Formal Recommendation
From: The National Organic Standards Board (NOSB)
To: The National Organic Program (NOP)

Date: May 1, 2024
Subject: Technical Report (TR) update
NOSB Chair: Kyla Smith

The NOSB hereby recommends to the NOP the following:
Rulemaking Action:
Guidance Statement:
Other: X

Statement of the Recommendation:
The NOSB voted unanimously to update the Technical Review templates for Handling and Crops/Livestock.

Rationale Supporting Recommendation:
The Materials Subcommittee engaged in the process of revising the Technical Review template in an effort to make the information requests clearer to the TR writers, reduce redundancy, and align the questions with those in the petition template. Additionally, the MS added questions to fulfill the directions of the Policy and Procedure Manuel's (PPM) assertion that "A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that materials impact on the environment, human health, and it's compatibility with organic principles." (Pg 28). The PPM is also clear that "[t]he decision to request a third-party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review" of the substance on hold (pg. 28). The PPM is instructive to the NOSB process of evaluating materials, giving an extensive list of sources needed for the NOSB to write recommendations. The PPM instructs Board members to "[r]ead the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, public or board comments from the optional petition discussion document, and recommendations of a contracted panel of experts when utilized." (Pg 26). The PPM recognizes that Subcommittees must cast a wide net to gather enough information to "prepare a written review of the substance according to the OFPA criteria"(Pg 26).

NOSB Vote:
Motion to accept the changes to the Technical Reports (TR) templates
Motion by: Mindee Jeffery
Seconded by: Nate Lewis
Yes: 14 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Motion Passed

National Organic Standards Board
Materials/GMO Subcommittee
Proposal - Technical Review template update
February 13, 2024

Intro/Background:

The Materials Subcommittee (MS) is proposing updates to the Technical Review (TR) templates to better align with the petition process and OFPA criteria and to directly address excluded methods.

The NOSB Policy and Procedures Manual defines a technical review as follows: "Technical Review - A report prepared by a third-party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB." According to the PPM, "A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles." The two revised TR templates, one for Handling and one for Crops/Livestock are included as Appendices to this proposal. Also included as appendices are the two versions with redlining.

Discussion:

The Materials Subcommittee submitted a discussion document on the TR updates for comment at the Spring 2023 meeting. Public commenters were supportive of the initiative to reorganize the flow of questions, reduce redundancy, and suggested additional questions for ancillary substances, nanoparticles, and excluded methods. The suggested changes were incorporated into the templates, and in January 2024, the MS voted unanimously in support of the versions of the TR templates included in the appendices.

Questions to stakeholders:

Do the proposed revisions to the technical report (TR) templates for Handling and Crops/Livestock raise any concerns or challenges for stakeholders that create and/or use TRs?

Subcommittee Vote:

Motion to accept the technical Report template updates for Handling and Crops/Livestock.
Motion by: Mindee Jeffery
Seconded by: Nate Lewis
Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Appendix A1 - Redlined version of TR template: Handling
Appendix A2 - New version of TR template: Handling
Appendix B1 - Redlined version of TR template: Livestock/Crops
Appendix B1 - New version of TR template: Livestock/Crops

Name of Material

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
List all chemical names

Other Name:
List other names

Trade Names:
List trade names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes (e.g., INS number, E number, etc.)

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations (7 CFR Part 205).

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 1 through 4).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance as it relates to organic handling; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural handling/processing.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

Action of the Substance:
Describe Action of the Substance – focus should be given to describing mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List. Any known synergistic effects (either positive or negative) with other substances on the National List should be identified.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:
Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:
Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada~~, Canadian General Standards Board –~~

CAN/CGSB-32.310- Organic production systems-General principles and management standards
CAN/CGSB-32.311-~~2015~~, Organic Production Systems Permitted Substances List
~~http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172~~

CODEX Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
~~http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM~~
Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

European Economic Community (EEC) Council Regulation—EC No. 834/2007 and 889/2008
~~http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0889~~

Japan Agricultural Standard (JAS) for Organic Production
~~http://www.maff.go.jp/e/jas/specific/criteria_o.html~~

International Federation of Organic Agriculture Movements (IFOAM)
~~http://www.ifoam.bio/en/ifoam-norms~~

Evaluation Questions for Substances to be used in Organic Handling

[combination of old #1, 2 &3 – word smithed and added D, E and F]
Evaluation Question #1: ~~Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).~~ (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Discuss whether the petitioned substance is agricultural or Non-agricultural. If the substance is Non-agricultural, is it synthetic or non-synthetic? [7 U.S.C. §6502(21); NOP 5032-1; NOP 5033-2]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Does the substance in its raw or formulated forms contain ancillary substances (F) Is the substance created using Excluded Methods?

Data Required: ~~The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. For the purposes of this response, a chemical change could be the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.~~

(A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

(B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

(C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) NOP Guidance 5033-1 and NOP Guidance 5033-2, describe if the substance can be classified as agricultural or non-agricultural.

(D) Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

(E) Ancillary Substances: Does the substance in its raw or formulated forms contain ancillary substances as defined by the NOSB in the 2016 recommendation? (https://www.ams.usda.gov/sites/default/files/media/HS%20Ancillary%20Substance%20Proposal%20NOP.pdf)

(F) Excluded Methods:

i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

using invitro nucleic acid techniques, induced mutagenesis developed through in vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).

ii. If the substance is manufactured from agricultural raw materials, are those materials derived from genetically engineered crop, or crops resulting from excluded methods?

iii. If the substance is manufactured from other biological raw materials—such as those produced by fermentation or enzymatic action—are those biological materials, derived from genetically engineered organisms, or crops organisms resulting from excluded methods?

[old #4] Evaluation Question #2: ~~**Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.**~~ **Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.**

~~**Data Required**: For the purposes of this response, chemical processes are processes include, but are not limited to, acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.~~

~~If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods.~~

~~If the substance is created by a naturally occurring biological process, those process(es) must be described in detail. For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.~~

~~Information should be provided on whether the substance has been chemically modified from the source or origin of the substance, including whether the substance has been isolated from a natural source in a form that does not occur in nature, and whether any synthetic materials used in the production or extraction of a substance may remain in the final product.~~

~~For the purposes of this response, an agricultural source is any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption.~~

Purpose and necessity of the substance

[old #5] Evaluation Question #3: ~~**If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR 205.600(b)(1)).**~~ **Describe whether the primary technical function or purpose of the petitioned substance is a preservative (7 CFR 205.600(b)(4)).**

Data Required: ~~The response must discuss whether non-synthetic or natural sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. The following information on any naturally sourced versions should be provided in the report:~~

- ~~literature, including product or practice description, on performance and test data;~~
- ~~name and address of the manufacturer(s), if applicable; and,~~

- ~~types of products the substance is currently used in.~~

The response must explain why the primary function of the substance is or is not as a preservative.

[old #6] Evaluation Question #4: ~~**Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.**~~ **Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law). If so, how? (7 CFR 205.600(b)(4)).**

Date Required: ~~The response must indicate whether or not the substance has been determined to be GRAS by FDA. This information may be found in 21 CFR Parts 182, 184, and 186. If not determined to be GRAS by FDA, indicate whether it appears on FDA's "GRAS Notice Inventory" available at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing.~~

~~The response should cite the FDA regulatory citation confirming GRAS status or whether FDA has provided a response letter of no objection to a manufacturer's notification of GRAS status.~~ When replacement or improvement of nutrients is required or allowed by regulation, the report evaluators should cite the appropriate regulations.

[old #7] Evaluation Question #5: ~~**Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR 205.600(b)(4)).**~~ **Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).**

Data Required: ~~The response must explain why the primary function of the substance is or is not as a preservative.~~ The response must indicate whether the use of the petitioned substance affects the levels of nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product. Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.

Environment and human health effects

[old #8] Evaluation Question #6: ~~**Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR 205.600(b)(4)).**~~ **List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).**

Data Required: ~~When replacement or improvement of nutrients is required or allowed by regulation, the report evaluators should cite the appropriate regulations.~~ The response must indicate whether the petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed See the latest edition of Food Chemicals Codex (National Research Council) for accepted reference standards for metals and other contaminants in food ingredients in the U.S.

[old #9] Evaluation Question #7: ~~**Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).**~~ **Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

Data Required: ~~The response must indicate whether the use of the petitioned substance affects the levels of nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product. Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients~~. In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe

the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (*e.g.*, predators and parasitic hymenoptera), pollinators, bats and birds.

[old #10] Evaluation Question #8: ~~**List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).**~~ **Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).**

Data Required: ~~The response must indicate whether the petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. These action levels can be found at https://www.fda.gov/food/guidanceregulation/ucm077969. See the latest edition of Food Chemicals Codex (National Research Council) for accepted reference standards for metals and other contaminants in food ingredients in the U.S.~~ Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.

Alternatives

[old #3] Evaluation Question #9: ~~**Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**~~ **Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR 205.600(b)(1)).**

Data Required: ~~In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (*e.g.*, predators and parasitic hymenoptera), pollinators, bats and birds.~~
The response must discuss whether natural (nonsynthetic) sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. Briefly describe any naturally sourced alternatives by summarizing:

- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and,
- types of products the substance is currently used in.

[old #12] Evaluation Question #10: ~~**Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).**~~ **Describe all nonagricultural non-synthetic substances or products which may be used in place of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Additionally, identify which of those are currently allowed under the NOP regulations.**

Data Required: ~~Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.~~
The response must describe the availability of a nonagricultural non-synthetic or natural substance(s) which could be substituted for petitioned substance. Briefly describe any nonagricultural nonsynthetically sourced alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;
- Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.

- A comparison of reported risks to human health associated with the substitute non-synthetic (natural) product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute non-synthetic (natural) product to the petitioned substance;
- Literature, including product or practice description, on performance and test data; and
- Types of products and range of uses for the alternative substance

[old #13] Evaluation Question #11: ~~**Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).**~~ **Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).**

Data Required: ~~The response to this request for development of technical information must describe the availability of an alternative practice(s) to the use of the petitioned substance. Many research based alternative practices may be found at: http://eorganic.info/, https://www.sare.org/, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. When assessing alternative practices, the report should address:~~

- ~~Literature, including practice description, on performance and test data;~~
- ~~A comparison of the function and effectiveness of the proposed alternative practice to the petitioned substance; and,~~
- ~~Types of products produced and scope of use of alternative practices.~~

The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/, https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. Briefly describe the organic agriculturally derived alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance;
- Commercial availability of substitute organic products, both domestically and globally
- A comparison of reported risks to human health associated with the substitute organic agricultural product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute organic agricultural product to the petitioned substance;
- Any literature, including product description, on performance and test data;
- The name and address of the supplier/manufacturer, if applicable; and
- Types of products and range of uses for the alternative substance.

[old #11] Evaluation Question #12: ~~**Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518(m)(6)).**~~ **Describe if there are any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).**

Data Required: ~~The response must describe the availability of a non-synthetic or natural substance(s) which could be substituted for petitioned substance. Many natural substances may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/, https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. The examination should address:~~

- ~~A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;~~

- ~~Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.~~
- ~~A comparison of reported risks to human health associated with the substitute non-synthetic (natural) product to the petitioned substance;~~
- ~~A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute non-synthetic (natural) product to the petitioned substance;~~
- ~~Literature, including product or practice description, on performance and test data; and~~
- ~~Types of products and range of uses for the alternative substance; and,~~

The response to this request for development of technical information must describe the availability of an alternative practice(s) to the use of the petitioned substance. Many research-based alternative practices may be found at: http://eorganic.info/, https://www.sare.org/, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. Briefly describe alternative practices by summarizing:

- Literature, including practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice to the petitioned substance; and,
- Types of products produced and scope of use of alternative practices.

~~**Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).**~~

~~**Data Required:** The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/, https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. In developing the list, the following should be considered:~~

- ~~A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance;~~
- ~~Commercial availability of substitute organic products, both domestically and globally~~
- ~~A comparison of reported risks to human health associated with the substitute organic agricultural product to the petitioned substance;~~
- ~~A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute organic agricultural product to the petitioned substance;~~
- ~~Any literature, including product description, on performance and test data;~~
- ~~The name and address of the supplier/manufacturer, if applicable; and~~
- ~~Types of products and range of uses for the alternative substance.~~

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

All citations listed in the report must be included in references section using MLA format.
A minimum of 20 current scientific references must be cited in the report to provide adequate scientific credibility and thorough review. Citation using MLA format must be included appropriately within the text to avoid plagiarism.

Name of Material

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
List all chemical names

Other Name:
List other names

Trade Names:
List trade names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes (e.g., INS number, E number, etc.)

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Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance as it relates to organic handling; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural handling/processing.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

Action of the Substance:
Describe Action of the Substance – focus should be given to describing mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List. Any known synergistic effects (either positive or negative) with other substances on the National List should be identified.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:
Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:
Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada

CAN/CGSB-32.310- Organic production systems-General principles and management standards

CAN/CGSB-32.311, Organic Production Systems-Permitted Substances List
http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172

CODEX Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM
Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

European Economic Community (EEC) Council Regulation—EC No. 834/2007 and 889/2008
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R1165&from=EN#d1e32-48-1

Japan Agricultural Standard (JAS) for Organic Production
http://www.maff.go.jp/e/jas/specific/criteria_o.html

IFOAM-Organics International
http://www.ifoam.bio/en/ifoam-norms

Evaluation Questions for Substances to be used in Organic Handling

Classification of the substance

Evaluation Question #1: (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Discuss whether the petitioned substance is agricultural or Non-agricultural. If the substance is Non-agricultural, is it synthetic or non-synthetic? [7 U.S.C. §6502(21); NOP 5032-1; NOP 5033-2]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Does the substance in its raw or formulated forms contain ancillary substances (F) Is the substance created using Excluded Methods?

Data Required:

(A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods. If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

(B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

(C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) NOP Guidance 5033-1 and NOP Guidance 5033-2, describe if the substance can be classified as agricultural or non-agricultural.

(D) Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

(E) Ancillary Substances: Does the substance in its raw or formulated forms contain ancillary substances as defined by the NOSB in the 2016 recommendation? (https://www.ams.usda.gov/sites/default/files/media/HS%20Ancillary%20Substance%20Proposal%20NOP.pdf)

(F) Excluded Methods:

i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

using invitro nucleic acid techniques, induced mutagenesis developed through in vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).

ii. If the substance is manufactured from agricultural raw materials, are those materials derived from genetically engineered crop, or crops resulting from excluded methods?

iii. If the substance is manufactured from other biological raw materials—such as those produced by fermentation or enzymatic action—are those biological materials, derived from genetically engineered organisms, or crops organisms resulting from excluded methods?

Evaluation Question #2: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR 205.600(b)(5)). If not categorized as GRAS, describe the regulatory status.

Purpose and necessity of the substance

Evaluation Question #3: Describe whether the primary technical function or purpose of the petitioned substance is a preservative (7 CFR 205.600(b)(4)).

Data Required: The response must explain why the primary function of the substance is or is not as a preservative.

Evaluation Question #4: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law). If so, how? (7 CFR 205.600(b)(4)).

Data Required: When replacement or improvement of nutrients is required or allowed by regulation, the report evaluators should cite the appropriate regulations.

Evaluation Question #5: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR 205.600(b)(3)).

Data Required: The response must indicate whether the use of the petitioned substance affects the levels of nutrients (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product. Effects may include increasing or decreasing the amount and/or bioavailability of the nutrients.

Environment and human health effects

Evaluation Question #6: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR 205.600(b)(5)).

Data Required: The response must indicate whether the petitioned substance may contain residues of substances that exceed FDA's Action Levels for Poisonous or Deleterious Substances in Human Food. For the most part, these action levels will relate to residues found in agricultural products. Heavy metals or contaminants are addressed through FDA's action levels. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed See the latest edition of Food Chemicals Codex (National Research Council) for accepted reference standards for metals and other contaminants in food ingredients in the U.S.

Evaluation Question #7: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Data Required: In consideration of the petitioned substance, its manufacturing process, and its breakdown products, describe the mode of action of the substance with respect to its effects on biological, chemical and physical effects on the environment or biodiversity. The analysis must include consideration of potential effects on both terrestrial and aquatic systems and effects on arthropod natural enemies (*e.g.*, predators and parasitic hymenoptera), pollinators, bats and birds

Evaluation Question #8: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(i), 7 U.S.C. § 6517(c)(2)(A)(i)) and 7 U.S.C. § 6518(m)(4)).

Data Required: Describe reported health effects and causation that may be attributed to the use of the petitioned substance and/or its breakdown products.

Alternatives

Evaluation Question #9: Are there alternative natural (nonsynthetic) source(s) of the substance? (7 CFR 205.600(b)(1)).

Data Required: The response must discuss whether natural (nonsynthetic) sources of the petitioned substance exist and are available. The report contractor should examine the effect, form, function, quality, and quantity of the naturally sourced version of the petitioned substance, in comparison to manufactured versions. Briefly describe any naturally sourced alternatives by summarizing:

- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and,
- types of products the substance is currently used in.

Evaluation Question #10: Describe all nonagricultural non-synthetic substances or products which may be used in place of the petitioned substance (7 U.S.C. § 6517(c)(1)(A)(ii)). Additionally, identify which of those are currently allowed under the NOP regulations.

Data Required: The response must describe the availability of a nonagricultural non-synthetic or natural substance(s) which could be substituted for petitioned substance. . Briefly describe any nonagricultural nonsynthetically sourced alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic (natural) product with the petitioned substance;
- Commercial availability of substitute non-synthetic (natural) products, both domestically and globally.
- A comparison of reported risks to human health associated with the substitute non-synthetic (natural) product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute non-synthetic (natural) product to the petitioned substance;
- Literature, including product or practice description, on performance and test data; and
- Types of products and range of uses for the alternative substance

Evaluation Information #11: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR 205.600(b)(1)).

Data Required: The list should be based upon a comparison of the effect, form, function, quality, and quantity of the recommended organic agricultural product with the petitioned substance. Many organic products may be found at: https://organic.ams.usda.gov/Integrity/default.aspx, http://eorganic.info/,

https://www.sare.org/, https://www.omri.org/, www.606organic.com, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. Briefly describe the organic agriculturally derived alternatives by summarizing:

- A comparison of the effect, form, function, quality, and quantity of the substitute organic agricultural product to the petitioned substance;
- Commercial availability of substitute organic products, both domestically and globally
- A comparison of reported risks to human health associated with the substitute organic agricultural product to the petitioned substance;
- A comparison of reported environmental effects (both aquatic and terrestrial) associated with the substitute organic agricultural product to the petitioned substance;
- Any literature, including product description, on performance and test data;
- The name and address of the supplier/manufacturer, if applicable; and
- Types of products and range of uses for the alternative substance.

Evaluation Question #12: Describe if there are any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518(m)(6)).

Data Required: The response to this request for development of technical information must describe the availability of an alternative practice(s) to the use of the petitioned substance. Many research-based alternative practices may be found at: http://eorganic.info/, https://www.sare.org/, and https://attra.ncat.org/; these resources should be consulted before exhausting search for alternative practices. Briefly describe alternative practices by summarizing:

- Literature, including practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice to the petitioned substance; and,
- Types of products produced and scope of use of alternative practices.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

All citations listed in the report must be included in references section using MLA format.
A minimum of 20 current scientific references must be cited in the report to provide adequate scientific credibility and thorough review. Citation using MLA format must be included appropriately within the text to avoid plagiarism.

Name of Material

Crops or Livestock

Identification of Petitioned Substance

Chemical Names:
List all chemical names

CAS Numbers:
List CAS numbers

Other Name:
List other names

Other Codes:
List other codes

Trade Names:
List Trade Names

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations.

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 2 and 3).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural crop or livestock production.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

Action of the Substance:
Describe the Mode Action of the Substance – focus should be given to describing the mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:
Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:
Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada ~~– Canadian General Standards Board Permitted Substances List. This list was updated in November 2015.~~
CAN/CGSB-32.310- Organic production systems-General principles and management standards
CAN/CGSB-32.311~~-2015~~ — Organic production systems - Permitted substances lists
~~http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/lsp-psl-eng.html~~

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -

Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

~~http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1~~
~~http://www.codexalimentarius.org/download/standards/360/cxg_032e.pdf~~

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

~~http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:250:0001:0084:EN:PDF~~

Japan Agricultural Standard (JAS) for Organic Production –
~~http://www.maff.go.jp/e/jas/specific/criteria_o.html~~

International Federation of Organic Agriculture Movements (IFOAM) –
~~http://www.ifoam.bio/en/ifoam-norms~~

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Classification of the substance

[combination of old #2 & 3 – word smithed and added D and E]

Evaluation Question #1: ~~**Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers?**~~ **(A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources.** ~~**(B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological**~~

~~**concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?**~~ **(B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Based on the manufacturing process description, discuss if the substance is classified as synthetic or a nonsynthetic. [7 U.S.C. §6502(21)]; NOP 5033-1]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Is the substance created using Excluded Methods?**

Data Required:

(A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods.If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

(B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

(C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a nonsynthetic. Synthetic substances have been chemically modified from the source or origin or have been isolated from a natural source in a form that does not occur in nature.

(D) Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

(E) Excluded Methods:

i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed

using invitro nucleic acid techniques, induced mutagenesis developed through in vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).

ii. If the substance is manufactured from agricultural raw materials, are those materials derived from genetically engineered crop, or crops resulting from excluded methods?

iii. If the substance is manufactured from other biological raw materials—such as those produced by fermentation or enzymatic action—are those biological materials derived from genetically engineered organisms, or crops organisms resulting from excluded methods?

[old #1] Evaluation Question #2: ~~**Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).**~~ **For substances classified as synthetic: Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?**

~~**Data Required**: The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.~~

[old #7] Evaluation Question #3: ~~**Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).**~~ **Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. (7 U.S.C. § 6518(m)(1)).**

Data Required: ~~For the purposes of this response, chemical processes are processes include, but are not limited to, acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.~~

~~If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods.~~

~~If the substance is created by a naturally occurring biological process, those process(es) must be described in detail. For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.~~

~~Information should be provided on whether the substance has been chemically modified from the source or origin of the substance, including whether the substance has been isolated from a natural source in a form that does not occur in nature, and whether any synthetic materials used in the production or~~

~~extraction of a substance may remain in the final product.~~ The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions.

[combination of old #4 & 5] Evaluation Question #4: ~~**Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).**~~ **Discuss (A) the toxicity and mode of action of the substance; (B) the toxicity and mode of action of its breakdown products or any contaminants; and (C) their persistence and areas of concentration in the environment (7 U.S.C. §6518(m)(2)).**

Data Required: ~~The response must describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned.~~

- **(A)** Describe whether the petitioned substance has been reported to have toxic effects and if its mode of action can cause adverse health and/or environmental effects.
- **(B)** Describe whether the petitioned substance contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time.
- **(C)** Describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned.

[old #6] Evaluation Question #5: ~~**Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).**~~ **Discuss the probability of environmental contamination during manufacture, use, misuse or disposal of the substance (7 U.S.C. §6518(m)(3)).**

Data Required: ~~The response must describe whether the petitioned substance, its contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time.~~ The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. Data or reports from U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available. This data may also be available through review of assessments performed per EPA, FDA, and/or NIEHS review.

[old #8] Evaluation Question #6: ~~**Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).**~~ **Discuss the effects of the substance on biological and chemical interactions in the agroecosystem. Include the physiological effects of the substance on soil, crops, livestock or other organisms (such as aquatic) that could be affected by the substance when used as petitioned. (7 U.S.C. §6518(m)(5))**

Data Required: ~~The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. This data may be available through review of assessments performed per EPA, FDA, and/or NIEHS review. Data or reports from other U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available.~~ The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem.

The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.

In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.

[old #9] Evaluation Question #7: ~~**Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).**~~ **Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

Data Required: ~~The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions and whether they may cause adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time. Toxicity, mode of action, and persistence of the substance and its breakdown products should be explained.~~ Considering the information described in questions #1-6 and any other relevant information, discuss if the petitioned substance and/ or its breakdown products can cause harmful effects on the environment. Describe the biological, chemical and physical factors that may be affected by the use of the substance and/ or its breakdown products.

Harm to Human Health

[old #10] Evaluation Question #8: ~~**Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).**~~ **Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).**

Data Required: ~~The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem. The effects of these substances, including toxicity, mode of action and environmental persistence of the substance and its breakdown products should be explained.~~

~~The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.~~

~~In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.~~ Drawing upon responses

to above questions #1-7 and any other relevant information, describe the reported health effects that may be attributed to the petitioned substance and/or its breakdown products.

Necessity and Alternatives

[old #11] Evaluation Question #9: ~~**Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**~~ **Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

Data Required: ~~Drawing upon responses to above questions #2-8, and any other relevant information, describe the biological, chemical and physical agents capable of causing harmful environmental effects and the causation, that may be attributed to the use of the petitioned substance and/or its breakdown products.~~ The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:

- a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;
- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and
- For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.

[old #12] Evaluation Question #10: ~~**Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).**~~ **Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

Data Required: ~~Drawing upon responses to above questions #2-8 and any other relevant information, describe the reported health effects and causation that may be attributed to the petitioned substance and/or its breakdown products.~~ The response to this request for development of technical information must describe the availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.

When assessing alternative practices, the report should address:

- Literature, including specific practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and,
- Frequency or prevalence of use of alternatives, if known.

~~**Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**~~

~~**Data Required**: The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:~~

- ~~a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;~~
- ~~literature, including product or practice description, on performance and test data;~~
- ~~name and address of the manufacturer(s), if applicable; and~~
- ~~For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.~~

~~Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).~~

~~**Data Required**: The response to this request for development of technical information must describe the availability of alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.~~

~~Alternative cultural methods including methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances. Examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames; or wind breaks.~~

~~Other alternative practices may include, but are not limited to, crop rotation, mulching with fully biodegradable materials, mechanical cultivation, augmentation or introduction of predators or parasites of the pest species; development of habitat for natural enemies of pests; nonsynthetic controls such as lures, traps, and repellents; sanitation measures and management practices which suppress the spread of disease organisms.~~

~~Alternative practices used in livestock production may include, but are not limited to, selection of species and types of livestock with regard to suitability for site-specific conditions, resistance to diseases and parasites; site selection , housing, pasture and sanitation practices that minimize occurrence and spread of disease and parasites; stocking density; and seasonal production practices.~~

~~When assessing alternative practices, the report should address:~~

- ~~Literature, including practice description, on performance and test data;~~
- ~~A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and,~~
- ~~Frequency or prevalence of use of alternatives, if known.~~

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References

Name of Material

Crops or Livestock

Identification of Petitioned Substance

Chemical Names:
List all chemical names

CAS Numbers:
List CAS numbers

Other Name:
List other names

Other Codes:
List other codes

Trade Names:
List Trade Names

Summary of Petitioned Use

For petitions to add or amend a substance, describe the petitioned use of the substance. For substances currently on the National List, summarize the allowed uses under the USDA organic regulations.

Characterization of Petitioned Substance

Composition of the Substance:
Describe Composition of the Substance

Source or Origin of the Substance:
Briefly describe the source or origin of the substance (to be addressed in more detail below under Evaluation Questions 2 and 3).

Properties of the Substance:
Describe Physical and Chemical Properties of the Substance

Specific Uses of the Substance:
Describe Specific Uses of the Substance - primary focus should be given to describing the petitioned use of the substance; secondary focus should be given to providing general information on other uses of the petitioned substance in agricultural crop or livestock production.

Approved Legal Uses of the Substance:
Describe the Status of the Petitioned Substance under applicable Federal Regulations (i.e., EPA, FDA, USDA (including APHIS or FSIS), NIEHS, etc.)

Action of the Substance:
Describe the Mode Action of the Substance – focus should be given to describing the mode of action of the substance, when used as petitioned.

Combinations of the Substance:
Describe Combinations of the Substance – focus should be given to describing whether the petitioned substance is a precursor to, component of, or commonly used in combination with a substance(s) identified on the National List.

In addition, information should be provided on whether any additional ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are generally added to commercially available forms of the petitioned substance.

Status

Historic Use:
Describe historic use of the substance in organic agricultural production (if no historic use in organic agricultural production, please describe historic use in conventional agricultural production).

Organic Foods Production Act, USDA Final Rule:
Describe whether the Petitioned Substance is Listed anywhere in the Organic Foods Production Act of 1990 (OFPA) or the USDA organic regulations, 7 CFR Part 205.

International

Describe the status of the substance among international organizations. Specifically, the report should address whether the petitioned substance is allowed or prohibited for use in other international organic standards such as:

Canada –

CAN/CGSB-32.310- Organic production systems-General principles and management standards

CAN/CGSB-32.311— Organic production systems - Permitted substances lists

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -

Note: For Codex, the reference should be cited as "guidelines," rather than as "standards".

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Japan Agricultural Standard (JAS) for Organic Production—

IFOAM – Organics International

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Classification of the substance

Evaluation Question #1: (A) Describe if the substance is extracted from naturally occurring plant, animal, or mineral sources. (B) Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Include any chemical changes that may occur during manufacture or formulation of the substance. (C) Based on the manufacturing process description, discuss if the substance is classified as synthetic or a nonsynthetic. [7 U.S.C. §6502(21)]; NOP 5033-1]. (D) Does the substance in its raw or formulated forms contain nanoparticles? (E) Is the substance created using Excluded Methods?

Data Required:

(A) If the substance is extracted from a natural material, information should be provided on any materials and methods used to extract, separate, isolate, or withdraw the substance, including any solvents used, acid-base extraction methods, or mechanical or physical separation methods.If the substance is created by a naturally occurring biological process, those process(es) must be described in detail.

For the purposes of this response, naturally occurring biological processes are processes that include but are not limited to, aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

(B) The response must describe the processes used to manufacture or formulate the substance, including a discussion of all precursors and/or feedstocks. A description of alternate manufacturing methods and the extent of their commercial use which are not included in the petition, if any, should be presented. The response must also describe, in detail, any chemical changes effected on any naturally occurring precursor or feedstock by all manufacturing or formulation processes. If any synthetic materials used in the production or extraction of a substance remain in the final product, describe them.

For the purposes of this response, a chemical change involves a process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances. This may include the addition or deletion of one atom to the substance's molecular structure or other description of chemical modification.

Chemical processes include, but are not limited to: acid base reactions, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation-reduction, polymerization, etc., obtained through process units such as compressors, cracking towers, heat exchangers, mixers, reactors, pumps, etc.

(C) Based on the information provided on (A) and (B), the definition of synthetic at 7 U.S.C. § 6502 (22) and NOP Guidance 5033-1, describe if the substance can be classified as synthetic or as a nonsynthetic. Synthetic substances have been chemically modified from the source or origin or have been isolated from a natural source in a form that does not occur in nature.

(D) Nano Particles: Does the substance in its raw or formulated forms contain nanoparticles? If so, are they engineered nanomaterials or incidental nanomaterials as defined by the NOSB and NOP? (Policy Memo 15-2)

(E) Excluded Methods:

i. Is the substance created using excluded methods? This includes but is not limited to the following list of techniques found to be "excluded methods" by the NOSB: Targeted genetic modification (TagMo), Synthetic gene technologies, Genome engineering, Gene editing, Gene targeting, Gene Silencing, Accelerated plant breeding techniques, Synthetic Biology, cloned animals and offspring, plastid transformation, cisgenesis, intragenesis, agro-infiltration, transposons developed using invitro nucleic acid techniques, induced mutagenesis developed through in vitro nucleic acid techniques, cell and protoplast fusion (NOP policy Memo 13-1).

ii. If the substance is manufactured from agricultural raw materials, are those materials derived from genetically engineered crop, or crops resulting from excluded methods?

iii. If the substance is manufactured from other biological raw materials—such as those produced by fermentation or enzymatic action—are those biological materials derived from genetically engineered organisms, or crops organisms resulting from excluded methods?

Evaluation Question #2: For substances classified as synthetic: Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

Evaluation Question #3: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. (7 U.S.C. § 6518(m)(1)).

Data Required: The response to this request for development of technical information must describe any known chemical interactions between the petitioned substance and other substances allowed for use in organic production or handling as applicable. Describe any common combinations of materials used with the petitioned substance. Describe any substances resulting from these interactions.

Evaluation Question #4: Discuss (A) the toxicity and mode of action of the substance; (B) the toxicity and mode of action of its breakdown products or any contaminants; and (C) their persistence and areas of concentration in the environment (7 U.S.C. §6518(m)(2)).

Data Required:

(A) Describe whether the petitioned substance has been reported to have toxic effects and if its mode of action can cause adverse health and/or environmental effects.

(B) Describe whether the petitioned substance contaminants, or any of its breakdown products have been reported to have toxic effects and are capable of causing adverse health and/or environmental effects either present in the substance or arising from the degradation of the substance over time.

(C) Describe whether and how the petitioned substance and/or the breakdown products are persistent or cumulative when used in organic crop or livestock production as petitioned.

Evaluation Question #5: Discuss the probability of environmental contamination during manufacture, use, misuse or disposal of the substance (7 U.S.C. §6518(m)(3)).

Data Required: The response must describe the occurrence and severity of environmental contamination during the manufacture, use, misuse, or disposal of the petitioned substance. Data or reports from U.S. or International universities, agencies, independent groups, or other news reports should be included in this response when available. This data may also be available through review of assessments performed per EPA, FDA, and/or NIEHS review.

Evaluation Question #6: Discuss the effects of the substance on biological and chemical interactions in the agroecosystem. Include the physiological effects of the substance on soil, crops, livestock or other organisms (such as aquatic) that could be affected by the substance when used as petitioned. (7 U.S.C. §6518(m)(5))

Data Required: The response must describe the substances (the petitioned substance and/or its byproducts in combination with naturally occurring substances over time) that are capable of affecting the agro-ecosystem.

The response should describe whether and how the petitioned substance affects the survival and/ or function of soil organisms, such as, but not limited to earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by changing soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility or other parameter. For crops, the response should also describe whether and how the substance affects plant physiology by creating changes in plant pH, nutrient or water utilization, or other parameters when used as petitioned. For livestock production, the response should also describe whether and how the substance affects animal physiology by creating changes in behavior, fertility, metabolism or other parameters.

In addition, the response should describe the potential or actual impacts of the substances upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity, if possible.

Evaluation Question #7: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Data Required: Considering the information described in questions #1-6 and any other relevant information, discuss if the petitioned substance and/ or its breakdown products can cause harmful effects on the environment. Describe the biological, chemical and physical factors that may be affected by the use of the substance and/ or its breakdown products.

Harm to Human Health

Evaluation Question #8: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Data Required: Drawing upon responses to above questions #1-7 and any other relevant information, describe the reported health effects that may be attributed to the petitioned substance and/or its breakdown products.

Necessity and Alternatives

Evaluation Question #9: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Data Required: The response must describe the availability of non-synthetic or natural substance(s), including organic agricultural products, which could be substituted for petitioned substance. The examination should address:

- a comparison of the effect, form, function, quality, and quantity of the substitute non-synthetic or natural product with the petitioned substance;
- literature, including product or practice description, on performance and test data;
- name and address of the manufacturer(s), if applicable; and
- For livestock (and pet food) feed substances, information on technical barriers to production of organic agricultural products that may serve as alternatives.

Evaluation Question #10: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Data Required: The response to this request for development of technical information must describe the availability of specific alternative practices, such as cultural, biological, and mechanical controls, to the use of the petitioned substance.

When assessing alternative practices, the report should address:

- Literature, including specific practice description, on performance and test data;
- A comparison of the function and effectiveness of the proposed alternative practice with the petitioned substance; and,
- Frequency or prevalence of use of alternatives, if known.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Name, Title, Organization
- Name, Title, Organization
- Name, Title, Organization

All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

References