Salts). In addition, *Chondrus* extract (carrageenin) [5] is listed as Generally Recognized as Safe at 21 CFR 182.7255 when used in accordance with good manufacturing practice. Under FDA's prescribed conditions, carrageenan can be safely used in the amount necessary as an emulsifier, stabilizer, or thickener in foods, except those standardized foods that do not provide for such use.

Consistent with a 1995 NOSB recommendation, AMS first included carrageenan on the National List as an allowed nonsynthetic in organic processed products on November 3, 2003 (68 FR 61987).[6] The NOSB reviewed carrageenan again as part of the 2008 Sunset Review and recommended that its allowance in organic handling be renewed without any restrictive annotation. Based on the NOSB recommendation, AMS renewed the allowance for carrageenan through a final rule effective on November 3, 2008 (73 FR 59479). In the November 3, 2008 final rule, AMS described the comments received on substances under the 2008 Sunset Review, citing that we received five comments specifically in support for renewing carrageenan on the National List. At that time, AMS did not receive any comments that opposed its continued use in organic processed products.

On June 1, 2011, AMS published an ANPR to inform stakeholders that the NOSB would be reviewing carrageenan as part of its 2013 Sunset Review. AMS received 15 comments specifically supporting a continued allowance for carrageenan. Many comments cited carrageenan's function as a unique stabilizer in a range of organic foods, particularly in dairy products, as the basis for their support. Three of these comments stated that carrageenan has been used safely as an ingredient in foods for many years. Two comments specifically referenced FDA as the regulatory agency that authorizes the use of carrageenan as a safe food additive under the conditions specified in FDA regulations. At that time, AMS did not receive any comments that opposed its continued use in organic processed products.

In preparation for its Sunset 2013 review, the NOSB Handling Subcommittee reviewed the comments submitted in response to the ANPR and obtained a new technical evaluation report for carrageenan.[7] On February 21, 2012, the NOSB Handling

[3] On September 30, 2010, NOP issued NOP 5008: Reassessed Inert Ingredients, a guidance document describing the applicability of NOP's regulatory references to List 3 and 4 inerts (EPA is no longer using these lists in their classification system) used in pesticide products. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5086874.*

[4] NOSB Recommendation on List 3 Inert Ingredients. May 2012. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098912.*

[5] This is the spelling provided at this regulatory reference.

[6] This final rule added ''carageenan'' to the National List rather than the correct spelling ''carrageenan''. The spelling for this substance was corrected as a technical correction in the final rule for the 2008 Sunset Review (73 FR 59480).

[7] Technical Evaluation Report on Carrageenan. October 3, 2011. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5096567.*

Subcommittee finalized its 2013 Sunset Review proposal for carrageenan; this proposal was published for public comment on April 9, 2012 in conjunction with the NOSB May 2012 public meeting notice (77 FR 21067). In its proposal, the NOSB Handling Subcommittee proposal stated that the technical evaluation report confirmed the food uses of carrageenan have not changed substantially since the original Technical Advisory Panel (TAP) review was conducted in 1995. The proposal explained that carrageenan continues to be an important material used by the organic community. The NOSB Handling Subcommittee proposal also stated that carrageenan may be safely used as a food additive for human consumption as long as its use is in accordance with FDA requirements at 21 CFR 172.620. The NOSB Handling Subcommittee further stated that, based on information in the 2011 technical evaluation report, it believed that different manufacturing methods of carrageenan could change the classification of the substance from nonsynthetic to synthetic.[8]

As a result of this information, the NOSB Handling Subcommittee proposed to continue the allowance for carrageenan in all organic processed products by removing carrageenan as an allowed nonsynthetic from section 205.605(a) and instead listing carrageenan as an allowed synthetic without restriction under section 205.605(b) of the National List. The NOSB Handling Subcommittee proposed this classification change to address the different manufacturing processes described by the 2011 technical evaluation report.

After publication of this NOSB Handling Subcommittee proposal, some public comments raised concerns regarding potential adverse health effects caused by the use of carrageenan, particularly degraded carrageenan, a low-molecular weight polysaccharide, in food. Other comments cited evidence in support of the safety of food-grade carrageenan in food, and stated that degraded carrageenan is not used in food products. Numerous other stakeholders stated that organic handlers producing a wide range of products that rely on carrageenan do not have functional alternatives to the substance. The comments in response to the NOSB Handling Subcommittee proposal can be retrieved at *www.regulations.gov* (search for docket number AMS–NOP–12–0017).

At its May 2012 public meeting, the NOSB Handling Subcommittee chose to present a revised proposal. The NOSB Handling Subcommittee recommended to relist carrageenan as a nonsynthetic, rather than change its classification to synthetic, and to include new language in its listing that would specify the food grade forms of carrageenan using Chemical Abstract Service (CAS) numbers. The CAS numbers are intended to align with the forms that have been approved by FDA for use as food ingredients. The proposal also included an annotation that, if codified through rulemaking, would prohibit the use of any form of carrageenan in infant formula. The revised proposal from the NOSB Handling Subcommittee further stated that carrageenan would still be allowed in foods for older infants (older than six months) and ''weaning foods'' for ''young children''. The NOSB passed this proposal as its first recommendation with a vote of 10 ''yes'' and 5 ''no.'' Aligned with the NOSB's Sunset Review policy, the NOSB also issued a second recommendation with a vote of 11 ''yes'' and 4 ''no'' to renew the existing listing for carrageenan which does not have any restrictive annotation.[9]

In its first recommendation, the NOSB stated that the restrictive annotation to prohibit the use of carrageenan in infant formula was based on concerns, specifically related to newborns, raised by a March 2003 opinion of the EU Scientific Committee on Food (SCF). The SCF provided scientific advice to the EU Commission.[10] The NOSB stated that the SCF's concern was based on facts from the Pediatric Nutrition Handbook, a publication of American Association of Pediatrics (AAP), in that newborn infants have immature digestive systems that may absorb macromolecules.

In considering the May 2012 NOSB recommendation, AMS reviewed the March 2003 opinion of the EU SCF as NOSB's justification for restricting the use of carrageenan. The EU SCF opinion cited in the May 2012 NOSB recommendation concluded that ''there is no evidence of any adverse effects in humans from exposure to food-grade carrageenan, or that exposure to degraded carrageenan from use of food-grade carrageenan is occurring'' (p. 5).[11] The EU SCF opinion cited in the May 2012 NOSB recommendation further states that, given the absence of information on potential absorption of carrageenan in the digestive system of young infants, carrageenan in infant formula is ''inadvisable'' (p. 6). The EU SCF opinion, however, does not reference the AAP's Pediatric Nutrition Handbook, and the Handbook does not reference any concerns with carrageenan. Therefore, it is unclear how the Handbook is linked to the EU SCF opinion or supportive of the NOSB's proposed prohibition on the use of carrageenan in infant formula.

In the U.S., carrageenan is allowed under FDA regulations at 21 CFR 172.620 as a direct food additive and is considered safe when used in the amount necessary as an emulsifier, stabilizer, or thickener in foods, except those standardized foods that do not provide for such use. The FDA, as the U.S. food safety authority, has not prohibited the use of carrageenan in infant formula. If used in infant formula, FDA reviews carrageenan in a given formulation as part of the infant formula notification process required by section 412 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 350(a)).

The NOSB's recommendation to prohibit the use of carrageenan in infant formula was based solely on food safety concerns despite carrageenan's status as a safe food additive when used as specified by FDA regulations and despite FDA's review of carrageenan in infant formula formulations under the FFDCA. Therefore, AMS is not implementing this recommendation. This proposed rule would implement the NOSB's second recommendation by renewing the exemption for carrageenan as currently listed as a nonsynthetic substance at section 205.605(a).

Cellulose

Cellulose is currently included on the National List in section 205.605(a) as an allowed nonagricultural, synthetic substance for use in organic handling. As part of the 2013 Sunset review, the NOSB Handling Subcommittee reviewed the original NOSB recommendation, the 2001 Technical Advisory Panel (TAP) review, historical documents, the 2007 Sunset recommendation, and public comments on cellulose.[12] The NOSB Handling

[8] NOSB Handling Subcommittee Proposal on Carrageenan. February 21, 2012. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097825&acct=nosb.*

[9] NOSB Recommendation on Carrageenan. May 25, 2012. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098921.*

[10] After 2003, the SCF was transferred to the European Food Safety Authority. *http://ec.europa.eu/food/committees/scientific/index_en.htm.*

[11] Opinion of the Scientific Committee on Food on Carrageenan (2003). *http://ec.europa.eu/food/fs/sc/scf/out164_en.pdf.*

[12] Technical Advisory Panel Report on Cellulose. September 28, 2001. Available at the NOP Web site:

Continued

Subcommittee issued a proposal to renew the listing for cellulose at section 205.605(b) that was considered by the NOSB at its May 2012 meeting.[13] At this meeting, the NOSB received public comment in support of relisting. One commenter requested that the NOSB ensure the microcrystalline form of cellulose is not allowed, and another commenter requested a new technical review and opposed the listing of the microcrystalline form of cellulose.[14] The NOSB responded that the 2001 TAP review examined three forms of cellulose that were considered for various uses: Powdered cellulose, regenerated cellulose casing, and microcrystalline cellulose, and the intent of the current annotation was to allow powdered cellulose and the form used in regenerative casings. At its meeting, the NOSB acknowledged that both powdered and microcrystalline cellulose can be used to serve the same functions, namely as a filtering aid or an anti-caking agent. The NOSB then recommended changing the annotation to explicitly state which forms are allowed, thereby prohibiting the use of the microcrystalline form.[15] Concurrent with Sunset Review policy, the NOSB also issued a second recommendation to renew the existing listing for cellulose.

Evidence gathered at the meeting suggested that the organic industry is not using the microcrystalline form of cellulose. However, AMS needs more information from the industry to confirm that the microcrystalline form of cellulose is not currently in use in organic processed products. Therefore, through this proposed rule, AMS is proposing to address the NOSB's second recommendation to renew the exemption for cellulose as currently listed at section 205.605(b) and is seeking public comments on the NOSB's first recommendation to restrict its use in organic processed products. This approach would meet the timeframe required by the Sunset provision of OFPA and, based on the public comment, enable AMS to consider a restriction on its use for a future rulemaking.

Nonrenewals

Tartaric Acid

As indicated in Table 1, there are two sources of tartaric acid currently on the National List: Nonsynthetic tartaric acid made from grape wine on section 205.605(a), and synthetic tartaric acid made from malic acid on section 205.605(b). As part of its Sunset 2013 review, the NOSB requested and obtained a new technical evaluation report for tartaric acid.[16] The NOSB Handling Subcommittee also received a petition to remove the synthetic source of tartaric acid.[17] The petition argued that: (1) The annotation for synthetic tartaric acid is incorrect; (2) the two listings of tartaric acid are the same form and serve the same function; and (3) tartaric acid made from grape wine is widely commercially available. The technical evaluation report findings confirmed the petitioner's three arguments: (1) Synthetic tartaric acid is typically manufactured from maleic anhydride, not malic acid as written in the current annotation; (2) both the nonsynthetic and synthetic listings are the same form of tartaric acid, which is generally referred to as the 'dextro form'; and (3) tartaric acid from grape wine is commercially available from a large number of distributors throughout the world. Based on review of the technical report and public comment, the NOSB agreed there is insufficient evidence to support the continued need for the synthetic form of tartaric acid and recommended its removal from the National List at section 205.605(b). This rule proposes removal of this substance as part of this Sunset 2013 rulemaking.

Peracetic Acid

On August 12, 2008, a petition was submitted to NOP requesting that the annotation for peracetic acid be amended on the National List.[18] The petition was submitted to ensure that hydrogen peroxide products can also list peracetic acid as an active ingredient on the product label. This would be consistent with EPA labeling requirements. The NOSB reviewed the petition in 2009 and issued a recommendation for an annotation change for the two peracetic acid listings at section 205.601.[19] To date, AMS has not implemented these recommendations for peracetic acid.

During its Sunset 2013 deliberations, the NOSB received public comments in support of the continued need for peracetic acid. As a result, the NOSB recommended renewing the two listings for peracetic acid in organic crop production at section 205.601 of the National List. Given that OFPA recognizes the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136–136(y)), AMS addressed the two listings for peracetic acid in a proposed rule (78 FR 8040) published on February 5, 2013 to implement the 2009 NOSB recommendation and ensure the listings for peracetic acid on the National List allow for conformance to EPA labeling requirements. AMS intends to conclude that rulemaking prior to the November 3, 2013 sunset date. As a result, the renewals for peracetic acid are not addressed in this proposed rule for Sunset 2013.

III. Related Documents

An advanced notice of proposed rulemaking with request for comments was published in **Federal Register** on June 1, 2011 (76 FR 31495) to notify the public that the listings discussed in this proposed rule would expire on November 3, 2013 if not reviewed by the NOSB and renewed by the Secretary.

IV. Statutory and Regulatory Authority

OFPA, as amended (7 U.S.C. 6501–6522), 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 section 205.607 of the USDA organic regulations. The current petition process was published on January 18, 2007 (72 FR 2167) and can be accessed through the NOP Web site at *http://www.ams.usda.gov/nop.*

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066975&acct=nopgeninfo.

[13] NOSB Handling Subcommittee Proposal on Cellulose. March 20, 2012. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097827&acct=nosb.*

[14] Transcript from the May 22–25, 2012 NOSB meeting is available under the NOSB section of the NOP Web site at: *http://www.ams.usda.gov/nop.*

[15] NOSB Recommendation on Cellulose. May 25, 2012. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098923.*

[16] Technical Evaluation Report on Tartaric Acid. October 13, 2011. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5094932.*

[17] The petition was submitted by Brenn-O-Kem and is available at the NOP Web site: *http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[18] The petition was submitted by BioSafe Systems LLC, and is available from the NOP Web site in the Petitioned Substances Database: *http:www.ams.usda.gov/NOPPetitionedSubstancesDatabase.*

[19] NOSB Recommendation on Peracetic Acid. November 2009. Available at the NOP Web site: *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5092050&acct=nosb.*

A. Executive Order 12866

This action has been determined to be not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under 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 section 2115(b) of OFPA (7 U.S.C. 6514(b)). States are also preempted under section 2104 through 2108 of 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 OFPA.

Pursuant to section 2108(b)(2) of 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 OFPA, (b) not be inconsistent with 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 OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), 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. 301–399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136–136(y)).

Section 2121 of 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. 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. 601–612) 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 of the RFA 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, AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the continued use of additional substances in agricultural production and handling. AMS concludes that the economic impact of continuing the allowance for Sunset 2013 substances would avoid market disruption and would be beneficial to small agricultural service firms. The effect of the removal of one substance, tartaric acid, would be minimal to small agricultural firms since another form of tartaric acid from grape wine is commercially available and is proposed to be renewed under this rule. Accordingly, AMS 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 $7,000,000 and small agricultural producers are defined as those having annual receipts of less than $750,000.

According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.5 million acres in 2011.[20] According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 17,750 in 2012. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA. U.S. sales of organic food and non-food have grown from $1 billion in 1990 to $31.4 billion in 2011. Sales in 2011 represented 9.5 percent growth over 2010 sales.[21] In addition, the USDA has 85 accredited certifying agents who 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 accredited certifying agents would be considered small entities under the criteria established by the SBA. Certifying agents reported approximately 25,000 certified operations worldwide in 2012.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35, or OMB's implementing regulations at 5 CFR part 1320.

E. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted to the Secretary by the NOSB for substances on the National List of Allowed and Prohibited Substances that, under the Sunset review provisions of OFPA, would otherwise expire on November 3, 2013. A 30-day period for interested

[20] U.S. Department of Agriculture, National Agricultural Statistics Service. October 2012. 2011 Certified Organic Productions Survey. *http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf.*

[21] Organic Trade Association. 2012. Organic Industry Survey. *www.ota.com.*

persons to comment on this rule is provided. Thirty days is deemed appropriate because the review of these listings was widely publicized through an ANPR and two NOSB meeting notices; the use or prohibition of these substances, as applicable, are critical to organic production and handling; and this rulemaking must be completed before the sunset date of November 3, 2013.

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 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.

§ 205.605 [Amended]

■ 2. Section 205.605 is amended by removing ''Tartaric acid—made from malic acid'' from paragraph (b).

Dated: April 30, 2013.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2013–10556 Filed 5–2–13; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

RIN 3150–AI30

[NRC–2009–0044]

Revisions to the Petition for Rulemaking Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to streamline its process for addressing petitions for rulemaking (PRMs). The proposed amendments are intended to improve transparency and make the PRM process more efficient and effective.

DATES: Submit comments by July 17, 2013. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2009–0044. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.

• *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

• *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

FOR FURTHER INFORMATION CONTACT: Christina England, Office of Nuclear Reactor Regulation, telephone: 301–415–3138, email: *Christina.England@nrc.gov*, or Cindy Bladey, Office of Administration, telephone: 301–492–3667, email: *Cindy.Bladey@nrc.gov*; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2009–0044 when contacting the NRC about the availability of information for this proposed rule. You may access information related to this proposed rule, which the NRC possesses and is publicly available, by any of the following methods:

• Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2009–0044.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in the section of this document entitled, Availability of Documents.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2009–0044 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

The NRC's requirements, policies, and practices governing the PRM process have remained substantially unchanged since their initial issuance in 1979 (44 FR 61322; October 25, 1979). During the past 20 years, the NRC has received an average of nine PRMs per year and plans its budget and assigns resources based