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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule addresses 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 final rule continues 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 rule also removes one synthetic substance from the National List.

DATES: This rule is effective November 3, 2013.

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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 of Allowed and Prohibited Substances (National List). The National List, a subpart within the USDA organic regulations (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 substances 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.

On June 1, 2011, the Agricultural Marketing Service (AMS) published an Advanced Notice of Proposed Rulemaking (ANPR) (76 FR 31495) in the Federal Register, announcing the NOSB's review of exempted and prohibited substances due to sunset in 2013. AMS posted these comments for public review and provided these comments to the NOSB in advance of their review of these substances. At its November 2011 and May 2012 meetings, the NOSB reviewed the substances shown in Table 1 under the 2013 Sunset review. Based on its review, the NOSB provided the following recommendations for consideration by 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. The NOSB also issued second recommendations for EPA List-3 Inerts, cellulose, and carrageenan for the purpose of renewing their existing listings if carrying out the NOSB recommendations to restrict these substances was not feasible. Based on the NOSB recommendations, AMS published a proposed rule in the Federal Register (78 FR 25879) on May 3, 2013, to address the continued use or prohibition of these substances on the National List in organic production and handling. Comments received on the proposed rule and AMS' response is addressed in

COMMENTS RECEIVED ON PROPOSED RULE NOP-10-13PR.

In response to the sunset provision in OFPA, this final rule addresses multiple recommendations submitted to the Secretary by the NOSB pertaining to substances due to sunset (i.e. expire) from the National List in 2013. In consideration of the impending Sunset date of November 3, 2013 for these substances, the information available, the requirements of OFPA, and the need to look at the potential impacts on small businesses, this final rule renews, without change, multiple exemptions (uses) and a prohibition on the National List (along with any restrictive annotations) for 5 years. A list of these substances and AMS' actions are provided in Table 1. This final rule also removes the exemption for one substance on the National List.

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 May 28, 2013 (78 FR 31815).

II. Overview of Final Actions.

Table 1 provides an overview of final actions for designated sections of the National List. The actions pertaining to all listings will be effective on November 3, 2013. Pursuant to the sunset provisions in OFPA, the new sunset date for all listings is five years from the effective date of their renewal.

Table 1. Overview of Final Actions for Sunset 2013

National List Section	Substance Listing	Final 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. ¹	Addressed through separate rulemaking action; see May 28, 2013 final rule (78 FR 31815).
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. ¹	Addressed through separate rulemaking action; see May 28, 2013 final rule (78 FR 31815).
205.601(m)(2)	EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.	Renew.

¹ The current annotations for peracetic acid can be found at 7 CFR Part 205.601(a)(6) and (i)(8).

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.
205.605(b)	Tartaric acid—made from malic acid.	Remove.

RENEWALS

Consistent with the NOSB recommendations and in consideration of the public comments received on the proposed rule (78 FR 25879), this final rule renews multiple listings pertaining to the National List.

This final rule continues 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.

This final rule continues the prohibition at section 205.602, along with its restrictive use annotation, for the nonsynthetic substance prohibited for use in organic

crop production as shown in Table 1: calcium chloride.

This final rule continues the exemptions at section 205.605(a), along with any restrictive annotations, for the 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))” as shown in Table 1: agar-agar, animal enzymes, carrageenan, tartaric acid - made from grape wine, calcium sulfate, and glucono delta-lactone.

This final rule continues the exemption at section 205.605(b), along with its restrictive annotation, for the nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic” as shown in Table 1: cellulose.

NONRENEWALS

Section 205.601 Synthetic substances allowed for use in organic crop production

The renewals for peracetic acid are not addressed in this final rule for Sunset 2013. Instead, AMS completed rulemaking on a 2009 NOSB recommendation to ensure the listings for peracetic acid on the National List aligned with EPA labeling requirements. This final rule amended the section 205.601(a)(6) and 205.601(i)(8) exemptions for peracetic acid on May 28, 2013 (78 FR 31815). This amendment was completed prior to the November 3, 2013, sunset date for peracetic acid; therefore, the previous listings for peracetic acid do not need to be renewed under this rulemaking action.

Section 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients in or on Processed Products Labeled as “Organic” or “Made With Organic (Specified

Ingredients or Food Group(s))”

This final rule amends section 205.605(b) of the National List by removing the exemption for the listing for tartaric acid - made from malic acid. This amendment is effective on November 3, 2013.

III. Related Documents

An Advance Notice of Proposed Rulemaking (ANPR) 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 final rule would expire on November 3, 2013 if not reviewed by the NOSB and renewed by the Secretary. Substances and recommendations addressed through this final rule were announced for NOSB deliberations in the following Federal Register notices: (1) October 7, 2011 (76 FR 62336); and (2) April 9, 2012 (77 FR 21067). The proposal to address the substances in this final rule was published as a proposed rule in the Federal Register on May 3, 2013 (78 FR 25879).

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>.

A. Executive Order 12866 and Executive Order 13563

AMS has determined that according to the criteria defined in Executive Order 12866 and Executive Order 13563, this rule change is not a significant regulatory action. As such, the rule is not subject to Office of Management and Budget review.

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 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 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.

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 2011.² 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. There were also 10,850 certified organic handling operations worldwide 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.³

In addition, the USDA has 84 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.

Pursuant to the requirements set forth in the RFA, AMS considered the economic

² 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>.

³ Organic Trade Association. 2012. Organic Industry Survey. www.ota.com.

impact of this action on small entities. The impact on entities affected by this final rule would not be significant. The effect of this final 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 synthetic substance, tartaric acid, would be minimal to small agricultural firms since a nonsynthetic form of tartaric acid from grape wine is commercially available and is the predominant form of this substance used in organic processed products. The allowance for nonsynthetic tartaric acid will 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.

D. Paperwork Reduction Act

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, Chapter 35, or OMB's implementing regulations at 5 CFR part 1320.

E. Executive Order 13175

This final 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. Comments Received on Proposed Rule NOP-10-13PR.

AMS received over 3,100 comments on proposed rule AMS–NOP–11–0003;

NOP–10–13PR. Comments were received from organic crop producers, crop distributors, organic handlers, consumers, accredited certifying agents, trade associations, non-profit organizations, growers associations, and advocacy groups. AMS also received two comments that were submitted after the close of the comment period and therefore were not considered herein.

Some comments presented concerns that are not within the scope of the sunset review action. Several comments stated their general opposition to the allowance of synthetics in organic production and some commenters restated this and specifically cited their opposition to all of the substances proposed for renewal in the proposed rule.

All comments on the proposed renewal for animal enzymes, calcium chloride, ozone gas and tartaric acid made from grape wine were supportive of the action as proposed. Therefore, AMS is finalizing the amendments as proposed through this final rule.

As stated in the proposed rule, the NOSB provided AMS with two recommendations for each of the following three substances – EPA List 3 Inerts, carrageenan, and cellulose. The NOSB provided the two recommendations based on the “Sunset Review Process” section of the NOSB’s Policy and Procedures Manual. The first NOSB Sunset recommendation for each of these substances recommended new restrictions on their allowance in organic production or handling as follows:

- a. EPA List 3 Inerts: amend the current listing and also include an expiration date of October 21, 2017, after which these substances could not be used;

- b. carrageenan: (1) indicate specific allowed forms of carrageenan by Chemical Abstracts Service (CAS) number; and (2) prohibit its use in organic infant formula; and
- c. cellulose: prohibit the microcrystalline form of this substance by specifying the forms that are allowed.

The second NOSB recommendation for each substance recommended to renew the existing listings as codified. Based on our review, AMS proposed to implement the NOSB's second recommendations to renew the existing listings instead of adding new restrictions on these three substances. For this reason, over 2,400 comments requested the withdrawal of the proposed rule. The commenter's reasons for this request are described below in conjunction with AMS' response.

Numerous comments asserted that the NOSB's second recommendations to renew EPA List 3 Inerts, carrageenan and cellulose were intended for the Secretary to act upon only if an unavoidable administrative delay makes completion of rulemaking regarding the first recommendations for these substances impossible before the November 3, 2013 sunset date. These comments state that AMS' action to implement the NOSB recommendations to renew on grounds other than an administrative delay is equivalent to a violation of OFPA. Most of these same commenters also stated that the NOSB first recommendations to amend the annotations for these three substances were based on NOSB's findings of unacceptable human health and environmental effects associated with their current allowance. Many commenters also cited that these renewals would constitute an addition of a synthetic substance to the National List by AMS, which would violate 7 U.S.C. 6517(d)(2).

AMS disagrees with these positions. Carrageenan is listed as a nonsynthetic substance, and therefore its renewal could not be in violation of OFPA (7 U.S.C. 6517(d)(2)) because it is not a synthetic substance. The NOSB provided AMS with two NOSB recommendations for each of these substances – one to renew the listing and one to add new restrictions to its current use. Consistent with the provisions of OFPA, AMS has determined that the second recommendation in each case should be implemented. The proposed rule reflected AMS’s independent review and explained in detail why accepting the NOSB’s first recommendations to amend the annotations for EPA List 3 Inerts, carrageenan, and cellulose was not appropriate and, therefore, rulemaking action could not be implemented prior to the November 3, 2013 sunset date. Further, AMS has collected additional feedback through public comment submitted in response to the proposed rule that supports its proposal. For these reasons, AMS is implementing the NOSB’s second recommendations to renew these substances through this final rule. A summary of AMS’ justification for each of the three substances is provided below.

EPA List 3—Inerts of unknown toxicity

AMS received approximately 60 comments on the proposed action to renew the listing for EPA List 3 Inert ingredients. The majority of comments stated that AMS should not adopt the proposed rule; instead, the commenters supported the NOSB’s first recommendation to add new restrictions on alternative EPA List 3 Inerts. A minority of commenters opposed the allowance of any synthetic materials in organic crop production, but did not provide information on alternative practices or alternative substances that may substitute for the use of EPA List 3 inert ingredients. Two commenters supported the action as proposed by AMS.

Comments that did not support the proposed action claimed that: (1) The

proposed action violated OFPA; (2) AMS ignored an NOSB recommendation for EPA List 3 Inerts; and (3) the renewal of the listing without an expiration date would delay or prevent the NOSB review of inert ingredients.

Some commenters indicated that AMS should issue a new proposed rule consistent with the NOSB's first recommendation for EPA List 3 Inerts. This recommendation included the following changes to the listing for EPA List 3 Inerts: (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.

In the proposed rule, AMS proposed renewal of the current listing for EPA List 3 Inerts, without any changes or addition of an expiration date. The NOSB provided two recommendations regarding EPA List 3 Inerts, and the proposed rule, implemented as final through this action, aligns with the second recommendation, which meets the requirements under OFPA. As stated in the proposed rule, AMS recognizes the intent of the NOSB to address the complex challenges presented by the out-of-date listings for EPA List 3 and EPA List 4 Inerts in a timely manner. However, a rulemaking action to add an expiration date to the listing for EPA List 3 Inerts as part of the Sunset Review would not be appropriate if the timeline for the ongoing NOSB Inerts review takes longer than projected.

One commenter noted that the NOSB's expiration date should not be problematic because there is only a small number of EPA List 3 materials to review before October 2017 and that NOP and NOSB could prioritize this work. Other commenters indicated that the intent of the NOSB with its first recommendation was to ensure that inert ingredients are reviewed prior to October 2017.

Currently, there is also ongoing work within the NOSB to review additional (e.g., EPA List 4) inert ingredients that will be addressed by the NOSB in other recommendations on inert ingredients. The NOSB, as part of an Inerts Working Group, is in the process of establishing reviews for all inert ingredients in pesticides used in organic production. These include former EPA List 3 and EPA List 4 Inerts. The overall review of inerts represents a larger number of substances than that which was indicated by one of the commenters. Given these circumstances, it is appropriate to accept the NOSB's second recommendation so that the NOSB has sufficient time to address inert ingredients and make additional recommendations.

One commenter supported the proposed relisting of EPA List 3 Inerts as proposed by AMS and noted that the expiration date of October 21, 2017 was arbitrary given that the NOSB review of inert ingredients may not complete by that date. The commenter noted that the expiration in 2017 would have detrimental impacts on organic operators and input suppliers. AMS agrees with the commenter and is not adding the 2017 expiration date to the EPA List 3 Inerts listing for this reason.

One commenter suggested that AMS adopt the renewed listing as an interim rule, and secondarily ask the NOSB to reconsider the sunset extension based on the specific agency concerns. AMS has not adopted this suggestion. The NOSB should continue its

review of EPA List 3 Inerts under its current process for reviewing Inerts, rather than redirect its efforts to provide additional support for its previous sunset recommendation to change the listing in advance of completion of this work.

In summary, after consideration of the recommendation and the comments received, AMS is implementing the second NOSB recommendation to renew the existing listing for EPA List 3 Inerts through this final rule as proposed.

Carrageenan

AMS received approximately 130 comments specific to the proposed action to renew the existing listing for carrageenan. The majority of comments stated that AMS should not adopt the proposed rule; instead, the commenters supported either the NOSB's first recommendation to prohibit the use of carrageenan in infant formula and add CAS numbers or a prohibition of the use of the substance in organic processed products altogether. AMS also received a comment from a non-profit organization which had gathered over 14,000 signatures in support of removing carrageenan from the National List. Approximately 40 commenters supported the action as proposed.

Comments that did not support the proposed action claimed that: (1) carrageenan in food and infant formula is not safe for human consumption; and (2) the proposed action is not based on sound science. One commenter stated that he had submitted two petitions to the FDA requesting (1) that the food additive regulations be amended to prohibit the use of carrageenan in infant formula; and (2) that the FDA designation of "Generally recognized as safe" (GRAS) for carrageenan in infant formula be reconsidered.

Prior to the May 2012 NOSB meeting, the Handling Subcommittee conducted a

review of past NOSB recommendations, technical reports, historical documents, and public comments and concluded that the available information indicates that the substance is essential for organic production, is compatible with organic production practices, and does not reveal unacceptable risks to the environment, human, or animal health as a result of its use or manufacture.⁴ Neither the Handling Subcommittee proposal submitted prior to the NOSB meeting nor the full NOSB issued a recommendation stating that carrageenan use in food should be prohibited.⁵ AMS concurs with this determination.

Both commenters and the FDA have identified many deficiencies in the literature regarding the gastrointestinal toxicity of carrageenan, concluding there is no information clearly demonstrating that there is evidence for a carcinogenic effect for food grade carrageenan use in foods or infant formula. Other commenters stated that subsequent research has continued to support the conclusion that food grade carrageenan is safe. AMS conducted an independent review which included consultation with the FDA to gain a detailed understanding of the relevant regulations allowing for the use of carrageenan in foods or infant formula. The FDA, as the food safety authority in the U.S., maintains that carrageenan is safe for use in foods and infant formulas as codified. If in the future the FDA does issue a finding supporting a prohibition of carrageenan in any or all foods, AMS will take appropriate action, if needed, to come into alignment with this finding. A request to amend the annotation for this substance or remove it from the National List would require a petition to the NOSB.

In summary, the NOSB provided two recommendations regarding carrageenan,

⁴ 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>

⁵ NOSB Recommendation on Carrageenan. May 25, 2012. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5098921>.

and the proposed rule aligns with the second recommendation, which meets the requirements under OFPA. After consideration of the recommendation and the comments received, AMS has determined that it is appropriate to accept the NOSB's second recommendation and renew the listing for carrageenan through this final rule as proposed.

Cellulose

AMS received approximately 20 comments on the proposed action specific to cellulose. Roughly half of these comments opposed the proposed action. These statements concurred with the NOSB's first recommendation that contrary to the powdered form of cellulose, the microcrystalline form of cellulose is a heavily processed substance and the impacts of its use would be incompatible with organic production. One commenter requested that USDA evaluate the data concerning availability of nonsynthetic and organic forms of cellulose for these uses, including organic rice concentrate, and for USDA to exercise its authority to develop a more restrictive standard in this case. Another commenter asked that AMS consider restricting the use of microcrystalline cellulose in future rulemaking. The remaining public comments supported the proposed action but did not state whether they used or supported the use of microcrystalline cellulose. To date, AMS has not received information to indicate that the organic industry is using the microcrystalline form of cellulose; however, AMS has not completed its research of this topic and needs more information from the industry to confirm that the microcrystalline form of cellulose is not currently in use in organic processed products and will consider a restriction on its use for future rulemaking.

The NOSB provided two recommendations regarding cellulose, which meets the

requirements under OFPA. Consistent with the NOSB's second recommendation, AMS is renewing listing for cellulose through this final rule as proposed.

Other comments suggesting changes to the proposed rule for other substances under sunset review are described below in conjunction with AMS' response, including any amendments that will be addressed through this final rule. Some commenters requested changes to substance annotations which were either different from the NOSB recommendation or would result in the expanded use of an exempted material. Such requests would require a petition to the NOSB, which can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Copper sulfate

The Crops Subcommittee put forth a proposal prior to the Fall 2011 NOSB meeting to further restrict the use of copper sulfate. The proposal stated that conversations with rice growers led them to believe that cultural practices (drill-seeding) would eliminate the need for copper sulfate use except in particular weather conditions. AMS received one comment stating that the use of copper sulfate in organic rice production is inconsistent with organic agricultural practices. This comment stated that the Crops Subcommittee proposal for placing further restrictions on the use of this substance was well-supported with evidence illustrating that copper products are toxic to aquatic organisms. The NOSB deliberated on the available information as well as written and in-person public comment on copper sulfate at the November 29-December 2, 2011 NOSB meeting in Savannah, GA. At this meeting, the Crops Subcommittee revised its proposal on the grounds that prescribing specific cultural practices within the annotation

would be duplicative of the organic system plan requirements of the USDA organic regulations. As a result, the Crops Subcommittee put forward a motion to renew the current listing that received a unanimous vote of support. The Crops Subcommittee also requested that alternatives for copper sulfate in rice production be added to the next Materials Subcommittee Research Priorities proposal.⁶ The Crops Subcommittee's proposal was recommended by the full NOSB.

AMS also received one comment stating that the current annotation for copper sulfate should be amended to change its listing from limited use of once per a 24-month period for rice shrimp control to allowing its use to be dependent upon the weather conditions that induce the growth of algae (also called scum) and rice shrimp. The commenter suggested the annotation should be amended to match the listing for fixed coppers at section 205.601(i), which allows the substance to be "used in a manner that minimizes accumulation of copper in the soil and shall not be used as herbicides." Commenter requests for changes to listings that would result in the expanded use or removal of an exempted material and would need to be petitioned and reviewed by the NOSB.

Consistent with the NOSB's recommendation, AMS is renewing listing for copper sulfate through this final rule as proposed.

Animal enzymes

Eleven commenters submitted statements of support for the continued allowance of animal enzymes in organic handling and processing. Consistent with the NOSB's recommendation, AMS is renewing listing for animal enzymes through this final rule as

⁶ The topic of "Copper sulfate in rice production" was included in the Materials Subcommittee's August 17, 2012 Proposal for Research Priorities for 2012. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101295>

proposed.

Agar-agar

The Handling Subcommittee's put forth a proposal prior to the Fall 2011 NOSB meeting to relist agar-agar as a nonsynthetic on section 205.605(a) and add an additional listing as a synthetic on section 205.605(b). The Subcommittee based this proposal on information obtained from the most recent technical report. This report indicated that there are certain processing methods for agar-agar that would result in a chemical change that would render it synthetic. The Subcommittee then determined that it would withdraw the proposal to reclassify agar-agar and asked that the NOP revisit the classification of this substance following the publication of final guidance on the classification of materials.⁷ The NOSB then recommended to renew agar-agar as listed on section 205.605(a).

AMS received one comment which supported the Handling Subcommittee's proposal. AMS also received one comment in support for the continued allowance of agar-agar based on its physical properties that enable it to act as a replacement for gelatin in vegetarian formulations of processed products.

Consistent with the NOSB's recommendation, AMS is renewing listing for agar-agar through this final rule as proposed.

Calcium sulfate

AMS received one comment requesting that the listing for calcium sulfate be restricted to use only as a coagulant for bean curd on the grounds that there was not

⁷ U.S. Department of Agriculture. "National Organic Program: Notice of Draft Guidance on Classification of Materials and Materials for Organic Crop Production." 78 *Federal Register* 63 (April 2, 2013), pp. 19637-19638. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5103326>.

sufficient evidence for its essentiality for the production of other processed products. The Handling Subcommittee conducted a review of past NOSB recommendations, technical reports, historical documents, and public comments and concluded that the available information indicates that the substance is essential for organic production, is compatible with organic production practices, and does not reveal unacceptable risks to the environment, human, or animal health as a result of its use or manufacture. AMS concurs with this determination.

AMS also received one comment in support of the continued allowance of calcium sulfate as an aid in developing the texture of bean curd for the production of firm tofu. Another commenter stated that calcium sulfate allows them to produce a desired texture and flavor of tofu that is not achievable with alternative ingredients.

Consistent with the NOSB's recommendation, AMS is renewing listing for calcium sulfate through this final rule as proposed.

Glucono delta-lactone

AMS received one comment requesting that the listing for glucono delta-lactone be restricted to use only as a coagulant in bean curd on the grounds that there was not sufficient evidence for its essentiality for the production of other processed products. The Handling Subcommittee's review of previous technical reports, NOSB recommendations, historical documents, and public comments and concluded that the available information indicates that the substance is essential for organic production, is compatible with organic production practices, and does not reveal unacceptable risks to the environment, human, or animal health as a result of its use or manufacture.⁸ The NOSB's recommendation

⁸ Handling Subcommittee Proposal on Glucono Delta-Lactone. March 20, 2012. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5097826&acct=nosb>

stated that there is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list and again re-list this material, and no public comments were submitted that provided any information to the contrary.

Consistent with the NOSB's recommendation, AMS is renewing listing for glucono delta-lactone through this final rule as proposed.

Tartaric acid (made from malic acid)

There were two comments submitted from a trade association, one of which supported the proposed action, and the other did not support the proposed action. Another two comments on the proposed removal of tartaric acid made from malic acid were not supportive of the proposed action. There were no comments submitted that provided information justifying their position.

Consistent with the NOSB's recommendation, AMS is removing the listing for tartaric acid made from malic acid through this final rule as proposed.

G. 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(e) of the OFPA. OFPA requires the NOSB to review each substance on the National List within 5 years of its adoption or review (7 U.S.C. 6517(e)). The substances reauthorized for use on the National List were most recently authorized for use in organic agriculture on November 3, 2008. Because these substances are critical to organic production and handling operations, producers and handlers should be able to continue to use these substances for a full 5-year period beyond their sunset date of November 3, 2013. Accordingly, pursuant to 5 U.S.C.553, it is found and determined that good cause exists for not postponing the

effective date of this rule until 30 days after publication in the Federal Register. This rule shall be effective on 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.

2. Section 205.605 is amended by removing the entry “Tartaric acid—made from malic acid” from paragraph (b).

Dated: September 30, 2013.

Rex A. Barnes,
Associate Administrator,
Agricultural Marketing Service.

Billing Code: 3410-02 P

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