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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-16-0052; NOP-16-03]

RIN 0581-AD52

National Organic Program (NOP);

Sunset 2017 Amendments to the National List

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 October 2015 meeting. These recommendations pertain to the 2017 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 remove eleven substances from the National List for use in organic production and handling.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250-0268.

Instructions: All submissions received must include the docket number AMS-NOP-16-0052; NOP-16-03, and/or Regulatory Information Number (RIN) 0581-AD52 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 2642-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: Robert Pooler, Standards Division,
email: bob.pooler@ams.usda.gov, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products. Since becoming effective, the USDA organic regulations have been frequently amended, mostly for changes to the National List in 7 CFR 205.601 – 205.606.

This National List identifies the synthetic substances that may be used and the nonsynthetic substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The OFPA and the USDA organic regulations, as indicated in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural substance and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

As stipulated by the OFPA, recommendations to propose amendment of the National List are developed by the NOSB, operating in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.), to assist in the evaluation of substances to be used or not used in organic production and handling, and to advise the Secretary on the USDA organic regulations. The OFPA also requires a sunset review of all substances by the NOSB included on the National List within five years of their addition to or renewal on the list. If a listed substance is not reviewed by the NOSB and renewed by the USDA within the five-year period, its allowance or prohibition on the National List is no longer in effect. Under the authority of the OFPA, the Secretary can amend the National List through rulemaking based upon proposed amendments recommended by the NOSB.

The NOSB's review of existing exemptions and prohibitions include the NOSB's evaluation of technical information, public comments, and supporting evidence that demonstrate whether the 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; or (c) inconsistent with organic farming and handling practices (7 U.S.C. 6517(c)).

In accordance with the sunset review process published in the Federal Register on September 16, 2013 (78 FR 61154), this proposed rule would amend the National List to reflect 2017 sunset review recommendations submitted to the Secretary by the NOSB on October 29, 2015, to amend the National List to remove eleven substances allowed as substances used in organic production or as ingredients in or on processed products labeled as "organic." The exemptions of each substance appearing on the National List

for use in organic production and handling are evaluated by the NOSB using the evaluation criteria specified in the OFPA (7 U.S.C. §§ 6517 – 6518).

II Overview of Proposed Amendments

Nonrenewals

At the completion of their 2017 sunset review of National List substances with five year review periods ending in 2017, the NOSB recommended the removal of eleven substances from the National List. During this sunset review, the NOSB determined that one substance exemption each in § 205.601(a), § 205.603(a), § 205.605(b) and eight substance exemptions in § 205.606 are no longer necessary for organic production or handling. AMS has reviewed and proposes to accept the eleven NOSB recommendations for removal. Based upon these NOSB recommendations, this action proposes to amend the National List to remove the exemptions for lignin sulfonate, furosemide, magnesium carbonate, Chia, dillweed oil, frozen galangal, inulin, frozen lemongrass, chipotle chile peppers, turkish bay leaves, and whey protein concentrate.

Lignin sulfonate

The USDA organic regulations include an exemption on the National List for lignin sulfonate for use as a floating agent in postharvest handling at § 205.601(l)(1) as follows: lignin sulfonate. In April 1995, lignin sulfonate was recommended by the NOSB for addition onto the National List as a plant or soil amendment for use as a chelating agent, dust suppressant, or floatation agent in organic crop production. AMS accepted this NOSB recommendation and included lignin sulfonate in the proposed rule and the final rule establishing the National Organic Program and the original National List that was published in the Federal Register on December 21, 2000 (65 FR 80548).

Lignin sulfonate was included on the National List in § 205.601(j)(4) as a chelating agent, dust suppressant, or floatation agent, and in § 205.601(l)(1) as a floating agent in post-harvest handling. This proposed rule only addresses the listing of lignin sulfonate in § 205.601(l)(1). As required by OFPA, the NOSB recommended the renewal of lignin sulfonate during the 2007 and 2012 sunset reviews which was renewed by the Secretary on October 16, 2007 (72 FR 58469) and June 6, 2012 (77 FR 33290). Subsequently, the NOSB completed their 2017 sunset review of the exemption for lignin sulfonate at their October 2015 meeting. Two notices of the public meetings on the 2017 sunset review, with request for comments, were published in Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the lignin sulfonate exemption discussed in this proposed rule would expire on September 12, 2016, if not reviewed by the NOSB and renewed by the Secretary. During their 2017 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–15–0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB’s recommendation on lignin sulfonate is available on the NOP web site at <http://www.ams.usda.gov/nop>. During their sunset review of lignin sulfonate the NOSB considered two lignin sulfonate technical reports that were requested by and developed for the NOSB in 2011 and 2013. The latter technical report reviewed lignin sulfonate use in aquaculture production. Both technical reports are available for review

in the petitioned substance database on the NOP website,

<https://www.ams.usda.gov/rules-regulations/organic/national-list>.

Public comments received by the NOSB on lignin sulfonate in § 205.601(l)(1) indicated public support for removing lignin sulfonate as a floating agent in postharvest handling from the National List. Based upon these comments, the NOSB determined that the exemption for lignin sulfonate on the National List in § 205.601(l)(1) is no longer necessary or essential for organic postharvest handling. Subsequently, the NOSB recommended removal of lignin sulfonate from § 205.601(l)(1) from the National List at their October 2015 public meeting.

AMS accepts the NOSB's recommendation on removing lignin sulfonate from the National List. This proposed rule would amend National List § 205.601 by removing the substance exemption for lignin sulfonate listed in § 205.601(l)(1). This amendment is proposed to be effective on the current sunset date for lignin sulfonate, which is June 27, 2017.

Furosemide

The USDA organic regulations include an exemption on the National List for furosemide for use as medical treatment at § 205.603(a)(10) as follows: Furosemide (CAS #-54-31-9) in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA. In December 2000, furosemide was petitioned for addition to § 205.603(a) for use as a medical treatment – a diuretic that reduces edema. In May 2003, the NOSB recommended adding furosemide to the National List in § 205.603(a). The NOSB

included a restrictive annotation for twice the required FDA furosemide withdrawal time within their recommendation to add furosemide to the National List.

AMS accepted the NOSB's recommendation and furosemide was added to the National List on December 12, 2007 (72 FR 70479). As required by OFPA, the NOSB recommended the renewal of furosemide during their 2012 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the furosemide exemption on the National List on June 6, 2012 (77 FR 33290). Subsequently, the exemption for furosemide as included on the National List was considered during the NOSB's 2017 sunset review. Two notices of the public meetings on the 2017 sunset review with request for comments were published in Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the furosemide exemption discussed in this proposed rule would expire on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary.

During their 2017 sunset review, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS - NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB's recommendation on furosemide is available on the NOP web site at <http://www.ams.usda.gov/nop>. During their sunset review of furosemide the NOSB considered a furosemide technical report that were requested by and developed for the NOSB in 2003. This technical report is available for review in the petitioned substance

database on the NOP website, <https://www.ams.usda.gov/rules-regulations/organic/national-list>.

Public comments received by the NOSB on furosemide indicated alternatives to furosemide are available to organic livestock producers. Based upon these comments, the NOSB determined that the exemption for furosemide in § 205.603(a)(10) is no longer necessary or essential for organic livestock production. Subsequently, the NOSB recommended the removal of furosemide from § 205.603(a)(10) from the National List at their October 2015 public meeting.

AMS accepts the NOSB's recommendation on removing furosemide from the National List. This proposed rule would amend National List § 205.603 by removing the substance exemption for furosemide sulfonate listed in § 205.603(a)(10). This amendment is proposed to be effective on the current sunset date for furosemide, which is June 27, 2017.

Magnesium carbonate

The USDA organic regulations include an exemption on the National List for magnesium carbonate as a synthetic ingredient for use in or on processed products at § 205.605 (b) as follows: Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic.” In September 1996, magnesium carbonate was petitioned for addition to the National List under § 205.605 (b). The NOSB recommended that magnesium carbonate be added to the National List under § 205.605 (b) with an annotation limiting its use to products labeled "made with organic (specified ingredients or food group(s))". AMS accepted this recommendation and included

magnesium carbonate in the proposed and the final rule establishing the National Organic Program and the original National List that was published in the Federal Register on December 21, 2000 (65 FR 80548). In this final rule, magnesium carbonate was included on the National List under § 205.605 (b)(16).

As required by OFPA, the NOSB recommended the renewal of magnesium carbonate during the 2007 and 2012 sunset reviews, which were renewed by the Secretary on October 16, 2007 (72 FR 58469) and June 6, 2012 (77 FR 33290). The NOSB completed their 2017 sunset review of the exemption for magnesium carbonate at their October 2015 meeting. Two notices of the public meetings on the 2017 sunset review with request for comments were published in the Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to alert the public that the exemption for magnesium carbonate would expire on June 27, 2017 if not reviewed and recommended by the NOSB and renewed by the Secretary. During their 2017 sunset review, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB's recommendation on magnesium carbonate is available on the NOP website at <http://www.ams.usda.gov/nop>.

Public comments received by the NOSB regarding magnesium carbonate under § 205.605 (b) indicated that the material is not a necessity and recommended its removal

from the National List. Based on the review of the material and the public comments received, the NOSB determined that magnesium carbonate is no longer necessary for organic production. As a result, the NOSB recommended the removal of magnesium carbonate from the National List at their October 2015 meeting.

AMS accepts the NOSB's recommendation to remove magnesium carbonate from the National List. This proposed rule would amend National List § 205.605 by removing the substance exemption for magnesium carbonate at § 205.605 (b). This amendment is proposed to be effective on the current sunset date for magnesium carbonate, which is June 27, 2017.

Chia

The USDA organic regulations include an exemption on the National List for Chia for use as an ingredient in or on processed products labeled as "organic" at § 205.606 (c) as follows: Chia (Salvia hispanica L.). In January 2007, Chia was petitioned for addition to § 205.606 as an ingredient due to the lack of availability of certified organic Chia. In April 2007, the NOSB recommended that Chia be added to the National List under § 205.606. AMS accepted this recommendation and included Chia in the proposed rule and the final rule amending the National List that was published in the Federal Register on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of Chia during the 2012 sunset review, which was renewed by the Secretary on June 6, 2012 (77 FR 33290). The NOSB completed their 2017 sunset review of the exemption for Chia at their October 2015 meeting. Two notices of the public meetings on the 2017 sunset review with request for comments were published in the Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR

53759). The purpose of these notices was to alert the public that the exemption for Chia would expire on June 27, 2017 if not reviewed and recommended by the NOSB and renewed by the Secretary. During their 2017 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB's recommendation on Chia is available on the NOP website at <http://www.ams.usda.gov/nop>.

Regarding Chia, the NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Several comments from a cross-section of the organic community were received in support of delisting Chia noting its wide commercial availability. No specific comments received supported relisting or addressed commercial unavailability of Chia. Based on the review of Chia and the public comments received, the NOSB determined that this material is now widely available from organic sources. Subsequently, the NOSB recommended the removal of Chia from § 205.606 of the National List at their October 2015 meeting. AMS accepts the NOSB's recommendation to remove Chia from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for Chia at § 205.606 (c). This amendment is proposed to be effective on the current sunset date for Chia, which is June 27, 2017.

Dillweed oil

The USDA organic regulations include an exemption on the National List for dillweed oil for use as an ingredient in or on processed products labeled as “organic” at § 205.606 (e) as follows: Dillweed oil (CAS #458-37-7). In December 2006, dillweed oil was petitioned for addition to § 205.606. In April 2007, the NOSB recommended that dillweed oil be added to the National List under § 205.606. AMS accepted this recommendation and included dillweed oil in the proposed rule and the final rule amending the National List that was published in the Federal Register on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of dillweed oil during the 2012 sunset review, which was renewed by the Secretary on June 6, 2012 (77 FR 33290). The NOSB completed their 2017 sunset review of the exemption for dillweed oil at their October 2015 meeting. Two notices of the public meetings on the 2017 sunset review with request for comments were published in the Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to alert the public that the exemption for dillweed oil would expire on June 27, 2017 if not reviewed and recommended by the NOSB and renewed by the Secretary. During their 2017 sunset review, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB’s recommendation on dillweed oil is available on the NOP website at <http://www.ams.usda.gov/nop>.

In the review of dillweed oil, the NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received that supported relisting or addressed commercial unavailability of dillweed oil. Based on the NOSB's review of dillweed oil and the public comments received, the NOSB determined that this substance is now available from organic sources. Subsequently, the NOSB recommended the removal of dillweed oil from § 205.606 of the National List at their October 2015 meeting. AMS accepts the NOSB's recommendation to remove dillweed oil from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for dillweed oil at § 205.606 (e). This amendment is proposed to be effective on the current sunset date for dillweed oil, which is June 27, 2017.

Galangal, frozen

The USDA organic regulations include an exemption on the National List for galangal for use as an ingredient in or on processed products labeled as "organic" at § 205.606 (h) as follows: Galangal (frozen). In November 2006, galangal was petitioned for addition to § 205.606. In April 2007, the NOSB recommended that galangal be added to the National List under § 205.606. AMS accepted this recommendation and included galangal in the proposed rule and the final rule amending the National List that was published in the Federal Register on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of galangal during the 2012 sunset review, which was renewed by the Secretary on June 6, 2012 (77 FR 33290). The NOSB completed their 2017 sunset review of the exemption for galangal at their October 2015 meeting. Two notices of the public meetings on the 2017 sunset review with request for comments

were published in the Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to alert the public that the exemption for galangal would expire on June 27, 2017 if not reviewed and recommended by the NOSB and renewed by the Secretary. During their 2017 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB’s recommendation on galangal is available on the NOP website at <http://www.ams.usda.gov/nop>.

In its review of galangal, the NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments were received that supported relisting or addressed commercial unavailability of frozen galangal. Based on the NOSB’s review of galangal and the public comments received, the NOSB determined that this material is now available from organic sources. Subsequently, the NOSB recommended the removal of galangal from § 205.606 of the National List at their October 2015 meeting. AMS accepts the NOSB’s recommendation to remove galangal from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for galangal at § 205.606 (h). This amendment is proposed to be effective on the current sunset date for galangal, which is June 27, 2017.

Inulin – oligofructose enriched

The USDA organic regulations include an exemption on the National List for inulin – oligofructose enriched, allowed as an ingredient in or on processed products labeled as “organic” in § 205.606(l) as follows: inulin – oligofructose enriched (CAS # 9005-80-5). In January 2007, inulin was petitioned for addition to § 205.606 for use as an ingredient in or on organic processed products. In April 2007, the NOSB recommended adding inulin – oligofructose enriched to the National List in § 205.606.

AMS accepted the NOSB’s recommendation and inulin – oligofructose enriched was added to the National List on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of inulin – oligofructose enriched during their 2012 sunset review. The Secretary accepted the NOSB’s recommendation and published a notice renewing the inulin – oligofructose enriched exemption on the National List on June 6, 2012 (77 FR 33290). Subsequently, the exemption for inulin – oligofructose enriched on the National List was considered during the NOSB’s 2017 sunset review. Two notices of the public meetings on the 2017 sunset review with request for comments were published in Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the inulin – oligofructose enriched exemption discussed in this proposed rule would expire on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary. During their 2017 sunset review, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–15–0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also

considered oral comments received during these public meetings. The NOSB's recommendation on inulin – oligofructose enriched is available on the NOP web site at <http://www.ams.usda.gov/nop>. During their sunset review of inulin – oligofructose enriched the NOSB considered an inulin – oligofructose enriched technical report that was requested by and developed for the NOSB in 2015. This technical report is available for review in the petitioned substance database on the NOP website, <https://www.ams.usda.gov/rules-regulations/organic/national-list>.

Public comments on inulin – oligofructose enriched received by the NOSB during their 2017 Sunset review indicated that organic inulin – oligofructose enriched sources are available to organic processors. Based upon these comments, the NOSB determined that the exemption for inulin – oligofructose enriched in § 205.606(l) is no longer necessary or essential for organic handling / processing. From this determination, the NOSB recommended the removal of inulin – oligofructose enriched from § 205.603(l) from the National List at their October 2015 public meeting. AMS accepts the NOSB's recommendation on removing inulin – oligofructose enriched from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for inulin – oligofructose enriched as listed in § 205.606(l). This amendment is proposed to be effective on the current sunset date for inulin – oligofructose enriched, which is June 27, 2017.

Lemon grass, frozen

The USDA organic regulations include an exemption on the National List for lemon grass, allowed as an ingredient in or on processed products labeled as “organic” in § 205.606(p) as follows: lemon grass, frozen. In November 2006, lemon grass was

petitioned for addition onto § 205.606 for use as an ingredient in or on organic processed products. In March 2007, the NOSB recommended adding lemon grass to the National List in § 205.606.

AMS accepted the NOSB's recommendation and lemon grass was added to the National List on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of lemon grass during their 2012 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the lemon grass exemption on the National List on June 6, 2012 (77 FR 33290). Subsequently, the exemption for lemon grass was considered during the NOSB's 2017 sunset review. Two notices of the public meetings on the 2017 sunset review with request for comments were published in Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the lemon grass exemption discussed in this proposed rule would expire on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary.

During their 2017 sunset review, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB's recommendation on lemon grass is available on the NOP web site at <http://www.ams.usda.gov/nop>. Since the NOSB has not requested the development of a technical review on lemon grass, either for the original lemon grass

petition process or for sunset reviews, the NOSB did not review a technical report on lemon grass during their 2017 sunset review.

Public comments on lemon grass received by the NOSB during their 2017 Sunset review indicated that sources of organic lemon grass are available to organic processors. Based upon these comments, the NOSB determined that the exemption for lemon grass in § 205.606(p) is no longer necessary or essential for organic handling / processing. From this determination, the NOSB recommended the removal of lemon grass from § 205.606(p) from the National List at their October 2015 public meeting. AMS accepts the NOSB's recommendation on removing lemon grass from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for lemon grass as listed in § 205.606(p). This amendment is proposed to be effective on the current sunset date for lemon grass, which is June 27, 2017.

Peppers (chipotle chile)

The USDA organic regulations include an exemption on the National List for chipotle chile peppers for use as an ingredient in or on processed products labeled as “organic” at § 205.606 (s) as follows: Peppers (Chipotle chile). Chipotle chile peppers were petitioned for addition to § 205.606 in November 2006 and January 2007. In April 2007, the NOSB recommended that chipotle chile peppers be added to the National List under § 205.606. AMS accepted this recommendation and included chipotle chile peppers in the proposed rule and the final rule amending the National List that was published in the Federal Register on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of chipotle chile peppers during the 2012 sunset review, which was renewed by the Secretary on June 6, 2012 (77 FR 33290). The NOSB

completed their 2017 sunset review of the exemption for chipotle chile peppers at their October 2015 meeting. Two notices of the public meetings on the 2017 sunset review with request for comments were published in the Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to alert the public that the exemption for chipotle chile peppers would expire on June 27, 2017 if not reviewed and recommended by the NOSB and renewed by the Secretary. During their 2017 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB’s recommendation on chipotle chile peppers is available on the NOP website at <http://www.ams.usda.gov/nop>.

Regarding chipotle chile, the NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. Several comments from a cross-section of the organic community were received in support of delisting chipotle chiles noting commercial availability. No specific comments received supported relisting or addressed commercial unavailability of chipotle chiles. Based on the NOSB’s review of chipotle chile peppers and the public comments received, the NOSB determined that this material is now available from organic sources. Subsequently, the NOSB recommended the removal of chipotle chile peppers from § 205.606 of the National List at their October 2015 meeting. AMS accepts

the NOSB's recommendation to remove chipotle chile peppers from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for chipotle chile peppers at § 205.606 (s). This amendment is proposed to be effective on the current sunset date for chipotle chile peppers, which is June 27, 2017.

Turkish bay leaves

The USDA organic regulations include an exemption on the National List for Turkish bay leaves, allowed as an ingredient in or on processed products labeled as “organic” in § 205.606(w) as follows: Turkish bay leaves. In November 2006, Turkish bay leaves was petitioned for addition to § 205.606 for use as an ingredient in or on organic processed products. In April 2007, the NOSB recommended adding Turkish bay leaves to the National List in § 205.606. AMS accepted the NOSB's recommendation and Turkish bay leaves was added to the National List on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of Turkish bay leaves during their 2012 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the Turkish bay leaves exemption on the National List on June 6, 2012 (77 FR 33290). Subsequently, the exemption for Turkish bay leaves on the National List was considered during the NOSB's 2017 sunset review. Two notices of the public meetings on the 2017 sunset review with request for comments were published in Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the Turkish bay leaves exemption discussed in this proposed rule would expire on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary.

During their 2017 sunset review, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–15–0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB’s recommendation on Turkish bay leaves is available on the NOP web site at <http://www.ams.usda.gov/nop>. During their sunset review of Turkish bay leaves the NOSB did not review a technical report on Turkish bay leaves since the NOSB has not requested the development of a Turkish bay leaves technical report for the original petition review or any subsequent sunset reviews.

Public comments on Turkish bay leaves received by the NOSB during their 2017 Sunset review indicated that organic Turkish bay leaves sources are available to organic handlers/processors. The original petitioner of Turkish bay leaves also commented they now use organic Turkish bay leaves for their products. Based upon these comments, the NOSB determined that the exemption for Turkish bay leaves in § 205.606(w) is no longer necessary or essential for organic handling/processing. From this determination, the NOSB recommended the removal of Turkish bay leaves from § 205.606(w) from the National List at their October 2015 public meeting. AMS accepts the NOSB’s recommendation on removing Turkish bay leaves from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for Turkish bay leaves listed in § 205.606(w). This amendment is proposed to be effective on the current sunset date for Turkish bay leaves, which is June 27, 2017.

Whey protein concentrate

The USDA organic regulations include an exemption on the National List for whey protein concentrate, allowed as an ingredient in or on processed products labeled as “organic” in § 205.606(y) as follows: whey protein concentrate. In February 2007, whey protein concentrate was petitioned for addition to § 205.606 for use as an ingredient in or on organic processed products. In April 2007, the NOSB recommended adding whey protein concentrate to the National List in § 205.606. AMS accepted the NOSB’s recommendation and whey protein concentrate was added to the National List on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of whey protein concentrate during their 2012 sunset review. The Secretary accepted the NOSB’s recommendation and published a notice renewing the whey protein concentrate exemption on the National List on June 6, 2012 (77 FR 33290). Subsequently, the exemption for whey protein concentrate on the National List was considered during the NOSB’s 2017 sunset review. Two notices of the public meetings on the 2017 sunset review with request for comments were published in Federal Register on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the whey protein concentrate exemption discussed in this proposed rule would expire on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary.

During their 2017 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS–NOP–15–

0002 (April 2015 public meeting) and AMS – NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB’s recommendation on whey protein concentrate is available on the NOP web site at <http://www.ams.usda.gov/nop>. During their sunset review of whey protein concentrate the NOSB considered a whey protein concentrate technical report that were requested by and developed for the NOSB in 2015. This technical report is available for review in the petitioned substance database on the NOP website, <https://www.ams.usda.gov/rules-regulations/organic/national-list>.

Public comments on whey protein concentrate received by the NOSB during their 2017 Sunset review indicated that organic whey protein concentrate sources are available to organic processors. Based upon these comments, the NOSB determined that the exemption for whey protein concentrate in § 205.606(y) is no longer necessary or essential for organic handling / processing. From this determination, the NOSB recommended the removal of whey protein concentrate from § 205.606(y) from the National List at their October 2015 public meeting. AMS accepts the NOSB’s recommendation on removing whey protein concentrate from the National List. This proposed rule would amend National List § 205.606 by removing the substance exemption for whey protein concentrate listed in § 205.606(y). This amendment is proposed to be effective on the current sunset date for whey protein concentrate, which is June 27, 2017.

III. Related Documents

Two notices of public meetings with request for comments were published in Federal Register on March 12, 2015 (80 FR 12975) and on September 8, 2015 (80 FR 53759) in order to notify the public that the 2017 sunset review listings discussed in this proposed rule would expire on June 27, 2017, 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 recommendations developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the USDA organic regulations. The current petition process was published on March 10, 2016 (81 FR 12680) and can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined to be 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 prohibit the use of eleven

non-organic non-agricultural or non-organic agricultural substances that have limited public support and may no longer be used since alternatives to these substances may have been developed and implemented by organic producers or organic handlers (food processors). AMS concludes that the economic impact of removing lignin sulfonate, furosemide, magnesium carbonate, Chia, dillweed oil, frozen galangal, inulin, frozen lemongrass, chipotle chile peppers, Turkish bay leaves, and whey protein concentrate from the National List would be minimal to small agricultural firms since alternative products or ingredients may be commercially available. As such, these substances are proposed to be removed from the National List 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 3.6 million acres in 2014.¹ According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 21,764 in March 2016. The list of certified operations is available on the NOP website at <http://apps.ams.usda.gov/nop/>. AMS believes that most of these entities would be considered small entities under the criteria established by the

¹ U.S. Department of Agriculture, National Agricultural Statistics Service. 2014 Organic Survey, https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Organics/organics_1_001_001.pdf

SBA. U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to \$43 billion in 2015.² In addition, the USDA has 80 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.

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 June 27, 2017. A 60-day period for interested persons to comment on this rule is provided. Sixty days is deemed appropriate because the review of these listings was widely publicized through two NOSB meeting notices; the use or prohibition of these substances, as applicable, are

² Organic Trade Association. 2015. Organic Industry Survey. www.ota.com.

critical to organic production and handling; and this rulemaking must be completed before the sunset date of June 27, 2017.

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 proposed to be 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. Amend §205.601 by revising paragraph (l) to read as follows:

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

(l) As floating agents in postharvest handling. Sodium silicate – for tree fruit and fiber processing.

§ 205.603 [Amended].

3. Amend §205.603 by removing paragraph (a)(10) and redesignating paragraphs (a)(11) through (a)(23) as paragraphs (a)(10) through (a)(22).

§205.605 [Amended].

4. Amend §205.605 by removing the entry “Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”” from paragraph (b).

§205.606 [Amended].

5. Amend §205.606 by removing paragraphs (c), (e), (h), (k), (o), (s), (w) and (y) and redesignating paragraphs (d), (f), (g), (i), (j),(l), (m), (n), (p), (q), (r), (t), (u) and (x) as paragraphs (c) through (q).

Dated: January 9, 2017

Elanor Starmer
Administrator, Agricultural Marketing Service

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