National Organic Standards Board
Materials/GMO Subcommittee
Discussion Document - Technical Report (TR) Template Update
Spring 2023

Intro/Background:
The Materials Subcommittee (MS) is seeking feedback on an update to the Technical Report (TR) template. The NOSB Policy and Procedures Manual (PPM)[1] defines a Technical Report as:

> *"… 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 (Appendix A), *"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 NOSB is presenting this discussion document to provide the community of experts with an opportunity to comment on updates to the format and an opportunity to include relevant questions for materials that are at risk for Excluded Methods. The Materials Subcommittee, with technical assistance from the National Organic Program (NOP) and the Organic Materials Review Institute (OMRI), has included the existing TR template for Handling (Appendix B1) and Crops/Livestock (Appendix C1), along with proposed updated templates for Handling (Appendix B2) and Crops/Livestock (Appendix C2).

Note: the NOSB has within its mandate to add specific questions to the TR template when necessary

Goals:
a. Harmonize the flow of information requested in the TR with the petition template (NOP 3011, 4.2[2]) and the Organic Foods Production Act (OFPA) criteria[3], while reducing redundancy.
b. Add relevant questions/sections for Excluded Methods discovery.

Discussion:
The Materials Subcommittee requests help to try to solve a gap/problem with the scope and format of TRs. The intended use of TRs is for the evaluation of specific substances. However, the Materials Subcommittee would like to request a TR for breeding methods, like induced mutagenesis, which may fall in the class of Excluded Methods. In the course of this work, the Materials Subcommittee discussed the possibility of using the TR process to evaluate many kinds of methods and practices in addition to the evaluation of specific substances. Excluded Methods may include both unique methods and specific materials in the creation/manufacture of a technique that is being evaluated for use in an organic system. The Materials Subcommittee is not advocating for a change in the TR process, but instead has

[1]National Organic Standards Board Policy and Procedures Manual https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf
[2]NOP 3011 Procedure - National List Petition Guidelines, 4.2: Items to be Included in a Petition, https://www.ams.usda.gov/sites/default/files/media/NOP3011PetitionProcedures.pdf
[3]Organic Foods Production Act, 7 U.S.C. 6517(c)(1)(B)(i), https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section6517&num=0&edition=prelim

framed several questions around the issue. The Materials Subcommittee asks the community's feedback/ideas on how best to proceed.

Questions to our Stakeholders:

1. Are there other relevant sections of OFPA, or the NOSB PPM, that refer to the TRs that could provide further information on improving the TR process? Is the Materials Subcommittee missing resources outside of OFPA and the NOSB PPM?
2. Where in the TRs is the best places for questions? What questions should be included to help the NOSB identify excluded methods in the organic supply chain?
3. Who uses TRs and for what purposes?
4. Is the TR template functional for all types of materials, methods, and practices? If not, does the NOSB need to develop another report template for methods/practices?

Subcommittee Vote

Motion to accept the discussion document on the TR template updates.
Motion by: Mindee Jeffery
Seconded by: Dilip Nandwani
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Appendix A

Policy and Procedures Manual – Pages 23-28[4]

propose to remove a material from the National List by developing a proposal for consideration by the whole Board, provided that all criteria in OFPA at Section 6518(m) are documented as having been addressed in the proposal. Procedures for such a petition will be the same as for changes to annotations or classification of materials, as amended at H2 in this PPM.

Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines sufficiency of the petition. If found insufficient, the subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.
3. Subcommittee (SC) determines if a technical review (TR) is needed.
4. SC may develop a discussion document based on the petition and forward that document to the full board for posting, and to solicit public discussion.
5. Technical report is completed and sent to the subcommittee for review.
6. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
7. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting ~45 days prior to public meeting.
8. The NOSB members analyze comments and vote on the proposal at the public meeting.
9. The NOSB chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
  - OFPA Checklist, NOP 3005-1
  - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

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[4] National Organic Standards Board Policy and Procedures Manual https://www.ams.usda.gov/sites/default/files/media/NOSB-PolicyManual.pdf

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

Step 2: Subcommittee (SC) determines sufficiency of the petition

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine if the petition is sufficient for SC review. This decision may be based on the following:

- Is there sufficient information in the petition for the SC to determine why or for what purpose the material is being petitioned?
- what is the petitioners proposed wording for listing the material?
- Is the information presented in the petition clear and consistent so that a proposal may easily be developed?

If the petition is found insufficient, the Subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.

Step 3: Subcommittee determines whether a Third-Party Technical Review is required

During this phase, which may occur simultaneously with the determination of petition sufficiency, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third-party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition that makes a technical review unnecessary?
- Do any previous technical reviews of other materials provide sufficient information?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides the Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)
OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List."(7 USC 6518 (k)(3))
The NOSB has not convened independent Technical Advisory Panels since 2005.
Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations
In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 4: Subcommittee may develop a discussion document based on the petition and forward that document to the full board and post it for public discussion

At the discretion of the Subcommittee (SC), the SC may develop a discussion document to:

- Solicit public comment about the material prior to a proposal being developed
- Provide opportunity for full board discussion prior to a proposal being written
- Allow the petitioner to hear public and board comments and give them an opportunity to submit petition addendums prior to a Subcommittee proposal and vote

A petition discussion document is optional, but if used, could allow for full board discussion of a material while a technical review is in process or if the SC determines a full board discussion would benefit the writing of the SC proposal on the material.

Step 5: Third Party Technical Review
During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third-party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.
- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS

Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 6: Technical Review Sufficiency Determination

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that it:

- Is consistent in format, level of detail, and tone
- Is technically objective and free from opinions or conjecture
- Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
- Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
- Is based on the best available information that can be obtained within the designated time frame
- Is thoroughly supported using literature citations
- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor. Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 7: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Read 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.
- Subcommittee members will prepare a written review of the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, will be finalized as a proposal for the next meeting.
- All proposals must be submitted to NOP for posting 45 days before the public meeting date.

Step 8: Action by Full NOSB

During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, listen to public comments, and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the Subcommittee, and the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.
- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

Step 9: The NOSB Chair will review all final recommendations and submit them to the NOP

Changes to annotations, classification of materials, or proposal to remove.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation, a reclassification of the substance, or removal of a substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

Additional considerations concerning Technical Reviews

Basic principles that should be considered when consulting with a third-party expert:

- 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 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 new petitions on hold.

- The Subcommittee determines the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third-party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.

  The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.
  Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf

Definitions

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.

Technical Advisory Panel (TAP) - Group of third-party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

Priority 1: A petition or proposal to remove a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - Priority 1, above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

Priority 2: A petition or proposal to remove a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a Priority 2, behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

Priority 3: A petition to add a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as Priority 3.

Priority 4: A petition to reconsider adding a material that had previously been rejected by a

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-32.311-2015, 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

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)).

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.

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.

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.

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)).

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.

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.

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.

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)).

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

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)).

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

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)).

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.

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)).

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.

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)).

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 #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)).

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

Evaluation Question #11: 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 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.

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)).

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,

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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Characterization of Petitioned Substance

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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) https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title7-chapter94&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGU3LWNoYXB0ZXI5NC1mcm9udA%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim or the USDA organic regulations, 7 CFR part 205 https://www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-M/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
https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.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(22); NOP 5032-1; NOP 5033-2]

(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.

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.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

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)).
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)).
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)).*
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)).
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)).
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. 518(m)(4)).
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)).
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 USDA organic regulations (7 CFR 205.605(a)).
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.

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 Information #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)).

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-32.311-2015 — 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

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? (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?

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)).

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.

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)).

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.

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)).

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.

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)).

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.

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)).

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.

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)).

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.

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)).

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.

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)).

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.

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)).

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.

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

Other Name:
List other names

Trade Names:
List Trade Names

CAS Numbers:
List CAS numbers

Other Codes:
List other codes

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 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 (OFPA), 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
https://inspection.canada.ca/organic-products/standards/eng/1300368619837/1300368673172

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.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
834/2007: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R0834&from=EN
889/2008: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0889&from=EN

Japan Agricultural Standard (JAS) for Organic Production—
https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html

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

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(22); NOP 5033-1]

(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.

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 (7 U.S.C. 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)). 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)).

(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)).
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))
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 parameters. 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)).
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)).
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)).
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.

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

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

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.