

NOSB MATERIALS COMMITTEE DRAFT

Sunset and the National List of Allowed and Prohibited Substances

Introduction - Need for Guidelines on Sunset of the National List

The Organic Foods Production Act of 1990 (OFPA or the Act) authorized a National List of Allowed and Prohibited Substances. The Act also provides that no allowed or prohibited substance would remain on the National List for a period exceeding 5 years unless the exemption or prohibition is reviewed and recommended for renewal by the National Organic Standards Board (NOSB) and adopted by the Secretary of Agriculture. This expiration is commonly referred to as sunset of the National List. The National List that was implemented on October 21, 2002 contained over 200 substances. This first sunset of the National List triggers a review process that must be concluded no later than October 21, 2007. If renewal is not concluded by that date, the use or prohibition of hundreds of materials will no longer be valid for the organic industry, causing most if not all of the organic industry to be in noncompliance with the National Organic Standards. Because this first sunset process involves Federal rulemaking that will likely span 3 years, the NOSB and the National Organic Program (NOP) are issuing this guidance in order to avoid expiration of the National List that became effective on October 21, 2002.

Background

Many laws or regulations are subject to periodic sunsets. The sunset may simply be an expiration of the law or regulation at a set date. Most often, though, a sunset includes the opportunity to revisit the continued need for the regulation, based on the conditions that justified the creation of the regulation in the first instance. And if a review is not concluded within a prescribed time period, expiration of the regulation is the usual outcome. If a review finds that the initial conditions still exist, the regulation is renewed for an additional prescribed time period, at which time the sunset review process begins again.

Thus, the regulation itself is not revisited except within the context of conditions or environment that may (or may not) have changed. An analogy is the biennial sunset of Federal advisory committees (e.g., the NOSB) and their operating charters. Every two years, the charter expires unless the Secretary reviews and renews the charter. Review and renewal does not entail rewriting the charter or amending the composition of the advisory committee. Review consists of evaluating the environment that caused the advisory committee to be created and determining that the need for the advisory committee remains based on that environment or set of conditions.

We consider the Congressionally-mandated sunset of exemptions and prohibitions contained in the National List to be a similar review and renewal process – that of the conditions that justified the exemption or prohibition in the first instance.

Overview of the National List Sunset Process

Section 6517 (e) of the Organic Foods Production Act of 1990 (OFPA) states “no exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition...within 5 years of...being adopted...and the Secretary has renewed such exemption or prohibition.”

In the case of the exemptions and prohibitions contained in the National List, the process begins with a notice to the public that sunset will occur. This is followed with a review by the NOSB of the conditions warranting the existing exemptions and prohibitions. The process concludes with the Secretary using public notice and comment rulemaking to renew the exemptions and prohibitions that were reviewed and recommended for continuation by the NOSB.

If the sunset process is not concluded within 5 years of the effective date that initiated the exemption or prohibition, the exemption or prohibition is automatically revoked. Accordingly, previously allowed substances become prohibited and previously prohibited substances on the National List become allowed for use in organic agricultural production and handling.

What Does Not Occur During Sunset?

The sunset process is not used to petition to add new substances to the National List, nor is it used to change an existing annotation. Sunset is only for the purpose of review of the continued need for substances already approved or prohibited for use in organic agricultural production and handling. The sunset process also does not mean a repeat of the original process that resulted in adding the substance to the List (e.g., technical advisory panels, or TAPs, are not automatically triggered for each material already on the National List). The sunset process acknowledges deliberations of past Boards and the evolution of the materials review process. The NOSB has determined, based on scientific evaluations and consideration of public comment, that substances currently on the National List are already compatible and consistent with OFPA and its implementing regulations. Since the substances have already been found compatible and consistent with OFPA and its implementing regulations through the petition process (65 FR 43259), the sunset review should focus on the continued need for these substances in organic agricultural production and handling.

At this time, there is no evidence to conclude that previous deliberations and recommendations made by the NOSB are no longer valid for the organic industry. This conclusion is based on the lack of petitions received to remove an approved or prohibited substance from the National List. The National List petition process allows any person to petition the Secretary at any time for the purpose of having the NOSB re-evaluate a substance on the National List and consider withdrawing its exemption or prohibition. Since implementation of the NOP standards, one petition to remove a substance has been received (to withdraw the exemption for sodium nitrate as an allowed substance in organic crop production). The re-evaluation of sodium nitrate engendered the support of the organic industry through public comment to the NOSB. As a result of the NOSB's re-evaluation and consideration of public comment, the NOSB recommended the continued use of sodium nitrate, and this recommendation was supported by the Secretary.

Is This the Only Process for Sunset?

In contemplating and preparing for the sunset of the National List, the NOSB and NOP researched sunset provisions of various Federal agency regulations and laws as well as State laws and regulations. The process described here is consistent with other sunset processes for laws and regulations. It provides the legal sufficiency needed to comply with OFPA, the Administrative Procedure Act, Regulatory Flexibility Act, Executive Order 12866, Executive Order 12988, and other Federal mandates related to rulemaking. It also ensures that decisions made through this sunset review are non-arbitrary and transparent. This process is also the most efficient among alternatives that were considered, which we discuss below.

1. **Repeat the Original National List Process** – One method of addressing the sunset of the National List is to simply start over. That is, assume that all of the substances on the National List were being considered as if the National List was being created anew, and would be implemented on October 21, 2007. There are approximately 250 substances on the National List that became effective for use by organic producers and processors on October 21, 2002. Those substances being added to the National List were the result of hundreds of hours of meetings and hearings held from 1995 to December 2000. Starting over, using the process now in place to add an exemption to the National List, each material would go through a TAP review, followed by a request for public input at a Board meeting, before a recommendation would be made to the Secretary. A TAP review of 250 materials would cost over \$1 million – roughly the entire fiscal year budget for the NOP – and each material could take up to 270 days of research. Even assuming the TAP reviews could be cut in half in terms of time and cost, the entire process of re-generating the original National List would take over 10 years. Moreover, sunset is not a one-time event. Sunset occurs for each material every five years. Thus, in 2012, the 250 materials from the original National List, plus any materials added in 2007, will need to be renewed. In fact, every year after 2007, materials that were added to the National List beginning in 2003 will need to be renewed or their exemption or prohibition will expire. As time passes, sunset will become a larger process each year, as long as substances continue to be added to the National List.

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2. **Select Substances to Review During Sunset** – Another suggestion might be to simply pick and choose substances from the National List to review during sunset, thus paring down the number of substances that would receive review. This option would require some type of criteria for selecting the substances that receive review. The criteria themselves would need to be part of a rulemaking procedure, however, in order to ensure transparency and public input. The larger problem with this option is that by law, **every** substance's exemption or prohibition becomes invalid after 5 years without review. And there is no basis in either the Act or the regulations for selective review. The goal of providing closer scrutiny for certain substances can be accomplished within the sunset process we are outlining here, once public comment has been received and the NOSB has reviewed the public comment for indications that some substances may merit further review and analysis. Finally, this option circumvents the full review required by the Act and is likely to invite legal challenge.

Recommendation for the First Sunset Scheduled to Conclude by October 21, 2007

Given the magnitude of the initial sunset process, the NOSB and NOP believe that review must begin immediately. With public involvement, NOSB review, and a major rulemaking involving interagency clearance and Congressional review, NOP estimates it will take over 3 years to complete this initial sunset process. With approximately 40 months until the expiration of the National List, any delays could jeopardize the conclusion of the sunset review process and cause problems for industry. Also during this time period, sunset will be triggered for substances whose exemptions and prohibitions expire in 2008 (all substances that were added to the National List in 2003). The process outlined here must be suitable to use for all subsequent sunsets that occur following the sunset that concludes in 2007. A detailed timeframe of the National List Sunset Review process is attached to this document (attachment A).

The sunset process outlined here is a rulemaking process. NOP will initiate the Federal rulemaking process through the publication of a Federal Register notice announcing the expiration of designated substances on the National List. This notice will also invite the public to comment on the continued need for the use or prohibition of the designated substances contained on the National List. Through this opportunity to comment, the public should provide documentation to support any positions made about specific materials on the National List. Comments must be supported by scientific, environmental, and industry data, manufacturing information, and other relevant evidence that addresses the criteria in OFPA and its implementing regulations.

NOP will receive public comments and forward them to the NOSB for review. During the sunset process, the NOSB will work extensively with the public to review the need for the continued allowance or prohibition of substances contained on the National List. The NOSB will use public comment to help identify which approved or prohibited substances are of concern to the organic industry. Based on public comment received, the NOSB may decide that certain substances warrant a more in-depth review, requiring additional information or research that considers new scientific data and technological and market advances. TAP (Technical Advisory Panel) review may be requested by the NOSB. After consideration of public comment and review of data, the NOSB will make a recommendation to the Secretary regarding the continued use or prohibition of substances on the National List.

Recommendations Must Be Based on Evidence

When original recommendations were made for materials to be added to the National List, recommendations were based on TAP analyses, public input during Board meetings, and public input provided to the Secretary during rulemaking. Exemptions were accepted because the evidence available to the NOSB at the time of review demonstrated that the substances were found not harmful to human health or the environment; the substances were necessary because of the unavailability of wholly nonsynthetic alternatives; and the substances were consistent and compatible with organic practices. This same approach is required in order for the Secretary to publish a recommendation to discontinue an exemption on the National List: the NOSB must base its recommendation on scientific, environmental, and industry impact (attachment B), in addition to evidence of inconsistency and incompatibility.

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For example, to recommend that an **active synthetic substance or a synthetic inert ingredient be discontinued** for use in organic crop or livestock production, the recommendation must provide scientific, environmental, and industry impact, manufacturing information, and other relevant evidence that shows that the synthetic substance is (1) harmful to human health or the environment; (2) not necessary to the production of the agricultural product because of the availability of wholly nonsynthetic substitute products; and (3) not consistent with organic farming and handling. The Decision Sheets in attachment C will be used by the NOSB to demonstrate the success or failure of the substance to meet the OFPA criteria. The public should review the Decision Sheets in order to provide the most useful information to help the NOSB in formulating their recommendation to the Secretary.

In the case of a recommendation to **allow a previously prohibited nonsynthetic** substance in organic crop or livestock production, the recommendation must present new arguments that do not simply restate prior positions and evidence on which prior Boards have ruled. The recommendation must provide scientific and environmental data, manufacturing information, and other relevant evidence showing the nonsynthetic substance is not harmful to human health or the environment and that it is now consistent and compatible with organic farming, OFPA, and its implementing regulations. The Decision Sheets in attachment C will be used by the NOSB to demonstrate the substance complies or does not comply with the OFPA criteria. The public should review the Decision Sheets in order to provide the most useful information to help the NOSB in formulating their recommendation to the Secretary.

In recommending the **discontinued use of an allowed nonsynthetic or synthetic** substance in organic handling, the recommendation must provide scientific, environmental, and industry impact, manufacturing information, and other relevant evidence that show how the synthetic substance is (1) harmful to human health or the environment; (2) not necessary to the production of the agricultural product because of the availability of wholly nonsynthetic substitute products; and (3) not consistent with organic farming and handling. The recommendation must also provide evidence demonstrating how the substance meets or does not meet the criteria specified in section 205.600(b) of the NOP regulations. The Decision Sheets in attachment C will be used by the NOSB to demonstrate the failure of the substance to comply with OFPA. The public should review the Decision Sheets in order to provide the most useful information to help the NOSB in formulating their recommendation to the Secretary.

Alternatives to Allowed Substances Must Be Available

All recommendations to discontinue the use of allowed substances require the availability of viable alternatives. Evidence should be presented that adequately demonstrates that the recommended alternative's function and effect are equal or superior to that of the substance under review. When asserting that an alternative substance(s) exists, commenters should cite the name and address of the manufacturer of the alternative(s). Further, the commenters should include any literature, including product or practice description, performance and test data, and reference standards, name and address of producers who have used the alternative(s) under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following chart illustrates the types of alternatives that must be recommended to replace substances being recommended for discontinuation on the National List.

If the substance is used in the following production system...	And is a (an)...	Then the recommended alternative must be a (an)...
Crop or Livestock	Active Synthetic	Allowed Synthetic or Nonsynthetic Substance or management practice
Crop or Livestock	Synthetic Inert (pesticidal)	Nonsynthetic (non-ag) Inert (pesticidal)
Handling	Synthetic	Allowed Synthetic or Nonsynthetic (non-ag) Substance or management practice

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Handling	Nonsynthetic (non-ag)	Agricultural Product or management practice
Handling	Nonorganic Agricultural Product	Organic Agricultural Product

Once the NOP receives the recommendation from the NOSB regarding the continuation of substances on the National List, the NOP will review the NOSB recommendation and accompanying documentation and publish a proposed rule to renew the National List. The public will have 90 days to comment on the proposed rule. All comments will be made available on the NOP website. Once public comment is received, the NOP will review the comments to the proposal and publish a final rule to renew the National List.

[Note – The Materials Committee notes that this document does not address the following: 1) the need for a national database to track all petitioned, approved, and rejected materials; 2) the procedures and criteria the NOSB will use to prioritize and conduct reviews of substances which require additional information, and therefore will not be included in the first list submitted to the Secretary; and 3) the need to establish a staggered review schedule so that future boards are not burdened by the majority of the National List expiring at the same time in the future. These items are to be retained as committee and Board work plan items.]

Conclusion

The first sunset of the National List triggers a review process that must be concluded no later than October 21, 2007. If renewal is not concluded by that date, the use or prohibition of hundreds of materials will no longer be valid for the organic industry. Because the first sunset process involves Federal rulemaking that will likely span 3 years, the NOSB and the National Organic Program (NOP) are issuing this guidance in order to avoid expiration of the National List that became effective on October 21, 2002.

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Attachment A Sunset Review Process

1. NOP develops Regulatory Review work plan and drafts Advanced Notice of Public Rulemaking **(60 days)**
2. OGC Review and Departmental Clearance **(60 days)**
3. NOP publishes a FR Notice for an Advanced Notice of Public Rulemaking regarding expiration of applicable National List provisions **(Allow 60 days for public comment)**
 - a. Comments for the continued use of a substance(s) should provide reasons why the substance(s) remain necessary for use or prohibition in the production or handling of organic agricultural products. Supportive documentation should be included.
 - b. Comments against the continuation of a substance(s) should provide reasons why the substance(s) are **not** necessary for use or prohibition in the production or handling of organic agricultural products. Supportive documentation should be included.
4. NOP receives comments, forwards to NOSB, and posts to the NOP website
 - a. As comments are received, they are forwarded to the NOSB.
 - b. All comments received by the NOP should be in NOSB possession **no later than 7 days** after the closing date for public comment.
5. NOSB reviews comments and makes recommendation to NOP **(90 days)** [Items where public comment indicates a need for additional technical review may need longer than 90 days for the NOSB to gather information, conduct a TAP review (if warranted), and complete a recommendation.]
 - a. Recommendations for the continuation of a substance(s) will be supported by prior rulemaking to include such substances on the National List.
 - b. Recommendations that suggest a substance(s) is no longer needed for use in organic agricultural production or handling must document:
 - i. Why the substance(s) is no longer needed on the National List and
 - ii. How the, applicable:
 - Synthetic crop or livestock substance(s):
 - Does not meet OFPA criteria;
 - Has an identified allowed synthetic or nonsynthetic alternative that is available in the appropriate form, quality, or quantity to fulfill the essential function in the organic production system; or
 - Has an allowed management practice that makes use of the substance unnecessary.
 1. *Recommendation must fully demonstrate that the listed substance does not meet OFPA criteria by using Decision Sheets.*
 2. *Recommendation must be supported with scientific data, production data, manufacturing information, industry impact that substantiates the position against the listed substance and for the identified allowed synthetic, nonsynthetic or management alternative.*
 - Prohibited nonsynthetic crop or livestock substance is “now” compatible and consistent with OFPA and its implementing regulations.
 - *Recommendation must demonstrate that the substance meets OFPA criteria by using Decision Sheets;*
 - *Recommendation must be supported with scientific data, production data, manufacturing information, and other relevant material that substantiates position; and*
 - *Recommendation must strive to present new arguments that do not simply restate prior positions and evidence on which prior Boards have ruled.*
 - Synthetic handling substance(s):
 - Does not meet OFPA or NOP 205.600(b) criteria;
 - Has an identified nonsynthetic or allowed synthetic alternative that is available in the appropriate form, quality, or quantity to fulfill the essential function in the organic handling system; or

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- Has an allowed management practice that makes use of the substance unnecessary.
 - *Recommendation must fully demonstrate that the listed substance does not meet OFPA or NOP 205.600(b) criteria by using Decision Sheets.*
 - *Recommendation must be supported with scientific data, production data, manufacturing information, industry impact that substantiates the position against the listed substance and for the identified nonsynthetic or allowed synthetic alternative.*
 - Nonsynthetic handling substance(s):
 1. Does not meet OFPA or NOP 205.600(b) criteria;
 2. Has an identified allowed synthetic or nonsynthetic, nonorganic agricultural alternative that is available in the appropriate form, quality, or quantity to fulfill the essential function in the organic production system; or
 - Has an allowed management practice that makes use of the substance unnecessary.
 - *Recommendation must fully demonstrate that the listed nonsynthetic does not meet OFPA and NOP 205.600(b) criteria and its implementing regulations by using Decision Sheets.*
 - *Recommendation must be supported with scientific data, production data, manufacturing information, industry impact that substantiates position against the listed substance and for the identified alternative.*
 - Nonorganic agricultural product used in handling:
 - Has an identified organic agricultural alternative that is available in the appropriate form, quality, or quantity to fulfill the essential function in the organic production system.
 - o *Comments should be supported with production data, manufacturing information, and industry impact that substantiates position for the alternative product. [Note – Evaluation of commercial availability should follow procedures specified in the NOSB recommendation adopted April 29, 2004.]*
6. NOP drafts proposed rule **(90 days)**
 7. OGC Review **(90 days)**
 8. Interagency Review **(90 days)**
 9. OMB Review **(90 days)**
 10. NOP publishes proposed rule **(90 day public comment period)**
 11. NOP receives comments and posts to the web
 12. NOP reviews and responds to public comment. **(90 days)**
 13. NOP drafts Final Rule **(90 days)**
 14. **OGC Review (90 days)**
 15. Interagency Review **(90 days)**
 16. OMB Review **(90 days)**
 17. Congressional Review **(60 days)**
 18. Final Rule is Final

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Attachment B

The following list includes, but is not limited to, suggested documentation to submit with a recommendation to remove a substance from the National List:

1. Name of the substance to be removed;
2. Justification statement explaining why the substance should be removed from the National List.
3. Category on the National List (crops or livestock) from which the substance is being recommended to be removed;
4. Source of the substance;
5. Use(s) of the substance;
6. Manufacturing information (*from the source of the ingredients used to manufacture the substance to the final product*);
7. Evidence that an alternative substance(s) or management practice(s) is available in the appropriate form, quality, or quantity to fulfill the essential function in the organic production or handling system:
 - o This evidence may include, but is not limited to:
 - Research or field trials comparing the effectiveness of the alternative to the approved substance;
 - Analysis of research data comparing the alternative to the approved substance;
 - Environmental impact data regarding the alternative;
 - Qualitative data concerning the alternative;
 - Quantitative data regarding production and distribution of alternative;
 - Physical and chemical composition of alternative;
 - Federal regulatory status of alternative;
 - Source of alternative;
 - Production and marketing data (quantity, distribution, sales, manufacturing, etc.)
8. Scientific evidence demonstrating the beneficial effects that use of the identified alternative would have on the environment, human health, or farm ecosystem.
9. Scientific evidence demonstrating the adverse effects to the environment, human health, or farm ecosystem from use of the currently listed substance.
10. EPA, FDA, and State regulatory authority registrations and provisions on use of the currently listed substance;
11. The listed substance's physical properties and chemical mode of action including the:
 - chemical interactions with other substances,
 - toxicity and environmental persistence,
 - environmental impacts from its use or manufacture,
 - effects on human health, and
 - effects on soil organisms, crops, or livestock;
12. Safety information about the listed substance, including a:
 - Material Safety Data Sheet (MSDS);
 - Substance report from the National Institute of Environmental Health Studies;
 - Health and safety data and research from FDA and EPA or any other Federal regulatory authority (e.g. Food Safety and Inspection Service, Animal and Plant Health Inspection Service, etc).
13. New research information about the listed substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to the recommendation for the substance's removal from the National List.

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Attachment C

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO OR REMOVED FROM THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance _____

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]				
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]				
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]				
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]				

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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Category 2. Is the Substance Essential for Organic Production?

Substance _____

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]				
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]				
3. Is the substance created by naturally occurring biological processes? [6502 (21)]				
4. Is there a natural source of the substance? [§205.600 b.1]				
5. Is there an organic substitute? [§205.600 b.1]				
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]				
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
9. Is there any alternative substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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Category 3. Is the substance compatible with organic production practices?

Substance _____

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]				
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]				
5. Is the primary use as a preservative? [§205.600 b.4]				
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]				
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;				
b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.