



**National Organic Standards Board Meeting  
Tucson University Hotel, Tucson, AZ  
April 25-27, 2018**

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**National Organic Standards Board  
Compliance, Accreditation and Certification Subcommittee  
Import Oversight Discussion Document  
February 25, 2018**

## **I. INTRODUCTION**

Since the passage of the Organic Foods Protection Act into law in 1990, organic trade has grown to a nearly \$50 billion market in U.S. sales alone. Strong year over year growth has led to an increase in imports, particularly in grains. Integral to past and future growth is consumer confidence in the integrity of the USDA organic label. Recent press, NOP enforcement actions, and testimony from stakeholders have raised concerns around fraudulent imports of organic products. Organic supply chain integrity relies on a public/private partnership that has different roles for industry (growers and handlers), certifiers, and the USDA in a global organic control system. It is important that further actions are taken to improve the integrity of the organic supply chain and global control system to ensure U.S. businesses do not lose market share to fraudulent products and U.S. consumers get the product they expect.

## **II. BACKGROUND**

On August 10, 2017, the USDA issued a memo to the NOSB on oversight of imported organic products. In this memo, the USDA outlined a number of actions taken by the NOP to deter fraudulent shipments. Additionally, the memo expressed the AMS's priority to explore additional measure that would strengthen the global organic control system. AMS specifically requested the NOSB "provide recommendations on improving the oversight and control procedures that are used by AMS, certified and operations to verify organic claims for imported organic products."

To support this work AMS convened a panel at the Fall 2017 NOSB meeting. This panel was composed of federal agencies including representatives from NOP, AMS, APHIS, and CBP to discuss the federal perspective and tools used in relation to imports of agricultural products. The NOP also provided suggestions on areas of work. The NOP is convening a panel at the Spring 2018 NOSB meeting with representatives from certification agencies and industry representatives to provide testimony on import oversight.

## **IV. DISCUSSION**

In order to gain further insight and background on the diverse perspective and opportunities to increase integrity in the global organic control system, the NOSB is seeking input from the public. Several specific subject areas are outlined below with questions. We also ask the public to provide their perspective on what actions or opportunities would have the greatest impact to increase integrity in the global organic control systems, whether listed here or not.

The NOSB plans to develop proposals for Board voting once we have received sufficient input and background information, as soon as the Fall 2018 NOSB meeting.

## **VI. REQUEST FOR PUBLIC COMMENT**

We present over 75 questions below across 10 different subject matters and a broad area asking what areas we are missing. We realize most members of the public will not be able to answer all questions – we encourage all credible responses, even if they address just one or a few of the questions.

## 1) Role of documents in an organic supply chain with a focus on imports.

There are a number of documents created or utilized to import agricultural commodities. These documents are created by multiple parties, including but not limited to: export governments, U.S. government, exporter, importer, shipping company, and third parties. Some of the documents are: sales contracts, pro forma invoices, commercial invoices, customs invoices, inspection certificates, insurance certificates, phytosanitary certificates, sanitary certificates, health certificates, fumigation certificates, certificate of origin, packing lists, bill of lading, waybills, export permit/license, import permit/license. These documents may or may not document the organic status of the shipment since organic verification documents like organic certificates or transaction certificates are issued in addition to these other documents.

### *Questions:*

- a) Should it be a requirement that the organic status of a product be recorded on all documents including those listed above? How would this increase organic integrity? What impact would this have on the industry?
- b) Which documents (listed above or in addition) are necessary to verify an import supply chain? How well do these documents serve to prevent fraud?
- c) Some imported products change hands once or several times while in transit. How do these documents appropriately trace and verify the organic status of the products for the ultimate importer?
- d) Different documents in the import supply chain are issued by different parties. Are some documents or issuing parties (like export governments) more reliable than others? Should these documents be required?
- e) Should the use of organic tariff codes (when they exist) be required when organic products fall under those codes? If so, should failing to use an organic tariff code negate the organic status of the imported product? Should the U.S. government be working actively to vastly increase the number of organic tariff codes? What impact would these changes have on the industry?
- f) Do organic import certificates (as required in the EU) or organic transaction certificates provide value in documenting the organic status of a shipment? What are the strengths and weaknesses of this system, and what can be done to further strengthen this process? Should a similar document be required for the import of organic products into the U.S., and if so, who should issue the document? What impact would this have on the industry? How do certifiers currently issuing Transaction Certificates utilize this data in audits of the certified operation?
- g) Are there procedures or systems that could be put in place that are not reliant strictly upon documentation, such as direct communication between the certifiers of the commodities being traded, that verifies the organic status of items being bought and sold?

## 2) Role of Importers in the organic supply chain.

Several international organic standards, like the EU or Japanese, require the certification of importers regardless of their interaction with organic products. Similarly, U.S. government regulations like FSMA have special requirements for importers of record as the first U.S. entity taking some level of responsibility for the imported product.

### *Questions:*

- a) Should importers of organic products be required to be certified regardless of how they handle a product? What impact would this have on the industry?
- b) The organic control system relies on a process that generally checks the organic status of a product one step back to the last certified operations. Should importers be held to a stricter standard of documentation or other forms of communication to verify the organic status of products being imported into the U.S.? What additional requirements should be placed on

importers given their critical spot in the supply chain? What impact would this have on the industry?

- c) What documents or system should be developed for an importer to verify the organic status of a shipment?

### **3) Role of uncertified operations in the supply chain.**

The current regulations exempt several types of operations from organic certification based on how products are handled. Operations may be involved in the import supply chain but not be certified - for example, brokers and traders who do not take possession but take ownership of a product are not required to be certified. Similarly, transport operations and customs brokers who are involved in the logistical transport or clearance of shipments are not required to be certified. CBP licensed private entities known as Customs Brokers serve a unique role in ensuring imports meet the documentation/regulatory requirements for import into the U.S.

- a) What are examples of uncertified handlers in import or domestic supply chains? Should these operators be certified or not, what additional value would this bring, and what impact would this have on the industry?
- b) Should operations that take ownership of products or operations that market but don't own products be required to be certified? What impact would this have on the industry, and how would this improve supply chain integrity?
- c) What role do customs brokers play in the organic control system? How could customs brokers be further engaged with organic integrity through regulation or other means? What impact do uncertified customs brokers have on the organic control system?
- d) How can audit trail documentation as well as systems of verification be improved with these types of operations?

### **4) Global and National organic crop acreage information.**

Several data points are required by the USDA, either as part of annual reporting requirements or to populate the Organic Integrity database. A piece of information not required is acreage and yield information at the production level.

*Questions:*

- a) Would including production acreage and yield information in the Organic Integrity database serve to strengthen global organic control systems? If so, how would this information be used? What concerns do producers have in making this information public?
- b) Is acreage and/or yield information currently being accumulated by certifiers? What concerns do certifiers have in collecting and communicating the information to the NOP?
- c) Is both acreage and yield information important?
- d) Should acreage and yield information be proprietary to the operations and not be communicated? What would be the impact of sharing the information with certifiers and ultimately the NOP and public (thru the Organic Integrity database)? If privacy and other concerns prevent publishing individual information, would aggregate data be helpful and at what level of aggregation (state, country, etc.).
- e) Are there other means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis?
- f) Should these reporting requirements also be required of countries operating under an equivalency agreement?
- g) Can this acreage and yield information be a basis by which certifiers can track the approximate volume of product an entity would be allowed to sell under their organic certificate?

**5) Equivalencies, Recognition Agreements and certified operation databases (like the Organic Integrity database).**

The NOP designed and maintained Organic Integrity database serves as a way to independently and rapidly verify the authenticity of an organic certificate. This database includes all operations certified to USDA organic regulations by an NOP accredited certifier. This database does not include operations in equivalent countries eligible to export to the U.S. as organic nor operations certified to the USDA regulations by a certifier operating under a recognition agreement.

*Questions:*

- a) Should the NOP require foreign governments to maintain a similar database with certified operator data in its equivalency and recognition agreements?
- b) Should this data be required to be integrated into the Organic Integrity Database?
- c) How would this data serve to strengthen the global organic control system? Is this system currently being utilized by industry or certifiers, and if so, how?

**6) The role of residue testing to verify bulk shipments of grain.**

USDA organic regulations require certifiers, on an annual basis, sample and test from a minimum of five percent of the operations they certify. Testing for residues has been an integral part of some organic control systems. For example, this is commonly required in Europe and is part of the procedures of the California State Organic Program.

*Questions:*

- a) Should testing of imports be required? Does testing provide useful information, or is it situational? If situational, please provide situations where it is useful or not useful. What burden would this put on the industry? What party (importer, exporter, other) should be responsible for testing?
- b) Should testing be required if the shipment passes a certain market value or size threshold?
- c) If testing should be completed, what type of testing should be done?

**7) Verification of organic status in perishable supply chains.**

Fresh produce supply chains are unique. Such products cannot be fully packaged due to their nature and requirements for refrigeration, inspection, sampling, and respiration. This makes fresh produce especially vulnerable to cross contamination and difficult to label and track. Fresh produce transactions often occur very quickly due to their perishable nature.

*Questions:*

- a) What additional actions can be taken to increase supply chain integrity in fresh produce supply chains?
- b) Are there difficulties experienced by the industry in documenting the organic status of organic produce offered for purchase? What are some potential solutions to better ascertain the organic status of produce offered for purchase?
- c) In an organic fresh produce supply chain, which operators should be certified (transport operators, storage warehouse, distributors, retail distributors, brokers, etc.)? What impact would this have on the industry?  
Is there repacking of fresh produce currently occurring by non-certified handlers?

**8) Role of certifier/operation when certifying a commodity in a third country with import controls on the commodity.**

Some commodities imported into the U.S. from certain origins may be subject to fumigation or other treatment in order to be imported into the U.S. as a requirement of APHIS, another government agency, or by statute. The Fruits and Vegetables Import Requirements (FAVIR)

database lists the requirements for fresh fruits and vegetables, and the Seeds Not for Planting lists several other requirements for non-fruit or vegetable commodities.

- a) Should certifiers of operators who are producing commodities subject to import restrictions or mandatory fumigation conduct further assessments to verify a compliant marketing plan is in place for said commodities?
- b) Is this currently being done by certifiers, and have certifiers operating abroad had this activity verified during NOP accreditation audits?
- c) Should certified operators importing products from abroad conduct specific assessments related to mandatory fumigations or treatments? Is this currently done by certifier's who are certifying importers?
- d) Do certifiers have the expertise, training, and ability to conduct these audits/risk assessments? What additional training would be helpful to certifiers and operators?

**9) Additional controls for origins with documented fraud or integrity issues.**

It is common in other import regimes for food control or phytosanitary regulations to impose additional requirements from regions with documented issues or fraud. In August 2017, additional control and reporting requirements were imposed by NOP for a set period of time on certifiers of handling operations in regions identified as high risk. Similar actions have been taken by the EU in regards to the import of certain organic products from some countries.

- a) Should the NOP develop an ongoing system to impose additional requirements on operations doing business in or with countries or regions with documented fraud?
- b) Should testing be mandatory for shipments from these regions? If so, where should testing be done?
- c) What criteria should be used to identify a region of increased concern? What role do changes in USDA ERS import data play in these evaluations?
- d) What impact would this have on the industry?
- e) Should the NOP develop specific channels of communication with our global organic certification partners, to better identify, track, deter and prevent fraudulent organic products? Are there examples of this type of communication already present and how could this be improved and implemented?

**10) Full Supply Chain audits.**

Organic control systems currently rely on checking the organic status one step back from the party from which products are being purchased or the last certified operation in the supply chain). The control system makes it difficult to conduct full supply chain audits (from shelf to field) if each operation and certifier is only looking one-step back.

*Questions:*

- a) Do full supply chain audits offer value in ensuring organic integrity? If so, who should conduct these audits, and when?
- b) What are the challenges of completing full supply chain audits?
- c) How could the start and end points of a supply chain audit be defined in a systematic and repeatable way (commodity-based, geography-based, other criteria)?
- d) What are possible approaches that a full supply chain audit could take (desk audits, physical audits, etc.)?

**11) Other Areas/Questions/Opportunities/Threats.**

- a) What other areas should the NOSB focus on in order to have the greatest impact on strengthening the global organic control system or to deter fraud in an organic supply chain? What are the areas of greatest weakness in the global organic control system, and what can be done to improve them?

- b) What other information would be helpful to inform the NOSB deliberations and work on composing recommendations?
- c) Can the NOP accreditation system play a role in providing consistency in the oversight of both domestic and international certifiers in the area of global trade? Do you have suggestions for specific activities or systems that could be implemented?

**Subcommittee vote**

Motion to approve this discussion document on Import Oversight

Motion by: Tom Chapman

Seconded by: Ashley Swaffar

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 1



**National Organic Standards Board**  
**Compliance, Accreditation and Certification Subcommittee Proposal**  
**Inspector Qualifications and Training**  
**February 26, 2018**

## **I. INTRODUCTION**

Since passage of federal organic standards over twenty years ago, the organic sector has seen rapid growth to nearly \$50 billion in sales in the U.S. Such growth has driven expansion in organic production around the globe, and in turn, the growth of increasingly complex organic supply chains. With well-publicized incidents of proven fraudulent imports in the last year, and recognition such fraud impacts all players in the trade, the need for qualified inspectors experienced in a broad range of operations diverse in scope and scale has never been greater.

Inspectors play an essential role in organic certification, often serving as the sole public face of a certification agency (certifier) to the certified operation. Inspectors are the eyes and ears of the certifier, responsible for verifying and documenting organic control points. They play a crucial role in protecting the integrity of the organic supply chain.

USDA organic regulations require that certification staff, including inspectors, have sufficient expertise in organic production and handling techniques (7CFR 205.501(a)). This proposal seeks to highlight the criteria for qualifications and training necessary to be an effective and competent inspector. The Subcommittee acknowledges this discussion can just as easily relate to certification reviewers—and certifiers at large—as it does to inspectors. The criteria outlined below should be considered essential for all individuals and certifiers; however, for the purpose of this document we are focused on the inspector.

The Subcommittee recognizes the extensive body of work that has already been created in an effort to build the foundation for a skilled pool of organic inspectors. We do not intend for this to substitute for that work but to further build on this foundation, with particular focus on complex organic supply chains.

Many resources regarding inspector training and qualification exist and there are general agreements among certifiers on the minimum qualifications they outline. Nevertheless, USDA organic regulations do not include mandatory requirements for inspector qualifications or training. The Subcommittee proposes that the establishment of mandatory qualifications, ideal levels of experience or background, and compulsory continuing education tied to the scope and scale of operations to which inspectors would be assigned, would strengthen the certification system.

## **II. BACKGROUND**

The initial and continuing training of inspectors and the establishment of minimum and ideal qualifications is not a new topic. Since 1991, the International Organic Inspectors Association (IOIA) has promoted and provided inspector training to provide a basis for consistency and integrity in certification. Certifiers and independent training organizations provide training for staff and contract inspectors, addressing changes and updates to the regulations to provide a basis for consistency and integrity in certification. Certifiers provide specific training to ensure that the contract inspectors they work with are familiar with the forms, procedures, and processes of their agencies. Training resources include the International Organic Inspectors Association (IOIA), the American National Standards Institute (ANSI), the International Organization for Standardization (ISO), the Accredited Certifiers Association (ACA), state agency-sponsored investigative trainings, and others.

Inspectors may be independent contractors working for one or more certifiers, or they may be directly employed by a certifier. Most certifiers have policies stating minimum qualifications for contracted and staff inspectors and may be responsible for the initial training of an inspector. However, independent contractors are responsible for establishing their own knowledge base, maintaining their knowledge, and keeping their expertise current through continuing education. Such diverse backgrounds and training schemes make for an inconsistent baseline of knowledge and practice, exposing the certification system to potential weaknesses.

In an April 2012 memo to certifiers, the NOP recognized the vital role inspectors play in ensuring organic integrity. The memo reminded certifiers of the importance of a rigorous hiring and selection process when considering inspection personnel. The NOP noted plans to release draft guidance covering the qualifications necessary for inspectors and reviewers, however, guidance was not published.

In 2011, NOP entered into a contract with IOIA to further describe baseline qualifications and continuing education of inspectors. In using this work, in early 2018 the ACA developed a best practices document for organic inspector qualifications. Both have provided valuable insight into the development of this discussion document.

### **III. RELEVANT AREAS OF THE RULE AND RELATED DOCUMENTS**

#### **[205.501\(a\) General requirements for accreditation.](#)**

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

- (1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;
- (4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;
- (5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.
- (6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

**[NOP Memo to Accredited Certifying Agents: Criteria and Qualifications for Organic Inspectors, April 2012](#)**

**[NOP 2027, Instruction: Personnel Performance Evaluations, March 2017](#)**

**[CACs Proposal: Personnel Performance Evaluations of Inspectors, April 2017](#)**

**[Accredited Certifiers Association Guidance on Organic Inspector Qualifications, February 2018](#)**

## **IOIA Criteria for Inspectors and Reviewers working for NOP Accredited Certifying Agencies, November 2011 (See Appendix 1)**

### **IV. DISCUSSION**

Inspector qualifications can be broken down into several distinct areas:

#### **1. Knowledge**

Inspector knowledge includes proficiency in inspection & auditing techniques; strong understanding and knowledge of the USDA organic regulations; understanding of organic certification and inspection processes; and familiarity with the documents and procedures of the certifier whom they represent. It is essential this knowledge base be in the scope and scale of production in which the inspector is working.

#### **2. Skills**

Essential skills include keen observation; clear communication in spoken and written form as well as an ability to articulate regulations and requests for information; a high level of organization; and strong investigative skills. As much as an inspector must be able to communicate and observe, they must also know how to read a situation and interviewee, to listen and to allow an operator the space to convey answers to questions and the knowledge they hold of their operation.

Other skills and abilities vital to the inspector's role are a code of honest and ethical work practice; diplomacy; impartiality; and an overall professional approach to their work.

#### **3. Experience**

An inspector must have experience inspecting the specific scope of operations to which they are assigned. For example, while an inspector may have experience with and deep knowledge of poultry operations, they may have little experience in other production under the livestock scope such as dairy, beef, or goats, production systems with unique aspects.

Similarly, an inspector may have experience evaluating small flocks of birds or several cows on a diversified farm. But they may not have had the experience of evaluating large-scale production systems with multiple barns or larger herds. Thus, they should not be assigned or accept work evaluating these operations until they have gained the capability and training to do so.

Mentorships, though often challenging for independent inspectors to arrange, can provide a pathway for gaining experience.

Such experience also applies to handling operations. An inspector may have experience verifying small production lines, value-added on-farm processing, or basic multi-ingredient products. However, applicable skills and experience are necessary for tracing back complex supply chains across multiple handlers and geographical trade boundaries and navigating the varying standards and protocols these supply chains entail.

#### **4. Training (Initial and Continuing)**

Training can come in a variety of ways and often ties directly to experience gained working in other roles in the organic sector. Though valuable, related experience does not supplant the need for intensive, inspection-specific training. Additionally, training does not end once initial proficiencies are reached and deemed sufficient. As in any profession, investment in continuing education is crucial to keeping current with evolving regulations, technologies, and trade.

Prior to taking the lead on inspections, an inspector must know the scope of operation; be educated in the tenets of auditing; be deeply familiar with the relevant regulations; and have familiarity with the certifier's procedures and forms. Only when these minimum qualifications have been met should an inspector begin in-field training and evaluation.

As noted above, a variety of resources exist to provide initial training in organic inspection, and the Subcommittee encourages referencing these for greater detail in establishing minimum baselines. Additionally, certifiers provide training of their own, often coupling in-house training with independent training, and then following with shadowed or mentored inspections with seasoned staff. However, as noted above, there is a lack of mentorship opportunities for the independent inspector seeking to gain direct experience in the field.

Continuing education can take the form of advanced in-person training or webinars to increase competency in areas such as complex trace back and mass balance audits, and updates to regulations that require additional evaluation methods. No matter the method, continuing education must be a part of maintaining and improving professional competence in the field.

## **5. Evaluation**

Evaluation is essential to both the beginning inspector and the inspector with many seasons and varieties of operations under their belt. For the beginning inspector, evaluation should be incorporated in initial training so that productive feedback may be offered, positive practices reinforced, and areas for improvement identified. Especially helpful is coordinating inspections with seasoned inspectors with experience in the scope and scale inspected so that a new inspector may shadow, partner, and then lead on inspections while training. This provides opportunity for feedback and support as the inspector becomes comfortable and competent in their role.

An earlier proposal, Personnel Performance Evaluations of Inspectors, was discussed at the Spring 2017 NOSB meeting and addressed criteria for the field evaluation of existing inspectors.

## **V. RECOMMENDATIONS**

The Subcommittee recommends the National Organic Program develop minimum qualifications and training, and continuing education guidelines to ensure a professional and competent inspector pool to meet the demands of ever-evolving and complex organic supply chains. These should include considerations of the criteria included above in the Discussion area of the document. The Subcommittee encourages the program to use existing resources in this area.

## **VI. REQUEST FOR PUBLIC COMMENT**

The NOSB is requesting public comment from the community on the following questions:

- Are the criteria and qualifications laid out in the ACA Best Practices for Inspector Qualifications sufficient to establish a baseline for inspector competency? What changes do you suggest?
- What other resources are available to train new and seasoned inspectors?
- Should there be a licensing system for inspectors by scope and/or scale in recognition of their specific skills? How do you think such a system should work?
- While this document focuses on inspectors, what other roles should the CACS consider (e.g., initial and final reviewers as well as other certifier personnel)?

- What models from other industries that facilitate high quality personnel through training and oversight could the organic industry emulate?

**Subcommittee vote**

Motion to approve this discussion document on inspector qualifications

Motion by: Harriet Behar

Seconded by: Ashley Swaffar

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 0

**Approved by Scott Rice, CACS Chair, to transmit to NOSB February 26, 2018**

**Appendix 1**

**Task 1**

**Criteria for Inspectors and Reviewers working for  
NOP Accredited Certifying Agencies**

Revision November 6, 2011

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## 1. Overview

These proposed ACA Inspector and Reviewer Criteria reflect the maturing of the organic sector domestically and worldwide. The professions of organic inspector and reviewer are barely thirty years old. While recognizing the variation in ACAs (private, state) and of work arrangements (contractual, full time, part-time), **these proposals address the need for consistency inherent in a regulatory environment, while recognizing the tremendous diversity throughout - and fundamental to - the organic sector.**

In this document, ACA Inspector and Reviewer Criteria are considered within the four scopes of the National Organic Program (NOP) Regulations, i.e., crop production, wild crop harvesting, livestock production and handling.

**Section 2** describes the responsibilities of organic inspectors. Specific knowledge, skills, abilities and personal attributes for organic inspectors are discussed. Specific work place experience, training and inspection experience are also recommended. Based on these criteria, Performance Evaluation Standards are then set forth. Finally, examples of Professional Development Activities are listed.

**Section 3**, similarly, describes criteria for Initial Reviewers and Final Reviewers, followed by specific knowledge, skills, abilities, personal attributes, work place experience, training and review experience. Section 3 concludes with Performance Evaluation Criteria and Professional Development Activities for reviewers.

**Section 4** defines specific terms for the reader.

**Section 5** is based on the Organic Food Production Act of 1990, the NOP Regulations, numerous published guidance and policy documents, as well on the work of non-profit organizations with considerable expertise in the field.

**Appendix, Section 6** suggests guidelines for preparation, inspection and reporting time for various inspections.

## 2. Inspectors

### 2.1 Inspector Responsibilities (Key Activities)

Organic inspections are an evidence-based and standards-based verification of the accuracy of the Organic System Plan to verify whether or not the Organic System Plan is implemented and to determine whether production/handling operations and inputs used are in compliance with NOP Regulations.<sup>1</sup>

Scopes of inspections are crops, wild crop harvesting operations, livestock operations or handling (processing) operations. Throughout the inspection, the inspector is gathering information by interviewing personnel, observing production/handling practices, and verifying records. Each step of the way, information is assessed against the applicable standards and issues of concern are identified.

**Inspections can be broken down into the following tasks:**



1. Review file and assignment from Accredited Certifying Agent (ACA); prepare an inspection plan and make arrangements with operator, taking care to schedule the inspection at a time in the production cycle when organic operations can be observed<sup>2</sup>;
2. Conduct an opening interview with the operator and relevant personnel (includes verifying scope of inspection, operator understanding of ACA forms, etc.)<sup>3</sup>
3. Verify accuracy of OSP and all other information supplied by operator, with particular attention to areas where organic integrity is at risk (i.e., buffers, inputs). Verify production/handling capacity of the operation (yield estimates) and conduct on-site inspection of in/out balance and traceability<sup>4</sup>;
4. Verifying label and packaging;
5. Clarify issues of concern which were identified in the pre-inspection review;
6. Assess corrective actions taken to address minor non-compliances for certified operators<sup>5</sup>;
7. Identify and summarize areas of potential non-compliance<sup>6</sup>;
8. Identify and communicate additional information to be submitted by operator<sup>7</sup>;
9. Gather samples, provide inspected party with a receipt and maintain chain of custody<sup>8</sup>;
10. Conduct and document an exit interview with the operator according to NOP Regulations and ACA procedures<sup>9</sup>;
11. Communicate the findings to the ACA according to ACA procedures<sup>10</sup>.

In addition, the following tasks are to be carried out by the inspector:

**For organic crop producers:**

Evaluate soil management, assess adjoining land use, assess buffer zones; review land history, assessing production capacity of the land, evaluate seeds and planting stock used, examine crop rotation practices, assess pest control practices, assess harvest, labeling and shipping procedures.

**For organic wild crop harvest producers:**

Evaluate designated harvest areas, sustainable harvest practices, and procedures that ensure an adequate audit trail.

**For organic livestock producers:**

Inspectors evaluate soil management, adjoining land use, buffers, land history, production capacity of the land, seeds and planting stock used, health care practices, origin of livestock, livestock living conditions, conditions for temporary confinement of livestock, and pasture management practices.

**For organic handlers:**

Evaluate receiving, processing, pest control, storage, labeling and shipping, as well as practices to prevent commingling and contact with prohibited substances.

**For split<sup>11</sup> operations** (operations that handle both organic and non-organic):

NOP 205.100, NOP 201(a)(5) and NOP 205.400(c) specifically describe that on split operations, 'the inspector must inspect non-certified production and handling areas, structures and offices to assess:

- 1) the potential for commingling;
- 2) steps taken to prevent commingling and contact with prohibited substances and
- 3) if any non-organic or contaminated products are being sold as organic.

Most inspections are regular annual inspections, either of first-time operators or of certified operators<sup>12</sup> going through the annual renewal process. In the organic inspection system, annual inspections are full inspections, which cover every aspect of the production/handling operation regulated by the organic standard. At the request of the ACA, an inspector may also conduct a follow-up inspection, which has a more limited scope. These typically focus on previously identified non-compliances and issues of concern, or a change in the operation (i.e. addition of new acreage or production line). Finally, inspectors may conduct unannounced inspections, on operations selected by the ACA based on particularly high risk levels, complaints, or other parameters established by the ACA, including random selection and fulfillment of ACA accreditation requirements<sup>13</sup>.

Because organic certification is not only about end products, organic inspection involves understanding and assessing entire production systems and processes<sup>14</sup>, which can be very complex and time-consuming. Some examples of simple to highly complex operations are in Appendix 1, with estimated inspection times indicated for each example. It is recommended that beginning inspectors not be assigned highly complex inspections until inspection experience is gained and a certain proficiency is mastered.

Most inspectors work individually. Teams may be assigned for particularly adverse compliance situations where additional witnesses may be desirable.

## 2.2 Recommended Requirements

Recommended requirements for inspectors depend on the complexity and scope of the operations being inspected (crop, wild crop, livestock and handling).

### 2.2.1 Knowledge

There are six bodies of knowledge and facts required of organic inspectors.

- a. Regardless of the type of inspection (crop, wild crop, livestock, handling), a good understanding of inspection (auditing) techniques and protocols is required<sup>15</sup>.
- b. Inspectors must have a demonstrated understanding of organic certification and inspection processes<sup>16</sup>, knowing their role and limitations within them.
- c. Specific to the inspection category, a demonstrated understanding of the applicable organic regulations (CFR Title 7 Part 205 NOP and OFPA) are required. This does not just mean knowing what the regulations say and where to find it, but most importantly, how to apply the regulations to practical situations. The inspector must be able to explain applicable standards and certification procedures to the operator.
- d. A good understanding of production/handling processes is a critical requirement. Having a good knowledge of current practices in the operators' conventional counterpart is a necessary tool for organic inspectors, enabling effective identification of risks to organic integrity in the organic production/handling process.
- e. Inspectors should be proficient – and current – in their understanding of the specific procedures, documentary requirements and forms of the ACA<sup>17</sup> for whom they work. ACAs each have their own ways of gathering organic product recipes, input profiles, or finished product labels.
- f. Organic inspectors should be aware of other rules and regulations applicable to the inspection category, notable food safety requirements<sup>18</sup>. Although such regulations are technically beyond the scope of organic inspections, if the organic inspector observes obvious violations of them, they are typically addressed in an addendum to the inspection report, for the ACA's attention.

### 2.2.2 Skills (areas of expertise)

Nine key skills (areas of expertise) are needed to conduct organic inspections and enable the organic inspector to fulfill inspection assignments effectively and efficiently.

- a. **Observation skills:** When conducting evidence-based inspections, a significant part of the on-site time is spent in the field or on the production floor, understanding the 'big picture' of a production system and observing the details which support (or contradict) the Organic System Plan.
- b. **Communication:**
  1. **Interviewing** is a technique inspectors use to gather information so appropriate interviewing techniques are required. Some good interview techniques are <sup>19</sup>

asking open ended questions, asking the same question a different way and paraphrasing.

2. **Documenting/writing**<sup>20</sup>: This includes correct grammar and spelling; accurate writing that is clear, concise, and easily understood by the operator and reviewer; facts vs. opinion; reference supporting documentation; citation of appropriate NOP regulations; and explanation of issues of concern.
  3. **Active listening**: Active listening is a structured way of listening and responding. The elements of active listening are comprehending, retaining, and responding. The listener asks questions and paraphrases back to the speaker to clarify understanding. Listening carefully to operator responses reduces redundancy during the inspection, improves accuracy, and shows respect.
- c. **Intermediate Math skills**: Inspectors need to be able to convert easily from one unit of measure to another, calculate yields, calculate annual feed requirements in livestock operations, use formulas to verify in/out balances, and use percentages to validate recipes and production reports etc.
  - d. **Organization skills and time management**<sup>21</sup>: managing preparation time, travel time, on-site time (e.g., multiple sites) and reporting time efficiently; respect ACA deadlines; use travel resources efficiently. Inspectors need to plan well, be prepared<sup>22</sup>, and be on-site at a time when organic operations can be verified<sup>23</sup>. The inspections must be conducted with the authorized operator representative is present, moving smoothly from one area of operations to another.
  - e. **Information management** and basic computer skills<sup>24</sup> are required skills for inspectors, both in the office and on-site. Specific risks and conditions to certification are flagged in the preparation before inspection; these areas must be properly investigated, observations noted in an orderly way, and conclusions communicated to the ACA. Evidence of potential non-compliances must be substantiated, documented, tracked and accurately reported. Working documents need to be appropriately kept secure, archived and/or destroyed<sup>25</sup>. Demonstrated proficiency in word processing, use of spreadsheets and data base management is required.
  - f. **Investigative skills**<sup>26</sup> are required for all inspections, and especially those where the inspector finds inconsistencies during the on-site inspection (i.e., if prohibited substance use is suspected), when conducting complaint related inspections and in cases of suspected fraud.
  - g. **Sampling procedures**: Correct sampling methods, appropriate handling of samples (packing, labeling, shipping) and proper chain of custody impact the validity of test results. These activities must be done according to the ACA's contracted laboratory procedures.
  - h. **Skills specific to inspection scope**: Additionally, numerous skills specific to the scope of the inspection are required. The following table gives several examples for each scope but this list is by no means exhaustive.

Inspection scope	Examples of skills specific to inspection scope
Crop	<ul style="list-style-type: none"> <li>- able to recognize weed species and assess impact</li> <li>- able to assess soil structure and fertility, by consulting soil test results, observing crop performance and observing signs of compaction, good tillth etc.</li> <li>- able to assess possible sources of contamination and recognize signs of pesticide injury to crops or other vegetation<sup>27</sup></li> <li>- able to use GPS to validate field sizes and boundaries</li> <li>-able to assess crop rotations and management of pasture as a crop</li> <li>- able to evaluate farm inputs</li> <li>-able to evaluate manure and compost management</li> </ul>
Wild crop	<ul style="list-style-type: none"> <li>- able to assess sustainability of harvesting practices</li> <li>- able to read maps</li> <li>- able to recognize possible source of contamination and signs of damage to wild crops or other vegetation</li> <li>- able to determine damage to harvested crop and dependent species (plant and/or animal) by harvesting or over-harvesting<sup>28</sup></li> </ul>
Livestock	<ul style="list-style-type: none"> <li>- able to calculate dry matter intake for ruminant animals</li> <li>- able to assess native and tame pasture production</li> <li>- able to assess overall condition of herd/flock (animal behavior, physical appearance</li> <li>- able to asses adequate nutrition and evidence of malnutrition or parasites etc.)<sup>29</sup></li> <li>- able to evaluate synthetics used</li> <li>- able to assess the general animal husbandry practices used for species on operation</li> <li>- able to assess input for farms with livestock</li> <li>- able to assess feed handling procedures to avoid contamination on split operations</li> </ul>
Handling	<ul style="list-style-type: none"> <li>- able to compare proposed recipes, actual production and finished product labels</li> <li>- able to verify compliance of organic ingredients, non-organic ingredients, food additives and processing aids</li> <li>- able to assess compliance of facility pest management protocols</li> <li>- able to assess equipment for commingling or contamination potential</li> <li>- able to assess label compliance</li> <li>- able to identify and report major and obvious food safety concerns<sup>30</sup></li> </ul>

### 2.2.3 Abilities (capacity, talent)

Beyond knowledge and specific skills, it is recommended that organic inspectors develop certain abilities to facilitate their work:

- a. attention to detail without losing sight of the whole
- b. able to differentiate between inspection and advice<sup>31</sup>
- c. discernment<sup>32</sup>: differentiate between evidence and opinions<sup>33</sup> judgment to interpret and adapt general guidelines to specific situations
- d. analytical
- e. accuracy<sup>34</sup>
- f. consistency
- g. awareness of trends and developments in conventional and organic aspects of agriculture or food science

- h. self-assessment: can recognize own opportunities for improvement, can accept constructive criticism

#### 2.2.4 Personal Attributes

Inspectors should possess personal attributes<sup>35</sup> to enable them to perform inspections in accordance with principles of auditing. An inspector should be:

- a. Honest and ethical. Integrity of the certification system rests on the integrity of its players, including inspectors and reviewers. In quality systems, inspectors must be free of conflicts of interest with the operations for which they inspect. Conflicts of interest are declared annually<sup>36</sup> and inspectors should defer any inspection assigned to them by an ACA with which they have a conflict of interest. Confidentiality<sup>37</sup> is also important. Information learned about operations must be kept confidential in order to gain trust of operators and not be used by inspectors for personal gain. Inspectors also have a responsibility to report suspected fraud.
- b. Impartial and non-discriminatory: Inspectors should be fair and objective<sup>38</sup> during inspections and when reporting their observations to ACAs. Inspectors should be open-minded to the types of people and management strategies they encounter. They need to treat all operators with respect and without bias. An inspector should also be aware of the cultural environment in which he/she is working.<sup>39</sup>
- c. Professional in their conduct. Inspectors must be fit and in good mental health. As most inspectors work alone, they need to be self-reliant and able to function autonomously and decisively. During the inspection, the inspector represents an ACA and must follow ACA policies and procedures. They must follow all governmental laws that apply to their status, whether employees or contractors (ex. valid drivers license, liability insurance, reporting income, etc.) They should be punctual for appointments as well as meeting ACA deadlines. Inspectors should wear appropriate attire, pay attention to bio-security requirements, and have an awareness of personal safety. They should turn down work if too busy or if proposed assignment is beyond their realm of competence. Inspectors must be willing to travel and economical in their use of travel allowances.
- d. Curious and tenacious. Asking questions is an important method used by inspectors to gather information. They must be curious about the systems they are observing in order to ask appropriate questions. They also must be systematic and continue asking questions until they have a good understanding that compliance is met.
- e. Perceptive and versatile. Inspectors must be perceptive to quickly grasp an understanding of the variety of operations they encounter. They should have the flexibility to adjust to different situations and people.
- f. Diplomatic. Inspectors must strive to maintain a pleasant and non-confrontational atmosphere throughout the inspection even while asking difficult questions. The inspection can be an exhausting process for the operator because it covers many areas of his/her operation in a relatively short period of time and patience of the operator may wear thin.

- g. Support goals of organic farming and handling. This last personal attribute is important as the attitude of the inspector toward his/her work is evident to the operator during an inspection. A lack of support can undermine the authority needed by an inspector.

### 2.2.5 Work Experience

Organic inspectors should have a **minimum of one year work place experience in the category**<sup>40</sup> in which they will be inspecting. Examples of possible work place experience are given below:

Inspection category	Examples of work place experience
Crop	Growing up on a farm and actively participating in the daily and seasonal tasks Operate own farming operation Employment on farming operation Farm manager Educator at community college
Wild crop	Experience as harvester of wild crops Work in a field of natural resource management
Livestock	Growing up on a livestock farm and actively participating in the daily and seasonal tasks Operate own livestock farming operation Employment on livestock operation Livestock farm manager Herdsman Veterinarian or veterinary assistant Extensive 4-H or FFA experience Trainer at community college
Handling	Production worker in food processing facility Management or shift foreman Employment in food retail and/or preparation Research and development in food processing

## 2.2.6 Training

It is recommended that five kinds of training be required before beginning supervised inspection work:

1. Education in the category
2. General auditor training
3. Standards training
4. Specific organic inspection training
5. Training to ACA procedures and paperwork

Initially, this training will be intense and over an extended period of time. As inspection experience is gained, training will take the form of refresher courses or specialty modules. This is summarized in the table below; in the table, 'category' refers to crop, wild crop, livestock or handling:

Recommended training requirements	Inspector <sup>41</sup>	Licensed Inspector	Master Inspector
<b>Sector education</b>	College degree in agriculture or food science or related field, or relevant work place experience	Training in related discipline 10 hrs/yr	Training in related discipline 7 hrs/yr
<b>Auditor training</b>	ISO auditing overview (1-2 hrs)	Relevant training from private training providers 15 hrs/yr (suggested, not required)	Lead auditor training 40 hrs (suggested, not required)
<b>Standards training</b>	Basic standards training  Crop (6 hrs) Livestock (6 hrs) Wild crop (4 hrs) Handling (8 hrs)	Annual update to standards and national list  1-2 hrs per category per year, depending on changes which have been adopted	Annual update to standards and national list  1-2 hrs per category per year, depending on changes which have been adopted
<b>Organic inspection training</b>	Basic organic inspection training in appropriate category(level 100) 4.5 days/category <sup>42</sup> Field Training with mentor (3 supervised inspections and 7 supervised inspection reports) <sup>43</sup>	Intermediate organic inspection modules related to appropriate category (level 200) 10 hrs/yr	Advanced organic inspection modules related to appropriate category (level 300) 3-5 hrs/year
<b>ACA procedures and paperwork training</b>	Training to ACA procedures	Annual update to ACA procedures	Annual update to ACA procedures

## 2.2.7 Inspection Experience

Only in exceptional circumstances can a perfect combination of knowledge, skills, abilities, personal attributes, prior work experience and training be sufficient to autonomously conduct organic inspections. Some ACAs ensure that new inspectors are mentored by experienced inspectors. Inspections are conducted by the apprentice under supervision of the mentor; exit



interview documents and reports are written by the apprentice but approved and co-signed by mentor.

Furthermore, it is recommended that beginning inspectors should only be assigned simple inspections, Licensed inspectors can be assigned simple and intermediate inspections, and only Master inspectors should be assigned inspections at all levels of complexity. ACAs might occasionally need to assign a lower level inspector, but these deviations should be rare. ACAs should have a systemic way to document the level of inspector and the corresponding level of complexity of the operations they have been assigned. In this way, operators will work with inspectors sufficiently trained for their type of operation, inspections will be efficient, and organic compliance issues will be systematically addressed.

Finally, only Master inspectors would have the qualifications to mentor apprentices.

	<b>Inspector</b>	<b>Licensed Inspector<sup>44</sup></b>	<b>Master Inspector</b>
<b>Inspection Experience</b>	Field training (three supervised inspections and 7 additional inspection reports reviewed by a supervisor/mentor) per category	Have demonstrated proficiency in simple inspections in appropriate category, 10 unsupervised inspections per category	Have demonstrated proficiency in simple and medium inspections in appropriate category over a period of 2 years or 30 inspections per category  Can mentor apprentices.

Notes:

- Category refers to crop, wild crop, livestock or handling
- In cases where a single inspection takes several days, length of experience can be expressed as time rather than in number of inspections, where 1 inspection = 0.5 days on-site inspection

## 2.3 Recommended Performance Evaluation Standards

Annual performance evaluations contribute to the continuous improvement of inspectors as well as being a requirement pursuant to the NOP Final Rule, 205.501(a)(6) and 205.510(a)(4). Observation during inspection by a representative from the ACA would be periodic but not necessarily annual. Observation during inspection may also include an inspection witnessed by a peer (another inspector).

	<b>Area of competence to be evaluated</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
<b>2.1 Responsibilities</b>	Review file and assignment from ACA; prepare an inspection plan and make arrangements with operator, taking care to schedule the inspection at a time in the production cycle when organic operations can be observed	Inspection well-prepared (audit plan, checklist for use during inspection) Inspection appropriately scheduled	Feedback from operators Observation during inspection Interview inspector
	Conduct an opening interview with the operator and relevant personnel	Opening interview covers essential elements (scope, audit plan, safety/bio-security, confidentiality, verifying accuracy of information provided by operator etc.)	Observation during inspection

	<b>Area of competence to be evaluated</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
	Verify accuracy of OSP and all other information, with particular attention to areas where organic integrity is at risk (buffers, inputs, split operations)	Organic Control Points systematically verified. Materials appropriately reviewed.	Observation during inspection Review of inspection report
	Verify production/handling capacity (yield estimates); conduct on-site inspection of in/out balance and traceability	Record keeping system assessed. Random trace back conducted. In/out balance completed.	Review of inspection reports Observation during inspection
	Verifying label and packaging	Labels and packaging verified.	Review of inspection reports Observation during inspection
	Clarify issues of concern which were identified in the pre-inspection review.	Issues of concern which were identified in the pre-inspection review are clarified.	Review of inspection reports Observation during inspection
	Assess corrective actions taken to address minor non-compliances for certified operators.	Previous conditions reviewed and verified.	Review of inspection reports Observation during inspection
	Identify and summarize areas of potential non-compliance	Potential areas of non-compliance identified and summarized.	Review of inspection reports Observation during inspection
	Identify and communicate additional information to be submitted by operator.	Missing information identified and communicated.	Review of inspection reports Observation during inspection
	Gather samples, provide receipt, maintain chain of custody, and according to ACA procedures	Samples gathered as per ACA and contracted laboratory procedures.	Review of inspection reports Observation during inspection
	Conduct and document an exit interview with the operator according to ACA procedures	Exit interview conducted, covering all essential elements.	Review of inspection reports Observation during inspection
	Communicate the findings to the ACA according to ACA procedures.	Report filed punctually. Report well-written, clear, concise and needing no further information from inspector.	Review of inspection reports
<b>2.2.1 Knowledge</b>	Auditing techniques protocols	Auditing protocols followed.	Review of training record, course content and result Observation during inspection
	Organic certification and inspection processes	Certification and inspection procedures understood and followed.	Observation during inspection.
	NOP regulations	Organic requirements understood; could clearly	Review of training record, course content

	<b>Area of competence to be evaluated</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
		explain to operator.	and result Review of inspection reports Observation during inspection
	Organic (and conventional) production and handling processes	Understands system being inspected; using terminology specific to system being inspected; thorough assessment of Organic Control Points.	Review of training record, course content and result Observation during inspection
	ACA procedures	Uses ACA forms correctly. Follows ACA procedures.	Review of training record, course content and result Review of inspection reports Feedback from reviewers
	Related laws and regulations.	Asks questions and makes observations during inspection pertaining to related laws and regulations. Accurately reports findings.	Review of training record, course content and result Observation during inspection Review of inspection report
<b>2.2.2 Skills</b>	Observation	Attention to detail Relevance of questions	Observation during inspection
	Communication: Interviewing Documenting/writing Listening	Use of open-ended questions, paraphrasing Correct grammar, spelling Accurate, clear, concise Active listening	Observation during inspection Review of inspection reports
	Evaluation	Analyzes data, draws conclusions based on evidence, identifies and assesses OCPs	Observation during inspection Review of inspection reports
	Math	Verification of rations, DMI, recipes etc. Verification of in/out balances Logical analysis of results	Review of training record, course content and result Review of inspection reports
	Organizational skills and time management	Plans well Punctual In control of agenda Efficient	Observation during inspection Review of time began and time ended inspection Submission of inspection report
	Information management	Well organized Prepared - and uses - checklists Demonstrate appropriate computer skills	Observation during inspection Review of inspection report
	Investigative skills	Asks good questions.	Observation during

	<b>Area of competence to be evaluated</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
		Is inquisitive. Documents findings. Evidence based approach.	inspection Review of inspection report
	Sampling procedures	Samples gathered as per ACA and contracted laboratory procedures. Maintains sample integrity and chain of custody.	Review of training record, course content and result
	Skills specific to inspection scope (see examples in table 2.2.2.i)	Demonstrates competence specific to inspection scope	Observation during inspection Review of reports Feedback from operators
<b>2.2.3 Abilities</b>	Attention to detail	Satisfactory performance: reviewers do not need to get further information from the inspector, inspection paperwork is clear and complete as submitted	Observation during inspection Review of reports Feedback from reviewers
	Able to differentiate between inspection and advice	Does not provide advice to the operation; does not assist operators to overcome barriers to certification	Observation during inspection
	Discernment	Demonstrates good sense of judgment; shows ability to interpret and adapt general guidelines to specific situations	Observation during inspection Review of reports
	Analytical	Demonstrate logical approach	Observations during inspection (specifically traceability tests)
	Accuracy	Absence of error	Review of reports Feedback from operators
	Consistency	Methodical approach	Review of reports Feedback from reviewers
	Awareness of trends and developments in conventional and organic – aspects of agriculture or food science	Appears to be up to date and knowledgeable	Review of training records
	Capacity for self-assessment	Open to constructive criticism Pro-active in seeking additional training opportunities	Annual performance review
<b>2.2.4</b>	Integrity, confidentiality, freedom from conflict of interest, ethical,	Satisfactory performance Declarations kept current	Feedback from operators

	<b>Area of competence to be evaluated</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
<b>Personal attributes</b>	open-mindedness, diplomacy, observant, perceptive, versatile, tenacity, decisiveness, self-reliance, punctuality; does not provide advice for inspected operations; professional in their conduct at all times; confidential; be fit and in good mental health; economical in their use of travel allowances; cultural sensitivity, willing to travel	(confidentiality, C of I)	Observation during inspection Review of complaints filed naming the inspector Review of annual documentation

## 2.4 Recommended Professional Development Activities

There are a wide range of professional development activities in which organic inspectors should participate. They should be documented and included in their résumé, supported by course certificates and content lists whenever possible. This is a partial list of possible professional development activities:

- Conferences
- Workshops
- Community college and university courses
- eOrganic webinars
- ATTRA
- On-farm demonstrations
- Subscriptions to trade magazines
- Independent study/reading
- Networking<sup>45</sup> (professional associations, listserves, etc.)
- Peer review: the IOIA 2010 survey refers to these as 'witness audit with peers'. This concept rates highly as an additional element for inspector accreditation (licensing).
- Performance review from certifiers: Per NOP regulation and accreditation requirements, ACAs must conduct an annual performance review of their inspection staff/contractors. At a minimum, reports, training records, feedback from operators, and complaints naming the inspector must be reviewed. Additionally, it is recommended that periodically (not every year) a qualified ACA representative accompany the inspector on an inspection and assess their performance, then meets with the inspector to give verbal and written feedback and discuss opportunities for improvement.
- Private coaching
- IOIA 200 level courses and 300 level courses<sup>46</sup> (IOIA Training Institute) (advanced and specialty modules)
- IOIA training modules with tests<sup>47</sup>

Content lists for training activities are presented in Task 2.

## 3 Reviewers

### 3.1 Reviewer Responsibilities (Key Activities)

There are two levels of review in the organic certification system: initial review<sup>48</sup> (pre-inspection) and final review/certification decision (post-inspection)<sup>49</sup>. Initial review may be done by the same person as inspection, but the final certification decision, including identification of noncompliances, must not be made by the same person who did the initial review or inspection<sup>50</sup>. Depending on ACA procedures, the final reviewer makes the certification determination or the certification determination can be made by a different person, or even by a committee.

#### Initial Review

The initial reviewers' primary role is to verify, through thorough document review, whether or not the Organic System Plan (OSP) as submitted by the operator is complete and accurate<sup>51</sup>, has the potential to be in compliance with NOP Regulations and ACA requirements<sup>52</sup>, and is scheduled for on-site inspection<sup>53</sup>. Additional information from the operator may be requested. The initial reviewer must verify that an operator who previously applied through another ACA and received a notification of non-compliance or a denial has addressed those issues<sup>54</sup>. Initial reviewers may review applications and/or continuation of certification documentation for all four scopes (crop, wild crop harvesting, livestock, or handling).

Depending on the size and staffing of the ACA, initial reviewers may be generalists or may specialize in one production/handling sector or another. Initial reviewers may also consider requests for temporary variances, labels and market information, as well as important changes to the OSP which a certified operator may report between annual inspection dates. Initial reviewers may also evaluate inputs, although some ACAs may have specialized staff for this<sup>55</sup>. Initial reviewers may prepare files for inspection and even do the inspection assignments, although these tasks may be performed by other administrative staff.

#### Final review

The final reviewers' primary role is to verify, through study of the OSP, exit interview document, inspection report and results of analyses for substances conducted, whether the operators' production/handling system should be certified, and whether any requirements for the correction of minor non-compliances must be made<sup>56</sup>. Final reviewers may need additional information or clarification from the inspector regarding their inspection report<sup>57</sup>.

Final reviewers communicate findings to operators, along with copies of inspection reports and any test results<sup>58</sup>. Final reviewers must verify compliance of labels. Final reviewers also review corrective action, rebuttal, appeal and mediation documentation submitted by the operator<sup>59</sup>. They may recommend or require a follow-up or unannounced inspection<sup>60</sup>.

Final reviewers who make the certification decision monitor deadlines for non-compliance correction and denial, rebuttal, revocation or suspension of certification. Final reviewers may mentor reviewers and often provide inspector and inspection report evaluations to the ACA. In the overall structure of quality management systems, complaint management is often assigned to final reviewers or others in the certification decision team/department.

**Initial and final review tasks can be summarized as follows:**

### Initial Review

1. Answer questions about certification, standards and materials, timeliness<sup>61</sup>.
2. Review OSP and supporting documentation for completeness and potential compliance<sup>62</sup>:
  - in the case of growers, this includes, but is not limited to, review of land history, contamination risks, crop rotation, fertility management, seed and planting stock use, pest, disease and weed management, input materials<sup>63</sup>, equipment, labeling<sup>64</sup>, and types of records for compliance to NOP;
  - in the case of wild crop harvesters this includes but is not limited to, review of land history, contamination risks, sustainability, equipment, labeling<sup>65</sup>, and types of records for compliance to NOP;
  - in the case of livestock operations, this includes but is not limited to, review of livestock living conditions, origins of livestock, feed composition and feed sources, pasture management, veterinary practices, and types of records for compliance to NOP;
  - in the case of handlers, this includes, but is not limited to, review of labels, product formulations, ingredient suppliers, facility pest management, sanitation materials, food additives, and types of record keeping for compliance to NOP.
3. If the operation was previously certified by another ACA, previous non-compliance issues need to be verified for resolution<sup>66</sup>.
4. Communicate with operator for additional information as needed<sup>67</sup>.
5. Prepare file for inspection, including special instructions if necessary (number of products to trace, number of input/output balances to conduct, for example) and previous report if applicable<sup>68</sup>.
6. Assign inspector, matching competency, availability, absence of conflict of interest etc.<sup>69</sup>
7. Inform operator of which inspector has been assigned and manage changes to assignment, if needed.
8. Monitor deadlines for continuation of certification<sup>70</sup>: ensure operators update OSPs on time and ensure inspections are scheduled in a timely fashion etc.
9. Review temporary variance requests.
10. Review reported changes to OSP.
11. Process requests for approval of inputs.<sup>71</sup>

### Final review

1. Review OSP and supporting documentation, exit interview documentation, inspection reports and the results of any analyses for substances conducted.
2. Communicate with inspector for further clarification if needed.
3. Communicate with operator for additional information, if needed.
4. Provide copy of inspection report to operator<sup>72</sup>.
5. Provide copy of laboratory results (if applicable) to operator<sup>73</sup>.
- 6a. Grant certification including requirements for the correction<sup>74</sup> of identified minor non-compliances within a specified period of time<sup>75</sup> and a consistent manner;  
or
- 6b. Issue notification of non-compliance (or even notification of denial, in accordance with the requirements of the NOP regulations),<sup>76</sup> including the evidence and date by which the operator must rebut or correct each non-compliance.
7. Review rebuttals and responses to non-compliances and determine if compliant.
8. Monitor deadlines for corrective actions, follow-up inspections etc; communicating with operators when there are missed deadlines.



9. Require follow-up inspections if necessary.
10. Issue certification certificates.
11. Communicate decision (including any requirements for the correction of minor non-compliances) back to inspector<sup>77</sup>.
12. Notify the NOP in cases of certification denial, and notices of noncompliance, proposed suspension or revocation<sup>78</sup>.
13. Verify compliance of finished product labels.
14. Contribute to performance review of inspectors in conjunction with human resources personnel.
15. Contribute to performance review of initial reviewers in conjunction with human resources personnel.

#### Peripheral responsibilities for reviewers

- provide information to potential and actual organic operators
- ensuring maintenance of quality system and of the ACAs accreditation<sup>79</sup>
- contribute to ACA policy development
- participate in educational programming of ACA
- represent ACA at trade shows, conferences, industry events
- contribute to optimizing the certification services
- contribute to continuous improvement of inspection services
- mentor and train initial reviewers (and inspectors)

## 3.2 Recommended Requirements

### 3.2.1 Knowledge

Not unlike the position of organic inspectors, there are five bodies of knowledge and facts required of initial and final reviewers:

- a. Regardless of the certification category (crop, wild crop, livestock, handling), a good understanding of accreditation<sup>80</sup>, certification and quality systems is required<sup>81</sup>.
- b. Specific to the certification category, a good understanding of the NOP Regulations (CFR Title 7 Part 205 NOP and OFPA) is also required<sup>82</sup>. This does not just mean knowing what the standard says and where to find it, but most importantly, how to apply the standard to practical situations. The reviewer must also be able to explain applicable standards (and certification procedures) to the operator, when questions arise..
- c. Very specific to the file under review, a good understanding of organic **production/handling processes** is a critical requirement. Having a good knowledge of current practices in the operators' conventional counterpart is also an excellent tool for reviewers, enabling effective identification of risks to organic integrity in the organic production/handling process. Understanding the specific terms and jargon specific to the field under review is essential.
- d. Reviewers must be proficient – and current – in their understanding of the **specific procedures, documentary requirements and forms of the ACA**<sup>83</sup> which employs them or of every ACA which they contract to<sup>84</sup>. ACAs each have their own document control system, their own specific procedures for reviewing OSPs and supporting

documentation, and prescribed ways of gathering organic product recipes, input profiles, or finished product labels. They have different ways of documenting changes to operator documents - and these processes change from time to time. Some ACAs have a data base for recording decisions, interpretations and precedents, which reviewers need to know how to use, input into and keep current. They need to know when they have the authority to make a determination and when they need to consult with other members of staff.

- e. It is recommended that organic reviewers be aware of **other rules and regulations applicable** to the inspection category, such as food safety requirements<sup>85</sup>. Although such regulations are technically beyond the scope of organic inspections, when the organic inspector observes and reports obvious violations of them, reviewers need to know what is the appropriate action to take.

### 3.2.2 Skills

The recommended skills for initial and final reviewers are as follows:

- a. Computer skills/information management
- b. Organizational; project management
- c. Writing: correct grammar and spelling; concise and easy to understand by the targeted reader
- d. Good verbal communication
- e. Time management, meeting deadlines, following up on deadlines imposed on operators
- f. Meticulous: systematic about documenting and archiving conversations, emails, decisions etc.
- g. Intermediate Math skills: needed to verify feed rations and recipe formulations, etc.

### 3.2.3 Abilities

The recommended abilities for initial and final reviewers are as follows:

- a. Ability to work under pressure
- b. Ability to interface with operators, inspectors and other ACA staff
- c. Attention to detail<sup>86</sup>
- d. Thorough, meticulous
- e. Analytical<sup>87</sup>
- f. Accurate
- g. Consistency: making the same determination and decision in similar circumstances
- h. Reaches decisions in a timely manner based on logical reasoning and analysis
- i. Self-assessment: can recognize own opportunities for improvement, can accept constructive criticism

### 3.2.4 Personal Attributes

Initial and final reviewers should possess personal attributes<sup>88</sup> enabling them to handle a wide variety of situations in accordance with the requirements of an accredited quality system. A reviewer should be:

- a. Honest and ethical. Integrity of the certification system rests on the integrity of its players, including inspectors and reviewers. In quality systems, reviewers must be free of conflicts of interest with the operations they review. Conflicts of interest are declared annually<sup>89</sup> and reviewers must not review any operation's files with which they have a conflict of interest. Confidentiality<sup>90</sup> is also important. Information learned about operations must be kept confidential in order to gain trust of operators and not be used by reviewers for personal gain. Reviewers also have a responsibility to act on and investigate suspected fraud.
- b. Impartial and non-discriminatory<sup>91</sup>. Reviewers should be fair and objective, and review operator files consistently. They need to treat all operators with respect and without bias.
- c. Professional in their conduct. Reviewers represent ACAs and must follow ACA policies and procedures, including meeting deadlines.
- d. Diplomatic and tactful. Reviewers have a variety of contact with operators throughout the certification process, from answering certification questions, notification of initial review, additional information needed, decision making and identification of non-compliances and follow-up. This can be a trying process for operators, as their livelihood may depend on organic certification. Reviewers need to maintain a calm atmosphere in the office.
- e. Decisiveness. Both initial and final reviewers make decisions about additional information needed from the operator, whether inputs are approved, and whether previous non-compliances have been corrected. Final reviewers also make a decision regarding whether an operation is certified including identification of non-compliances. Consistency is needed as well as the ability to make those hard decisions.
- f. Support goals of organic farming and handling. This last personal attribute is important as the attitude of the reviewer toward his/her work is evident to the operator. A lack of support can undermine the authority needed by the ACA.

### 3.2.5 Work Experience

The recommended work experience required of reviewers varies from one ACA to another. Generally, ACAs require final reviewers to have demonstrated their competence as initial reviewers or as inspectors prior to moving into final review positions. As examples, the following table suggests some of the relevant work experiences possible for the two review levels:

Review level	Initial reviewer (pre-inspection)	Final reviewer (post-inspection)
<b>Relevant work experiences possible</b>	One or more years in professional office environment and/or quality assurance	One or more years in professional office environment and/or quality assurance
	Volunteering or interning on an organic farm	Auditing/regulatory compliance experience
	1-2 years in the production/handling sector <sup>92</sup>	1-2 years in the production/handling sector <sup>93</sup>
	1-2 years experience as an organic inspector	1-2 years experience as an organic inspector
		Demonstrated competence as an initial reviewer

### 3.2.6 Training

As with inspectors, the training required of reviewers falls into several different fields, notably:

- Sector (crop, wild crop, livestock, handling)
- Regulatory/quality system
- Organic inspection
- NOP Regulations
- Accreditation requirements
- ACA procedures, forms, data management

Recommended training requirements	Level of review	
	Initial (pre-inspection)	Final (post-inspection)
<b>Sector education</b>	Bachelors degree or higher in agriculture, food technology or related field, or equivalent work experience <sup>94</sup>	Training in related discipline 10 hrs/yr
<b>Regulatory, Quality systems</b>	Basic quality system auditing or organic inspector training <sup>95</sup>	Basic quality system auditing or organic inspector training
<b>Standards training</b>	Basic NOP Regulations training  Crop (and wild crop) 6 hrs Livestock 6 hrs Wild crop (included in crop) Handling 6 hrs	Annual update to NOP Regulations and National List  1-2 hrs per category per year, depending on changes
<b>Accreditation requirements</b>	Training to NOP Accreditation and ISO 65	Update every 2 years
<b>ACA procedures and paperwork training</b>	Training to ACA procedures <sup>96</sup>	Annual update to ACA procedures

### 3.2.7 Reviewer Experience

- Entry level reviewers are not expected to have review experience; initially they are under supervision of experienced reviewer.<sup>97</sup>
- Initial review work or organic inspection is often - but not always – a prerequisite for final review work

### 3.3 Recommended Performance Evaluation Standards

Annual performance evaluations are required<sup>98</sup>. It is recommended that performance evaluation be conducted by peers (other review personnel) in conjunction with human resources staff. The following table suggests standards which such reviews can address.

	Area of competence to evaluate	Evaluation criteria	Evaluation method
<b>3.1 Responsibilities: Initial reviewer</b>	Answer questions about certification, standards and materials, timelines	Knowledgeable about standards, allowed substances, certification process	Review customer satisfaction
	Review application and supporting documentation for completeness and potential compliance (refer to narrative for detailed examples for each scope).	Incomplete applications and potentially non-compliant practices/materials are correctly flagged.	Sample files.
	If the operation was previously certified by another ACA, previous non-compliance (NC) issues need to be verified for resolution.	NCs from an operator's previous ACA are consistently verified for resolution.	Examine files of operators previously certified by another ACA.
	Communicate with operator for additional information as needed.	Operators are contacted for more information as needed.	Sample files.
	Prepare file for inspection, including special instructions if necessary and previous report if applicable.	Files are correctly prepared for inspector.	Inspector satisfaction. Sample files.
	Assign inspector, matching competency, availability, absence of conflict of interest.	Assignments are correctly made.	Sample files.
	Inform operator of which inspector has been assigned <sup>99</sup> and manage changes to assignment if needed.	Changes in assignments are made according to ACA procedure.	Examine assignment records.
	Monitor deadlines for continuation of certification, ensure operators update OSP on time and ensure inspections are scheduled in a timely fashion.	Deadlines are respected.	Analyze performance.
	Review temporary variance requests	Temporary variance requests are processed according to ACA procedure.	Review records of temporary variances.
	Review reported changes to OSPs	Changes to OSPs are reviewed and processed according to ACA procedure.	Sample files.

	<b>Area of competence to evaluate</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
	Process requests for approval of inputs	Input approval requests are processed according to ACA procedure.	Sample files.
<b>3.1 Responsibilities: Final reviewer</b>	Review OSP and supporting documentation, exit interview documentation, and inspection reports and results of analyses for substances conducted	Files are thoroughly reviewed. Review is documented.	Sample files.
	Communicate with inspector for further clarification if needed	Communications with inspectors are made when needed and documented.	Sample files.
	Communicate with operator for additional information if needed.		
	Provide copy of inspection report to operator	Reports are provided to operator.	Sample files.
	Provide copy of laboratory results (if applicable) to operator	Lab results are provided to operator.	Sample files.
	Grant certification including requirements for correction of identified minor non-compliances within a specified time and in a consistent manner OR Issue notification of non-compliance (or denial) including evidence and date by which operator must rebut or correct each non-compliance.	Decisions are made based on evidence, in a consistent manner and documented.	Sample files.
	Review rebuttals and responses to non-compliances and determine if compliance is met.	Rebuttals and responses are reviewed and assessed; conclusions are documented.	Sample files.
	Monitor deadlines for corrective actions, follow-up inspections etc; communicating with operators when there are missed deadlines	Deadlines are respected.	Analyze performance.
	Require follow-up inspections if necessary	Follow-up inspections are required when appropriate.	Sample files.
	Issue certification certificates	Accurate certificates are issued.	Sample files.
	Communicate decision (including any requirements for the correction of minor non-compliances) back to inspector.	Inspectors are notified of review outcomes.	Sample files.
	Notify the NOP in cases of certification denial and notices of proposed suspension or revocation	NOP is notified of certification denials, and of proposed suspensions and revocations.	Review files (internal audit).
	Verify compliance of finished product labels.	Labels are reviewed using checklist; review documented.	Sample files.
	Contribute to performance review of inspectors in conjunction with Human	Inspector performance evaluated using HR	Review files (internal audit).

	<b>Area of competence to evaluate</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
	resources personnel	checklist.	
	Contribute to performance review of initial reviewers in conjunction with human resources personnel.	Initial reviewer performance evaluated using HR checklist.	Review files (internal audit).
	Peripheral responsibilities <sup>100</sup>		
<b>3.2.1 Knowledge</b>	Accreditation, certification and quality systems		Review of training record
	NOP Regulations	Demonstrates understanding of NOP regulations	Review of training record; observation at work
	Organic production/handling processes	Understands system being inspected; using jargon specific to system being inspected.	Review of training record
	ACA procedures and policies	Uses ACA forms correctly. Follows ACA procedures.	Review of training record Review of operator files
	Other applicable regulations		Review of training record
<b>3.2.2 Skills</b>	Computer skills/ Information management	Uses programs competently and efficiently.	Performance review.
	Organizational; project management	Is well organized.	Performance review.
	Writing: correct grammar and spelling; concise and easy to understand by the targeted reader	Writes concisely and uses language correctly.	Review of files.
	Good verbal communication	Makes her/himself easily understood.	Observation in workplace.
	Time management, deadlines, following up on deadlines imposed on operators	Manages deadlines effectively.	Performance review.
	Meticulous: systematic about documenting and archiving all conversations, emails, decisions etc	Keeps proper records of all communications etc.	Review of files.
	Math: needed to verify feed rations and formulations	Correctly asses rations, recipes.	Review of files.
<b>3.2.3 Abilities</b>	Ability to work under pressure	Stays calm and focused meets deadlines	Employee interview Review staff turnover
	Ability to interface with operators, inspectors and other ACA staff	Courteous, people skills	Analysis of complaints naming reviewer.
	Attention to detail	Works with attention to detail.	Review of files.
	Thorough, meticulous	Works meticulously	
	Analytical	Bases decisions on facts	Review of files.
	Accurate	Does not make mistakes.	Review of files.



	<b>Area of competence to evaluate</b>	<b>Evaluation criteria</b>	<b>Evaluation method</b>
	Consistent	Handles similar situations the same way.	Review of files.
	Reaches decisions in a timely manner based on logical reasoning and analysis	Evidence based decisions	Review of files
	Self assessment	Accepts constructive criticism Recognizes opportunities for improvement	Interview, annual performance review
<b>3.2.4 Personal attributes</b>	Tact, diplomacy; Impartiality and objectivity; Supporting goals of organic farming and handling; Professionalism: in presentation ACA values; Integrity: honesty, fairness and lack of bias; Confidentiality; free of conflict of interest disclosure report; Decisiveness: reaches decisions in a timely manner based on logical reasoning and analysis	Satisfactory performance Declarations kept current (confidentiality, C of I)	Feedback from operators Review of complaints filed naming the reviewer Review of annual documentation Observation at work

### 3.4 Recommended Professional Development Activities

Initial and final reviewers should participate in a wide range of professional development activities. They should be documented and included in their résumé, supported by course certificates and content lists whenever possible. This is a partial list of possible professional development activities:

- Conferences
- Workshops
- ACA training programs
- NOP ACA Training Programs
- University and community college courses
- eOrganic webinars
- On-farm demonstrations
- Subscriptions to trade magazines
- Independent study/reading
- Networking<sup>101</sup> (professional associations, relevant listserv groups, etc.)
- Peer review
- Interface of review teams with inspector teams
- Performance review from certifiers (see previous section)
- Private coaching
- IOIA webinars, seminars and training activities
- ATTRA documents

Content lists for training activities are presented in Task 2.

## 4 Definition of Terms

Term	Definition	Source
Ability	capacity, power, cleverness, talent, mental power	Oxford American Dictionary 1999
ACA	Accredited certifying agents	
Area of operation	The types of operation: crops, livestock, wild crop harvesting or handling or any combination thereof that a certifying agent may be accredited to certify under this part.	NOP 205.2
Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.	ISO 19011, 3
Audit in/out balance	Examination of production records, inventory reports, receiving (purchase) reports and sales summaries for the purpose of verifying whether or not sales of organic product reconcile with production and receiving (purchases).	
Audit trail	Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as '100% organic', the organic ingredients of any agricultural product labeled as 'organic' or 'made with organic(specified ingredients) or the organic ingredients of any agricultural product containing less than 70% organic ingredients identified as organic in an ingredient statement.	NOP 205.2
Certification (or certified)	A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.	NOP 205.2
Certified operation	A crop or livestock production, wild crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agency as utilizing a system of organic production or handling s described by the Act and the regulations in this part.	NOP 205.2
Certifying agent	Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.	NOP 205.2
Competence	Demonstrated personal attributes and demonstrated ability to apply knowledge and skills.	ISO 19011
Competent authority	The official government agency having jurisdiction.	Codex Alimentarius 2.2
Credentials	Evidence of a person's achievements or trustworthiness, usually in the form of certificates, references, etc.	Oxford American Dictionary, 1999
Immediate family	The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate	NOP 205.2

	household of a certifying agent or an employee, inspector contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector contractor, or other personnel of the certifying agent.	
Inspection	The examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements. For organic food, inspection includes the examination of the production and processing systems.	Codex Alimentarius 2.2
Inspector	Any person retained or used by the certifying agent to conduct inspections of certification operators or certified production or handling operations.	NOP 205.2
Investigation	A systematic gathering of facts and evidence to support or refute an allegation.	NOP Online Training: <i>Investigating Complaints: What ACAs Should Know</i> , Compliance & Enforcement Branch, June 2009
Knowledge	Specific information; facts or intelligence about something	Oxford American Dictionary 1999
Material evaluation program	An organic certification or other program, independent from the crop producer or input manufacturer, with the expertise to verify compliance of inputs used in organic production and handling with NOP regulations. The expertise and approval of material evaluation programs will be a component of the NOP accreditation program. Approved material evaluation programs include NOP accredited certifying agents and the Organic Materials Review Institute (OMRI). ACAs and OMRI are audited regularly to evaluate their compliance with the NOP regulations and this policy.	NOP Handbook PM 11-4
Official accreditation	The procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services. For organic production, the competent authority (official government agency having jurisdiction) may delegate the accreditation function to a private body.	Codex Alimentarius 2.2
Organic control point (OCP)	Any point or procedures in an organic production, processing or handling system where there is a high probability that improper control may cause, allow or contribute to the loss of integrity. OCPs are points where there is contamination or commingling risks to organic crops or products.	IFOAM/IOIA International Organic Inspection Manual, p 45
Organic production	A production system that is managed in accordance with the Act and regulations in this part to respond to site specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance and	NOP 205.2

	conserve biodiversity.	
Organic System Plan (OSP)	A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent, and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.	NOP 205.2
Public-Private Partnership (PPP)	A contractual agreement between a public agency and a private sector entity. Through this agreement, the skills and assets of each sector (public and private) are shared in delivering a service.	National Council for Public-Private Partnerships, <a href="http://www.ncppp.org">www.ncppp.org</a>
Records	Any information in written, visual or electronic form that documents the activities undertaken by a producer, handler or certifying agent to comply with the Act and regulations in this part.	NOP 205.2
Residue testing	An official or validated analytical procedure that detects, identifies and measures the presence of chemical substances, their metabolites or degradation products in or raw or processed agricultural products.	NOP 205.2
Responsibly connected	Any person who is a partner, officer, director, holder, manager or owner of 10 or more of the voting stock of an operator or a recipient of certification or accreditation	NOP 205.2
Skill	Expertness, practiced ability	Oxford American Dictionary 1999
State Organic Program (SOP)	A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.	NOP Regulations 205.2
Traceability test or trace-back	Verification that an operator has a recording keeping system in place which enables <ul style="list-style-type: none"> <li>• Backward tracking of sales through production to ingredient/input purchasing</li> <li>• Forward tracking of inputs through production, warehousing and sales to final customers</li> </ul>	IOIA training
Witness audit	The witnessing of the certification body's conformity assessment activities during an inspection of a supplier, including an examination of the inspector's preparation for the inspection and the implementation of the certification body's inspection procedures. The inspection of the supplier may be a demonstration when it is not possible to conduct an actual inspection.	USDA AMS ARC ISO Guide 65 Program: Accreditation for Certification Bodies Section 4: Definitions

## 5 References

- ACA Compilation of Certifier Position Descriptions for Inspectors and Reviewers; August 2011
- IFOAM /IOIA International Organic Inspection Manual; 2000.
- ISO 19011 Guidelines for quality and/or environmental management systems auditing; 2002
- Organic Products Regulation (Canada) 2009 SOR/2009-176; current to July 11 2011
- Guidelines for the Production, Processing, Labeling and Marketing of Organically produced foods, adopted by the 23<sup>rd</sup> session of the Codex Alimentarius commission in 1999; revised in 2001
- National Organic Program Handbook (Winter edition 2011)
- NOP Online Training: *Investigating Complaints: What ACAs Should Know*, Compliance & Enforcement Branch, June 2009
- National Organic Program Final Rule 7 CFR, 2010
- National Organic Standards Board Principles of Organic Production and Handling, 2001
- ATTRA Workbooks, Checklists, OSP Technical Guide, Templates and Documentation Forms and Inspection forms IFOAM Accreditation Criteria for Bodies Certifying Organic Production and Processing, version 2005
- ISO/IEC Guide 65, 1996
- Organic Food Production Act (OFPA) of 1990 (USA)
- IOIA Accreditation Program August 2002
- OCC/IOIA Inspector Apprenticeship Program December 1998
- IOIA Apprentice-Mentor Guidelines October 2007
- IOIA Basic Training curriculum - Crops revised 2007
- IOIA Basic Training curriculum – Livestock revised 2008
- IOIA Basic Training curriculum – Handling revised 2008
- IOIA Code of Ethics revised 2001
- IOIA Code of Conduct revised 2001
- IOIA Draft Inspection Guide April 2006
- IOIA Training Institute Summary April 2011
- IOIA Training Program Guide revised 2008
- USDA AMS ARC ISO Guide 65 Program: Accreditation for Certification Bodies, Section 4 Definitions

## 6 Appendices

### Guidelines for Preparation, Inspection and Reporting Times

Level of complexity	Example	Preparation time estimate	On site inspection time estimate	Post inspection time estimate <sup>102</sup>
Apprentice	15 acres organic strawberries, in rotation with green manures; one location; no conventional or transition, no on-farm processing	0.5 hr	2-3 hr	1 hr
	400 acres organic cash crops; one location; no conventional or transition, no on-farm processing	0.5-1 hr	3 hr	1 hr
	Organic pasta production, 10 employees, one location, no conventional	0.5-1 hr	3-4 hr	1.5-2 hr
Licensed	30 acres organic vegetables, in rotation with green manures; 2 locations; no conventional or transition, no on-farm processing	0.5-1 hr	4-5 hr	1.5-2 hr
	250 acres organic feed crops, 40 head organic dairy herd, no conventional or transition, no on-farm processing	0.5-1 hr	4-5 hr	1.5-2 hr
	Organic pasta sauces, 80 employees, 50% organic products, 50% conventional products, off-site warehousing	1-2 hrs	6-8 hrs	2-3 hrs
	Specialty crops /innovative processes			
Master	1800 acres cash crops, 8 locations, some land still in transition and under conventional management; 2 storage sites; on-farm cleaning and bagging	2 hrs	up to 1.5 days	2-3 hrs
	2000 head organic cow/calf; organic pasture; multiple locations, purchased feeds, custom slaughter house; custom sausage making. 15 different recipes, some in 95%, some 70%+, some MWO.	4 hrs	2 days or more	4-5 hrs
	Processes with in-process inventories (fermentations for example)			
	Inspections (un-announced or follow-up) related to suspected fraud or serious complaints			

## 7 Endnotes

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<sup>1</sup> NOP 205.403 (c) (1)

<sup>2</sup> ISO 19011 6.2.5 and 6.3 and 6.4.1

<sup>3</sup> ISO 19011 6.5.1

<sup>4</sup> NOP Handbook ‘Five steps to certification’

<sup>5</sup> A common oversight identified by ARC auditors was the lack of follow-up to previous minor noncompliances.

<sup>6</sup> ISO 19011 6.5.2 and 6.5.5

<sup>7</sup> NOP 205.403(d)

<sup>8</sup> NOP 205.403 (c) (3) and 205.403 (e) ; NOP Handbook ‘Five steps to certification’

<sup>9</sup> NOP 205.403 (d); ISO 19011 6.5.7

<sup>10</sup> IOIA Training Program Guide p2

<sup>11</sup> see Definition of Terms

<sup>12</sup> Hereafter, first time operators and certified operators will be jointly referred to as operators.

<sup>13</sup> Although the NOP does not specify a % of operators who must be targeted annually by un-announced inspections, ACA procedures normally set a target percentage.

<sup>14</sup> IOIA Basic curriculum ‘Drawing the circle around an operation’

<sup>15</sup> ISO 19011 recommends 40 hours of auditor training for all entry level auditors

<sup>16</sup> NOP 205.403 and section 500;

<sup>17</sup> ACA inspector position descriptions

<sup>18</sup> NOP Program Handbook PM-11-6

<sup>19</sup> IFOAM/IOIA Inspection Manual 2.3.5; ASQ Auditing handbook; ISO 19011 6.5.4

<sup>20</sup> ISO 19011 6.6.1; ASQ Auditing Handbook p 141

<sup>21</sup> ISO 19011 7.3.1; ASQ Auditing Handbook

<sup>22</sup> ISO 19011 6.4.1 and 6.4.3

<sup>23</sup> NOP 205.403 (b)(2)

<sup>24</sup> IOIA Training program guide; ACA inspector position descriptions

<sup>25</sup> ARC job description, IOIA training manual

<sup>26</sup> ISO 19011 7.3.1; ASQ Auditing Handbook p 141

<sup>27</sup> IFOAM/IOIA International Organic Inspection Manual 4.1.1

<sup>28</sup> IFOAM/IOIA International Organic Inspection Manual 4.8

<sup>29</sup> IFOAM/IOIA International Organic Inspection Manual 5.1.2

<sup>30</sup> IFOAM/IOIA International Organic Inspection Manual 6.2 and 6.3

<sup>31</sup> NOP 205.501(a)(11); IOIA curriculum; ISO 65 42.2.o

<sup>32</sup> ISO 19011 6.5.5; ASQ Auditing Handbook p 141; IOIA Training program guide

<sup>33</sup> IOIA curriculum

<sup>34</sup> ISO 19011 6.5.5

<sup>35</sup> This is a compilation from a variety of sources: NOP Regulations; ISO 19011 6.6.2 and 7.2; ASQ Auditing Handbook; Codex Alimentarius 6.6.a; ISO 65 4.2.f; IOIA Codes of Conduct and Ethics, IOIA training program guide; IOIA crops and handling curriculum; IFOAM Accreditation Criteria 1.4.11; and ACA inspector position descriptions.

<sup>36</sup> NOP 205.504 (c)(2) requires that inspectors file an annual conflict of interest disclosure report form, identifying any food or agriculture related business interests, including business interests of immediate family members that cause a conflict of interest.

<sup>37</sup> NOP 205.501 (a)(10) requires inspectors hold information confidentially.

<sup>38</sup> The USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender or marital status (not all prohibited status apply to all programs),

<sup>39</sup> IOIA promotes a 2 defect guideline when inspecting foreign operations (see IOIA Code of Conduct and Ethics, which refers to knowledge of culture, language and crop. Also addressed in ARC job description.



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<sup>40</sup> IOIA training prerequisite

<sup>41</sup> This category describes entry-level inspectors who have completed basic training plus field training with a mentor. Other terms considered but not used were ‘apprentice’ and ‘provisional’. These could confer a connotation of inadequacy and were discarded in preference for the neutral term ‘inspector’. A one-year time frame was considered, but rejected. Some inspectors could move to licensing quite quickly while field training might take longer than 1 year for others. Mentor shortage could also lengthen time frames.

<sup>42</sup> IOIA basic trainings have traditionally been 4.5 days per category, on site (not web-based), with 4 days of instruction and 0.5 day of testing

<sup>43</sup> Note: It is not feasible to apply all requirements, especially field training, to the wild crop scope separately from crop. It is recommended that any inspector qualified to inspect crops could also inspect wild crops, provided they received training specific to wild crop standards and inspection. At this time, wild crop inspection has been included in 100 level training content. Specific 200 level wild crop training could be required for wild crop inspection.

<sup>44</sup> The term ‘licensed inspector’ is used for those who have taken the step to become competent to do solo inspections, including 200 level training and successful completion of a licensing exam.

<sup>45</sup> Documentation can be through verification of membership, listserv email, etc.

<sup>46</sup> IOIA Training Institute draft

<sup>47</sup> Testing and exams rated fairly highly in the 2010 IOIA certifier survey

<sup>48</sup> NOP 205.402

<sup>49</sup> NOP 205.404(a)

<sup>50</sup> NOP 205.501(a)(11)(vi)

<sup>51</sup> NOP 205.402(a)(1)

<sup>52</sup> NOP 205.402 (a)(2)

<sup>53</sup> NOP 205.402(a)(4)

<sup>54</sup> NOP 205.402(a)(3)

<sup>55</sup> See ‘TERMS: Materials Evaluation Program’

<sup>56</sup> NOP 205.404(a)

<sup>57</sup> According to IOIA 2010 survey, some ACAs need to refer back to inspectors up to 50% of the time, before being able to complete the final review.

<sup>58</sup> NOP 205.402(b)(2) and NOP 205.403(d)(2)

<sup>59</sup> NOP 205.405(a)(3), NOP 205.405(b)(1)

<sup>60</sup> NOP 205.405(c)(1)

<sup>61</sup> ACA reviewer position descriptions

<sup>62</sup> NOP 205.402(a)(1-2); ISO 19011 6.3

<sup>63</sup> NOP Handbook 2601 Instruction “Five Steps to Certification”

<sup>64</sup> NOP subpart D

<sup>65</sup> NOP subpart D

<sup>66</sup> NOP 205.402(a)(3)

<sup>67</sup> NOP 205.402(b)

<sup>68</sup> NOP 205.501(a)(18)

<sup>69</sup> ISO 19011 6.2.4

<sup>70</sup> NOP205.406(a)

<sup>71</sup> ACA reviewer position descriptions

<sup>72</sup> NOP 205.403 e(2)

<sup>73</sup> NOP 205.403 e(2)

<sup>74</sup> ISO guidelines for Quality system management use the terms Corrective Actions (measures taken to correct identified non-conformances) and Preventive Actions (measures put in place to ensure an identified Non conformance does not recur). ISO guidelines also differentiate between major and minor non-conformances.

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Although such terms can be very helpful, in the present document the authors have intentionally remained faithful to the language in the NOP Regulations.

<sup>75</sup> NOP 205.404(a)

<sup>76</sup> NOP 205.405(a); note that 205.405(c) details how notices of denial are to be issued

<sup>77</sup> NOP 205.501(a)(18)

<sup>78</sup> NOP 205.501(a)(15) and NOP 205.662 and NOP 205.665

<sup>79</sup> NOP 205.501(a)(2); ACA reviewer position descriptions

<sup>80</sup> Since not all NOP Accredited Certifying Agents are accredited to ISO 65, this has been kept general.

<sup>81</sup> ACA inspector position descriptions

<sup>82</sup> NOP 205.501(a)(1)

<sup>83</sup> Most of the skills in section 3.2 are based on the ACA inspector position descriptions

<sup>84</sup> It seems that most review work is done by staff, but some review work is contracted out, often to inspectors.

<sup>85</sup> NOP Handbook PM-11-6

<sup>86</sup> ACA inspector position descriptions

<sup>87</sup> ACA inspector position descriptions

<sup>88</sup> This is a compilation from a variety of sources: NOP Regulations; ISO 19011 6.6.2 and 7.2; ASQ Auditing Handbook; Codex Alimentarius 6.6.a; ISO 65 4.2.f; IOIA Codes of Conduct and Ethics, IOIA training program guide; IOIA crops and handling curriculum; IFOAM Accreditation Criteria 1.4.11; and ACA inspector position descriptions.

<sup>89</sup> NOP 205.504 (c)(2) requires that inspectors file an annual conflict of interest disclosure report form, identifying any food or agriculture related business interests, including business interests of immediate family members that cause a conflict of interest.

<sup>90</sup> NOP 205.501 (a)(10) requires inspectors hold information confidentially.

<sup>91</sup> The USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender or marital status (not all prohibited status apply to all programs),

<sup>92</sup> ACA inspector position descriptions

<sup>93</sup> ACA inspector position descriptions

<sup>94</sup> IFOAM 1.4.2; ACA reviewer position descriptions

<sup>95</sup> IOIA inspector training in the appropriate category (crops, livestock, handling) is required by many ACAs for their reviewer positions. Some ACAs even require that new reviewers accompany inspectors as part of their training. However, at present, IOIA training is geared more for inspectors than for reviewers. This speaks to the need for developing reviewer-specific training modules.

<sup>96</sup> ACA reviewer position descriptions

<sup>97</sup> ACA reviewer position descriptions

<sup>98</sup> NOP 205.501 (a)(6) and 205.510(a)(4)

<sup>99</sup> ISO 65 4.4(c) requirement for contracted personnel – ISO specifically states “obtain the applicant’s consent”

<sup>100</sup> The narrative text includes a list of peripheral responsibilities conferred to reviewers which do not pertain to file review. The authors have chosen NOT to include those peripheral responsibilities in the proposed performance evaluation.

<sup>101</sup> This can be documented by membership verification, listserve email, etc.

<sup>102</sup> Reporting time is very variable depending on ACA reporting procedures. Some ACAs have no post-inspection reporting (all reports completed on site) so in those cases, post-inspection time could be zero. Some ACAs require more narrative in reports. The times shown in this table are likely low for that reporting format.

**National Organic Standards Board**  
**Certification, Accreditation and Compliance Subcommittee**  
**Proposal**  
**Eliminating the Incentive to Convert Native Ecosystems to Organic Production**  
**February 27, 2018**

## **I INTRODUCTION**

The Organic Foods Production Act (OFPA) of 1990 (as amended) and Regulations promulgated by the National Organic Program (NOP) to implement the statute, NOP policy documents, and NOSB recommendations and principles, include a clear bias towards protection of the natural resources present on an organic operation, including the physical, hydrological, and biological features of the farm. The soil, water, wetlands, woodlands, and wildlife must be maintained or improved by the organic operator through production practices implemented in accordance with the Act and Regulations. This bias towards ecosystem preservation is also found within the organic marketplace with consumer expectations that organic farms and ranches will be examples of excellent land stewardship.

In addition to this strong environmental protection mandate within the regulatory framework that oversees organic production, is the requirement that land cannot produce organic crops or livestock until 36 months have passed between the application of a prohibited substance and the harvest of an organic crop. Using land that has not had any prohibited substances applied to it provides an immediate entry into the organic marketplace for crops or livestock, without the three year wait period. The lack of the three-year transition timeframe is an incentive to convert native ecosystems, some with fragile or endangered habitat, to immediate agricultural production. Over the last three years, the NOSB has received substantial public comment describing loss of native ecosystems when farmers transition to organic production.

The NOSB discussion document from January 10, 2016 and proposal of August 2017 resulted in significant numbers of public comment and support from a wide cross-section of stakeholders. This proposal responds to the improvements sought by the public to the proposal of August 2017.

## **II BACKGROUND**

The NOP provided Guidance on Biodiversity in 2016 (NOP 5020) encouraging the protection and maintenance of a high level of biodiversity on farms because it brings benefits not only to the entire ecosystem in that geographic area, but also to the farmer. This proposal deals with native ecosystems that were specifically not included in the NOP Biodiversity Guidance but were mentioned as an area that should have continued attention.

Many certification agencies around the world address this issue in their standards by banning converted native ecosystems from using the certified organic label at any time after this conversion. These certifiers were listed in the previous discussion document and proposal. The NOSB is not suggesting an outright ban. There may be issues, such as the area may have been converted by a different operator, that should not keep the current operator from choosing to use the environmentally beneficial practices of organic production and being rewarded with the use of the organic label. The NOSB feels the 10-year wait period between conversion of a native ecosystem and subsequent organic certification proposed in

its August 2017 proposal, if all other requirements are met, is a strong disincentive to conversion of these precious areas to organic production.

### **III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS**

The Organic Foods Production Act (OFPA) of 1990, as amended, 7 USC, Chapter 94:

7 USC 6504 (2) ...not be produced on land to which any prohibited substances, including synthetic chemicals have been applied during the 3 years immediately preceding the harvest of the agricultural products;

7 USC 6513(f) Management of wild crops; (2) include a 3 year history of the management of the area showing that no prohibited substances have been applied; (3) include a plan for the harvesting and gathering of wild crops assuring that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop;

The OFPA Preamble to the Final Rule establishing the NOP states: “[t]he use of ‘conserve’ [in the definition of organic production] establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation.” (76 FR 80563)

Previous documents on this issue have provided numerous instances of unaltered native ecosystems that are either at risk or have been destroyed for agricultural production. Numerous examples were provided that this destruction is occurring on land that subsequently is used for organic production, and therefore this issue must be addressed. There are other regulations within the U.S. law that seek to protect specific areas, such as the “sodsaver” provision which specifically addresses the protection of prairie potholes in the United States.

### **IV PUBLIC COMMENT**

**The August proposal of 2017 recommended rule making under 205.200 with this statement.**

*(a) A native ecosystem site that has not been previously grazed or cultivated cannot be certified as organic as provided for under this regulation for a period of 10 years from the date of conversion to crop or livestock production.*

The vast majority of public comments supported the Wild Farm Alliance’s response to the NOSB proposal above, which included the definition and a rule change below.

The suggested definition is as follows:

*Native ecosystems can be recognized in the field as retaining both dominant and characteristic plant species as described by established classifications of natural and seminatural vegetation. These will tend to be on lands that have not been previously cultivated, cleared, drained or otherwise irrevocably altered. However, they could include areas that had been substantially altered over 50-100 years ago, but have since recovered expected plant species composition and structure.*

The suggested regulatory change is as follows:

*205.200 (a) A site supporting a native ecosystem cannot be certified for organic production as provided for under this regulation for a period of 10 years from the date of conversion.*

## **V SUBCOMMITTEE DISCUSSION**

The public and NOSB understand the challenge presented by the public to determine if a native ecosystem has been destroyed for the purpose of growing organic crops. However, there are numerous governmental and privately available aerial photos and ecosystem surveys for both domestic and international production that can aid in determining what had been grown on any specific agricultural parcel for at least the past 50 years and even beyond. Areas where there was no agricultural production have also been surveyed, although there may not be as much detail. The Natural Resources Conservation Service (NRCS) has a database of the possible locations of endangered and threatened species they refer to when allowing manipulation of lands and wetlands. The Farm Service Agency (FSA) has aerial photos of agricultural land going back to 1938, with photos taken approximately once per decade. The U.S. geological service has aerial photos of nonagricultural land going back to the 1950s. NatureServe and other international organizations have similar items for international tracking. Links to many of these websites were provided in previous NOSB documents on this subject.

Wild harvested crops certified under 205.207 (a) and (b) would be not impacted by this proposal.

In addition, organic certification agencies would need to add a few questions to their organic system plan applications to address this issue. Certifiers could provide the readily accessible websites where the various sources of aerial photos and ecosystem tracking could be found to aid operators in answering the questions in their OSP. The questions listed below are examples for organic certifiers to use or modify, to aid them in implementing the proposed regulation of this proposal. These questions are not part of any regulatory change.

- A. Has the area been tilled, cleared, drained, intentionally burned or transplanted into in the past 50 years? *If yes, then ignore the rest of this section.*
- B. Has the land been managed by people for crop production or other purpose such as grazing in the past 50 years? *If yes, then ignore the rest of this section.*
- C. Did the land, 10 years ago to the present day, have a majority non-native or invasive species present? *If yes, then ignore the rest of this section.*
- D. Ten years ago, were native species present in this area and found in sufficient numbers, diversity and vitality to continually regenerate and maintain the biodiversity present? *If no, go to the next section of the OSP. If yes, then this land may be regulated under 205.200 (a). Further information may be requested by your organic certification agency, based upon publicly available aerial photos and ecosystem survey information.*
- E. Are you aware of any conversions from a native ecosystem in the past ten years on the land under application?

## VI MOTION TO APPROVE THIS PROPOSAL

Add the following definition to §205.2

***Native Ecosystem: Native ecosystems can be recognized in the field as retaining both dominant and characteristic plant species as described by established classifications of natural and semi natural vegetation. These will tend to be on lands that have not been previously cultivated, cleared, drained or otherwise irrevocably altered. However, they could include areas that had been substantially altered over 50-100 years ago, but have since recovered expected plant species composition and structure.***

Add this language to §205.200 General– addition is in bold

§205.200 The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

**(a) A site supporting a native ecosystem cannot be certified for organic production as provided for under this regulation for a period of 10 years from the date of conversion.**

Motion to approve the proposal on Eliminating the Incentive to Convert Native Ecosystems to Organic Production

Motion by Harriet Behar

Seconded by Emily Oakley

Yes: 5 No: 1 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Scott Rice, Subcommittee Chair, to transmit to NOSB, February 27, 2018**

**Sunset 2020 Review**  
**Meeting 1 - Request for Public Comment**  
**Livestock Substances §205.603, §205.604**  
**April 2018**

**Introduction**

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic livestock production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2020. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

**Request for Comments**

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2018 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2018 public meeting. These comments should be provided through [www.regulations.gov](http://www.regulations.gov) by April 4, 2018 as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

**Guidance on Submitting Your Comments**

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

**For Comments That Support Substances Under Review:**

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic livestock production.

**For Comments That Do Not Support Substances Under Review:**

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with livestock production.

**For Comments Addressing the Availability of Alternatives:**

Comments may present information about the viability of alternatives for a substance under sunset review.

Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative 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.

Written public comments will be accepted through April 4, 2018 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.



**Sunset 2020 Review Summary**  
**Meeting 1 - Request for Public Comment**  
**Livestock Substances §205.603, §205.604**  
**April 2018**

**Note:** The materials included in this list are undergoing early sunset review as part of November 18, 2016 [NOSB recommendation](#) on efficient workload re-organization.

**Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production**

[Alcohols: Ethanol, Isopropanol](#)

[Aspirin](#)

[Biologics, Vaccines](#)

[Electrolytes](#)

[Glycerine](#)

[Phosphoric acid](#)

[Lime, hydrated](#)

[Mineral oil](#)

[Sucrose octanoate esters](#)

## Alcohols

**Reference:** 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(1)(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive

**Technical Report:** [1995 TAP](#); [2014 TR Ethanol](#); [2014 TR Isopropanol](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

The United States Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision for Aliphatic Alcohols, ethanol and isopropanol were registered in the US as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products.

#### Manufacture:

Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. A variety of methods are available for the fermentative production of ethanol from carbon sources such as starch, sugar and cellulose using natural and genetically engineered strains of yeast or bacteria. Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene and as a by-product of certain industrial operations.

#### International Equivalency:

Several international organizations provide guidance on the application of synthetic ethanol in organic crop and livestock production as well as the processing of organic foods. Among these are international regulatory agencies (EU, Canada and Japan) and independent organic guidelines and standards organizations (Codex and IFOAM).

- **European Economic Community Council (EU)** – Alcohols, presumably including ethanol, may be used for cleaning and disinfecting livestock building installations and utensils.
- **Canada** – Canadian organic production standards permit the use of ethanol for a number of agricultural applications.
- **Japan** – Ethanol may be used in the processing, cleaning, storage, packaging and other post-harvest processes when physical or methods using naturally derived substances are insufficient.
- **Codex Alimentarius** – Ethanol is allowed when mechanical, physical and biological methods are inadequate for pest control.
- **IFOAM** – Synthetic ethanol is an approved additive and processing/post-harvest handling aid when organic and natural sources are not available.

**Environmental/Health Issues:**

Aside from accidental spills, the risk of environmental contamination from released ethanol is minimal. The release of strong acids and bases used in the production of ethanol due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments. However, no incidents involving the release of these chemical feedstocks from ethanol production facilities have been reported. Further, lesser amounts of ethanol are constantly released to the environment from animal wastes, plants, insects, forest fires, and microbes without causing environmental impairment (HSDB, 2012). It is therefore unlikely that large-scale spills and associated environmental contamination will occur under the allowed use of ethanol as a sanitizer and disinfectant in organic livestock production.

**Additional information requested by Subcommittee:**

1. Is the substance still considered to be essential for organic livestock production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

## Alcohols

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable

(1)(ii) Isopropanol-disinfectant only

**Technical Report:** [1995 TAP](#); [2014 TR Ethanol](#); [2014 TR Isopropanol](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:****Use:**

Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage. Agricultural uses of isopropanol include the disinfection of production tools and surfaces and topical antisepsis during medical treatments. Livestock producers may use alcohol (i.e., isopropanol and/or ethanol) solutions for sanitizing and disinfecting surfaces (e.g., production implements, troughs, and floor drains) and during medical treatments as a topical disinfectant (Jacob, 2013; Dvorak, 2008).

**Manufacture:**

Chemical synthetic procedures are used in the commercial production of isopropanol used in the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol

are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011).

#### **International Equivalency:**

A small number of international organizations provide guidance on the application of synthetic isopropanol in organic crop and livestock production as well as the processing of organic foods. Among these are the Canadian General Standards Board and the International Federation of Organic Agriculture Movements (IFOAM).

- **Canada** – Canadian organic production standards permit the use of isopropanol for a number of agricultural applications.
- **IFOAM** – Isopropanol is an approved synthetic equipment cleaner and equipment disinfectant. Isopropanol is also an allowed synthetic substance for pest and disease control and disinfection in livestock housing.

#### **Environmental/Health Issues:**

Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely. Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses. According to US EPA, isopropanol is slightly toxic to practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410 1995).

#### **Additional information requested by Subcommittee:**

1. Is the substance still considered to be essential for organic livestock production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

## **Aspirin**

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(2) Aspirin-approved for health care use to reduce inflammation

**Technical Report:** [1995 TAP](#); [2017 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:****Manufacturing Process:**

The most prevalent method of synthesizing aspirin is via an esterification. Salicylic acid is treated with acetic anhydride, an acid derivative, causing a quantitative chemical reaction that turns salicylic acid's hydroxyl group into an ester group ( $R-OH \rightarrow R-OCOCH_3$ ). This process yields aspirin and acetic acid, which are considered byproducts of this reaction. Small amounts of sulfuric acid (and occasionally phosphoric acid) are almost always used as a catalyst.

The chemical feedstocks for synthesizing aspirin are also manufactured through a chemical process. Salicylic acid is produced commercially via the Kolbe-Schmitt process. Here, phenol and sodium hydroxide react to make sodium phenoxide. The phenoxide comes into contact with  $CO_2$  to form sodium salicylate. The salicylate is acidified to give salicylic acid. The acid is usually crystallized from aqueous solution to give a technical grade 99.5% salicylic acid product. For a pharmaceutical grade product, salicylic acid is further purified by sublimation.

The commercial process for acetic anhydride was developed by Wacker Chemie in 1922 and uses a chemical reaction between acetic acid and ethenone at a low temperature and pressure.

**Specific Uses of the Substance:**

Aspirin (i.e. acetylsalicylic acid) is a nonsteroidal anti-inflammatory drug (NSAID) used for temporary relief of minor aches and pains due to headache, muscular aches, minor arthritis pain, toothache, backache, the common cold, and premenstrual and menstrual cramps. It is also used for temporarily reducing fever, the prevention of cardiovascular events, and the treatment of rheumatologic disorders.

**Approved Legal Uses of the Substance:**

Aspirin is considered a pain reliever and fever reducer in the over-the counter, tentative final monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use by the U.S. Food and Drug Administration (FDA) (53 Federal Register 46204, Nov. 16, 1988 and 21 CFR 343). Aspirin is included under 21 CFR 343.12 and 343.13 for the prevention of cardiovascular events and the treatment of rheumatologic disorders.

Aspirin is also listed at 7 CFR 205.603 as a synthetic substance allowed for the use in organic livestock production and is approved for health care use to reduce inflammation. Its half life is short in cattle and it is not as beneficial in reducing pain as flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency. Additionally, flunixin has annotation restricting its withdrawal time. A second pain medication approved for pain relief in organic livestock is butorphanol (21 CFR 603(a)(5)). Butorphanol is a synthetic opioid partial agonist analgesic; however, it also must be administered under a veterinarian's written orders, and it too is restricted by annotation to a withdrawal time.

**Action of the Substance:**

Aspirin inhibits the biosynthesis of certain hormone-like substances called prostaglandins, which accounts for most of its clinical effect. Depending on where in the body these prostaglandins are produced, they may trigger pain, inflammation, fever, or blood clotting. Following absorption, aspirin is hydrolyzed to salicylic acid, which is the active metabolite for its major clinical effects. Aspirin also inhibits platelet aggregation by irreversibly inhibiting prostaglandin cyclooxygenase.

### Additional information requested by Subcommittee:

1. Is the substance still considered to be essential for organic livestock production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

## Biologics - Vaccines

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(4) Biologics - Vaccines

**Technical Report:** [2011 TR \(Vaccines from Excluded Methods\)](#); [2014 TR \(Aquaculture\)](#)

**Petition(s):** [2012 Petition \(Aquaculture\)](#)

**Past NOSB Actions:** [11/2005 NOSB sunset recommendation](#); [11/2009 NOSB recommendation on Vaccines at §205.105](#); [10/2010 NOSB sunset recommendation](#); [10/2014 recommendation on Vaccines from Excluded Methods](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)) Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

In addition to the allowance of this category of synthetic materials on the National List, there are other areas that address “biologics—vaccines” in the NOP Final Rule.

#### Terms defined:

**Biologics.** All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

#### §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with §205.600(a);

#### §205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

- (a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

### Excerpts from NOSB meeting notes of April 2013:

In the Vaccine Working Group's interim report, we see challenges with changing technology, lack of disclosure, and verifying supply chains. Any expectation of verifying vaccines made with excluded methods will need a clear and practical framework of how to determine compliance. Also, even with a

stricter rule regarding GM vaccine use, exceptions may be needed for critical vaccines that are only available from GM sources. *The interim report states:*

....because there's a considerable amount of manufacturer confidential business information, the working group could not end up with getting this list that we would like to have for producers that would allow them to easily identify which vaccines to use and which not. We then explored it further... as to what in fact constitutes an excluded method.

### **Current situation in 2017**

The NOSB has improved and clarified their working definition of what methods would be considered genetic modification and therefore excluded from use under the USDA organic regulation. This work should aid the NOSB in moving ahead in looking at the issue of use of vaccines produced through the use of excluded methods.

The NOSB could propose to begin reviewing the known vaccines produced through excluded methods as listed in the TR from 2011, to place them individually on the National List as required in the regulation, 2015.105 (e). The NOSB could also propose to approve all vaccines produced through excluded methods as a “class” of vaccines, as suggested by the National Organic Program in the April 2013 NOSB meeting transcript. The NOSB could also choose to do nothing and maintain the current status quo of not addressing this issue, at this time.

The use of vaccines as a preventative measure to promote health in livestock is a necessary tool in organic livestock production. The Livestock Subcommittee does not want to lessen access to vaccines, both for routine maintenance of health, as well as in response to emergency situations. The allowance or prohibition of vaccines produced through the use of genetic engineering, or excluded methods, is not addressed in other organic standards around the world. As a result, all types of vaccines are allowed in various international organic standards.

*NOSB members are aware that there is a great lack of consistency between certifiers when addressing the issue of GMO vaccines. Some require documentation that every vaccine used is not a GMO. Others do not require that documentation. Some require documentation and allow the use of the GMO vaccine. Inconsistency in implementation of the organic regulations leads to lack of trust in the certification system, as well as in the marketplace. Since the NOSB is now in review of vaccines for their sunset listing, we believe it is the time to address this problem of regulatory inconsistency.*

*The NOSB understands that livestock diseases can happen anywhere in the world and can quickly become a problem for all types of producers. At times, a GMO vaccine may be the only available solution to the problem, and the NOSB does not want to constrict the options available to producers. The NOSB is aware of GMO vaccines that are currently being used on organic livestock operations. Some may not have a non-GMO equivalent and some may. The NOSB could begin review of these individual GMO vaccines now for placement on the national list, to bring these operations using them into compliance with the full regulation as currently written.*

*When an organic livestock producer loses one or more of their animals, there is more than just that animal's production capability lost, even though that is significant. Many times, there have been many years, even decades of breeding and genetic selection resulting in that specific animal. When that animal is lost to the farm, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and*

*vaccines remain an important tool in the organic livestock producer's toolbox.*

**Manufacturing Process:**

Vaccines are produced through a variety of methods that use natural pathogens grown in a culture (yeast, bacteria or cell), separation and purification of the vaccine, addition of other materials that may enhance the efficacy of the vaccine. These methods will result in a live, modified live or killed vaccine.

**Specific Use:**

Vaccination against bacterial or viral infections is a cost effective and efficient method of lessening animal suffering and disease. A vaccine contains, or produces in the vaccinated individual, an antigen that stimulates an immune response and enables protection from the disease and/or future infection.

**Additional information requested by Subcommittee:**

1. Should individual genetically modified vaccines be listed on the National List, or should all genetically modified vaccines be allowed as a class, perhaps with a commercial availability clause such as “use of GE vaccines as a class is allowed with documentation that no GE version of the specific vaccine is commercially available”.
2. What type of documentation are certification agencies currently requesting to determine non-GMO status for the vaccines used on organic livestock? How is this verified? Are they denying the use of GMO vaccines on organic livestock operations?
3. Is the current system where GMO vaccines are sometimes reviewed and either allowed or not, acceptable to the organic industry, and should it remain in place with no changes?
4. Are there alternative methods or materials that make vaccines no longer an essential material on the National List of approved synthetics?

## Electrolytes

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable

(8) Electrolytes—without antibiotics

**Technical Report:** [1995 TAP](#); [2015 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

Electrolytes are considered animal drugs by the FDA, and in USDA organic production they may only be used when preventative practices are inadequate to prevent illness, and may not be given in the absence of illness. Electrolytes are used to restore ionic balance, treating a variety of metabolic conditions such as hypocalcemia, scours, milk fever, dehydration, mastitis, ketosis, acidosis and more.



**Manufacturing Process:**

Electrolytes are produced through industrial processes, fermentation, or they may be mined. The major component of electrolyte formulations are salts and would have a variety of carriers or other ingredients that enhance their properties, such as dextrose, citric acid, glucose, glycine and more. The 2015 TR has a detailed description of the various manufacturing processes.

**Specific Use:**

Electrolyte balance is essential to maintain normal physiology and health of livestock. When there is an imbalance of cations such as sodium, potassium, calcium or magnesium, either too low or high, the health and life of the animal is at risk. Stages of life, environmental stresses, and stages of production such as birthing an animal, are all conditions that can throw the electrolyte balance off and would necessitate the use of this material to restore health and well-being to the animal.

**Additional information requested by Subcommittee:**

1. Is the substance essential for organic livestock production and is it used regularly?
2. Since the material was last reviewed, have additional commercially available natural alternatives emerged?

## Glycerine

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(12) Glycerine - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

**Technical Report:** [2010 TAP \(Livestock\)](#)

**Petition(s):** N/A

**Past NOSB Actions:** [1999 NOSB recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

Glycerin, or glycerol, is a by-product of the soap manufacturing process. The oldest method of manufacture is by hydrolysis of natural fats & oils (either animal or vegetable): heat, steam, and pressure “split” the glycerin from the oil. The glycerin is concentrated in multistage evaporators and refined. Purification is achieved through either an ion exchange process or a distillation system, but it can also be produced synthetically from propylene.

If only heat, steam or pressure is used to split the ester bonds to liberate free glycerol from fat (i.e. triglycerides), then this is a hydrolysis reaction catalyzed by physical forces and is compatible with the annotation for glycerin at § 205.603(a)(11) that requires production through hydrolysis of fats or oils. If glycerol is formed by the chemical reaction of sodium hydroxide, then glycerol is produced by a

chemically catalyzed hydrolysis reaction and may be considered synthetic.

**Specific Uses:** Glycerin has over 1,000 uses; however, glycerin is limited to being used as an ingredient in teat dips for the addition to § 205.603(a), As an ingredient in teat dips it prevents teat irritation and improves skin conditioning. Glycerin does have some germicidal activity (Fox et al., 1990).

Glycerin is widely used as a carrier for other medications because it does not detrimentally affect chemical interactions with other substances. Glycerin remains inert and does not change the properties of substance in which it is used. Furthermore, it acts as an emollient, reducing moisture evaporation of the skin.

**OFPA:** Glycerin falls under section 6517(1)(B)(i) of the OFPA code that describes livestock medicines.

**INTERNATIONAL:** The 2010 TAP review stated that livestock materials have not been addressed by Codex and that IFOAM Basic Standards do not mention glycerin, or other synthetics used as teat dips, but it does not appear to be prohibited.

**Effects on Human Health:** Glycerin mist can act as an inhalation irritant. It is easily digested with the same metabolism as the carbohydrates.

**Effects on the Environment:** Glycerol can never be sorted or come into direct contact with strong oxidizers such as potassium chlorate or potassium permanganate because it may produce an explosion.

#### **Alternatives:**

**Synthetic Alternatives:** Isopropyl Myristate, Isopropyl Palmitate, Polypropylene Glycol, Other Glycol Derivatives, Petroleum Fractions, High Molecular-Weight Alcohol, Allantoin, Synthetic Glycerin from petrochemicals.

**Natural Alternatives:** Castor and Vegetable Oil.

**Management tools:** Some management tools for controlling mastitis include: wiping debris from the teats, massaging the teat to loosen debris and stimulate milk letdown, wiping off the teat dip using individual cloths or paper towels, and applying the milking unit without air admission.

#### **Additional information requested by Subcommittee:**

1. In April 2015, the NOSB Handling Sub-committee recommended listing of glycerin at §205.606 and removal of glycerin from §205.605(b) after review of the manufacturing methods and sources. Are there non-food grade agricultural sources of glycerin produced by microbial fermentation of carbohydrate substances, and/or are there sources of glycerin produced from hydrolysis of fats and oils using mechanical/physical methods that are readily available as an ingredient for teat dips?
2. If there are non-food agricultural sources of glycerin available, should synthetic glycerin be removed from 205.603(a)?
3. Have there been updates in the International status for approval of synthetic glycerin used as livestock teat dips since the 2010 TAP was published?
4. How are certifiers tracking that the glycerin used as a teat dip is being produced through the hydrolysis of fats or oils?

## Phosphoric acid

**Reference:** **205.603(a)** As disinfectants, sanitizer, and medical treatments as applicable  
(20) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs

**Technical Report:** [2003 TAP \(Handling\)](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

Phosphoric acid, (H<sub>3</sub>PO<sub>4</sub>), has many uses. As a cleaner, it is generally used to remove rust and mineral deposits found on metal equipment such as boilers and steam producing equipment. In dairy operations, it is used to remove calcium and phosphate salt deposits from processing equipment.

Phosphoric acid is a hazardous substance. The exact dangers of it depend on the concentration strength of the solution, with higher concentrations presenting greater hazards. Phosphoric acid, at 85 wt. %, is considered a corrosive chemical solution that can cause, through skin exposure and inhalation, severe skin burns, permanent eye damage, sore throat, shortness of breath, and even death—among other things.

### Additional information requested by Subcommittee:

1. Is the substance essential for organic livestock production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

## Lime, hydrated

**Reference:** **§205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable  
(5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes

**Technical Report:** [1995 TAP](#); [2015 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### **Background from Subcommittee:**

Under the USDA organic regulations for livestock production, hydrated lime is only permitted for external pest control (7 CFR 205.603(b)(5)). Regarding livestock applications, the National List states that hydrated lime may not be used to cauterize physical alterations or deodorize animal wastes. Composition of hydrated or “slaked” lime consists primarily of calcium hydroxide [Ca(OH)<sub>2</sub>] and magnesium hydroxide [Mg(OH)<sub>2</sub>] at 50 – 95% and 0 – 50% of the substance, respectively. High purity forms of the substance contain greater than 90% calcium hydroxide. The USDA organic regulations currently permit the use of hydrated lime (calcium carbonate) for plant disease control in crop production (7 CFR 205.601(i)(4)) and external pest control in livestock production (7 CFR 205.603(b)(5)).

### **Manufacturing Process:**

According to USDA organic regulations, “synthetic” is defined as “a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources...” (7 CFR 205.2). Hydrated lime [Ca(OH)<sub>2</sub>] is produced through two sequential reactions: thermal decomposition of ground limestone (CaCO<sub>3</sub>) to quicklime (CaO) followed by hydration of quicklime at elevated temperatures and/or pressures. The limestone starting material is a naturally derived, non-synthetic substance. However, the NOSB classified calcium oxide (quicklime) as a synthetic substance due to the chemical change that occurs during the thermal reaction of natural limestone. Hydrated lime is therefore produced through chemically changing a synthetic substance (quicklime). Based on the “synthetic” definition, it is reasonable to conclude that hydrated lime used as an external parasiticide in organic livestock production is a synthetic substance. The NOSB has classified hydrated lime as synthetic since initially recommending addition of the substance to the National List for organic livestock production.

### **Specific Use:**

The USDA organic regulations currently permit the use of hydrated lime for plant disease control in crop production (7 CFR 205.601(i)(4)) and external pest control in livestock production (7 CFR 205.603(b)(5)). Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations or deodorize animal wastes.

### **Additional information requested by Subcommittee:**

1. Is the substance essential for organic livestock production and is it regularly used?
2. Since the material was last reviewed, have additional commercially available natural alternatives emerged?

## **Mineral oil**

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable (6) Mineral oil - for topical use and as a lubricant

**Technical Report:** [2002 TAP](#); [2015 TR](#)

**Petition(s):** [2002 Petition](#)

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

The USDA organic regulations currently permit the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(6). Regarding the former use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice and other parasites. Conventional operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants. This medical practice is not currently approved for organic production, but a proposed rule published by NOP on January 17, 2018 ([83 FR 2498](#)) would add mineral oil to the National List for relief of intestinal impaction (as recommended by the NOSB in 2002).

Mineral oils used in organic livestock production are hydrocarbon molecules containing 15 to about 50 carbon atoms (U.S. EPA, 2007; EFSA, 2012). Crude, untreated mineral oil mixtures consist of three major classes of compounds: paraffins (linear and branched alkenes), naphthenes (alkyl-substituted cyclo-alkanes) and aromatics (including polynuclear aromatic hydrocarbons (PAHs)), which are generally alkyl-substituted. These untreated mineral oils may also contain small amounts of nitrogen- and sulfur-containing compounds (EFSA, 2012).

**Manufacturing Process:**

The composition of mineral oil is dependent upon the crude petroleum oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions. In the 2007 risk assessment for mineral oils, U.S. EPA indicated that most manufacturers are currently using modified refining and cleanup processes to remove the more toxic components and generate refined minerals largely devoid of PAHs as well as nitrogen and sulfur compounds (U.S. EPA, 2007). Because of their complexity, it is not possible to resolve mineral oil mixtures into individual components for quantification. Indeed, an enormous number of individual components from compounds of varying carbon chain length to isomers of the same carbon chain length - are constituents of crude and refined mineral oil mixtures (EFSA, 2012).

**Specific Use:**

The USDA organic regulations currently permit the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(6). Regarding the former use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice and other parasites.

**Additional information requested by Subcommittee:**

1. Is this an essential material?
2. Is mineral oil being used orally?
3. Are organic farmers using mineral oil as a lubricant?

## Sucrose octanoate esters

**Reference: §205.603(b)** As topical treatment, external parasiticide or local anesthetic as applicable (8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling

**Technical Report:** [2005 TR](#)

**Petition(s):** [2004 petition](#); [05/2004 petition amendment](#); [09/2004 petition amendment](#)

**Past NOSB Actions:** [08/2005 NOSB recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs). SFAEs are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals. SOEs, marketed as biopesticides, are intended to mimic the pest control properties of *Nicotiana glauca* (wild tobacco) and other *Nicotiana* species. In addition to the tobacco plant, insecticidal sugar esters have been found in wild tomato and wild potato species and in the petunia plant (Chortyk et al., 1996). The petitioned substance is a soap derived from coconut oil fatty acids or palm kernel oil fatty acids. SOEs are listed at §205.601(e) as an insecticide (including acaricides or mite control), but the listing at §205.603(b) specifically addresses the petitioned use for livestock (i.e., honey bees).

### Specific Uses of the Substance:

Sucrose octanoate esters (SOEs) are an EPA-registered biopesticide. SOEs are permitted by EPA for use as a biopesticide for foliar spray in field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals), as well as on mushroom growing media and on adult honey bees. (U.S. EPA, 2002a).

### Effect on the Environment:

SOEs are an effective adult miticide (as well as controlling other pest types); they can be used at all plant growth stages; is not harmful to fish; it is not a hazard to bees (it is registered for use on bees to control *Varroa* mites); and it is not phytotoxic. When applied according to EPA-approved label directions, no direct exposure of birds or aquatic organisms to SOE is expected (U.S. EPA, 2002a).

In addition, SOEs biodegrade within approximately five days at approximately 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions, so there is minimal potential for exposure exists to insects, fish, and other non-target wildlife. U.S. EPA, 2002a). A limited number of experiments have shown SOEs do not affect a range of predators and parasitoids that are killed by insecticidal soaps. Impacts on soil fauna have not been established.

### Effect on Human Health:

SOEs have low toxicity to humans and are produced in a closed system. The 2005 TAP review states that no sub-chronic, chronic, immune, endocrine issues have been identified. An ocular risk exists but is unlikely if product is used according to label.

**Additional information requested by Subcommittee:**

1. The TR does not address the toxicity of SOEs to non-targeted organisms, including predators, parasitoids, soil fauna, and aquatic organisms when exposed by spray. Should there be further information requested about the toxicity of SOEs to non-target organisms?
2. Is this product still being used, or are there other synthetic products that are more effective?
3. If SOEs are not being used, do we need it to keep in the livestock toolbox to be rotated with other products?

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**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Glycolic Acid  
February 20, 2018**

**Summary of [Petition](#):**

The NOSB received a petition to add glycolic acid for use as a component of pre- and post-milking teat dips to control mastitis at §205.603(a) Synthetic substances allowed for use in organic livestock production as disinfectants, sanitizer and medical treatment as applicable).

**Summary of Review:**

**Specific Uses of the Substance:**

Glycolic acid has been shown to be an effective post-milking teat disinfectant for dairy cows (Godden et al., 2016). Specifically, its petitioned use is as a component in a post-milking teat dip to aid in the prevention of bovine mastitis. Teat dips may contain emollients, excipients, and other allowed disinfectants. Because glycolic acid conditions the skin by exfoliating cracked skin layers, it removes potential hiding places for mastitis causing bacteria, e.g. *Staphylococcus aureus*.

In addition to its uses in skin care, glycolic acid is used in a broad range of applications. For example glycolic acid is used as a descaler for cutting through hard water salts, as a cleaning agent, as a liquid scour in laundry systems, as a copper and aluminum cleaner including boilers and heat exchangers, and as a dairy and CIP cleaner to dissolve casein as well as hard water deposits.

Glycolic acid is certified by the National Sanitation Foundation (NSF) for use in cleaning potable water wells. It is used widely to rehabilitate the flow efficiency of water wells by enabling water-soluble compounds (chelates) to be easily rinsed away with low corrosion to metal parts. Glycolic acid removes hard water scale (calcium, magnesium, manganese salts), various iron deposits and polysaccharide deposits. Glycolic acid biodegrades rapidly. It is a liquid with low toxicity, low odor, is non-flammable and has negligible fumes.

**Approved Legal Uses of the Substance:**

The first product containing glycolic acid as an active ingredient was registered by the U.S. Environmental Protection Agency (EPA) in 2001 as a disinfecting cleaner and a disinfectant/sanitizer for non-food contacting, hard non-porous surfaces in residential and public access premises. Since then, additional products have been registered with the EPA. There are no tolerances, exemptions from tolerances, or tolerance petitions for this antimicrobial pesticide. Glycolic acid is approved by FDA as an indirect food additive for use in food packaging adhesives (21 CFR 175.105).

Glycolic acid is considered by the FDA to be a human cosmetic that is safe for use by consumers if the concentration is 10 percent or less, the pH is 3.5 or greater and the formulation protects the skin from increased sun sensitivity or the package directions instruct the consumer to use daily protection from the sun (FDA, 2015). Teat dips and udder washes classified as drugs, may currently be marketed without a New Animal Drug Application (NADA) approval. However, the FDA has developed non-binding guidelines for teat antiseptic product development. The guidelines were assembled to inform the drug industry of the types of data that will demonstrate that a teat antiseptic product: 1) is safe for the cow,

2) is effective and 3) fulfills human food safety, manufacturing and environmental requirements. Products to be marketed must be manufactured according the Current Good Manufacturing Practice (cGMP) regulations (21 CFR Part 211) for pharmaceutical dosage forms under the approved NADA process (FDA, 2016).

The USDA does not regulate glycolic acid for application as a teat dip. However, the USDA regularly reports survey results for the dairy industry including statistics of use and recommendations for pre and post milking teat dips (USDA, 2016).

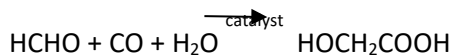
#### **Action of the Substance:**

Glycolic acid is mildly bactericidal. However, its effect on the hyperkeratinization of skin is significant. Hyperkeratinization is a primary event in many skin disorders. It is caused by dying and dead adherent skin cells trapped near a hair follicle in the layers of tightly bound living cells called corneocytes. Normally, the dead cells are sloughed off by the follicles in a process called desquamation, but in the case of hyperkeratinization the dead cells are stuck beneath the tightly bound corneocytes. Dry skin, in wintertime is particularly vulnerable to reduced desquamation and hyperkeratinization. Glycolic acid has a therapeutic effect on hyperkeratinization, and the cohesiveness of corneocytes (Scott and Ruey, 1984). One theory for the mechanism of action of glycolic acid is that it reduces the calcium ion concentration in the epidermis and removes calcium ions from the cell adhesions by chelation. The cell adhesions are thereby disrupted, resulting in desquamation (Wand, 1999).

Glycolic acid reduces cohesiveness in the lower, newly forming layers of corneocytes potentially by inhibition of an enzyme. Glycolic acid does not cause disaggregation of corneocytes of the mature upper layer corneocytes, which would result in damage to the skin. Loosening the corneocytes in the lower layers improves desquamation. Glycolic acid promotes a thinner lower corneocyte layer, which not only improves the skin surface smoothness because the dead cells can migrate to the follicles, but also to improves the flexibility of the lower corneocyte layers (aka corneum stratum). A thin stratum corneum bends more readily without cracking or fissuring than a thick stratum corneum. Glycolic acid improves desquamation even if the skin is dry (Scott and Ruey, 1984). Bacteria take advantage of hyperkeratinization by entering the skin through cracks and fissures and colonizing the dead cells. The action of routine glycolic acid use is to remove both entry and colonization sites for colonizing bacteria that may lead to mastitis.

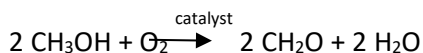
#### **Manufacture:**

Glycolic acid is a widely used industrial chemical with a large synthetic production footprint. It has commonly been produced by the Dupont process (hydratative carbonylation) from formaldehyde, carbon monoxide and water and in the presence of the catalyst sulfuric acid. The reaction is carried out at high pressure (300-700 bar) and temperature (200-250°C).



Catalysts such as hydrogen fluoride, hydrogen fluoride/boron trifluoride and strongly acidic (perfluorinated) ion exchangers were subsequently introduced in the Chevron and Mitsubishi processes that are effective at low CO pressure (100 bar). Exxon developed another catalytic method to obtain 70% glycolic acid at 150°C on a strongly acidic ion exchanger made from perfluorosulfonic acid resin (Weisserme and Arpe, 2003).

Formaldehyde is a naturally occurring substance. It is the smallest aldehyde. Formaldehyde is produced industrially by the catalytic oxidation of methanol. The most common catalysts are silver metal or a mixture of metal oxides. In the commonly used Formox process, methanol and oxygen react at ca. 250–400°C in presence of iron oxide in combination with molybdenum and/or vanadium to produce formaldehyde according to the chemical equation:



A silver-based catalytic process operates at a higher temperature, about 650 °C. Two chemical reactions on it simultaneously produce formaldehyde: that shown above and the dehydrogenation reaction:



In principle, formaldehyde could be generated by oxidation of methane, but this route is not industrially viable because the methanol is more easily oxidized than methane (Reuss et al., 2000).

### Category 1: Classification

1. Substance is for:  **Livestock**
2. For HANDLING and LIVESTOCK use:
  - a. Is the substance  **Agricultural** or  **Non-Agricultural?**
  - b. If the substance is **Non-agricultural**, is the substance  **Non-synthetic** or  **Synthetic?**

All glycolic acid commercially available today is made by one of three processes:

- a) High temperature/High pressure continuous flow route practiced by The Chemours Company (formerly DuPont). This is the dominant form of glycolic acid production globally. Formaldehyde and carbon monoxide are the raw materials.
- b) Neutralization and reacidification of monochloroacetic acid (MCA). This is small batch conversions of MCA to glycolic acid with chlorinated organic and salt impurities. MCA is made from chlorine gas and acetic acid. Sodium hydroxide neutralizes the MCA and HCl reacidifies the product to glycolic acid.
- c) Enzymatic conversion of glycolonitrile to glycolic acid. Glycolonitrile is made from hydrogen cyanide and formaldehyde and has a similar impurity profile as the high temperature and pressure route of manufacture.

All of these processes would be considered synthetic routes of manufacture. No “natural” source of glycolic acid is viable.

3. For **LIVESTOCK**:

This product would be listed at §205.603 Livestock Production-Synthetic. Glycolic Acid is a synthetic substance in that it is manufactured using a chemical process.

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Over the counter non-wipe post-milking dairy teat dips containing three percent glycolic acid (e.g. Ocean Blue Barrier®) are also likely to contain 5% glycerol, 5% sorbitol, xanthan gum, povidone k30, c9-11 Pareth-8, FD&C Blue No. 1, sodium hydroxide, water and sodium C14-16 olefin sulfonate. Package instructions do not suggest the use of one post-milking teat dip with another. The glycolic acid used for this formulation may be technical grade. Glycerin, an emollient, does not enhance the absorption of glycolic acid into the skin (Andersen, 1998). Sodium hydroxide is added to raise the pH of the teat dip. Low pH is a potential source of skin irritation when using glycolic acid to treat skin (FDA, 2015). Other ingredients used in teat dips include additional emollients, surfactants, colorants and plasticizers that permit adherence and identification of treated skin. Although there is general acceptance for the use of post milking teat dips, no advantage has been described for the use of multiple teat dip products in the same application (The National Mastitis Council, 2017).

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

In an early report, undiluted glycolic acid administered to rabbits was shown to cause acid-like burns to their skin and eyes (Carpenter and Smyth, 1946). Fifty and 70% Glycolic Acid applied to the backs of mini pigs for 15 minutes caused epidermal necrosis, inflammatory infiltrate and for 70% Glycolic Acid dermal necrosis after one day (Andersen, 1998). Reproductive, gastrointestinal, developmental and renal toxicity in rats, cats and guinea pigs have also been demonstrated with oral administration of high doses (70-100%) of glycolic acid (NIOSH, 2017). Glycolic acid is known to cause enhanced sensitivity to UV light. Short-term application of 10% glycolic acid sensitizes the skin to UV light. However, this photosensitivity is reversed within a week of terminating treatments (Kaidbey et al., 2003). Glycolic acid is an important metabolite of ethylene glycol. Increased glycolic acid in the blood correlates directly with acute ethylene glycol toxicity and renal failure (Hewlett et al., 1986). Glycolic acid has been widely studied because it is used in health products and cosmetics. However, many of the conclusions of these studies have been equivocal or even contradictory. Varying or unreported conditions, parameters and criteria such as the concentration and grade of glycolic acid used and duration of exposure have made it difficult to assess and compare them. The primary areas of concern for glycolic acid however, are its dermal irritation potential and its potential to increase sensitivity to sunlight. Both of these factors result from glycolic acid's ability to partially remove the stratum corneum layer of skin. Generally, for leave on products, glycolic acid concentrations not greater than 10% at pH no less than 3.0 will not produce unacceptable irritation. Glycolic acid does increase sensitivity to sunlight which should be considered in treatment (Andersen, 1998).

In six studies presented by the US Environmental Protection Agency, glycolic acid was noted to be slightly toxic to bluegill sunfish (Effective Concentration (EC)<sub>50</sub>=93 ppm), and practically non-toxic to bobwhite quail (Lethal Concentration (LC)<sub>50</sub>>5000 ppm), Mallard duck (LC<sub>50</sub>>5000 ppm), fathead minnow (LC<sub>50</sub>=164 ppm) and daphnia (EC<sub>50</sub>=141 ppm). In this same review, glycolic acid was noted to be only slightly toxic to mammals with an LC 50 of 1938 ppm (EPA, 2011).

Glycolic acid as glycolate is an important intermediary molecule in plant photorespiration, but in excess it is toxic and can inhibit photosynthesis (Ogren, 2003; Dellero et al., 2016). The degree of inhibition and

toxicity both depend on the particular species and variety of affected plant. In maize, for example, the accumulation of glycolate provokes the inhibition of ribulose bisphosphate carboxylase (RUBISCO) and the subsequent decrease in CO<sub>2</sub> assimilation (Gonzalez-Moro et al., 1997). Because it can inhibit photorespiration glycolic acid may be algistatic for some algal species, e.g. *Selenastrum capricornutum*, but since CO<sub>2</sub> absorption pathways may vary between algal species, e.g. *Chlorella* spp., the appearance of toxicity is likely to be dependent upon glycolic acid concentration (EPA, 2011; Fogg and Nalewajko, 1963; Raven et al., 2012).

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

Most of the glycolic acid is manufactured at a chemical production plant in Belle, West Virginia. This chemical plant is located in the Kanawha Valley which is known for its many chemical manufacturing facilities. There have not been any major spills or accidents at this plant since 2010, when the release of phosgene gas into the atmosphere caused the death of an employee. The State of West Virginia provided the plant operator with a permit to operate and produce glycolic acid in 2015 (West Virginia Department of Environmental Protection, 2015). The permit expires in 2020 and permits respectively maxima of 1.9, 15.5, 15.2 8.14 and 5.85 tons/year of formaldehyde, methanol, formic acid, carbon monoxide and NO<sub>x</sub> to be released to the atmosphere from the plant's thermal oxidizer.

The US EPA has not received any guideline environmental fate studies on glycolic acid, and has not required studies to be done. Since a toxicological concern has not been identified, the US EPA believes that, based on the currently registered use pattern of glycolic acid for household use as a disinfectant/sanitizer for hard non-porous surfaces in homes, guideline environmental fate or ecological effects studies are not necessary (EPA, 2011).

Various synthetic processes are available for preparing glycolic acid. Contaminants potentially found in downstream products are formaldehyde and monochloroacetic acid which are the starting materials. Residual reagents include sodium chloride, formic acid, methoxyacetic acid which are byproducts from the synthesis process. These impurities must be controlled for safety and the physical and chemical characteristics of the product (Liedtka, 2016). Glycolic Acid is available as a technical grade 70% solution and as higher purity grade solutions of 70% (Glypure 70) and 99% (Glypure 99) (Chemours, 2015). Because of the amount of impurities, technical-grade Glycolic Acid is not used in personal care applications (Andersen, 1998, Table 2). The US FDA found no concerns about the physical and chemical characterization when potential impurities, such as formaldehyde are controlled at acceptable levels. Glycolic acid is a well-characterized small molecule that is likely to be stable under ordinary storage conditions (Liedtka, 2016).

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

Labels for products containing 3% glycolic acid for use as a pre- and post-milking teat dip indicate only that the substance can cause eye irritation ([MSDS, OceanBlu Barrier, deLaval](#)). Glycolic acid at different concentrations is used for a number of human medical procedures as a keratolytic agent. Glycolic acid at 57-70% is corrosive to the skin and eyes. Ingestion of substantial amounts at this concentration may result in kidney failure (PubChem, 2017). Glycolic acid in cosmetic products used by the general public may cause skin and eye irritation when present at high concentrations and low pH values. In addition, manufacturers, importers and suppliers of consumer products should inform consumers that the use of

skin exfoliant cosmetic products may result in an enhanced sensitivity to sunburn, and that use of sunscreen protection is advised (NICNAS, 2000).

Occupational exposure to glycolic acid may occur through inhalation and dermal contact with this compound at workplaces where glycolic acid is produced or used. Monitoring and use data indicate that the general population may be exposed to glycolic acid via inhalation of ambient air, ingestion of food and dermal contact with consumer products containing glycolic acid (NCBI, 2017).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

The chemomechanic action of alphahydroxy acids (AHAs) in exfoliation is to reduce calcium ion concentration in the epidermis and remove calcium ions from the cell adhesions by chelation causing disruption in cell adhesions and desquamation. Glycolic acid can also suppress melanin formation by inhibition of tyrosinase activity. Intraperitoneal administration of 1000 mg/kg glycolic acid inhibits oxygen consumption and glucose metabolism in rat liver and myocardium *in vivo*, but does not affect brain oxygen consumption. Glycolic acid in high concentrations (70% solution and pure) causes local effects typical of a strong acid, such as dermal and eye irritation. In a 3-week dermal toxicity study in hairless guinea pigs, erythema and/or flaking of the skin were noted at 5% and 10% concentrations of glycolic acid. Glycolic acid induced calculi formation in rats in a 4- to 12-week repeat dose oral toxicity which also disclosed increased renal oxalate and nephrotoxic effects have been observed. In a 2 week study in rats, respiratory tract irritation, hepatocellular degeneration and thymus atrophy were observed. Glycolic acid was negative for mutagenicity in the Ames test and the mouse lymphoma assay and not considered genotoxic. Glycolic acid was negative for clastogenicity in an *in vitro* chromosome aberration assay and an *in vivo* micronucleus assay in mice.

Carcinogenicity from glycolic acid exposure has not been demonstrated. Oral (gavage) doses of glycolic acid up to 600 mg/kg/day were administered to female rats during gestation days 7-21 – Maternal toxicity was seen at doses  $\geq$  300 mg/kg/day – Developmental toxicity was also noted at doses  $\geq$  300 mg/kg/day, including fetal weight reduction and increases in skeletal malformation (FDA, 2005). Glycolic acid post milking treatment can affect keratin dynamics (The National Mastitis Council, 2017). Glycolic acid is non-toxic in dogs up to 100 milligrams/kilogram, but nephrotoxic effects result from doses of 250 mg/kg, and fatality occurs if greater than 500 mg/kg is ingested. Glycolic acid is also nephrotoxic to cats (Krop and Gold, 1944).

Glycolic acid is found in the fruit, leaf, stem and root portions of all plants. Glycolic acid is found naturally in extractable amounts in sugar cane and sugar beets (Thangaavelu, 2010; Stark et al., 1950). It is also excreted naturally by several algal species (Tolbert and Zill, 1956). Commonly consumed fruits and vegetables are reported to contain from 0.45-7.4 milligrams glycolic acid per 100 grams fresh wet weight. Tea, coffee, fruit juice and other beverages derived from plant sources may contain 5-7 mg glycolic acid per 100 mL. Foods of animal origin are generally low in glycolic acid, with milk and beef reported to contain 0.06-0.12 mg per 100 g (NICNAS, 2000). It is readily biodegradable in soil and water.

6. Are there any adverse impacts on biodiversity? (§205.200)

Glycolic acid is found in ruminant blood. Studies have shown that it is incorporated into casein, fat and lactose of milk (Peters et al., 1971).

There have not been any reports of adverse environmental events related to glycolic acid release. Approximately 0.15 ml of glycolic acid (3%) is used per udder quarter in a post milking test dip (Matti and Tinnis, 2015). Glycolic acid at a concentration of 70% is approved for use as an acid non-food cleaning agent for removal of rust, corrosion, scale or other deposits that are not readily removed by alkaline cleaners in dairies.

Glycolic acid is a significant industrial chemical (EPA, 2011). If released to air at an extrapolated vapor pressure of 0.02 mm Hg at 25 °C, glycolic acid will exist solely as a vapor. Vapor-phase glycolic acid will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 3.4 days. Glycolic acid does not contain chromophores that absorb at wavelengths >290 nm and, therefore, is not expected to be susceptible to direct photolysis by sunlight. If released into soil, glycolic acid is expected to have very high mobility based upon an estimated Koc of 0.14. Koc is a measure of the tendency of a chemical to bind to soils, corrected for soil organic carbon content. The pKa of glycolic acid is 3.6, indicating that this compound will exist almost entirely in anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Volatilization of glycolic acid from moist soil surfaces is not expected to be an important fate process because the compound exists as an anion and ions do not volatilize. Glycolic acid is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Tests for inherent biodegradability showed 86% of the theoretical BOD was reached in 2 weeks. This indicates that biodegradation is an important environmental fate process in soil and water. If released into water, glycolic acid is not expected to adsorb to suspended solids and sediment based upon the estimated low Koc. A pKa of 3.6 indicates glycolic acid will exist almost entirely in the anion form at pH values of 5 to 9 and, therefore, volatilization from water surfaces is not expected to be an important fate process. An estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

The pathogens that cause mastitis inhabit many locations throughout the dairy cow environment and infect multiple tissues in the udder. As a result, effective prevention and treatments for mastitis in the organic dairy can range from surface sanitation to parenteral administration of homeopathic medicines, but each alone may not be 100% effective. Thus, there are many possible substances that may serve in place of glycolic acid. Glycolic acid represents a unique approach to bovine teat health, inasmuch as the net effect is to prevent hyperkeratosis, although there is additionally some microbiocidal activity associated with its application.

Vitamin A is similar to glycolic acid in its action, however; the subset of skin cells that are affected are not the same (Scott and Ruey, 1984). Thus, vitamins and minerals to supplement nutrition such as vitamin, selenium, copper, zinc, vitamin A and  $\beta$ -carotene are important to both bolster both cellular and humoral immune response and to maintain skin and udder health (Heinrichs et al., 2009). Low blood plasma concentrations of vitamin A and  $\beta$ -carotene are directly associated with the severity of mastitis in cows (Chew et al., 1982).

Homeopathic pharmacies can provide pre-prepared remedies for mastitis in dairy cows. Udder liniments containing mint or anti-inflammatory agents are often used as support therapy with homeopathy (Hovi and Roderick, 1998). More examples include Belladonna for acute postpartum mastitis; Aconitum for

routine treatment for all acute cases, particularly those that develop rapidly after exposure to cold dry wind; *Apis Mellifica* is indicated for first calving, heifers with edema of and around the udder; *Bryonia Alba* is indicated for swollen and very hard udders; *Arnica Montana* for mastitis resulting from udder injuries; *Belia Perennis* for deeper injuries (e.g., neglected milkers); *Phytolacca* for clinical and chronic cases with sour, coagulated milk, small clots at mid-lactation; *Urtica Ulens* for clinical cases where edema forms plaques sometimes up to perineum; mixtures of Sulphur, Silica and Carbo Vegetabilis for clinical and subclinical cases; *Hepar Sulphuris* to aid suppuration and cleaning of udder in summer mastitis cases; *Silicea* for summer mastitis cases with purulent abscess and *Ipeca* for treating internal bleeding that produces pink or bloody milk (MacLeod, 1981). Homeopathic remedies used to treat mastitis also include: *Belladonna*, *Lachesis*, *Vipera Reddi*, *Conium maculatum* + *Plumbum iodanum*, *Phytolacca*, *Bryon* and *Silicea* (Quiquandon, 1982). Homeopathic remedies are not regulated for efficacy and quality as are veterinary drugs, therapies and medications. Furthermore, some research indicates that homeopathic approaches are not effective therapies for bovine mastitis (Ebert et al., 2017).

Currently only iodine (§205.603(a)(13) and §205.603(b)(3)), chlorhexidine §205.603(a)(6), glycerin §205.603(a)(11), and hydrogen peroxide §205.603(a)(12), are allowed to be used in organic dairy production for mastitis prevention and therapy. Teat dips containing the disinfectants iodine and chlorhexidine are effective in reducing intra-mammary infections (Enger et al., 2016). Iodine is effective as a pre- and post-milking teat dip or spray, however, small increases in milk iodide concentration can be expected with its use. Where sprays usually produce a larger increase than dip cup preparations (French et al., 2016). Chlorine materials (§205.603(a)(7)) and phosphoric acid (§205.603(a)(19)) are allowed for sanitizing equipment and facilities. Vaccines, anti-inflammatory drugs (e.g., aspirin and flunixin), electrolytes, and furosemide (with double the milk withholding period) can also be used for the treatment of clinical mastitis (Ruegg, 2014).

Post-milking teat disinfectants need to be persistent and effective in killing bacteria. They must also leave teats in good condition. Preservation of healthy teat skin is essential for maintaining its natural defense against infection because sore, dry, cracked teats may harbor mastitis-causing pathogens (Hogan et al., 1990; National Mastitis Council, 2017). Barrier type teat disinfectants have been developed to extend the germicidal properties of the disinfectant after the cow leaves the milking parlor. These products contain components that can provide a protective film and seal the teat from mastitis-causing bacteria (Lago et al., 2016). Glycerin is a humectant that is allowed for use as a skin conditioner in teat dips. Aloe is a naturally derived products with skin healing properties that may also be included in teat dips (Fox et al., 2006).

Teat irritation can be caused by interaction between teat dip and management or environmental factors in a herd. Teat dips may promote chapping during extremely cold weather especially with windy conditions. Emollients are incorporated such as glycerin or lanolin to minimize irritation and condition skin, however, the germicidal effectiveness of the teat dip may be diminished with too much emollient (Pankey, 1984). Emollients and humectants do not affect bacterial colonization of the skin (Rasmussen and Larsen, 1998).

2. **For Livestock substances, and Nonsynthetic substances used in Handling:** In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Yes, but it is unclear if this substance is needed in organic agriculture as alternatives exist. Therefore, the Subcommittee would like to pose the following questions:



1. Are there alternatives available for pre-and post-milking teat dips?
2. Is this product used in rotation with currently allowed pre-and post-milking teat dips?
3. Do alternatives work to control mastitis?

**Classification Motion:**

Motion to classify glycolic acid as synthetic  
Motion by: Ashley Swaffar  
Seconded by: Harriet Behar  
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**National List Motion:**

Motion to add glycolic acid as petitioned at 205.601  
Motion by: Ashley Swaffar  
Seconded by: Jesse Buie  
Yes: 3 No: 2 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Ashley Swaffar, Livestock Subcommittee Chair, to transmit to NOSB February 23, 2018**

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**National Organic Standards Board  
Livestock Subcommittee Proposal  
Clarifying “emergency” for use of synthetic parasiticides in organic livestock production  
February 20, 2018**

## **I. INTRODUCTION**

Organic farmers rely upon their management skills and knowledge to implement preventative practices such as sourcing disease-free animals into their herds or flocks, monitoring their herds for vigor and selecting breeds which have high resistance to parasites. All organic livestock must have access to the outdoors when appropriate for the region and animal’s stage of life. Organic farmers manage their land, especially ruminant pastures, in a manner that reduces the presence of parasites that might infect their animals. If an increased parasite load, for example, is noted in fecal egg counts, farmers have a broad array of alternative treatments available. But when all else fails and animals are not doing well, a farmer, perhaps working with a veterinarian, may need to use one of the synthetic parasiticides on the National List.

The use of approved synthetic parasiticides in organic livestock production under the current regulation is confined to “emergency use”. Use of these synthetic parasiticides in an emergency situation does not result in the livestock’s products being removed from the organic marketplace. These approved synthetic parasiticides cannot be used routinely. The organic status of animals must not result in the farmer withholding medical treatment. If there is no organically approved material or activity to solve the problem, the farmer must use a nonapproved material and then remove the products from this animal from sale into the organic marketplace (7 CFR 205.238(c)(7)).

A discussion document was circulated in Spring 2017 and a proposal circulated in Fall 2017 which sought public comment from a broad cross section of stakeholders to determine if any changes should be made to §205.238, Livestock Healthcare Practice Standard, as it pertains to parasite prevention plans, use of approved synthetic parasiticides, and if a definition or clarification of the term “emergency” was needed.

## **II. BACKGROUND**

In October 2015 the NOSB recommended continued listing of three parasiticides, ivermectin, moxidectin and fenbendazole, as part of its sunset review. In April 2016 the NOSB unanimously approved annotations amending the use of fenbendazole and moxidectin, and in November 2016 the NOSB unanimously (with one absence) approved removal of ivermectin from the National List. On January 19, 2018, a proposed rule to implement the NOSB recommendations from April 2016 was printed in the Federal Register for public comment ([83 FR 2498](#)).

During the two year period in which these changes to the annotations for these approved synthetic parasiticides were being considered, the NOSB received considerable public comment. In addition to providing factual, technical and scientific information in support of the changes, some stakeholders suggested that the term emergency was not sufficiently well defined and that use of synthetic parasiticides may be abused with the proposed shorter timeframe between use of the parasiticide and the sale of organic livestock products. Some stakeholders supported removal of ivermectin from the National List and the annotation changes to the other two parasiticides but urged clarification of what constitutes an “emergency”.

Two documents were presented to the public for comment specifically addressing the term “emergency” when considering the use of approved synthetic parasiticides for organic livestock. Organic producers, organic certifiers and nonprofits that aid transitioning producers commented that there must be a consistently implemented standard across all regions, sizes of farms, and types of farms. The organic standard should not encourage “certifier shopping” to seek out those that interpret the regulations in a looser manner than others, which could be encouraged by gray areas in the rule.

Organic farmers consistently ask the NOSB for strict standards with clear meanings, so they are confident all organic products in the marketplace meet the same standard. Producers also want to know there is an economic and production “level playing field” between themselves and their competition. Consistent implementation of the National Organic Program regulations, based upon clear and precise definitions contribute to both producer and consumer trust in the organic label. Clarification on emergency treatment when using parasiticides for organic livestock will contribute to lessening the gray area on this specific subject.

Providing this clarification also provides a better understanding of what organic certification agencies should look for in an organic system plan and operators should use as preventative management practices. The NOP proposed rule change to greatly lessen the withdrawal time between the use of the parasiticides and sale of organic products, has taken away a strong disincentive for the use of these synthetics. Clarification of when an emergency would allow use of synthetic parasiticides on organic livestock is a necessity to provide consistency, trust, and integrity.

### **III. RELEVANT AREAS OF THE RULE**

#### **Current regulation addressing livestock health care**

§205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
  - (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
  - (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
  - (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:
  - (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
  - (2) Dairy animals as allowed under §205.603.
  - (3) Fiber bearing animals, as allowed under §205.603.

§205.603 Synthetic substances allowed for use in organic livestock production.

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
- (18) Parasiticides—prohibited in slaughter stock. Allowed in emergency treatment for dairy and

breeder stock, when organic system plan-approved preventive management does not prevent infestation. Allowed in fiber bearing animals, when used a minimum of 90 days prior to production of fleece or wool that is to be sold, labeled, or represented as organic. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—For control of internal parasites only

**Proposed rule - January 17, 2018 (83 FR 2498 )**

Changes in bold for ease of identification.

Parasiticides § 205.603(a)(23)

Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. ~~Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.~~ **Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment.** In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. **Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.**

Fenbendazole § 205.603 (a)(23)(i)

**Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.**

Ivermectin

**Removed from the list of approved synthetics**

Moxidectin § 205.603(a)(23)(ii)

**Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species.**

#### IV. Public comment

The NOSB asked the following questions in the April 2017 discussion document:

1. Does the term “emergency” need to be defined?
2. If so, how should the term “emergency” be defined?
3. Should there be more specific guidelines, such as specific tests for parasite levels as part of the producer’s parasite prevention plan, before it is determined that emergency treatment with an approved parasiticide might be needed?
4. What are the challenges for producers, inspectors and certifiers in verifying the documentation and implementation of a parasite management plan in organic operations, and how might these be addressed?

Numerous certifiers and organic stakeholders agreed with the necessity of providing further clarification for the term “emergency” when reviewing the use of the synthetic parasiticides present on the National List of approved substances. Commenters asked for improved transparency of how these synthetics are used, and that use is restricted to times when all other methods have failed and the health of the animal is at risk. Some stated that describing expectations of what constitutes an “emergency” provides a consistent standard for all producers of organic livestock, as well as what the certification agency will review when verifying their operation for compliance to the organic regulation.

**Additional language to be added to §205.238(c)(4) [new text *in italics*] was proposed in our October 2017 proposal document.**

(4) Administer synthetic parasiticides on a routine basis. *The producer must first use management practices to prevent scientifically identified threshold levels of parasites in their livestock, and secondly use nonsynthetic products to manage parasites. When these two approaches are not effective, this could lead to the emergency treatment and use of National List approved synthetic parasiticides. Examples of materials, management activities and goals used could include:*

- i) *Grazing systems and living conditions that prevent livestock parasite infestations by keeping livestock out of paddocks or pens until the parasites are no longer viable in that area.*
- ii) *Maintaining forage diversity, height and grazing frequency to lessen transference of parasites during grazing.*
- iii) *Use of allowed non-synthetic botanicals, biologics and minerals, both internally and externally, to maintain parasite levels in the livestock well below the treatment threshold.*
- iv) *Use various monitoring and documentation methods through the season which inform the operator of the efficacy of their parasite management practices such as fecal sampling and FAMACHA.*
- v) *When the practices provided for in paragraphs (1) through (4) of this section are insufficient to prevent or control parasites within the accepted threshold of that parasite, and for that age of animal and species of animal, a parasiticide included on the National*

*List of synthetic substances allowed for use in organic livestock production may be used as an emergency treatment. Provided, That, the conditions for using the substance are documented in the organic system plan, and the organic operator documents proposed improvements to their organic system plan to lessen the need for these National List approved synthetic parasiticides.*

Numerous commenters stated this proposal was too prescriptive. While the NOSB was seeking to provide voluntary examples for preventative and monitoring activities similar to the pest management hierarchies found in the crops and handling sections of the rule, there was concern that having them listed in regulatory language resulted in these activities being mandated and not voluntary. There was comment that listing various activities in an NOP guidance document would be more useful for both producers and certifiers.

Many commenters preferred that a definition of emergency be placed in 205.2, with some suggesting this would be sufficient to address this issue. Others suggested a more general statement be added to the body of the regulation.

Numerous commenters suggested this definition:

***A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).***

**Many commenters suggested improvements to 205.238 (b) - suggestion in bold**

When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, that, such medications are allowed under §205.603. Parasiticides allowed under §205.603 may be used on:

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

Parasiticides allowed under §205.603 may be used on

- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy animals as allowed under §205.603.
- (3) Fiber bearing animals, as allowed under §205.603.
- (4) ***Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and reinfestation, forage height diversity, use of allowed nonsynthetic botanicals, biologics and minerals to maintain parasite levels below treatment***

***thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.***

## **V. Discussion**

The two items above, improvement to 205.238 (b) and a definition of emergency treatment of livestock for parasiticide use, when presented together, address both emergency assessment, and Organic System Plan practices. The wording in 205.238 (b) is not a mandate, but instead forms a strong foundation for operators and certifiers to use when reviewing and verifying an organic system that protects the health of the animals and meets the organic regulations.

Each region and operation has their own challenges. New-to-organic producers who may be accustomed to relying on synthetic parasiticides, could benefit from this language to help them understand what is required. Having these two descriptions in the rule could also provide the consistency between certifiers in the implementation of the rule, while giving flexibility to allow for operator response to their site-specific needs.

Each age and species of livestock has differing parasite threshold levels that could result in the use of a synthetic parasiticide. Scientifically identified threshold levels can be found within University Extension publications, or by speaking with a veterinarian and other livestock health professionals. The use of monitoring and fecal testing provides both the operator and the certifier tools they can use to judge if the situation is approaching an emergency.

Based upon monitoring, each operation's unique organic system plan should be modified to improve livestock living conditions as well as other practices that might lessen parasite loads before they reach the threshold levels. The use of synthetic parasiticides is a last resort after other activities have been exhausted.

The short wait time as indicated in the January 2018 NOP proposed rule, between use of synthetic parasiticides and the sale of organic livestock products, should only be allowed when there is a documented need for an emergency treatment. This proposal provides a framework to aid operators in understanding what is required for parasite management in their organic system plan as well as what type of documentation needs to be provided to certifiers in their review.

## **VI. Subcommittee Discussion**

The proposed addition to the regulation provides a clear path for operators and certifiers to promote consistency within the certification process. Monitoring, management, and natural products must be used before a synthetic is allowed. The wording above is practical for the operators and provides the verification tools needed by the certifiers, without being too prescriptive or adding excessive paperwork. The wording above meets the concerns of the vast majority of the public commenters, providing both a workable solution and the clarity requested. The definition as presented above, includes many requirements and is better placed within the regulation, rather than in the definition section of the rule.



## VII. MOTION TO APPROVE THIS PROPOSAL

### Add to § 205.2 Definitions

*Emergency (treatment for parasite control in breeding, dairy and fiber bearing animals).* An urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering.

### Add to § 205.238 (b)

[Note: assumes adoption of changes in NOP proposed rule (83 FR 2498, January 17, 2018)]

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(4) Organic breeding, dairy and fiber bearing animals when meeting the following conditions:

(i) Organic livestock has been managed according to 238(b) and 238(c)(2), 238(c)(4), and 603(a)(23) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, forage height and plant diversity to maintain parasite levels below treatment thresholds and monitoring with documentation of parasites through use of methods such as fecal monitoring and FAMACHA (FAffa Malan Chart—used for tracking anemia in goats and sheep).

(ii) The organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years.

Motion by: Harriet Behar

Seconded by: Jesse Buie

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Ashley Swaffar, Subcommittee Chair to transmit to NOSB February 28, 2018**

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**Sunset 2020 Review**  
**Meeting 1 - Request for Public Comment**  
**Handling Substances**  
**April 2018**

**Introduction**

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2020. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

**Request for Comments**

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2018 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2018 public meeting. These comments should be provided through [www.regulations.gov](http://www.regulations.gov) by April 4, 2018 as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

**Guidance on Submitting Your Comments**

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

**For Comments That Support Substances Under Review:**

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic crop production.

**For Comments That Do Not Support Substances Under Review:**

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

**For Comments Addressing the Availability of Alternatives:**

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative 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.

**For Comments on Nonorganic Agricultural Substances at Section 205.606.**

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 4, 2018 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

**Sunset 2020 Review Summary**  
**Meeting 1 - Request for Public Comment**  
**Handling Substances**  
**April 2018**

**Note:** With the exception of tragacanth and gellan gums, the materials included in this list are undergoing early sunset review as part of November 18, 2016 [NOSB recommendation](#) on efficient workload re-organization.

**Reference: 7 CFR 205.605 *Nonagricultural*** (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

**Reference: 7 CFR §205.605(a) Nonsynthetics allowed:**

[Calcium carbonate](#)

[Flavors](#)

[Gellan Gum](#)

[Oxygen](#)

[Potassium chloride](#)

**Reference: 7 CFR §205.605(b) Synthetics allowed:**

[Alginates](#)

[Calcium hydroxide](#)

[Ethylene](#)

[Glycerides: mono and di](#)

[Magnesium stearate](#)

[Phosphoric acid](#)

[Potassium carbonate](#)

[Sulfur dioxide](#)

[Xanthan gum](#)

**Reference: 7 CFR §205.606**

[Fructooligosaccharides](#)

[Gums: Arabic, Carob bean, Guar, Locust bean](#)

[Lecithin - de-oiled](#)

[Tragacanth gum](#)

## Calcium carbonate

**Reference:** 205.605(a)

**Technical Report:** [1995 TAP](#); [2018 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### **Background from Subcommittee:**

#### **Use:**

Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner, acidity regulator in wines, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, and as a nutritional fortification additive. The FDA allows the use of calcium carbonate as a binding agent in meat and poultry pieces. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List. Calcium carbonate has been used as a coloring agent. However, in historic organic food processing, both within the United States and internationally, calcium carbonate is not allowed for coloration purposes.

#### **Manufacture:**

Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. It is a mined mineral of at least 98% purity that is ground and screened.

### **International Equivalency:**

**Canada** - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015

- Allowed, prohibited for use as a coloring agent

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

- Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items
- Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3

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

- Appears in Annex VII, Section A - Food additives including carriers, shall not be used for colouring or calcium enrichment of products
- Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production

### **Japan Agricultural Standard (JAS) for Organic Production**

- Appears in Table 1, Food additives, Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance

## International Federation of Organic Agriculture Movements (IFOAM)

- Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handling aids

### Environmental/Health Issues:

The mining and processing of calcium carbonate can have negative environmental impacts. These may be impacts on above and below ground water systems. Mining may have impacts on biological diversity as the mining may draw down the water table and impact surface water features that play host to a variety of species.

Inhalation of calcium carbonate dust may cause upper respiratory irritation, and exposure may cause eye irritation. Personal protective equipment will avoid these issues. There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium intake reaches levels at or above 2000 mg.

**Additional information requested by Subcommittee:** None

## Flavors

**Reference:** 205.605(a), nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

**Technical Report:** [2005 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

**Use:** Natural flavors are derived from natural sources and are compound substances derived from plants, herbs, spices, botanicals and other substances. They are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product.<sup>1</sup> Flavorings significant function must be flavor rather than nutrition. The FDA defines Natural Flavors in 21 CFR 101.22 as:

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<sup>1</sup> <http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors, include the natural essence or extractives obtained from plants listed in subpart A of part 582 of this chapter, and the substances listed in 172.510 of this chapter.

**Manufacture:** Flavors can be derived via several different methods. Distillates are a clear, flavorful liquid produced from fruits, herbs, roots, etc., produced and condensed by distillation. Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer's shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture. Essential Oils are volatile oils that give a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It's made by steam distillation or cold pressing. Essential Oil Isolate is an isolate of an essential oil. Isolates are a chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass. Oleoresin are solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice. A single flavor chemical is a single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A Compounded flavor is a mixture of ingredients such as extracts, essential oils and natural isolates.<sup>2</sup> Processed flavors, also known as reaction flavors, are ones which are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins and fat, which must then be heated for a length of time to yield the desired profile.<sup>3</sup>

Flavoring components as listed here can typically make up 5-100% of the formulation of a flavor. The remaining 0-95% of flavor formulas contain carriers/solvents and/or non-flavor constituents used to stabilize or maintain the flavor. Non-synthetic flavors are also subject to the general requirement that they are not produced using sewage sludge, irradiation or GMOs.

Flavors can be further divided into "Natural" or containing only flavoring constituents from the named flavor; "WONF" or containing flavoring constituents from the named product as well as other natural flavors derived from other sources that enhance or support the named flavor; or "type" which contain non-flavoring constituents from the named product but still impart the characteristic named flavor.

**International:** Natural/Non-synthetic flavors are listed as allowed on the EU, Canadian, Japanese, IFOAM and Codex Standards.

**Ancillary Substances:** Ancillary substances are present in flavors and are reviewed for compliance against the criteria in the annotation: "must not be produced using synthetic solvents and carrier systems or any artificial preservative." Flavoring constituents are considered proprietary by flavoring companies and are not normally disclosed.

**Discussion:** During the Fall 2010 NOSB meeting, the NOSB completed its sunset review of flavors for re-listing and stated:

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<sup>2</sup> <http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

<sup>3</sup> [http://www.fona.com/sites/default/files/WhitePaper\\_DevelopmentResources.pdf](http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf)



The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors...The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was practical to individually list flavors on the National List, so chose to relist the category as a single listing...In order to avoid unnecessary disruption to industry, we are recommending relisting of flavors on §205.605(a), but we are also communicating our belief that the full category Sunset should not be relisted in five years when next reviewed for sunset. Instead, we are recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

On January 21, 2011 the NOP issued a Policy Memorandum on Use of Natural Flavors

This states in part:

In 1995 the NOSB reviewed the use of natural flavors and recognized that natural flavors are complex; they are derived from natural sources and are compound substances derived from plants, herbs, spices and botanicals....The NOP recognizes that some accredited certifying agents are certifying flavors that meet the NOP requirements for handling organic products, and that this organic market will continue to grow and develop...

On November 6th 2014, the NOP received a petition from the Organic Trade Association to change the flavor annotation to read:

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative

At the Fall 2015 NOSB meeting the NOSB approved a petition to revise the flavors listing annotation to read as follows:

Flavors – Non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

At the Fall 2015 meeting, substantial comment was received from industry, trade associations, and Accredited Certifying Agents (ACAs) supporting the continued listing of natural flavors as well as the adoption of the flavor petition.

On January 17, 2018, NOP published a proposed rule ([83 FR 2498](#)) to adopt the Fall 2015 recommendation and change the annotation for flavors at § 205.605(a) to:

Flavors, non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

**Additional information requested by Subcommittee:** None

## Gellan gum

**Reference:** 7 CFR 205.605(a) – high acyl form only - As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

**Technical Report:** [2006 TAP](#); [2018 TR](#)

**Petition(s):** [2004 Gellan gum](#)

**Past NOSB Actions:** [2007 Formal Recommendation](#); [2014 sunset recommendation](#)

**Regulatory Background:** Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 ([75 FR 7751](#)). Sunset renewal notice published 06/22/2015 ([80 FR 35177](#))

**Sunset Date:** 6/22/20

### Background from Subcommittee:

#### Material Use:

Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution (2006 TR 32-34, Petition pg 10). Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR 182-187, 2006 TR 37-41, Petition pg 2). Typical use of gellan gum is at <0.5% of a finished product formula (Petition pg 2). The firmness of the gel can be enhanced by the additions of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

**Table 1. Summary: General Properties of Gums**

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

**Manufacture:**

Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR 16-19, 66-70, 2018 TR 648-660). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR 662-670). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR 54-55). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g. potassium, calcium, magnesium); these deacylated forms are not approved on 205.605(a) (2006 TR 109-112). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR 107-117).

**International Equivalency:**

The material is FDA approved as a direct food additive in accordance with 21 CFR 172.665; it is also approved in many countries worldwide in food and non-food items. Gellan gum is listed by the World Health Organization Joint Expert Committee for Food Additives (Petition pg 5).

*Canadian Organic Regime’s Canadian General Standards Board Permitted Substances List* (Nov 2015 ed.) allows the use of gellan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Gellan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 TR 498-504).

*European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008*

Gellan gum is allowed for use as compliant with Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 TR 506-515).

*Japan Agricultural Standard (JAS) for Organic Production*

Gellan gum is neither listed as allowed, nor as prohibited (2018 TR 525-536).

*International Federation of Organic Agriculture Movements (IFOAM)*

Gellan gum is not listed as allowed, nor prohibited (2018 TR 538-541).

*Other international standards*

East African Organic Product Standard uses IFOAM and thus gellan gum is not prohibited, nor allowed (2018 TR 543-541).

#### **Ancillary Substances:**

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

#### **Background Information:**

The two available TRs did not list any notable human health or environmental concerns regarding the use of gellan gum.

Public comment in 2014 supported the ongoing essentiality of this material.

**Additional information requested by Subcommittee:** None

## Oxygen

**Reference:** 205.605(a) - oil-free grades.

**Technical Report:** [1995 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

#### **Background from Subcommittee**

**Use:** Oxygen is used in modified atmosphere packaging and the processing of olives.

**Manufacture:** Oxygen is separated from air cryogenically; super cold temperature liquefaction of air and

fractional distillation.

**International:** The use of oxygen is permitted in organic standards in Canada, CODEX, EU, IFOAM, and Japan.

**Ancillary Substances:** None.

This material was reviewed by the NOSB during 2015 and the Board voted to continue its listing on the National List.

**Additional information requested by Subcommittee:**

None

## Potassium chloride

**Reference:** (a) Nonsynthetics allowed:

**Technical Report:** [1995 TAP](#); [2015 TR Nutrient Vitamins and Minerals](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

**Manufacturing Process:**

Potassium Chloride is a metal halide salt composed of potassium and chloride. Potassium Chloride is extracted from minerals sylvite, carnalite and potash. It is also extracted from salt water and can be manufactured by crystallization from solution floatation or electrostatic separation from suitable minerals. It is a by-product of the production of nitric acid from potassium nitrate and hydrochloric acid. It is odorless and has a white or colorless vitreous crystal appearance.

**Specific Uses:**

According to the Food & Drug Administration, generally recognized as safe (GRAS) affirmed uses of potassium chloride in foods are as: a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. Like salt, potassium chloride provides a salty flavor and can also often play other functional roles (e.g. microbial management, protein modification, flavor enhancement) that impacts the taste, texture, and shelf life of food products.

Potassium chloride is generally used for two main purposes in food products. The first is to provide potassium enrichment to foods. The second is as a salt replacement to reduce the sodium content in foods.

### **Additional information requested by Subcommittee:**

1. Is the substance essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

## **Alginates**

**Reference:** 205.605(b) Synthetics allowed

**Technical Report:** [1995 TAP](#); [2015 TR](#)

**Petition(s):** [1995 Alginates](#)

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### **Background from Subcommittee:**

#### **Use:**

Alginates are useful as gelling, thickening and stabilizing agents in a wide variety of organic products, including drinks, ice cream, puddings, cookies, meat and pasta dishes. They are particularly useful in that they do not need heat to be activated. They can be used to gel cold products and do not melt if the product is heated. They can be used in coatings to help preserve moisture content, protect flavor and enhance shelf life. They can also be used to generate spheres with a thin membrane and liquid center that provide texture and flavor “pops” in certain foods. While not technically a preservative in themselves, they can be used as carriers for preservatives and may inhibit food deterioration due to moisture loss.

Despite their widespread use in a variety of foods, alginates have several limitations. They have limited solubility at low pH values and high calcium content foods can interfere with their activity.

Alginates have been accepted for use in organic foods since the National Organic Program Rule was published in 2000. They have been recommended for relisting in each of three sunset reviews. A 2015 technical report detailed the production, use and alternatives to alginates. Information from that technical report was used for the following summation.

#### **Manufacture:**

Alginates are normally extracted from the cell walls of seaweed, specifically, brown algae. While they can also be generated by bacterial fermentation, the fermentation process is not currently economically viable. To isolate alginate from seaweed, several isolation steps involving extraction, acid additions, purifications, and base additions are required. The final result is either alginic acid or the salt form, alginates. Alkali extraction renders alginates as synthetic.

**International (drawn from the 2015 TR):**

Canada – certain alginates are permitted under the Canada Organic Regime due to their appearance in the section titled “Non-organic Ingredients Classified as Food Additives, of the Organic Production Systems Permitted Substances List.” In this section, alginates (alginic acid, sodium alginate and potassium alginate) are included in Table 6.3 (Canadian General Standards Board 2011).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - certain alginates are permitted. Only potassium (402) and sodium (401) alginates are listed as allowed food additives in Table 3.1 as an ingredient of nonagricultural origin in the CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (Codex Alimentarius Commission 2014).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 - alginates (E401-E405) are permitted because they are included in the list of allowed food additives for use as thickeners and stabilizers (E400-E499). Alginates are classified as nonagricultural in the EU Organic Regulations (The Council of the European Union 2008). Sodium alginate (E 401) is listed as an approved food additive for use in certain unprocessed fruit and vegetables in an amendment to Annex II of the Commission Regulation (EC) No 969/2014 (The Council of the European Union 2014).

Japan Agricultural Standard (JAS) for Organic Production - certain alginates are permitted. The JAS for Organic Processed Foods identifies sodium alginate as an allowed food additive limited to use only in processed foods of plant origin, INS number 401 (The Japanese Organic Standard 2005).

International Federation of Organic Agriculture Movements (IFOAM) - certain alginates are permitted. Sodium and potassium alginate are recognized by IFOAM as approved additives for use in an organic processed products without annotation (IFOAM 2014) (Appendix 4: Table 1).

**Ancillary Substances:**

No ancillary substances (e.g. stabilizers, 352 preservatives or anti-caking agents) were listed on publically available specification sheets (2015 TR).

**Discussion:**

Alginates are Generally Recognized As Safe (GRAS) when used with good manufacturing practices. Alginates are not absorbed by the human body, making them useful as a low- calorie ingredient. While human health effects are generally recognized is minimal, there is evidence that alginates in foods may reduce iron absorption.

The production of alginates generally involves the harvesting of wild seaweed. Increased harvesting of seaweeds leads to questions about the sustainability. Seaweed populations are potentially impacted by overharvesting, the effects of increased ocean water temperatures, and pollution. Attempts at farming seaweed have not been economically successful, thus the sustainability of current wild harvesting is crucial to future alginate production.

While there are a number of alternative thickeners and gelling agents available to organic handlers, the property of alginates to make gels without the use of heat distinguishes them from many other products.

**Additional information requested by NOSB**

Are there any organic alternatives to alginates that have become available for use since the 2015 technical report was written?

## Calcium hydroxide

**Reference:** 205.605(b)

**Technical Report:** [1995 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Manufacturing Process:

Calcium hydroxide (also known as “slaked lime” or “hydrated lime”) is lime that is calcined in a kiln to obtain carbon dioxide and quick lime. The quicklime is mixed with water to produce calcium hydroxide.

#### Specific Uses of the Substance:

It is used as a component of aluminum free baking powder, to clarify sugar for molasses, and as a conditioner for corn tortillas.

#### Additional information requested by Subcommittee:

1. Is the substance essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

## Ethylene

**Reference:** 205.605(b) allowed for postharvest ripening of tropical fruit and degreening of citrus.

**Technical Report:** [1995 TAP](#); [1999 TAP - Processing](#)

**Petition(s):** 1995 N/A, [2008 Ethylene \(for use with pears\)](#)

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [10/1999 NOSB minutes and vote \(add tropical fruit and citrus\)](#); [11/2005 sunset recommendation](#); [11/2008 recommendation for pears](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:



**Use:**

Ethylene gas (CAS # 74-85-1) is currently listed at 205.605(b) as a material allowed for postharvest ripening of tropical fruit and degreening of citrus.

**Manufacture:**

Ethylene ( $\text{CH}_2=\text{CH}_2$ ) is a colorless gas at room temperature. It is produced naturally in small amounts by some plants and functions as a ripening agent. The commercially used form, which is synthetic, is chemically identical to the natural occurring form. The synthetic form is produced from hydrocarbon feedstocks, such as natural gas liquids or crude oil, and may also be derived from liquid ethanol.

Use of ethylene naturally produced by fruits has not been commercialized. Amounts produced for agriculture are small compared to emissions from car exhaust, petrochemical plants, or fires. It is used in the post-harvest ripening of tropical fruit and the de-greening of citrus.

**International (acceptance/nonacceptance) by other international certification agencies:**

Canada: allowed for post-harvest ripening of tropical fruit and degreening of citrus.

Japan: Limited to use after-ripening banana and kiwifruits.

IFOAM: De-greening of citrus and ripening

EU: Degreening bananas, kiwis and kakis; Degreening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus.

CODEX: For degreening of citrus for fruit fly prevention. As sprouting inhibitor for potatoes and onions.

**Environment/Health Issues:**

Ethylene is potentially flammable, and also an asphyxiate if high concentrations displace oxygen, but significant impacts on human health and the environment are likely minimal based on previous reviews.

**Discussion:**

In previous discussions, the Handling Subcommittee considered removing ethylene gas for use in the de-greening of citrus. However, historically there has been no opposition to relisting ethylene. The 2015 NOSB approved continued use of ethylene as a post-harvest ripening tool. The Handling subcommittee found ethylene to be compatible with current organic processing standards.

**Additional information requested by Subcommittee:**

The NOSB requests input on the continuing need for ethylene as a fruit ripening tool.

## Glycerides (mono and di)

**Reference:** 205.605(b) for use only in drum drying of food.

**Technical Report:** [1995 TAP](#); [2015 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life (Frank 2014). However, the only use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides help prevent sticking during processing, and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals (Fusaro 2012). The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (O'Brien 2004).

#### Manufacture:

Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources (FDA 2014). These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut or palm oil (Frank 2014), and their main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils. (TR 2015 56-62).

#### International:

Glycerides are permitted in organic standards in Canada, with the annotations: From organic sources if commercially available. For use in drum drying of products.

They do not appear in organic standards: CODEX, EU, IFOAM or Japan.

#### Ancillary Substances:

None.

**Alternatives:**

According to the 2015 TR, alternative ways to dry foods include spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Drum drying is said to be preferred for potato flakes. Freeze drying is said to be an acceptable alternative to drum drying.

Organic soy lecithin and gum arabic could be alternative substances to glycerides. Both are currently on the National List.

This material was reviewed by the NOSB during 2015 and the Board voted to continue its listing on the National List.

**Additional information requested by Subcommittee:**

1. The TR lists possible alternatives to drum drying, such as spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Why is drum drying preferred for the production of potato flakes? Have alternatives been tried? And if so, what were the results?
2. Have soy lecithin or gum arabic been tried as an alternative to glycerides (mono and di) in drum drying? What were the results?

**Magnesium stearate**

**Reference:** 205.605(b) - for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

**Technical Report:** [1995 TAP](#); [2018 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:****Use:**

Magnesium stearate (CAS # 557-04-0) is used as an anti-caking agent in salt. It is a flow agent, food processing machine lubricant, and may be an incidental additive. The most common use of magnesium stearate is as a binding agent in dietary supplements. Magnesium stearate is permitted for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))” but is prohibited in agricultural products labeled “organic.”

**Manufacture:**

Typically manufactured as a synthetic from hydrogenation of animal fats or vegetable oils. Magnesium stearate is produced by adding aqueous solution of magnesium chloride to sodium stearate. Stearic acid is made by saponification of edible fat (lye plus tallow) that is treated with an acid to form stearic acid.

**Alternatives:**

Organic flours and starches can replace magnesium stearate as an additive in some products. Non-synthetic flow agents are available as alternatives, depending on the product and process.

**International:**

As reviewed in the 2018 Technical Report:

“The Canadian General Standards Board (CGSB) includes nonsynthetic sources (and synthetic sources provided that nonsynthetic sources are not commercially available) of magnesium stearate as a permitted substance for organic production systems under CAN/CGSB-32.311-2015 for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients.

The Codex Alimentarius Commission’s “Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods” lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999).

Magnesium stearate was not found to be listed under any other international standard for organic handling and processing”.

**Environmental/Health Issues:**

Magnesium stearate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 184.1440). Magnesium stearate must meet the specifications outlined in the Food Chemicals Codex (21 CFR 184. 1440(b)) and can be used in food with no limitation other than current good manufacturing practice. There was no information provided indicating any significant human health impacts and historically there have not been comments recommending removal of this material from the National List.

**Discussion:**

In the past, the Subcommittee has requested public comment on availability of alternatives and any information on possible negative human health impacts. Public comment has been limited.

Magnesium stearate is allowed only in agricultural products labeled “made with organic” and is prohibited in agricultural products labeled “organic”.

**Additional information requested by Subcommittee:**

None

**Phosphoric acid**

**Reference:** 205.605(b) - cleaning of food-contact surfaces and equipment only

**Technical Report:** [2003 TAP](#)

**Petition(s):**N/A

**Past NOSB Actions:** [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:****Manufacturing Process:**

Phosphoric acid can be made in two ways: the wet process or the thermal process. In the wet process, mined phosphate ore is treated with sulfuric acid and then the resulting phosphoric acid is separated from the calcium sulfate crystals produced.

The process conserves most of the impurities found in the ore but the product can then be purified further for technical and food grade phosphoric acid. The thermally produced acid is made from the elemental phosphorus and is considerably more expensive and purer than the wet processed acid. The pure phosphorus is burned in excess air and the resulting phosphorus pentoxide is then hydrated and cooled, and the acid mist is collected.

**Specific Uses of the Substance:**

Phosphoric acid is used in cleaning operations to remove encrusted surface matter and mineral scale found on metal equipment such as boilers and steam producing equipment. Orthophosphoric acid is routinely used as a cleaning compound in its dilute form to remove oxidation from non-stainless steel surfaces, staining of stainless steel, lime and scale from heat exchangers and in Clean In Place cleaning operations, especially in dairy processing to remove buildup of calcium and phosphate salts from processing equipment.

**Additional Information requested by Subcommittee:**

1. Is the substance essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

The Handling Subcommittee encourages current users of phosphoric acid to provide detailed comments describing the situations in which it is the most effective cleaner for a given application.

## Potassium carbonate

**Reference:** 205.605(b)

**Technical Report:** [1995 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:****Use:**

Commonly used in the Dutch alkali process for processing cocoa and chocolate to reduce acidity. Used as a pH control; leavening agent; as a boiler water additive; as a tenderize tripe; and in soap production. Used in soft drinks and confections. Used as a buffering agent in making wine and mead to reduce acidity.

The 1995 Technical Advisory Report (TAP) notes that it be used only when sodium carbonate is not

appropriate. However it can be used to replace sodium carbonate when a lower sodium content is desired.

During the last sunset review, public comment indicated that it is not widely used.

**Manufacture:**

Potassium carbonate is a strongly alkaline white salt, a major component of the mined salt potash, which is made by passing carbon dioxide through a solution of potassium hydroxide. It is a caustic material with chlorine gas as a bi-product. During manufacture the gas is collected to avoid environmental pollution and human health impacts.

**International Equivalency:**

**Canada** - Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015

- Appears on Table 6.3—Ingredients classified as food additives

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

- Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items
- 05.0 Confectionery
- 06.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category
- 07.007.2 Fine Bakery wares (sweet, salty, savoury) and mixes; not permitted in food of animal origin
- Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3
- Drying of grape raisins

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

- Appears in Annex VII, Section A - Food additives including carriers
- Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production, drying of grapes

**Japan Agricultural Standard (JAS) for Organic Production**

- Appears in Table 1, Food additives, Limited to be used for drying processed fruit products, or used for grain processed foods, sugar, processed beans products, noodles, bread or confectionary.

**International Federation of Organic Agriculture Movements (IFOAM)**

- Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handling aids

**Additional information requested by Subcommittee:**

1. Is potassium carbonate in use in organic products?
2. What type of products is it used in?

## Sulfur dioxide

**Reference:** 205.605(b) for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.

**Technical Report:** [1995 TAP](#); [2011 TR](#)

**Petition(s):** 1995 N/A; [2010 Sulfur Dioxide](#)

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [12/2011 annotation change](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

Sulfur dioxide is primarily used to prevent spoilage and oxidation in wine. It may also be used to preserve meats, fruits and other products, however, there are limitations to its use. These limitations include foods used as a source for Vitamin B1, raw fruits and vegetables, foods consumed in large quantities or meats. The current organic annotation limits the use of sulfur dioxide to wine labeled “made with organic grapes” and further limits the sulfite concentration to not exceed 100 ppm. This annotation prevents the use of sulfur dioxide in products where the more serious health effects might be present.

Sulfur dioxide has undergone three sunset reviews and has been relisted each time. A technical report was done in 2011 and forms the bases of the comments summarized below:

In wines, sulfur dioxide is commonly referred to as ‘sulfite’ or ‘sulfites’. The sulfur dioxide inhibits microbial growth and prevents oxidation. Sulfur dioxide is often added to grapes to be fermented in very specific doses. Cultivated yeasts added to enhance fermentation of wines have been selected to be more tolerant of sulfur dioxide than wild yeasts. Enough sulfur dioxide is added to deter growth of the wild yeasts or bacteria present in the grape juice, while not exceeding a level that will deter the growth of the desired, added, yeasts to the juice. This process helps to prevent the formation of off flavors and helps to preserve the “freshness” flavor in white wines. While sulfur dioxide occurs naturally in wines, the level is too low to have pragmatic effect. Wines without added sulfur dioxide generally have to be kept in perfect storage conditions and have a shortened shelf life of around six months. This is often very difficult to achieve and the addition of sulfur dioxide has become accepted for meeting consumer expectations of wine quality.

#### Manufacture:

Sulfur dioxide can be produced commercially from several sources including elemental sulfur, ores of sulfide containing minerals, gypsum and anhydrite, and waste materials or flue gasses that contain sulfur. Most commonly, sulfur dioxide is generated by simply burning sulfur in devices that control air flow and that can capture the sulfur dioxide as it is generated.

#### International (drawn from the 2011 TR):

Canada – Canadian standards permit the use of sulfurous acid as preservative only in alcoholic beverages labeled as organic, but do allow those beverages to be made from grapes or other fruits, unlike the United States which limits its use to wine made from grapes. Furthermore, the Canadian

standards allow the alcohol to be labeled as “organic” and set a range of allowable sulfite concentrations that depend on the residual sugar content of the beverage.

The European Economic Community (EEC) allows sulfur dioxide at a maximum of 50 mg/L after fermentation in fruit wines, cider, perry or mead that do not have added sugar. They allow sulfur dioxide at a maximum of 100 mg/L after fermentation for cider and perry that have sugar added. All these beverages may be labeled as organic.

The CODEX Alimentarius Commission permits the use of sulfur dioxide for making cider, perry, mead, and wines made from grapes or other fruits.

**Ancillary substances:**

The 2011 TR makes no mention of ancillary substances associated with sulfur dioxide.

**Discussion:**

Sulfur dioxide is considered to be Generally Recognized As Safe (GRAS) by the Food and Drug Administration when used in accordance with good manufacturing practices, except it is not to be used in meats, food recognized as a source of vitamin B1, on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented as fresh (21 CFR 182.3862). It is recognized to be used in organic products internationally, although various restrictions are placed on its use, either in limitations of concentration or on the products it may be used in.

Sulfur dioxide may cause health effects in sensitive individuals. These effects range from allergic reactions in individuals born without the enzyme sulfite oxidase, asthma attacks, which vary depending on individual sensitivity, hives and swelling, to anaphylaxis.

There are no expected adverse environmental effects from the use of sulfur dioxide as currently listed in the organic rules.

The current annotation allows the use of sulfur dioxide only in wine made from grapes. The increasing interest in ciders, wines not made from grapes, and other fermented beverages has led to inquiries about possible use in these products, however, a petition to the NOSB would be required to change this annotation.

While alternatives to sulfur dioxide for winemaking have been investigated, the technical report notes that there are not organic alternatives that are satisfactory to prevent spoilage and oxidation in wine.

**Additional information requested by Subcommittee:**

Have any organic alternatives to sulfur dioxide for use in winemaking been identified since the issuance of the 2011 technical report?



## Xanthan gum

**Reference:** 205.605(b)

**Technical Report:** [1995 TAP](#); [2016 TR](#); [2018 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Material Use:

Xanthan gum is used in numerous foods products as a hydrocolloid (i.e. substances that disperse water, giving a thickening or gelling effect) including but not limited to: baked goods, beverages, dairy products, dressings, nutritional supplements, frozen foods, etc. (TR 758-759, 135-137). The gum is used in small percentages of the finished products, usually at <0.5% by weight (TR 145-146). Xanthan gum is used along with other gums to achieve the desired viscosities and product structures for firmness, water binding, flavor delivery, etc. (TR 229-236); it is particularly effective in frozen and chilled products where it can impart thickness, freeze-thaw protection, and stability during processing and shelf-life (TR 251-256). Common synergistic gums used along with xanthan gum are locust bean gums, guar gums, carrageenan gums (TR 229-236).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

**Table 1. Summary: General Properties of Gums**

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

**Manufacture:**

Xanthan gum is a high-molecular weight polysaccharide produced through natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried and milled (TR 36-38, 90-97). The gum is water soluble, stable at numerous pH, salt and temperature ranges (including frozen temperatures) (TR 120-124). The side chains carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 50-55). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (TR 48-50). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 Gums TR 424-432).

**International Equivalency:**

FDA has approved the use of xanthan gum as a food additive since 1969 without restrictions on quantity in finished applications (TR 162-163, 637-638); it must be isolated by isopropyl alcohol precipitation and made into a sodium, potassium, or calcium salt (TR 164-166). It is approved by FDA at 21 CFR 172.695 but is not GRAS; though three FDA notices for GRAS allow isolation of xanthan gum by ethanol and pyruvate, and in combination with konjac glucomannan and sodium alginate (TR 651-659).

*Canadian Organic Regime's Canadian General Standards Board Permitted Substances List* (Nov 2015 ed.) allows the use of xanthan gum as long as it is derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 Gums TR 491-496).

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

Xanthan gum is allowed and the CODEX General Standard for Food Additives (GSFA) 502 describes the compliant uses (2018 Gums TR 498-504).

*European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008*

Xanthan gum is allowed for use as compliant with General Standard for Food Additives Annex II and III in processed organic foods and as a food additive in the preparation of foodstuffs of plant or animal origin (2018 Gums TR 506-515).

*Japan Agricultural Standard (JAS) for Organic Production*

Xanthan gum is allowed in processed foods of animal origin limited to dairy or confectionary (2018 Gums TR 525-536).

*International Federation of Organic Agriculture Movements (IFOAM)*

Xanthan gum is allowed with no limitations on use (2018 Gums TR 538-541).

**Ancillary Substances:**

According to the 2016 TR (258-263), ancillary substances are not commonly added to commercially available forms of xanthan gum for use in foods. Through a search of publically available specification

sheets a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®.

#### **Background Information:**

Xanthan gum has been used for decades globally in the food system, and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 637-742). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR 933, 963-976). In 2011 there was a recall of a xanthan gum product that was being fed to premature babies due to the lack of destruction of potentially harmful bacteria that may lead to necrotizing enterocolitis; no conclusions were made regarding the safety of xanthan gum thickeners for premature baby formulas (TR 678-711).

There was no mention of specific environmental issues regarding the production of xanthan gum.

#### **Additional information requested by Subcommittee:**

None

## Fructooligosaccharides

**Reference:** 205.606(h) Fructooligosaccharides (CAS # 308066-66-2)

**Technical Report:** [2006 TAP](#); [2015 TR](#)

**Petition(s):** [2006 Petition](#)

**Past NOSB Actions:** [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

#### **Background from Subcommittee:**

**Use:** Fructooligosaccharides (FOS) is on the National List as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic.” FOS is a non-digestible carbohydrate that is used as a soluble prebiotic fiber, sweetening agent, flavor enhancer, bulking agent and humectant. It is used in many foods including yogurts, infant foods, medical food, baked goods, candies, soups, beverages and other dairy products. FOS are mostly indigestible by human digestive enzymes.

**Manufacture:** There are a two common commercial methods to produce FOS

- **Inulin derived.** Inulin, a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke (sunchoke), Agave and other plants. Chicory inulin is extracted from the source material via water extraction – the resulting inulin undergoes a partial enzymatic hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger*. The hydrolysis breaks long chain inulin into the shorter chain FOS.
- **Sucrose derived.** Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicus*. The *A. japonicus* cells must be immobilized for production of high-purity FOS, which

can be accomplished by creating beads of the *A. japonicus* culture suspended in calcium alginate, an immobilizer. *A. japonicus* cells hydrolyzes (breaks) the sucrose molecules into glucose and fructose and then transfers fructose molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicus* is generally inefficient, higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

Both processes also use heat and pH control to speed up the enzymatic reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid (a strong acid) or sodium hydroxide (a strong base); potassium phosphate is also used for pH control.

The FOS produced can then be further purified through filtration or further fermentation.

**Ancillary Substances:** According to the 2014 TR: “There are no ancillary substances intentionally included in the FOS formulations as described in the petition, and no ancillary substances are intentionally added to the FOS products in the selected high-purity FOS fermentation.”

**International:** FOS is not specifically listed in the Codex, EU, Japanese organic standards or Canadian standards. However non-organic agricultural products are not listed in these standards.

**Discussion:** During the 2015 sunset review the NOSB received limited feedback from users of this substance. However, comments were received in support of continued listing for usage in the baking industry and no sources of organic FOS were identified.

#### **Additional information requested by NOSB**

1. Have organic sources of FOS become available? What additional actions have organic industry users of FOS taken to source or develop organic FOS?
2. What functional essentiality does FOS have in current specific organic certified applications and would alternatives (i.e. other fibers, organic inulin, etc.) be functionally similar in the same application? If not, why?
3. Is the summary of both inulin derived and sucrose derived FOS correct? Do both of these processes meet the agricultural classification in line with NOP Guidance 5033 on Agricultural/Non-Agricultural classification?

### **Gums: (Arabic, Guar, Locust bean , and Carob bean)**

**Reference:** 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)

**Technical Report:** [1995 TAP](#); [2018 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [10/2010 NOSB sunset recommendation](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

## Material Use:

Gum arabic, locust bean gum, carob bean gum, and guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR 78-103). These gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (TAP pg 8, 2018 TR 443). These gums are used in various food applications due to their ability to modify viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR 182-187). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR 189-192).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 technical report distinguishes the different characteristics of common gums.

**Table 1. Summary: General Properties of Gums**

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

## Manufacture:

Gum arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder. (2018 TR 566-573)

Locust/carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR 594-595)

Guar gum is formed from the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR 584-586).

**International Equivalency:**

Gum arabic, locust/carob bean gum and guar gum are all listed by the FDA as Generally Recognized as Safe (GRAS) (2018 TR 750-752).

*Canadian Organic Regime's Canadian General Standards Board Permitted Substances List* (Nov 2015 ed.) allows the use of Gum Arabic, locust/carob bean gum, and guar gum as long as they are derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Gum Arabic (414), locust/carob bean gum (410), and guar gum (412) are allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

*European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008*

Gum Arabic, locust/carob bean gum, and guar gum are allowed for use in processed organic foods as a food additive in the preparation of foodstuffs of plant 508 or animal origin with no specific limitations (2018 TR 506-515).

*Japan Agricultural Standard (JAS) for Organic Production*

Arabian gum (INS 414) is limited to dairy products, edible fat, and oil and confectionary products (2018 TR 527).

Carob bean gum/locust bean gum (INS 410) is limited to dairy and processed meats. (2018 TR 529)

Guar gum (INS 412) can be used in processed foods of animal origin limited to dairy, canned meat or egg products. (2018 TR 531)

*International Federation of Organic Agriculture Movements (IFOAM)*

IFOAM allows locust bean gum (INS 410), guar gum (INS 412), tragacanth gum (INS 413), Arabic gum (INS 414) and xanthan gum (INS 415). There are no restrictions on how any of these items can be used (IFOAM, 2014). (2018 TR 539-541)

*East African Organic Product Standard*

Locust bean gum, guar gums are allowed with no restrictions. Arabic gum is allowed for milk products, fat products, confectionary, sweets and eggs (2018 TR 544-550).

**Ancillary Substances:**

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

**Background Information:**

No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) re-evaluated five gums in 2017 including

arabic, guar, and locust. The panel concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children, and recommend that additional data be generated.

In 2015 these gums were unanimously voted by the NOSB to remain on 205.606(k).

**Additional information requested by Subcommittee:**

Are organic versions of gum arabic, locust/carob bean gum, and guar gums commercially available?

## Lecithin -de-oiled

**Reference:** 205.606(o) Lecithin - de-oiled

**Technical Report:** [1995 TAP](#); [2009 TR](#)

**Petition(s):** [Lecithin, bleached \(remove 2008\)](#)

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [05/2009 recommendation \(remove from 605b\)](#); [05/2009 Recommendation \(amend 606\)](#); [10/2015 sunset recommendation](#)

**Recent Regulatory Background:** Annotation change effective 03/15/2012 ([77 FR 8089](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

**Use:**

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Lecithin has a wide range of food application, which includes emulsification, release properties, wetting, dispersing, and texturization. The major applications for lecithin include margarine, chocolates, instantizing powders, release sprays, and baked goods. It is used as a natural surfactant between oil and water systems as seen in margarine products. Lecithin also helps modify chocolates for better enrobing and reduces crystallization of cocoa fat. In release applications, lecithin modifies the cooking surface to allow products to be more easily removed. As an instantizing agent, lecithin reduces the hydration properties of powders that would otherwise clump during dispersion in water and milk products. In baking, the lecithin provides a multifunction application by emulsifying the fat and water and as an anti-staling agent by inhibiting starch retrogradation. Lecithin improves water absorption in baked goods and dough, increasing volume and shelf life, and improving uniformity of the products. It is also used as a packaging aid and directly on processing equipment as a lubricant. In addition, lecithin is used in pharmaceuticals (as dietary supplements, emulsifying agent for intravenous injections, and dispersant for vitamins); in cosmetics (as emulsifier and emollient in hair and make-up preparations, creams, and oils); and in animal feeds (as a nutritional ingredient, emulsifier, and wetting aid in calf milk replacers, pet foods, and many other types of feeds required high fat and oil contents). Bleached lecithin is used in applications where a lighter color is deemed important. Unbleached fluid lecithin has a dark brown color which does not permit high use levels in white or very light colored products; however, in some formulations, brown fluid lecithin can be used effectively at low concentrations (Scocca, 1976). Dry lecithin is used in commercial applications of food systems where liquid lecithin is more difficult to handle and the powdered or granular lecithin is more easily incorporated.

**Manufacture:**

Lecithin is the substance isolated as a gum following hydration of solvent-extracted soy, safflower or corn oils. Most commercial lecithin is made from crude soy oil extracted from soy flakes. The crude soy oil is then treated with water or steam to precipitate the lecithin as a gum. The wet gums is centrifuged, bleached (with hydrogen peroxide and/or benzoyl peroxide), and dried to become bleached lecithin.

**International:**

The Joint FAO/WHO Expert Committee on Food Additives— Lecithin (INS1: 322) functional uses as antioxidant and emulsifier agent. Acceptable daily intake is not limited.

Canadian Organic Standards— Lecithin bleached form is allowed when unbleached form is not suitable from organic sources only. Lecithin is listed in the table of “Food Additives” of the “Non-organic Ingredients” section under permitted substances lists for processing and sanitation

The EU Organic Regulation No 2092/91— The use of lecithin as (1) a fungicide, listed in the section “Substances of crop or animal origin”, for plant protections; and (2) a food additive, listed in the subsection “Food additives, including carriers” of the section “INGREDIENTS OF NON-AGRICULTURAL ORIGIN”, for preparation of foodstuffs composed essentially of one or more ingredients of plant and/or animal origin.

The Codex Guidelines for Organically Produced Foods— Lecithin used for pest and disease control need recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose, etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted for use in foods of plant origin and certain foods of animal origin (such as dairy products and analogues, fats and oils, fat emulsions, emulsified sauces, and infant formulae and follow-on formula) (2009 TR lines 159 -163).

**Environmental Health Issues:**

Lecithin is found in brain, nerve, liver, kidney, heart, blood, and other tissues. Because of its strong affinity for water, it facilitates the passage of fats in and out of the cells; and it probably plays a role in fat absorption from the intestine and transport of fats from the liver (Potter, 1973). No acute exposure studies were found for soybean-derived lecithin in humans. According to MSDS, the dust is predicated to be irritating to the eyes, skin, and respiratory tract from mechanical action. Inhalation of lecithin aerosols may cause pulmonary edema; it may cause occupational asthma from pulmonary sensitization. Acute ingestion may affect the liver (fatty liver degeneration). Safety glasses, lab coat, dust respirator, and gloves are needed for personal protection.

Soy has also been recognized as one of the eight most common food allergens. During manufacture of lecithin derived from soy, most, but not all, of the soy protein is removed. Soy allergens, to the extent they are present in lecithin, would be found in the protein fraction of the ingredient. Accurately measuring lecithin’s protein content presents challenges to current analytical methodology due to the ingredient’s oily matrix and low levels of protein.

**Discussion:**

During the sunset review in October 2006, the NOSB recommended renewing lecithin-bleached under 7 CFR 205.605(b) Synthetics allowed. In the committee summary, the Board further recognized that there are “plentiful non-synthetic and organic alternatives to synthetic bleached lecithin in liquid form” but that there is currently no such alternative for “bleached lecithin in dry, de-oiled form”. Because the sunset review provided no opportunities to add annotations, the board saw no alternative but to



recommend renewal of bleached lecithin. In its closing summary, the Board invited a petition to restrict the use of bleached lecithin to dry forms only. Since then, the supply of organic lecithin has evolved to the point that there is now certified organic lecithin available to replace the need for non-organic bleached lecithin. But, there still remains a question of whether there is an organic lecithin that is in dry, de-oiled form.

During the May 2009 NOSB meeting, several experts and lecithin industry members provided informational presentations describing the types of lecithin available, and the methods of manufacture for each. It was explained that it is the “de-oiling” process, not the bleaching process that differentiates the types and functionality of lecithin, and dictates in which products they could be used. At this time, there are now many forms of organic lecithin available, as well as organic and conventional non-synthetic gums, which make the use of this synthetic form of lecithin no longer essential in organic handling. The board voted to remove the “bleached” form of lecithin from 205.605(b), but in a separate vote, agreed to list “lecithin – de-oiled” in 205.606, making that form available to organic manufacturers who truly needed it, but subjecting its use to commercial availability scrutiny by certifiers. Both the petitioner and lecithin-using handlers present at the NOSB meeting were satisfied with this recommendation.

In 2009, the NOSB reviewed the arguments for and against renewal of lecithin. Those in favor of renewing pointed out that there is insufficient supply in an organic form, specifically from raw materials other than soy. Additionally other sources were not yet in production and were located in a country under political turmoil. Those in favor of removal argued the product was available in an organic form internationally. The majority of the NOSB concluded that it meets the OFPA criteria, is not available in an organic form, and should be renewed.

**Additional information requested by Subcommittee:**

Are there commercially available organic forms of lecithin in de-oiled form?

## Tragacanth gum

**Reference:** 7 CFR 205.606(x) - As nonorganically produced agricultural product allowed as ingredient in or on processed products.

**Technical Report:** [2018 TR](#)

**Original Petition:** [2007 Tragacanth Gum](#)

**Past NOSB Actions:** [2008 Final Recommendation](#); [2014 sunset recommendation](#)

**Regulatory Background:** Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 ([75 FR 7751](#)). Sunset renewal notice published 06/22/2015 ([80 FR 35177](#))

**Sunset Date:** 06/22/20

**Material Use:**

Tragacanth gum is a polysaccharide that forms gels and can be used as a thickener and emulsifier. This material is effective at low pH and at many temperatures; its stability at low pH is noted as one of its distinguishing characteristics and is commonly used in high acid products like salad dressings (2018 TR 218-225, 337). The percentage in final formulations is usually low, below 1% of a total formula (2018 TR 338).

Despite having some similar characteristics, not all gums are interchangeable. Due to the structure of the gums, some behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf-life and

product use. Many times these gums are used in combination to impart the correct properties in the finished goods (2018 TR 416). The table provided on line 285 in the 2018 Technical report distinguishes the different characteristics of common gums.

**Table 1. Summary: General Properties of Gums**

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

#### **Manufacture:**

Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species during July to September (2018 TR 576-581). Once collected it is dried and ground into powder and may, or may not, undergo a mitigation step to reduce the microbial load of the powder (2018 TR 578-581).

#### **International Equivalency:**

Tragacanth gum is listed as Generally Recognized as Safe (GRAS) by the FDA at 21 CFR 184.1351 (2018 TR 750-752).

*Canadian Organic Regime's Canadian General Standards Board Permitted Substances List* (Nov 2015 ed.) allows the use of tragacanth gum as long as it's derived using solvents on their Table 6.3 Extraction solvents, carriers, and precipitation aids [in the source document]. By exception isopropyl alcohol may also be used to derive gums (2018 TR 491-496).

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

Tragacanth gum (412) is allowed and the CODEX General Standard for Food Additives (GSFA) describes the compliant uses (2018 TR 498-504).

*European Economic Community (EEC) Council Regulation, EC Nos. 834/2007 and 889/2008*

Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR 506-515).

*Japan Agricultural Standard (JAS) for Organic Production*

Tragacanth gum is listed with no limitations (2018 TR 535).

*International Federation of Organic Agriculture Movements (IFOAM)*

IFOAM allows tragacanth gum (INS 413) with no restrictions on how any of this item can be used (IFOAM, 2014) (2018 TR 539-541).

*East African Organic Product Standard*

Tragacanth gum is allowed with no restrictions (2018 TR 547).

**Ancillary Substances:**

According to the 2018 TR (434-438) no information was found indicating that any additional materials are generally added to commercially available forms of the gums. However, according to the 2016 TR on xanthan gum two exceptions were identified during a review of publically available specification sheets: glucose used to standardize a xanthan and guar gum blend, and polysorbate 60 in GRINSTED®.

**Background Information:**

No environmental or health concerns were noted in the manufacture or use of this gum.

The NOSB Subcommittee noted in 2008 that due to limited growing regions (Turkey and Iran) and relevant trade embargoes, the supply of conventional tragacanth gum was fragile and limited. In October 2014 organic tragacanth gum was not known to be in production. The 2014 Subcommittee was unable to find evidence that tragacanth is available in organic form, and received testimony from a certifier and a producer who currently uses non-organic tragacanth.

**Additional information requested by Subcommittee:**

Is organic tragacanth now commercially available?

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**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Proposal  
Sodium Dodecylbenzene Sulfonate (SDBS)  
January 16, 2018**

**Summary of Petition ([October 2015 petition](#)):**

Sodium dodecylbenzene sulfonate (SDBS) is petitioned by Ecolab, Inc. for addition to the National List at §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”, (b) Synthetics Allowed. SDBS is one of two active ingredients (the second is lactic acid) in an antimicrobial formulation for use in treating fruits and vegetables in the premises of organic food retail establishments. The Ecolab, Inc. branded formulated antimicrobial material is labeled as Antimicrobial Fruit & Vegetable Treatment (AFVT). AFVT is used in food retail environments such as restaurants, cafeterias, food service operations, commissaries and kitchens. The petitioner states their product would help to provide the organic users a new reliable antimicrobial.

AFVT is used via a sink-mounted dispensing system, which controls the concentration released into wash water. The proposed use is for raw and processed fruits and vegetables and involves a minimum 90 second immersion in the antimicrobial wash water, followed by a draining stage prior to further processing and/or serving. When used at suggested label rates, the concentration of SDBS is 76-111 ppm. SDBS remains on the produce at produce species dependent levels up to 10 ppm.

SDBS is currently approved for use as an antimicrobial agent in produce wash water by the Food and Drug Administration (FDA) under 21 CFR 173.405. It is not listed as FDA Generally Recognized as Safe (GRAS). SDBS has been reviewed by the Environmental Protection Agency’s (EPA) Safer Choice Program and is included in the Safer Chemical Ingredients List (SCIL).

SDBS is an anionic surfactant used in industrial, institutional and chemical detergents & cleaners, specialty cleaners, sanitization products, emulsifiers, suspension or wetting agents, absorbents in pesticide and other agricultural chemicals, along with numerous other uses (TOXNET – Toxicology Data Network, 2014).

**Summary of Review:**

On October 13, 2015 the NOP received a petition from Ecolab, Inc. to add SDBS (CAS #25155-30-0) to the National List at §205.605. The petition was forwarded to the Handling Subcommittee on November 2, 2015 for review. At the time of initial review on December 1, 2015, the Handling Subcommittee deemed the petition sufficient and did not request a technical review (TR).

A proposal was brought to the 2016 Spring NOSB meeting and included several questions for the public to better inform the Board’s deliberation:

1. What are retailers currently using to address food safety concerns?
2. Are any of the alternatives mentioned in the petition currently used at the retail level and if so are they effective in addressing these areas of food safety concerns?
3. What is the level (if any) of impurities as mentioned in this (2016) document found in SDBS?

Public comment in advance of and during the Spring 2016 meeting did not sufficiently address the above questions. Several comments, including from the petitioner, generally supported the addition of SDBS to the National List. One commenter noted while SDBS has advantages over other antimicrobials, they

believe the NOSB should first conduct a thorough review of all antimicrobials and available products and favor those with fewer health impacts on workers and consumers. Several commenters noted the need for more data regarding potential harm to human health and the environment. Several commenters noted the availability of several alternative, already allowed antimicrobials and felt SDBS did not meet the essentiality criteria of OFPA. One commenter requested a TR be provided any time an antimicrobial material is petitioned.

Based on the comments received and its determination that more data was necessary to make a decision, the Board voted to refer the proposal back to the Handling Subcommittee. On May 18, 2016, the Handling Subcommittee requested a TR be commissioned to review SDBS. On May 30, 2017, the Program provided the TR to the Subcommittee, which deemed it sufficient on August 1, 2017. During its August 1, 2017 meeting, the Subcommittee also reviewed and found sufficient a petition addendum submitted by the petitioner.

The TR provided additional information on the manufacture of SDBS, alternatives to its use, and potential impact on human health and the environment. The petition addendum and comments from the petitioner submitted during the Spring 2017 public comment period also address these points. See below for further discussion on these criteria.

#### **Allouance under other Organic Standards**

- **Canadian General Standards Board Permitted Substances List**  
SDBS is not listed in the CAN/CGSB-32.311-2015 - Organic production systems - Permitted substances lists.
- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**  
SDBS is not listed in Codex Alimentarius GL 32-1999.
- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**  
SDBS is not listed in EC No. 834/2007 or 889/2008.
- **Japan Agricultural Standard (JAS) for Organic Production**  
SDBS is not listed in the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) standards for organic production.
- **International Federation of Organic Agriculture Movements (IFOAM) –**  
SDBS is not listed in the IFOAM norms for organic production.

#### **Category 1: Classification**

1. Substance is for: \_\_\_\_\_ Livestock      X   Handling

2. For HANDLING and LIVESTOCK use:

a. Is the substance \_\_\_\_\_ **Agricultural** or   X   **Non-Agricultural**

Describe reasoning for this decision using NOP 5033-2 as a guide:

SDBS is not a mineral or bacterial culture, is not a microorganism or enzyme, and is not a crop or livestock product nor derived from crops or livestock. There is no agricultural source or feedstock for the production of SDBS.

b. If the substance is **Non-agricultural**, is the substance \_\_\_\_\_ **Non-synthetic** or   X   **Synthetic**

Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

SDBS is not manufactured, produced or extracted from a natural source. It has undergone a chemical change so that it is chemically/structurally different than its source material. The chemical change is not created by a naturally occurring biological process, or by heating or burning biological matter.

The petitioner does not manufacture SDBS, but uses it as 1 of 2 active ingredients in their formulated product AFVT. The petition lists 3 manufacturers of SDBS:

1. Pilot Chemical Company - Santa Fe Springs, CA
2. Stepan Company - Northfield, IL
3. Unger Fabrikker A.S. - Fredrikstad, Norway

SDBS is manufactured from linear alkylbenzenesulfonate (LAS) produced from linear alkylbenzene (LAB). SDBS is the sodium salt of LAS. The manufacturing process determines SDBS's composition and specific application performance level.

SDBS manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS. SDBS is produced from kerosene or paraffin, and benzene from crude oil feedstocks. Sulfonation requires the use of sulfuric acids or burning elemental sulfur also from fossil fuel feedstocks. There is no agricultural source or feedstock for the production of SDBS.

Current manufacturing practice for LAS requires chemical catalysis which depending on the specific catalyst used can produce environmental pollution and equipment corrosion. The use of homogeneous zeolite catalysis can reduce much of the pollution associated with current catalytic methods, but the zeolite method is still in the developmental stages and there is still much work ahead in improving the manufacturing process (Aitani et al., 2014).

One of the questions posed to the public during the review of the first proposal requested information regarding the level of impurities in SDBS. SDBS may contain impurities that include neutral oil (unsulfonated materials), arsenic (As), iron (Fe), and lead (Pb). These impurities are not due to the manufacturing process but occur in the substance in background levels. The TR notes commercially prepared SDBS is usually greater than 96% pure. In the petition addendum, the petitioner states the SDBS used in their product is 91% pure. SDBS in the form and purity used in produce wash water does not normally contain toxic levels of the heavy metals or contaminants listed by the FDA in its list of chemical contaminants, metals, natural toxins and pesticide guidance documents and regulations, e.g. aflatoxins, acrylamides, dioxins, PCBs, melamine or radionuclides.

## **Category 2: Adverse Impacts**

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

SDBS is an ingredient in a formulated product for use as an antimicrobial in the preparation and

processing of raw fruit and vegetables. Used as directed, there is little potential for detrimental chemical interactions with other materials.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

#### *Mode of Action*

SDBS acts as a surfactant that disrupts bacterial membranes, subsequently changing their structure, attachability, and permeability. It denatures some bacterial proteins and inactivates some bacterial enzymes on the bacterial outer membrane involved in ionic transport.

Studies of the efficacy of various commercial detergent formulations in reducing human pathogens on inoculated fruits and vegetables and comparisons with other treatments have been reported for apples, strawberries, cantaloupe, tomatoes, and lettuce. Results from these studies indicate that detergent washes sometimes can achieve bacterial population reductions of 100 to 1000 fold, equaling or surpassing sodium hypochlorite, but in other cases showed no greater efficacy than water (Sapers, 2014). For example, a 0.2% (200 ppm) solution of SDBS had the same efficacy as a water wash in reducing *Escherichia coli* O157:H7 bacterial load on romaine lettuce (Keskinen 144 and Annous, 2011).

Other studies show that SDBS can be used in combination with phosphoric acid to reduce *Escherichia coli* O157:H7 on apples (Wright et al., 2000). Treatments with phosphoric acid and SDBS have an antimicrobial effect reducing bacterial populations by 10 to 100 fold (Sapers et al., 2001). Phosphoric acid is allowed in organic production for use as an equipment cleaner, cleaning of food contact surfaces only and to adjust the pH of liquid fish fertilizer [7 CFR 205.605(b), (j)(7)].

#### *Effect on the Environment*

The process of manufacture may determine the degree of negative impact on the environment, with alternative methods aimed at improving the manufacturing process. After use, surfactants are mainly discharged into sewage treatment systems and dispersed into the environment as effluent discharge into surface waters and sludge disposal on agricultural land (Ying, 2006). LAS, the progenitor of SDBS, is not acutely toxic to organisms at environmental concentrations. Concentrations of LAS found in municipal wastewater treatment systems is 1-10 mg/L (Manousaki et al., 2004). Aquatic chronic toxicity of surfactants occurs at concentrations usually greater than 0.1 mg/L (Ying, 2006).

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

The TR notes the preferred method for disposal of sewage sludge is as a soil fertilizer and so it is important to consider that LAS is slow to biodegrade under anaerobic conditions where oxygen is limited. Biodegradability may be improved through the use of low frequency ultrasound. However, several government public safety evaluators have concluded that LAS does not represent an environmental problem (HERA, 2013; OECD, 2005; EPA, 2006).

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

The TR provides references to studies of LAS exposure, noting LAS is readily absorbed from the



gastrointestinal tract. However, the TR also notes most of the absorbed dose is eliminated in the urine. Further, at the concentrations used, LAS is not a sensitizer or an irritant and is not carcinogenic. Exposure to concentrations of LAS higher than label use has shown to be an irritant to the skin and eyes.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

See information in question 3.

6. Are there any adverse impacts on biodiversity? (§205.200)

See information in question 2. For further data, refer to the TR, lines 308-329.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

Preventive practices are an essential aspect of organic production. As noted in the TR, keeping fresh produce free of soil and reducing the potential for bacterial contamination of produce during pre and postharvest is a FDA requirement. The addition of SDBS to produce wash water aids in the removal of bacteria from produce surfaces, however it is easier to prevent contamination than to remove it later (Sapers, 2003).

Aside from preventive practices during the pre and postharvest stages, there are a number of synthetic and non-synthetic materials available for use as an alternative to SDBS. Electrolyzed water, sodium and calcium hypochlorite and peroxyacetic acid are synthetic alternatives. Non-synthetic alternatives include organic acids (ascorbic acid, citric acid, lactic acid, lactates, tartaric acid, malic acid and organic vinegar (acetic acid)); essential oils such as cinnamon, rosemary, oregano and others; grapefruit seed extract; and egg white lysosome. Each has been shown to reduce microbial levels of *Listeria monocytogenes*, *Salmonella typhimurium*, *Escherichia coli* O157:H7, *Shigella dysenteriae*, *Bacillus cereus* and *Staphylococcus aureus*.

In the petition addendum, the petitioner includes some drawbacks to these alternatives. For peracetic acids, these products are less suitable or manageable in retail and foodservice settings: concerns for worker exposure, impractically large quantities in which they are sold, short storage life. For chlorine dioxide and ozone, the material must be generated onsite, there are concerns regarding worker exposure and use is limited to trained employees. For chlorine, sodium hypochlorite is easy to use, inexpensive and convenient. However, both the petitioner and TR note the corrosive properties of chlorine solutions as having the potential to shorten the life of stainless steel equipment used in produce processing.

2. For Livestock substances, and Nonsynthetic substances used in Handling: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Not applicable

**Category 4: Additional criteria for synthetic substances used in Handling** (does not apply to nonsynthetic or agricultural substances used in organic handling).

Describe how the petitioned substance meets or fails to meet each numbered criterion.

- (1) The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

SDBS cannot be manufactured from a natural source. Its manufacture is based on a chemical synthesis production scheme from petroleum feedstocks: dehydrogenation, alkylation and sulfonation with potentially halogenated intermediates. There is no natural process for producing SDBS.

Non-synthetic alternatives/substitutes include organic acids. See Category 3, question 1 above.

- (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

As noted above, SDBS's adverse effects can be minimized in the manner in which it is manufactured and the method of its disposal.

- (3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))

SDBS is introduced into wash water service to improve the removal of soil and bacteria attached to the surface of produce. If used according to the FDA instructions it does not penetrate into the produce being washed and subsequently its application does not affect the nutritional quality of the food (Sapers, 2014). Adverse effect on health is addressed in Category 2, question 4, above.

- (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

SDBS is added to fresh produce wash-water as an aid in the removal of surface bacteria. Except for residual SDBS remaining on the produce at produce species dependent levels up to 10 ppm, SDBS does not contribute to the flavor, color, texture or nutritive value of the product (Watanabe et al., 1972).

- (5) The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

SDBS is included in the [FDA Food Additive Status list](#). It is a substance that has a miscellaneous technical effect and is a food additive for which a petition has been filed and a regulation issued. It is specified in this list for < 0.2% in wash water as a surface active agent in commercial detergents used in washing fruits & vegetables, or to assist in lye peeling these products, 21 CFR 173.315. However, SDBS is not GRAS. SDBS has been reviewed by the Environmental Protection Agency's (EPA) Safer Choice Program and is included in the Safer Chemical Ingredients List (SCIL).

- (6) The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

SDBS is not essential. There are alternatives available. See Category 3, question 1, above.

- (7) In balancing the responses to the criteria in Category 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

The subcommittee notes the availability of allowed natural and synthetic alternatives to this substance. However, the subcommittee also recognizes the importance of having the ability to rotate among several materials in an antimicrobial regime to reduce the incidence of microbial resistance. In the absence of significant public comment advocating for the addition of SDBS to the National List and the availability of alternatives, the subcommittee does not see it as essential to organic production.

**Classification Motion:**

Motion to classify sodium dodecylbenzene sulfonate as petitioned as nonagricultural, synthetic.

Motion by: Scott Rice

Seconded by: A-dae Romero Briones

Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

**National List Motion:**

Motion to add sodium dodecylbenzene sulfonate as petitioned at 205.605(b).

Motion by: Joelle Mosso

Seconded by: Steve Ela

Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

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**Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOSB February 21, 2018**

**National Organic Standards Board  
Handling Subcommittee Proposal  
Reclassification of Magnesium Chloride  
December 19, 2017**

**Summary of Proposed Action:**

The Handling Subcommittee proposes to change the classification of magnesium chloride from a nonagricultural synthetic substance to a nonagricultural non-synthetic substance and move the substance from §205.605(b) to §205.605(a) of the National List.

**Subcommittee Review:**

During the 2015 sunset review, magnesium chloride was recommended for continued listing on the National List but issues related to classification were raised. The Handling Subcommittee requested public comment on whether or not this material should be reclassified as non-synthetic since it is simply derived from sea water by brine drying, with no ancillary substances. Public comment at the time supported the reclassification of magnesium chloride as non-synthetic and that it be moved from §205.605(b) to §205.605(a). However, information provided in the 2016 TR indicates that magnesium chloride can be produced both synthetically and non-synthetically, and the annotation “derived from seawater” can apply to both.

Magnesium chloride produced by reacting a magnesium compound or mineral with hydrochloric acid is considered synthetic. This is because the substance undergoes a chemical change so that it is chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352- 354)

Natural sources of magnesium chloride can be extracted by various means which may affect the classification of the final substance as synthetic or non-synthetic. Evaporation and crystallization are physical processes which do not result in chemical change. Magnesium chloride extracted from brine by the two-step process involving calcium hydroxide and carbon dioxide is not chemically or structurally different from how it naturally occurs in the source material. (TR 2016, 352-361)

During the 2017 sunset review of magnesium chloride, information from the 2016 TR was incorporated into the review. A series of questions was posed to the public requesting feedback on the impact of reclassification in regards to feasibility of moving its listing, sufficiency of supply, and functionality. Most public comment was focused on retaining magnesium chloride on the National List due to its essentiality in tofu production, as well as in infant formula and dietary supplements. Public comment that addressed the reclassification included: Two certifiers who commented that reclassification would result in a small impact on users; one manufacturer who uses the material was supportive of reclassification with the current annotation; one organization supported reclassification if the material was found to be non-synthetic and suggested an annotation restricting its use to making tofu, and one organization who requested clarification on which forms would become prohibited as a result of reclassification.

Evaluation questions #1 and #2 in the 2016 TR go into detail about where and how magnesium chloride can be produced non-synthetically from a variety of natural commercial sources including seawater, terminal lake brines, subsurface brine deposits, and mined mineral deposits. The Handling Subcommittee compared these processes to the Decision Tree for Classification of Materials as

Synthetic or Nonsynthetic (NOP 5033-1) and determined that magnesium chloride produced via these sources does not go through any chemical changes, and therefore is non-synthetic.

The Handling Subcommittee proposes that magnesium chloride remain on the National List. However, the Subcommittee is bringing forward this proposal to change the listing from §205.605(b) to §205.605(a) due to the determination that magnesium chloride is available in a non-synthetic form. Additionally, the Handling Subcommittee proposes the annotation “derived from seawater” is removed since there are multiple sources from which non-synthetic magnesium chloride can be derived.

**Vote in Subcommittee:**

Motion to remove the annotation that reads “derived from seawater”, and to reclassify magnesium chloride as non-synthetic and move it’s listing from §205.605(b) to §205.605(a)

Motion by: Lisa de Lima

Seconded by: Steve Ela

Yes: 4 No: 0 Abstain: 0 Absent: 3 Recuse: 0

**Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOSB February 21, 2018**

**Sunset 2020 Review**  
**Meeting 1 - Request for Public**  
**Comment Crops Substances**  
**April 2018**

**Introduction**

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2020. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

**Request for Comments**

While the NOSB will not complete its review and any recommendations on these substances until the Fall 2018 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2018 public meeting. These comments should be provided through [www.regulations.gov](http://www.regulations.gov) by April 4, 2018 as explained in the meeting notice published in the Federal Register.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

**Guidance on Submitting Your Comments**

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

**For Comments That Support Substances Under Review:**

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic crop production.

**For Comments That Do Not Support Substances Under Review:**

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

**For Comments Addressing the Availability of Alternatives:**

Comments may present information about the viability of alternatives for a substance under sunset review.

Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative 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.

Written public comments will be accepted through April 4, 2018 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.



**Sunset 2020 Review**  
**Meeting 1 - Request for Public Comment**  
**Crops Substances**  
**April 2018**

**Note:** With the exception of sodium carbonate peroxyhydrate, aqueous potassium silicate, and sulfurous acid, the materials included in this list are undergoing early sunset review as part of November 18, 2016 [NOSB recommendation](#) on efficient workload re-organization.

**Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.**

[Alcohols: Ethanol](#)

[Alcohols: Isopropanol](#)

[Sodium carbonate peroxyhydrate](#)

[Newspaper or other recycled paper](#)

[Plastic mulch and covers](#)

[Aqueous potassium silicate](#)

[Elemental sulfur](#)

[Lime sulfur](#)

[Sucrose octanoate esters](#)

[Hydrated lime](#)

[Liquid fish products](#)

[Ethylene](#)

[Sulfurous Acid](#)

[Microcrystalline cheesewax](#)

**Reference 7 CFR §205.602 Prohibited nonsynthetic substances**

[Potassium chloride](#)

## Alcohols (ethanol)

**Reference:** 205.601(a)(1)

(i) Ethanol. As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

**Technical Report(s):** [1995 TAP](#); [2014 TR - Ethanol](#); [2014 TR - Isopropanol](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### **Background from Subcommittee:**

#### **Use:**

The United States Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision for Aliphatic Alcohols, ethanol and isopropanol were registered in the US as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products.

#### **Manufacture:**

Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. A variety of methods are available for the fermentative production of ethanol from carbon sources such as starch, sugar and cellulose using natural and genetically engineered strains of yeast or bacteria. Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene and as a by-product of certain industrial operations.

#### **International Equivalency:**

Several international organizations provide guidance on the application of synthetic ethanol in organic crop and livestock production as well as the processing of organic foods. Among these are international regulatory agencies (EU, Canada and Japan) and independent organic guidelines and standards organizations (Codex and IFOAM).

#### **Environmental/Health Issues:**

Although ethanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of ethanol under the prescribed use pattern in organic crop production are unlikely. Ethanol is readily biodegradable in air, soil and water. According to US EPA, ethanol is practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies.

**Additional information requested by Subcommittee:** None

## Alcohols (isopropanol)

**Reference:** 205.601(a)(1)

(ii) Isopropanol. As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

**Technical Report(s):** [1995 TAP](#); [2014 TR - Ethanol](#); [2014 TR - Isopropanol](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage. Regarding crop production, isopropanol may be effectively used to decontaminate the lines of irrigation systems as well as a variety of agricultural implements. Alcohols, including isopropanol and ethanol, can provide rapid broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, but lack activity against bacterial spores (McDonnell, 1999).

#### Manufacture:

Chemical synthetic procedures are used in the commercial production of isopropanol used in the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011).

#### International Equivalency:

A small number of international organizations provide guidance on the application of synthetic isopropanol in organic crop and livestock production as well as the processing of organic foods. Among these are the Canadian General Standards Board and the International Federation of Organic Agriculture Movements (IFOAM).

#### Environmental/Health Issues:

Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely. Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses. According to US EPA, isopropanol is slightly toxic to practically non-toxic based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410 1995).

**Additional information requested by Subcommittee:** None

## Sodium carbonate peroxyhydrate

**Reference:** 205.601(a) – As an algaecide - Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

**Technical Report:** [2006 TAP](#); [2014 TR](#)

**Original Petition:** [2005 Sodium Carbonate Peroxyhydrate](#)

**Past NOSB Actions:** [11/2007 NOSB recommendation](#); [11/2007 NOSB Crops Subcommittee Recommendation](#); [10/2014 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Proposed rule (including justification) published 6/3/2009 ([74 FR 26591](#)). Added to National List 12/13/2010 ([75 FR 77521](#)). Sunset renewal notice published 06/19/15 ([80 FR 35177](#)).

**Sunset Date:** 6/22/20

### Background from Subcommittee:

#### Use:

Sodium carbonate peroxyhydrate is used as an algaecide in rice fields, ponds, ditches, and irrigation lines (TR lines 11-124). It was added to the National List in 2007 with the hope that growers would use it as an alternative to more problematic materials such as copper and chlorine; it has only been registered for use in rice since 2010. The 2014 technical report (TR) states that the material is a precursor to hydrogen peroxide and is used widely in household cleaners and detergents, as well as water bodies (lines 89-100).

#### Manufacture:

Sodium carbonate peroxyhydrate is produced by drying hydrogen peroxide in the presence of sodium carbonate and is a white granular crystalline powder. It rapidly dissolves in water and dissociates into hydrogen peroxide and sodium carbonate. It decomposes to leave only water, oxygen, and soda ash (TR lines 51-52 and 79-82).

### International Acceptance by Other Certification Agencies:

While most international standards do not mention sodium carbonate peroxyhydrate by name, they do allow both hydrogen peroxide and sodium carbonate, which are the components and the precursors of this substance (TR lines 164-202).

Canada - Canadian General Standards Board Permitted Substances List does not include sodium carbonate peroxyhydrate.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) does not permit the use of sodium carbonate peroxyhydrate for organic use.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 does not allow sodium carbonate peroxyhydrate for organic production.

Japan Agricultural Standard (JAS) for Organic Production does not list sodium carbonate peroxyhydrate.

International Federation of Organic Agriculture Movements (IFOAM) does not list sodium carbonate peroxyhydrate.

**Environmental/Health Issues:**

An emission of sodium carbonate peroxyhydrate to the environment could potentially occur during production, formulation, and use of the substance (TR lines 323-24). Sodium, carbonate and hydrogen peroxide do not adsorb to sediment (TR line 333). No new concerns were raised about human health or environmental effects since the earlier review in 2006; however, it is highly toxic to bees and it should not be allowed to drift to flowering plants or used when contact with bees might occur (TR lines 395-434).

**Discussion:**

In 2014, a new TR was commissioned to address alternatives and use patterns. Of the alternatives presented, copper sulfate is the most problematic and also the most widely used (on 97,757 acres vs. 1,177 acres in California in 2010, representing 17.4 and 0.3% of California rice acreage, respectively) (TR lines 448 - 457). Some of the proposed alternative controls, including Chinese herbs, garlic extracts, or panchagavya and amruthajalam, have not been tested in the U.S. and may not be available (TR lines 487 - 497).

During the Sunset 2015 Review, the NOSB sought input comparing this material with copper sulfate for control of algal scum in rice production and asked if it could replace copper sulfate for that use. Limited and conflicting comments were received. Points raised in favor of renewing the substance stated that it provides better control of algae, and its breakdown components of water and oxygen are more favorable than the accumulation of elemental copper associated with copper sulfate. Additionally, when utilized in irrigation ponds sodium carbonate peroxyhydrate has fewer corrosion issues with irrigation equipment than copper sulfate. The points raised against renewing the substance stated that it does not fit any OFPA categories, is not permitted in organic production internationally (TR lines 164-202), and was found by the NOSB in its 2007 recommendation to not meet the OFPA criteria of essentiality, compatibility with organic production, and no impacts on human health and the environment.

The CS conducted further investigation into points raised in public comment. In particular, a 2007 report of the California Rice Research Board studied the efficacy of this material and found it did not work well enough to recommend it for rice paddies. Further investigations into controlling algae by the same group in 2013 indicated that management of phosphorus fertilization can influence the severity of algal growth. Reducing phosphate concentrations in rice field water was not mentioned in the 2014 TR but may be a promising alternative practice.

**Additional information requested by Subcommittee:**

1. The 2014 TR states: "In 2010, in California, 450 million three hundred and eighteen thousand pounds of copper sulfate were applied in 1442 applications to 97,757 acres and sixteen thousand, six hundred and fifty pounds of sodium carbonate peroxyhydrate were applied in 31 applications to 1,177 acres" (lines 449 to 452). Given the significantly lower use of sodium carbonate peroxyhydrate as compared to copper sulfate, despite its lower toxicity, please describe when and why it is used in rice cropping systems.
2. In addition to use in rice fields, please elaborate on other applications for which producers are using sodium carbonate peroxyhydrate.

## Newspaper or other recycled paper

**Reference:** 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) newspaper or other recycled paper, without glossy or colored inks.

**Reference:** 205.601(c) - As compost feedstocks - Newspapers or other recycled paper, without glossy or colored inks.

**Technical Report:** [1995 TAP](#); [2006 TAP](#); [2017 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)) Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### **Background from Subcommittee:**

Several questions were raised during the 2015 NOSB review from Board members and the public that indicated that a Technical Report (TR) would be worthwhile for review of this material. While no substantiated issues of concern were raised regarding the OFPA criteria, there was little information about the ingredients and colored inks in newspaper, or their fate in the environment. The full board voted to renew this listing in 2015 and subsequently requested a TR to determine the need for a potential annotation change.

In summer 2017, a new TR was received and reviewed. The TR indicated that there has been some movement towards use of less toxic color inks, however, it is difficult or impossible to determine which inks are present in the newspaper. There is no methodology for separation between color inks that might be more acceptable for direct application to organic land, and those that are not. When reviewing the most recent TR, the NOSB decided the current annotation prohibiting glossy or colored inks should remain.

### **Additional information requested by Subcommittee:**

1. Does this material perform an essential function on organic farms?
2. Is this material used regularly on organic farms?

## Plastic mulch and covers

**Reference:** 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

**Technical Report:** [1995 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

Plastic mulches can be of various thicknesses and can be a film or woven type landscape cloth. Various colors are used for crop production enhancements in systems, such as red to increase tomato fruiting, silver to reflect and deter pests, black to warm the ground, white to cool the soil and more. Clear and translucent plastics are typically used as coverings for heated greenhouses or unheated high or low tunnels. There was a sunset review of a related material, biodegradable biobased mulch films, in fall of 2017, with the current annotation and National Organic Program guidance on this material retained as currently written. In addition to the allowance of plastic mulches and covers on the National List, there is this statement within the regulations:

§205.206 (c) Weed problems may be controlled through:

(6) Plastic or other synthetic mulches: Provided that, they are removed from the field at the end of the growing or harvest season.

When these plastic mulches are used for perennial crops, many, but not all, organic certification agencies have interpreted the regulations to allow this plastic mulch to remain in place for perennial crop production, since the harvest season is continuous from year to year. Long-term breakdown of the plastic films or plastic woven cloth can occur, especially if not protected from ultraviolet light from the sun.

### Manufacturing Process:

Plastic mulches and covers are thermoplastic resins of high melt viscosity, usually polyethylene. Resin pellets are melted into an extruder and pumped or blown through a die or tube to form the plastic in the desired shape.

### Specific Use:

Plastic mulches and covers are used extensively in both organic and nonorganic agriculture and are allowed for use under the EU, Canada and other organic standards. They offer numerous crop production benefits as a weed suppresser/barrier and can conserve water by lessening evaporation. Various colors of plastic mulch films provide benefits as well, as detailed above. There has been strong support for continued listing of plastic mulch and covers by the organic community at each of the previous sunset dates, this product is used extensively in both organic and nonorganic production systems. When this product is used as a mulch on the soil, it tends to get coated with soil which makes it very difficult to recycle, much of the plastic mulches removed at the end of the harvest season are landfilled. Greenhouse coverings and other uses of plastic where there is minimal soil attached, can

usually be recycled, especially in agricultural regions where companies have specialized in the recycling of these plastic materials.

**Additional information requested by Subcommittee:**

1. Are there alternative methods or natural materials that could replace the functionality of this petroleum based material in crop production?
2. Are you aware of plastic mulches (either films or woven cloth) being left in place on the ground for more than 1-2 years and are you seeing degradation? How do you lessen that degradation, or address degradation if it occurs? Are plastic shards or debris found in the soil that cannot be removed?
3. Should woven poly landscape cloth be addressed differently than plastic mulch films? Are there heavier weights and thicknesses of plastic film mulches that are similar to woven poly landscape cloth in its resistance to degradation?
4. When the plastic mulch or cloth is removed, is it piled on the farm, landfilled, recycled or processed in an appropriate manner?
5. Are you aware that burning plastic is illegal in many states due to the release of dioxin and other problematic chemicals into the atmosphere? If burning plastic is an issue in your state or country, would you like to see an annotation banning burning of plastic mulch or covers under the organic regulation?

## Aqueous potassium silicate

**Reference:**

205.601(e) – As an insecticide (including acaricides or mite control) - The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

205.601 (i) – As plant disease control—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

**Technical Report:** [2003 TAP](#); [2014 TR](#)

**Petition(s):** [2002 Potassium Silicate](#); [2006 Potassium Silicate Supplemental](#)

**Past NOSB Actions:** [11/2007 NOSB recommendation](#); [10/2014 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Proposed rule (including justification) published 6/3/2009 ([74 FR 26591](#)). Added to National List 12/13/2010 ([75 FR 77521](#)). Sunset renewal notice published 06/19/15 ([80 FR 35177](#)).

**Sunset Date:** 6/22/20

**Background from Subcommittee:**

**Use:**

Aqueous potassium silicate is used as a crop protectant for insect, mite and disease control, and suppression. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection.



**Manufacture:**

Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.

**International acceptance by other international certifying bodies:**

Internationally (Japan, Canada, EEC, CODEX, or IFOAM), natural sources of silica, not APS, are allowed (258-296).

**Environmental/Health Issues:**

Based on information in the January 6, 2014 technical review, the following concerns were raised by the Crops Subcommittee during the 2014 Sunset review:

Dermal exposure can lead to low-to-medium systemic toxicity and skin irritation (577-579);

Silicon reduces the availability of elements such as manganese, iron, and aluminum to roots (471-473)

Treatment with potassium silicate may not be appropriate when crops are used for feeding or as forage for livestock because it makes some forages less digestible (477-481);

The addition of potassium silicate as a foliar nutrient may result in the production of less tender fruits and vegetables or forage for grazing animals (479-481);

Silica supplementation can result in elongation and thickening of stems, delayed anthesis and flower deformation in some species (487-490);

In addition to morphological changes, changes in micronutrient in plants may occur as a result of silica supplementation (490-491);

New alternative materials suggested include other forms of silica that are available as approved supplements for the soil that can provide the same protection over a longer term against plant disease and compost made with silica-rich plants (592-594);

**Discussion:**

In 2007, the Crops Subcommittee recommended against listing aqueous potassium silicate (APS) because "multiple substitutes are available" and it is a "synthetic soil applied fertilizer not compatible with organic farming regulations." The substance was listed based on the following rationale: Public comment at the November 2007 NOSB meeting supported listing the substance as plant disease control. Commenters provided the historical 2003 NOSB consideration of the material, as well as more information from the petitioner and other interested stakeholders. New information was provided in a January 6, 2014 technical review. In 2014 the Crops Subcommittee voted 4 to 3 in favor of removing aqueous potassium silicate from the National List. At the Fall 2014 NOSB meeting in Kentucky, the motion to remove aqueous potassium silicate from the National List was not supported by the Board by a vote of 7 to remove and 9 against removal. Those voting for removal pointed to the bulleted items above while those voting not to remove saw the compound as an important pest control option for organic growers.

**Additional information requested by Subcommittee:**

There is little evidence that silicates are limiting in farmed soils. Please provide any additional data to aid in assessing the need for products that are intended to overcome soil deficiencies.

1. To what extent is aqueous potassium silicate used by growers?

2. To what extent does listing aqueous potassium silicate result in reductions in use of copper and sulfur based pest management?
3. If potassium silicate is taken up in the roots and moved throughout the plant via apoplast or symplast movement and then incorporated in sink tissue (the leaves) then the compound is behaving like a systemic, synthetic pesticide.
4. Is this compound systemic?
5. What evidence exists documenting the safety of animal and human ingestion of plants and forages with elevated silicate levels in leaf tissue?
6. Following on question 5, how does age and gender of animals and humans ingesting plant material with elevated silicate levels influence vulnerability?

## Elemental sulfur

**Reference:** 205.601(e)(5) - As insecticides (including acaricides or mite control).

**Reference:** 205.601(i)(10) - As plant disease control.

**Reference:** 205.601(j)(2) - As plant or soil amendments.

**Technical Report:** [1995 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** **Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2010 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

Elemental sulfur is on the National List at §205.601(e)(5) – As insecticides (including acaricides or mite control), §205,601(i)(10) – As plant disease control, and at §205.601 (j)(2) – As plant or soil amendments. As an insecticide under (e)(5) it is used to help control arthropods, mites, leprosis, and scab mites. As plant disease control under (i)(10) it helps control powdery mildew, rusts, scab, pear scab, brown rot, rose black spot, and peach leaf curl. As a plant or soil amendment under (j)(2) it is used to help assist in balancing the soil pH and is useful to both plant and soil beneficial insects. It can also help aid in increased water penetration.

#### Manufacture:

Elemental sulfur can come either from a natural mined source, or may be produced as a by-product from natural gas or petroleum operations and refinery process. The latter appears to be the primary source of most elemental sulfur currently being used. Elemental sulfur has been used for centuries and approved for use in the U.S since 1920.

**International (acceptance/nonacceptance) by other international certification agencies:**

Internationally approved for use by: The E.U., IFOAM. Codex Alimentarius Commission (CAC GL 32-1999) permits the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013). Also allowed by Canadian Organic Standards.

The Canadian General Standards Board (CGSB) includes non-synthetic elemental sulfur as a permitted substance for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. Chemically synthesized substances cannot be added, and chemical treatment is prohibited. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods" (GL 32-1999) lists elemental sulfur as an allowed substance for pest and disease control.

The European Economic Community (EEC) Council Regulation (EEC No 2092/91) and carried over by Article 16(3)(c) of Regulation No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production.

The Japan Agricultural Standard (JAS) for Organic Production (Notification No. 1605 of 2005) permits the use of sulfur as a fertilizer or soil improvement substance, and as a substance for plant pest and disease control.

The International Federation of Organic Agriculture Movement's (IFOAM) lists sulfur as an approved substance for pest and disease control, for use as fertilizer/soil conditioner, and for use as a crop protectant and growth regulator.

**Environmental/Health Issues:**

Sulfur is heavily used worldwide. It is the most heavily used pesticide in California, where over 50,000,000 pounds are used annually, representing more than 25% of all agricultural pesticide use in the state (sulfur use as a pesticide is distinct from use as a soil amendment). Accurate information on use in the organic sector is not available.

Sulfur is an essential plant nutrient, naturally present in our food and soil, and is part of normal human biochemistry. In the original TAP the reviewers found elemental sulfur to be relatively innocuous in the environment when used according to the product use label. It was also found to be of low toxicity (<http://extoxnet.orst.edu/pips/sulfur.htm>). It should not be used within one month of any horticultural oil product, as currently stated on most sulfur labels. Two previous Sunset Material Reviews (2005 & 2010) of Elemental sulfur have resulted in all 3 use listings being re-listed.

Although low in acute toxicity, sulfur is a respiratory, ocular, and dermal irritant and adversely impacts farmworker health. Farmworker exposures can be mitigated if label recommendations and proper PPE recommendations are followed. However, agricultural sulfur use may also impact community health. A recent study reported significant associations between agricultural use of sulfur and poorer respiratory health in children living near fields (<https://ehp.niehs.nih.gov/ehp528/>). The use of wettable formulations, in contrast to dust applications, likely reduce exposures because fewer sulfur particles drift offsite from applications. Several agricultural commissioners in California have encouraged a shift to

wettable formulations in vineyard applications and anecdotal information suggests fewer regulatory problems.

**Discussion:**

During previous reviews there has been strong support for the continued listing of sulfur, particularly for use against various bacterial and fungal diseases and other pests, and as a plant and soil amendment. Based on the original TAP, prior reviews, previous committee votes & discussions, and historical public comment, it would appear that elemental sulfur is still necessary in organic crop production.

**Additional information requested by Subcommittee:**

For this review, the Crops Subcommittee would like to consider additional information and input from the organic community in the following areas:

1. Have organic farmers, farmworkers, related family members, or residents living near treated fields, including young children, experienced adverse impacts of agricultural sulfur use?
2. If yes, what health problems have been encountered?
3. What mitigation steps were/are taken to address health impacts?
4. How many organic farmers use sulfur dust applications (in contrast to wettable spray applications) to control pest and disease problems?
5. Would an annotation requiring the use of wettable formulations for sulfur pesticide applications in organic crops be feasible?

## Lime sulfur

**Reference:** 205.601(e)(6) - As insecticides (including acaricides or mite control).

**Reference:** 205.601(i)(6) - As plant disease control.

**Technical Report:** [1995 TAP \(Livestock - hydrated lime\)](#); [2014 TR](#)

**Petition(s):** N/A

**Past NOSB Actions: Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

**Use:**

Lime sulfur is on the National List at §205.601(e)(6) as an insecticide (including acaricide or mite control) and at §205.601 (j)(6) for plant disease control. As an insecticide lime sulfur is used to control mites (spider mites and rust mites), aphid, and san jose scale in tree fruit and other organic crops. As a fungicide it is used to control powdery mildew, anthracnose, scab, peach leaf curl, and several other plant diseases in tree fruit and berry crops. It is also part of a process that when used in conjunction (or

in rotation) with other allowed materials as a replacement for the two recently removed antibiotics for assisting to control fire blight in organic apple and pear production.

**Manufacture:**

Lime sulfur is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [CaOH<sub>2</sub>] and ground sulfur (2014 TR). Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the U.S. EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.

**International:**

- Canada – allowed as a fungicide, insecticide, or acaricide/mite control. (CAN,21)
- Codex Alimentarius – although not mentioned specifically, organic production guidelines from Codex Alimentarius Commission (CAC GL 32-1999) permit the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013).
- European Union – permits the use of lime sulfur (calcium polysulfide).
- Japanese Ministry of Agriculture Forestry and Fisheries – permits the use of lime sulfur powder for plant pest and disease control.
- IFOAM – lists lime sulfur in Section II of Appendix 3: Crop Protectants and Growth Regulators (IFOAM, 2014).
- UK Soil Association – only allows the use of lime sulfur on a case-by-case basis, when there is a demonstrated major threat to a grower’s crop. (Soil Association, 2014).

**Environmental/Health Issues:**

Lime sulfur has a long history of use for crop production. The original technical advisory panel report (TAP) used the 1922 USDA Farm Bulletin as part of its fact finding. The 2014 technical evaluation report (TR) provided an extensive list of alternative materials and practices, however, a benefit of lime sulfur is that it can act both as an insecticide and fungicide. Alternative biological materials often need to be used preventatively whereas lime sulfur can sometimes be used to mitigate an existing crop issue. Lime sulfur can cause phytotoxicity in some crops, however, rates and timings can be used to avoid this problem. Similarly, the technical report notes that lime sulfur may impair some beneficial insects, but, once again, timing of use can minimize the negative effects. Lime sulfur is one leg of an integrated fire blight control program for pome fruits and has become especially important since antibiotics for fire blight control were removed from the National List.

The technical report noted potential human health concerns from lime sulfur primarily due to its high alkalinity or the release of hydrogen sulfide. This concern is largely mitigated during formulation or actual use if proper safety procedures are followed during manufacture and label directions are followed at application.

**Additional information requested by Subcommittee:**

Are there any alternatives to synthetic lime sulfur now in use since the 2014 technical report?

## Sucrose octanoate esters

**Reference:** 205.601(e)(10) - As insecticides (including acaricides or mite control).

**Technical Report:** [2005 TR](#)

**Petition(s):** [2004 Sucrose Octanoate Esters](#); [Amendment #1](#); [Amendment #2](#)

**Past NOSB Actions:** [08/2005 NOSB recommendation for addition to NL](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs). SFAEs are surfactants (or surface-active agents) that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals. Sucrose esters, as a class of related compounds, vary, depending on the number and locations of esters attached to the sucrose molecules. Sucrose has eight potential places where individual esters may attach (Montello Inc., n. d.). The substance under review is a mixture of mono-, di- and tri-esters (TR lines 24-31).

Sucrose esters were first isolated when researchers investigated the insecticidal properties of the tobacco leaf hairs. This insecticidal property of sucrose esters acts by dissolving the waxy protective coating (cuticle) of target pests, causing them to dry out and die (U.S. EPA, 2002b). SOEs marketed as biopesticides are intended to mimic the pest control properties of *Nicotiana glauca* Domin. (wild tobacco) and other *Nicotiana* species. In addition to the tobacco plant, insecticidal sugar esters have been found in wild tomato and wild potato species and in the petunia plant (Chortyk et al., 1996) (TR lines 33- 38).

### Approved Use:

SOEs are approved for use as a contact-type biochemical insecticide/miticide (EPA Registration Number 70950-2, OPP No. 035300) to control soft-bodied insects (TR lines 69 - 70). SOEs are permitted by EPA for use as a biopesticide for foliar spray in field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals), as well as on mushroom growing media and on adult honey bees. (U.S. EPA, 2002a).

### Environmental Impact Discussion:

According to the 2006 technical review, when SOEs are applied according to EPA approved label directions, no direct exposure of birds or aquatic organisms is expected (U.S. EPA, 2002a). In addition, SOEs biodegrade within approximately five days at approximately 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions, so minimal potential for exposure exists for insects, fish, and other non-target wildlife. (U.S. EPA, 2002a).

### Additional information requested by Subcommittee:

1. The TR does not address the toxicity of SOEs to non-targeted organisms, including predators, parasitoids, soil fauna, and aquatic organisms when exposed by spray. Is there further information available about the toxicity of SOEs to non-target organisms?
2. Is this product still being used, or are there other synthetic products that are more effective?
3. If SOEs are not being used, do we need it to keep in the crops toolbox to be rotated with other products?

## Hydrated lime

**Reference:** 205.601(i)(4) - As plant disease control.

**Technical Report:** [1995 TAP](#); [2001 TAP](#); [2002 TR for Calcium Hydroxide](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

Hydrated lime is used as a foliar application in combination with copper sulfate ( $\text{CuSO}_4$ ); this mixture is also referred to as the 'Bordeaux mix'. The role of the hydrated lime ( $\text{Ca}(\text{OH})_2$ ) is that of a precipitating agent making the copper available to prevent infestations of mildews and other pathogenic fungi in a range of fruit production systems.

#### Manufacture:

Hydrated lime is considered a synthetic substance. The production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone -which contains predominantly calcium carbonate ( $\text{CaCO}_3$ ) with smaller amounts of magnesium, silicon, aluminum and iron oxide compounds -is thermally transformed into quicklime. Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 °C results in conversion of the calcium carbonate content of limestone to calcium oxide ( $\text{CaO}$ ) in a material known as quicklime. This thermal transformation occurs with liberation of carbon dioxide ( $\text{CO}_2$ ) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide ( $\text{Ca}(\text{OH})_2$ ). After hydration, the slightly moist slaked lime is conveyed to a separator where coarse fractions are removed, and the powder is dried.

**International acceptance by international certifying bodies:**

The Canadian General Standards Board, the European Union and the International Federation of Organic Agriculture Movements allow hydrated lime for use as a foliar application to plants for disease suppression.

**Environmental/Health Issues:**

Careful procedures are needed for handling hydrated lime as it can severely irritate and burn the eyes, skin and mucous membranes. The hydroxide anions (OH<sup>-</sup>) generated from dissolution of calcium hydroxide in water or other fluids is the main driver of toxicity for the substance. The effects of the substance on biological and chemical interactions in the agroecosystem are limited given its use as a plant disease suppressant. It is important to note that much has been learned about the impact of hydrated lime as a soil liming agent to elevate soil pH. However, orders of magnitude smaller amounts of the substance are used in the requested application as the mixture is applied to the foliage of the plants to limit plant disease establishment and spread.

The primary environmental issues associated with production of hydrated lime include energy use and dust formation. Calcium oxide is obtained through thermal decomposition of calcium carbonate (limestone) in fuel-powered kilns, a process that requires large amounts of energy. Crushing and handling of limestone and the burning, processing and handling of quicklime and hydrated lime results in dust emissions. Significant advances in deploying filtration systems have mitigated these effects.

**Discussion:**

Two Technical Advisory Panel Reports were published in 1995 and 2001 and a third Technical Evaluation Report was compiled March 23, 2015. Hydrated lime, in the form and application that is petitioned, has been used for some time and is known to be an effective disease suppression practice. In the past sunset review conducted in Fall 2015 the NOSB voted unanimously not to remove hydrated lime from the National List.

**Additional information requested by Subcommittee:**

1. Describe any alternative practices for suppression of leaf-borne mildews and other foliar fungal pathogens that would make the use of hydrated lime unnecessary.
2. Are adequate safety procedures in place to prohibit fieldworker and applicator exposure to hydrated lime?

**Liquid fish products**

**Reference:** 205.601(j) As plant or soil amendments (7) Liquid fish products —can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

**Technical Report:** [1995 TAP](#); [2006 TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)



**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

**Use:**

Liquid fish products are used as fertilizers for the production of organic crops. These products contain fundamental nutrients and many trace minerals critical for use in organic farming. Liquid fish fertilizers are used in soil and container production systems. Liquid fish foliar applications improve crop yields and reduce both insects and diseases.

**Manufacture:**

Liquid fish products are made from fish byproducts that are chopped and then enzymatically digested and heated or enzymatically processed without heat (cold-processing) to produce fish hydrolysate. Liquid fish products are then stabilized with an acid such as phosphoric, sulfuric or citric acid to prevent microbial growth. Use of formic acid is prohibited due to phytotoxicity. A third method utilizes fermentation by bacteria that produce lactic acid, which preserves the fish. All methods cannot result in pH below 3.5.

**International (acceptance/non-acceptance) by other international certification agencies**

The Canadian Organic Standard allows for the use of liquid fish products. Acids are permitted to lower the pH to 3.5, but no prohibited preservatives can be used. CODEX Alimentarius allows processed animal products from slaughterhouses and fish industries contingent on recognition from a certification body or authority. The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources. IFOAM permits the use of fish and shell products and food processing of animal origin. Liquid fish is not on the EU Annex I list of approved fertilizers, but does allow fish meals.

**Environmental/Health Issues:**

Nutrient runoff from excessively or improperly applied fertilizers can cause eutrophication of surface waters, potentially harming fish and other aquatic animals.

**Discussion:**

Historically, there has been strong support for keeping liquid fish products on the National List. Concerns about the sustainability of source fish, including fish harvested for the sole purpose of producing liquid fertilizers, have been raised. The previous sunset review noted that “we do want to emphasize the importance of the sustainable harvesting of fisheries.” During the April 2016 NOSB meeting, the Board voted 11-4 to recommend that the addition of squid byproducts is consistent with the National List listing for liquid fish products that are pH adjusted with synthetic acid (7 CFR 205.601(j)(7)). Only squid byproducts originating from the food processing waste stream were recommended as acceptable for use in organic agriculture. The proposal was not intended to allow the use of whole squid in the manufacture of fertilizers.

**Additional information requested by Subcommittee:**

We are aware that the National Organic Program has received questions about the amount of acid used

and when to measure the pH to determine compliance. For example, if pH that drops below 3.5 during the manufacturing process, but drifts up to 3.5 before sale and use, would the product be compliant? Therefore, we would like to solicit public comment on the following questions as part of the Sunset 2020 review at the Spring 2018 meeting:

1. How do certifiers and material review organizations determine the minimum amount of acid needed to stabilize liquid fish products?
2. How do certifiers and material review organizations evaluate liquid fish products for compliance with the pH threshold in the listing? For example:
  - a. Must the pH be maintained at 3.5 or above throughout the entire manufacturing process?
  - b. If the pH drops below 3.5 during manufacturing, but drifts up to 3.5 or above before sale, how do certifiers and material review organizations evaluate the product?
3. Feedback is needed from liquid fish fertilizer manufacturers on the scientific and technical basis for the pH 3.5 threshold and pH changes that occur during the manufacturing process.

Based on historical discussions about the sustainability of fish stocks used for the manufacture of liquid fish products, the Crops Subcommittee also asks for comments on the following questions:

4. What percentage of fish and/or fish by-products used as fertilizer is derived from farmed versus wild-harvested stocks?
5. For wild-harvested fish and/or fish by-products used as fertilizers, what percentage is derived from
  - a. Waste from processing of wild market fish?
  - b. Whole fish solely harvested for fertilizer? Please identify the species.
  - c. By-catch (fish inadvertently killed when harvesting market fish)?
6. Are any manufacturers using exclusively wild-caught fish to manufacture fertilizers?
7. Is any new information available about the impact of liquid fish product manufacturing on the sustainability of wild fish stocks harvested solely for fertilizer production?
8. Please provide feedback on a possible annotation to this listing that would exclude the use of wild-caught *native* fish harvested exclusively for fertilizer.

## Sulfurous acid

**Reference:** 205.601(j) – As plant or soil amendment —for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

**Technical Report:** [2010 TAP](#); [2014 TR](#)

**Original Petition:** [2008 Sulfurous Acid](#)

**Past NOSB Actions:** [05/2009 NOSB Recommendation](#); [10/2014 NOSB sunset recommendation](#)

**Regulatory Background:** Added to National List 7/6/2010 ([75 FR 38693](#)); Sunset renewal notice published 06/19/15 ([80 FR 35177](#)).

**Sunset Date:** 6/22/20

**Background from Subcommittee:****Use:**

Sulfurous acid is used to quickly acidify water in areas of the country where soils are alkaline or saline. Application of the acidic irrigation water can help to alleviate nutrient deficiencies created when saline or alkaline conditions tie up essential micronutrients. This in turn can improve crop yields and help to reduce soil degradation from salinity buildup. While similar reactions can eventually be obtained by applying soil sulfur, the reaction time of sulfur in the soil is relatively slow and the effect may take months or years to be realized (2014 TR). The last technical report was completed in 2014 and comments below draw from that report.

**Manufacture:**

Sulfurous acid is created by spraying water through smoke and fumes created by burning elemental sulfur. Several substances are created in this process, including sulfur dioxide, hydrogen sulfide and hydrogen sulfite (bisulfite). The sulfur dioxide dissolved in water is often termed sulfurous acid, however, the sulfurous acid is unstable and almost immediately forms hydrogen sulfite. The hydrogen sulfite is acidic and lowers the pH of the water (2014 Technical Report). This process is often done on-farm with a device called a sulfur burner and the effluent from the sulfur burner is used to acidify irrigation water.

Sulfurous acid does not require a tolerance or an exemption from tolerance and appears on the EPA non-food inert list. While sulfur dioxide, a potential pollutant, is generated by the burner, that sulfur dioxide is captured in the irrigation water and the release of sulfur dioxide to the atmosphere is minimal. EPA does not regulate this emission. In fact, the sulfur used to burn in these sulfurous acid generators is often sourced from scrubbers cleaning the emissions from oil, gas and coal industries.

**International:**

Canada – allowed for use in wine production but no mention of use as a soil amendment

CODEX Alimentarius Commission, European Economic Community - does not mention use as a soil amendment

Japan Agricultural Standard – mentions use of sulfur powder substances for pest or disease control

International Federation of Organic Agriculture Movements (IFOAM) – not listed explicitly as a fertilizer or soil conditioner, however the IFOAM Norms state that “Operators shall prevent or remedy soil or water salinization where these pose a problem”. Sulfurous acid is one way to remedy these problems.

**Environmental Issues:**

Sulfurous acid is a weak acid and does not produce notably toxic effects on fish, aquatic invertebrates or plants, and many bacteria possess sulfite reductase enabling them to metabolize sulfurous acid. In cases where sulfurous acid is used to acidify irrigation water, soils are often low in sulfur and the application of the sulfurous acid can be beneficial.

**Additional information requested by Subcommittee:**

None

## Ethylene gas

**Reference:** 205.601(k) - As plant growth regulators. Ethylene gas - for regulation of pineapple flowering.

**Technical Report:** [2000 Supplemental TAP](#); [2007 TAP](#); [2011 Supplemental TR](#)

**Petition(s):** N/A

**Past NOSB Actions:** [10/1995 NOSB recommendation](#); [10/2001 recommendation](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

### Background from Subcommittee:

#### Use:

Ethylene gas is listed as a growth regulator for organic pineapple production only. It is used to induce uniform flowering in pineapples and is applied 7-15 months after planting. Application can be repeated two to three times after the initial application (TR lines 53-56).

#### Manufacture:

Made from hydrocarbon feedstocks, such as natural gas liquids or crude oil. It is produced almost exclusively from the pyrolysis of hydrocarbons in tubular reactor coils installed in externally fired heaters. Ethylene may also be produced from ethanol in fixed or fluid-bed reaction systems (2007 TAP).

#### International Acceptance by Other Certification Agencies:

*Canada - Canadian General Standards Board Permitted Substances List* permits use of ethylene “for post-harvest ripening of tropical fruit and degreening of citrus”.

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)* permits use of ethylene “as a flowering agent for pineapples”.

*European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008* has no mention of ethylene.

*Japan Agricultural Standard (JAS) for Organic Production* limits to the use of ethylene for the “afterripening [of] banana, kiwifruits, and avocado”.

*International Federation of Organic Agriculture Movements (IFOAM)* states: “Ethylene gas is permitted for ripening”.

#### Environmental/Health Issues:

The main safety concern in relation to ethylene use has been the explosive nature of the gas in the air. Operators should be well trained and prepared, though the safety concern to workers is limited when correctly used and monitored (2007 TAP).

#### Discussion:

The most recent technical report (TR) for this material was a supplement developed in 2011 that addressed questions of continued need, use according to scale of operation, and new alternatives.

The TR found that small-scale operations likely cannot afford the expensive equipment needed for whole plant application of ethylene gas in large fields (TR lines 215-16). Various technologies for applying ethylene were reported, including some limited evidence that smaller-scale producers are successfully adapting ethylene using handheld booms and manual application techniques in East and West Africa. Experiments involving cold treatment were reported in Taiwan, though actual use patterns in the field are unknown (TR lines 191-210). Alternative natural methods to induce flowering have not changed since the initial material review in 1999 and include cold stress, smoke, exposure to ripe fruits, and selective tilling of the weeds and cutting back of trees in agroforestry systems (TR lines 73-75).

This material was reviewed in 2015 ahead of its 2017 sunset date. The NOSB was concerned about the lack of comments from pineapple producers for the spring meeting, and they included another request to hear from stakeholders in the proposal for the fall meeting. Subsequently, organic pineapple producers, primarily from Costa Rica, presented a large number of both written and oral comments. These comments, along with historic information, previous sunset reviews, and discussions at the fall meeting helped to provide the NOSB with information about this material, how it is used by operations of various sizes, and the significance it plays in crop production. There have been concerns in the past that this material is used only by larger operations; the Fall 2015 grower comments showed that organic pineapple producers of all sizes use this material. Public testimony indicated that the current level of organic pineapple production is dependent on the availability of this material. No new issues of human health or environmental concerns were raised that had not been addressed in previous review cycles.

**Additional information requested by Subcommittee:**

The 2011 supplemental TR states that “no direct evidence has been found in the available information that allowance of ethylene gas for use in organic farming is placing small-scale producers at a disadvantage” (lines 217-18). A similar conclusion was reached during the 2015 sunset review. Does this remain true today, and if so, please elaborate on ways in which smaller-scale producers are applying alternative technologies and ethylene application methods?

## Microcrystalline cheesewax

**Reference:** 205.601(o) - As production aids. Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)-for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

**Technical Report:** none

**Petition(s):** [2007 Petition](#); [2008 Petitioner response to questions](#)

**Past NOSB Actions:** [05/2008 NOSB recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Federal Register rule amendment published 02/14/12 ([77 FR 8089](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:**

Microcrystalline waxes are a type of wax derived from the refining of the heavy petroleum distillates during the petroleum refining process. It is recovered from crude oil through a series of filtration, solidifying, and solvent extraction steps. The by-product must then be de-oiled at a wax refinery, resulting in the three components of the cheesewax. Depending on the end use and desired specification, the product may then have its odor removed and color removed (which typically starts as a brown or dark yellow). This is usually done by means of a filtration method or by hydro-treating the wax material. All the solvents in the process are recovered, with none remaining in the final product.

Microcrystalline wax is used in mushroom production, and is used to seal plug holes in Shiitake logs in which mushroom spawn is inserted. The original petition stated that there is no contact with the growing mushrooms at any time.

Microcrystalline cheesewax has been approved by the United States Food and Drug Administration (FDA) : 21 CFR § 172.888 as a “synthetic petroleum wax,” for use as a “masticatory substance,” in chewing gum, a “protective coating,” on cheese and raw fruits and vegetables, and a “defoamer in food.” Microcrystalline cheesewax as a petroleum wax is also listed by the FDA at 21 CFR 178.3710 as an allowed “component of nonfood articles in contact with food.”

**Approved Use:**

Microcrystalline cheesewax is used as a sealant to hold in the moisture and to physically hold the mushroom spawn in place when placed over the hole in the log in which the spawn has been inserted.

**International acceptance by OFPA and International Certifying Bodies:**

Organic Foods Production Act and USDA Final Rule: Microcrystalline cheesewax is not listed in the Organic Foods Production Act of 1990. Microcrystalline cheesewax is currently listed under the National Organic Program (NOP) regulations at 7 CFR §205.601(o) as a synthetic substance allowed as a “production aid,” for “use in log grown mushroom production,” with the exception that the wax “must be made without either ethylene-propylene co-polymer or synthetic colors.”

**Canadian General Standards Board Permitted Substances List**

CAN/CGSB-32.311 “Table 6.5 Processing aids” prohibits the use of microcrystalline wax “either alone or in formulations with paraffin wax.”

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

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the CODEX (GL 32-1999).

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

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in EC No. 834-2007 nor EC No. 889/2008.

**Japan Agricultural Standard (JAS) for Organic Production**

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the JAS for Organic Production.

**International Federation of Organic Agriculture Movements (IFOAM)**

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in IFOAM.

**Human Health Impact:**

Microcrystalline cheesewax is melted to a liquid state to be placed in the spawn hole. During the melting process, petrochemical fumes might be released, causing mild respiratory irritation, according to the Materials Safety Data Sheet. The cheesewax does meet the FDA requirements for use in non-food articles in contact with food and for use in food (21 CFR 178.3710 and 21 CFR 172.886). Formulations of the microcrystalline cheesewax do contain BHT as an antioxidant preservative.

**Environmental Impact:**

Microcrystalline cheesewax breaks down readily in the environment, is not toxic to soil flora and fauna, and does not dissolve readily in water.

**Additional information requested by Subcommittee:**

1. During the 2008 NOSB recommendation review it was determined that there were no effective approved natural or synthetic materials that could replace microcrystalline cheesewax for plugging Shiitake mushroom log-grown substrates. Is there now an effective natural or approved synthetic replacement for the microcrystalline cheesewax that is derived from petroleum by-products?
2. Should an annotation be added that requires removal of residues of the microcrystalline cheesewax that remain in the environment once the Shiitake Logs are finished fruiting?
3. Canada and Japan, and perhaps other countries, also produce organic Shiitake mushrooms, but do not allow the use of microcrystalline cheesewax in their organic production. Why do these countries not allow the microcrystalline cheesewax and/or what other types of substances are those producers using as a sealant?

## Potassium chloride

**Reference:** 205.602(e) - unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

**Technical Report:** [1995 TAP](#)

**Petition(s):** N/A

**Past NOSB Actions:** [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#); [10/2015 NOSB sunset recommendation](#)

**Recent Regulatory Background:** Sunset renewal notice published 06/06/12 ([77 FR 33290](#)); Sunset renewal notice published 03/21/17 ([82 FR 14420](#))

**Sunset Date:** 3/15/2022

**Background from Subcommittee:****Material Use:**

Potassium is required for health in humans, plants, and microorganisms (TAP pg. 4, 14). Potassium is an essential element for plants as they use it to regulate water movement, regulate photosynthesis, assist in enzyme activation, and in the movement of nutrients within the plant. While potassium is found in many soils, it may not naturally be in high enough concentration, and/or it may be present but in a bound format rendering it unavailable, and/or the available concentration of soil potassium over time

may not be sufficient to allow for successful growing of crops through their life cycle. Potassium is commonly used by growers either alone, as a complex in potassium chloride, or as an ingredient in a fertilizer blend for soil supplementation. Chloride is also an essential element for plants (TAP pg. 12); however, monitoring of chloride use is required to assure soil salinity is managed appropriately. Current NOP regulation stipulates monitoring in the current annotation for potassium chloride to prevent chloride accumulation.

**Manufacture:**

Potassium chloride is produced through mining or through solar evaporation of natural brines (TAP pg. 13). Processing of the mined potassium chloride involves physical separation processes and may potentially use conditioning agents to aid in separation of potassium chloride from sodium chloride and other impurities in the mined ore (TAP pg. 13). Natural resources of potassium are abundant within the U.S. in North Dakota, New Mexico, Utah and California (TAP pg. 13, 14).

**International Equivalency:**

*Canada - Canadian General Standards Board Permitted Substances List* permits use of potassium chloride in crop production as long as the source of the material is from muriate of potash and rock potash, and its use cannot cause salt accumulation in the soil.

*CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)* permits use of potassium salts with origins from Rock potash, mined potassium salts (e.g. kainite, sylvinite) and requires that it must be less than 60% chloride in composition.

*European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008* allows for the use of “Crude potassium salt or kainit” in fertilizer and soil amendments.

*Japan Agricultural Standard (JAS) for Organic Production* allows for use of potassium “formed by pulverizing or washing and refining the natural ore or those produced from sea water or lake water without the use of chemical treatment”.

*International Federation of Organic Agriculture Movements (IFOAM)* allows mineral potassium (e.g. sulfate of potash, muriate of potash, kainite, sylvanite, patenkali) but stipulates that it “shall be obtained by physical procedures but not enriched by chemical processes”.

**Environmental Issues:**

No significant concern for environmental issues were noted in the TAP review given the high amount of potash reservoirs, and that the discharge (sodium chloride) is not being directly released into the environment due to regulations preventing such practices (TAP pg 15).

**Background Information:**

During the last sunset review in 2015, the NOSB unanimously voted to relist potassium chloride at \$205.602(e) with the current annotation requiring origin from a mined source, and that it is applied in a manner to prevent chloride accumulation in the soil.

**Additional information requested by Subcommittee:**

Is potassium chloride still required for growers? Or, are non-chloride potassium products available to organic growers that would eliminate the concern for chloride accumulation in the soil?



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Polyoxin D Zinc Salt  
February 19, 2018**

**Summary of Polyoxin D Zinc Salt [Petition](#):**

Two petitions for polyoxin D zinc salt were submitted to the National Organic Program. Both propose to amend 7 CFR 205.601 to add polyoxin D zinc salt as a synthetic substance allowed for use in organic crop production. The February 2, 2018 petition addendum more precisely specifies that the requested amendment is for 7 CFR 205.601(i). At the April 2013 National Organic Standards Board meeting, the NOSB was unable to reach the required 10 votes to place this material as an approved synthetic on §205.601, by a vote of 9 yes and 6 no. The NOSB found this material non-essential, and there were concerns over its broad-spectrum mode of action as well as environmental concerns for soil bacteria, fungi, and overall environmental health.

The second petition, submitted in May 2016, brought forward data to evaluate the effects on beneficial soil organisms and insects as well as an analysis by the petitioner of grower need.

**Summary of Review:**

Polyoxin D zinc salt is categorized as a biofungicide or biochemical pesticide. While the polyoxin D might be considered a nonsynthetic product, the addition of the zinc salt makes it a synthetic. The zinc salt makes this product more useful by lessening its water solubility and prevents the product from washing off the application area too quickly to yield significant effectiveness.

The petitioner has made a case that there are few to no alternatives for some fungal diseases on various species of plants, such as cottonball disease on cranberries, black rot, downy mildew, powdery mildew and bunch rot on grapes, mummyberry on blueberries, phomopsis leaf spot on strawberries, downy mildew on basil as well as a host of other fungal diseases on fruits. The petitioner states there are OMRI listed alternatives, but their product is either more effective or offers another tool for producers in rotation to prevent resistance.

While this material is of lower toxicity than some other products used for similar treatments, the Crops Subcommittee expressed varied views regarding its essentiality.

**Category 1: Classification**

1. For CROP use: Is the substance \_\_\_\_\_ Non-synthetic or   x   Synthetic?  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

Polyoxin D is converted to polyoxin D zinc salt via a chemical reaction.

2. For CROPS: Reference to appropriate OFPA category:

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

Polyoxin D zinc salt is a “toxin derived from a naturally bacteria.” Polyoxin D is produced via fermentation of a naturally-occurring (non-GMO) bacteria, *Streptomyces cacaoi* var. *aroensis*, isolated from a soil sample collected in Japan (TR Lines 179 and 187-188).

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The petitioner acknowledges polyoxin D zinc salt could kill beneficial soil fungi, and specific brand name products (Bio-Tam and Rootshield) used by organic producers would be rendered ineffective if they were in contact with polyoxin D zinc salt. However, in their own studies, they found little to no toxic effects on beneficial soil fungi.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19).

As described in the 2012 petition (page 18):

“The active portion of polyoxin D zinc salt is polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells. Polyoxin D zinc salt does not kill the fungi; it simply stops the fungal growth. The action of Polyoxin D is highly specific; it does not affect bacteria, viruses, or mammals.”

Per comments from the members of the NOSB during the 2013 public hearing, further information regarding the elucidation of the mode of action is included in the May 31, 2016 petition.

The December 12, 2017 TR states (lines 206-210):

“Soil half-life from aerobic microbial metabolism is reported to be 15.9 days (Esteem Report). Polyoxin D Zinc Salt was shown to undergo aqueous abiotic hydrolysis at pH = 7 and pH= 9 (Esteem Report). Photolytic degradation was observed, DT<sub>50</sub> = 1.6 d in spring conditions (Esteem Report). Data reviewed by EPA indicated that polyoxin D Zinc Salt biodegrades within 2-3 days of application, with a low toxicity profile [73 FR 69559].”

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

There is no concern during the manufacture, use, or disposal other than that this product should not be used nearby to, or in, water since it is moderately toxic to aquatic invertebrates and fish. A brand name product label (VEGGIETURBO 5SC Suspension Concentrate Fungicide) containing polyoxin D zinc salt has this warning:

*“For terrestrial use. This pesticide is moderately toxic to aquatic invertebrates and fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not allow runoff into lakes, streams, ponds or public waterways. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Observe the most restrictive labeling limitations and precautions of all products used in mixtures.”*

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

The Technical Review of polyoxin D zinc salt from December 2017 states there is very low acute toxicity to humans by oral, dermal, or inhalation routes, and it did not demonstrate mutagenic potential. However, there are warnings on the label about possible skin irritation effects, as well as eye irritation.

Specifically, the TR states (lines 218-230):

*“In animal models, Polyoxin D Zinc Salt was shown to have very low acute toxicity by oral, dermal, and inhalation routes. Only very minor skin irritation was observed for Polyoxin D Zinc Salt, which was not sufficient to warrant classification. Polyoxin D Zinc Salt was shown to cause mild eye irritation. Polyoxin D Zinc Salt was shown not to be a contact sensitizer. Polyoxin D did not demonstrate a mutagenic potential though it did reveal some clastogenic potential with and without metabolic activation. In general, low toxicity was observed for Polyoxin D Zinc Salt in all investigations. During toxicity studies, Polyoxin D Zinc Salt is poorly absorbed with the vast majority of the product (>90%) being excreted unchanged directly in the feces. Polyoxin D Zinc Salt has been used for many years without any notable, consistent adverse human reactions being recorded. Polyoxin D Zinc Salt has been in use as an antifungal agent for over 40 years in Japan on rice, and approved in the USA and Mexico on food crops for over 5 and 3 years respectively and for non-food crops in the USA for over 16 years. The product is derived naturally in Japan from *Streptomyces cacaoi* var *asoensis* and has a unique mode of activity by inhibiting fungal cell wall synthesis. The risk to humans is considered to be extremely low.”*

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

In response to NOSB questions of toxicity to beneficial soil fungi, honeybees, or ladybird beetles, the petitioner, Kaken, commissioned their own studies and found no negative effects on any of these organisms. (See petition from May 2016)

6. Are there any adverse impacts on biodiversity? (§205.200)

The technical review states this product rapidly degrades in the environment, approximately 2-3 days, and therefore it was concluded there was low environmental risk.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There are numerous OMRI and certifier-approved materials that can be used as alternatives, as well as cultural methods, to control fungal disease. The petitioner has stated that practices and OMRI-listed alternative materials are insufficient to meet organic grower needs.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Yes, in balancing the responses to the criteria above, polyoxin D zinc salt to other products is compatible with a system of sustainable agriculture.

**Classification Motion:**

Motion to classify polyoxin D zinc salt as a synthetic substance.

Motion by: Jesse Buie

Seconded by: Emily Oakley

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**National List Motion:**

Motion to add polyoxin D zinc salt as petitioned at §205.601(i).

Motion by: Jesse Buie

Seconded by: Sue Baird

Yes: 3 No: 1 Abstain: 2 Absent: 1 Recuse: 0

**Approved by Steve Ela, Crops Subcommittee Chair, to transmit to NOSB February 23, 2018**

**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Proposal  
Sulfur as Slug and Snail Bait  
February 20, 2018**

**Summary of Sulfur as a Molluscicide [Petition](#):**

OR CAL, Inc. has petitioned for inclusion of sulfur as a synthetic substance allowed for use in organic crop production under Section 205.601(h) of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances, as a slug and snail bait.

The petition notes that elemental sulfur is currently NOP Listed under section 205.601(e)(5) as an insecticide (including acaricide or miticide), 205.601(i) as a plant disease control, and 205.601(j)(2) as a plant or soil amendment. The NOSB also recommended (Fall 2017) the addition of elemental sulfur to the National List for use as a pesticide on domestic livestock (petitioner: Georgia Gulf Sulfur Corporation of Valdosta, Georgia).

Many stakeholders have experience with sulfur use in organic agriculture and extensive information is available. The petition provides EPA registration information and pesticide label requirements. The petition relies on the [March 2017 Sulfur Livestock technical report](#) for background information. In the original [1995 technical advisory panel \(TAP\) review](#), the reviewers found elemental sulfur to be relatively innocuous in the environment when used according to the product use label. It was also found to be of low toxicity. It should not be used within one month of any horticultural oil product, as currently stated on most sulfur labels. An updated draft Technical Report (TR) for sulfur has been completed and reviewed by the NOSB Crops Subcommittee (anticipated publication on [NOP website](#) March/April 2017). Based on review of the draft Sulfur TR, no new information is likely to change the information available for this proposed use as a molluscicide. Overall, sulfur is considered a low toxicity/low risk material. It is a known respiratory and eye irritant and causes dermatitis. Direct exposures to farm workers can be mitigated if label recommendations and proper personal protective equipment (PPE) recommendations are followed. New research suggests associations with agricultural field applications and poorer respiratory function in children living in agricultural communities. The pellet formulation of the proposed use will likely minimize eye, skin, or respiratory exposures, but these exposures should be evaluated by applicators. Any adverse exposures incidents should be reported to local pesticide regulatory agencies and the NOSB.

**Summary of Review:**

The Crops Subcommittee reviewed extensive information about sulfur used in organic agriculture, including the TR for sulfur use on livestock, the draft TR for elemental sulfur, the petitioner's request, and other scientific information. As organic farmers have worked to reduce tillage, slugs have emerged as a serious pest in organic matter rich soils, particularly when that organic matter is largely left on the soil surface. New tools addressing these pests are needed. This product address a key concern when farmers find that slugs have emerged as a serious pest in organic matter rich soils (Peigne et al. 2007: <http://onlinelibrary.wiley.com/doi/10.1111/j.1475-2743.2006.00082.x/full>). Sulfur has a long history of use in organic farming and is minimally toxic to humans and the environment. Sulfur is an ocular, respiratory, and dermal irritant. However the proposed use under this petition is unlikely to result in adverse exposures to farmers, workers, and surrounding communities. Appropriate protections should be used as needed.

## International Standards:

Internationally approved for use by: The E.U., IFOAM. Codex Alimentarius Commission (CAC GL 32-1999) permits the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013). Also allowed by Canadian Organic Standards.

The Canadian General Standards Board (CGSB) includes non-synthetic elemental sulfur as a permitted substance for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. Chemically synthesized substances cannot be added, and chemical treatment is prohibited. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods" (GL 32-1999) lists elemental sulfur as an allowed substance for pest and disease control.

The European Economic Community (EEC) Council Regulation (EEC No 2092/91) and carried over by Article 16(3)(c) of Regulation No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production.

The Japan Agricultural Standard (JAS) for Organic Production (Notification No. 1605 of 2005) permits the use of sulfur as a fertilizer or soil improvement substance, and as a substance for plant pest and disease control.

The International Federation of Organic Agriculture Movement's (IFOAM) lists sulfur as an approved substance for pest and disease control, for use as fertilizer/soil conditioner, and for use as a crop protectant and growth regulator.

## Category 1: Classification

1. For CROP use: Is the substance \_\_\_\_\_ **Non-synthetic** or X **Synthetic**?  
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

Elemental sulfur can come either from a natural mined source, or may be produced as a by-product from natural gas or petroleum operations and refinery process. The latter appears to be the primary source of most elemental sulfur currently being used. Because the sulfur is chemically extracted from fossil-fuel feedstock, it is considered synthetic.

2. Reference to appropriate [OFPA](#) category:  
Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in

production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inert of toxicological concern?

Sulfur is a sulfur compound and falls under §6517(c)(1)(B)(i). As summarized in the draft TR, Sulfur is currently registered for use under the U.S. Environmental Protection Agency's (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3 as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock (and livestock quarters), and indoor and outdoor residential sites. Use sites include tree fruit, berries, vegetables, root crops, field crops, pets (dogs), ornamentals, and turf (including residential lawns and golf courses).

## Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

Sulfur is a naturally occurring element, and essential nutrient for plants, and part of normal animal biology. As noted in the draft TR, "the major environmental concern with elemental sulfur is that upon oxidation it forms sulfuric acid, which can acidify soil or water ecosystems. In soil management systems, elemental sulfur is a common soil amendment used to acidify calcareous soil and increase the sulfur fertility; it is expected to have a similar effect when used as a pesticide. In soil and water management systems, the application of lime (i.e.,  $\text{CaCO}_3$ ) is recommended to neutralize the acidity generated via sulfur oxidation.... there are no known reports that suggest any specific chemical interactions between elemental sulfur and other substances used in organic crop or livestock production or handling. Elemental sulfur does react vigorously with chlorates, nitrates, and other oxidizing agents...To the best of our knowledge, there are no known reports that suggest any specific chemical interactions between elemental sulfur and other substances used in organic crop or livestock production or handling".

Sulfur as used in the proposed pellet formulation is unlikely to have detrimental chemical interactions with other materials used in organic farming systems.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

Information on the specific mode of action of sulfur on mollusks is not provided. Sulfur is a contact fungicide, and also kills mites. Sulfur may inhibit arachidonic acid metabolism and platelet plasma membrane function. Consumption by ruminants of a high dietary percentage of sulfur as elemental sulfur or sulfate can cause toxic effects. Sulfur bacteria may produce the poisonous gases hydrogen sulfide and sulfur dioxide that affect respiration.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

As described in the Livestock Sulfur TR, elemental sulfur is transported from mining, manufacturing and transshipping sites in pipelines and in tank cars in molten form. Molten sulfur has the potential to emit hydrogen sulfide gas, which 1) presents a safety hazard to those working in the vicinity and 2) an environmental hazard, since  $\text{H}_2\text{S}$  is very toxic. Pollution of the soils can take place where elemental sulfur is stored in the open. Wind eroding fine dust from

stored in the open is deposited downwind of the manufacturing or storage facility. Over several years surrounding soils can become acidified with pH as low as 1.

4. Discuss the effect of the substance on human health. [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)].

Overall, sulfur is considered a low toxicity/low risk material (<http://extoxnet.orst.edu/pips/sulfur.htm>). It is a known respiratory and eye irritant and causes dermatitis. Direct exposures to farm workers can be mitigated if label recommendations and proper personal protective equipment recommendations are followed. New research suggests associations with agricultural field applications and poorer respiratory function in children living in agricultural communities (Raanan et al. 2017: <https://www.ncbi.nlm.nih.gov/pubmed/28886594>). However, the proposed use as a snail and slug bait in pellets will likely not result in eye, skin, or respiratory protections. Appropriate protection should be provided to workers handling sulfur products as needed (eye protection, gloves, respirator). Any adverse exposures incidents should be reported to local pesticide regulatory agencies and the NOSB.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

Sulfur is a naturally-occurring element and is ubiquitous in the environment. Too much sulfur (e.g., from a sulfur storage or manufacturing facility) will cause the pH of soil to drop very low. High sulfur contamination and subsequent acidification can negatively affect earthworms, snails, and some ground beetle.

6. Are there any adverse impacts on biodiversity? (§205.200)

The use as proposed is unlikely to adversely impact biodiversity.

### **Category 3: Alternatives/Compatibility**

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

As noted in prior petitions for ferric phosphate and repeated by the current petitioner, “slugs can be captured in traps and killed manually by the farmer. These traps can consist of: a) holes in the ground with a covering; b) boards; and c) various manufactured traps that use bait, e.g. beer, yeast. There are also biological controls for slugs. Various birds will eat slugs and snails. The problem with using animals as control methods is that they also tend to damage the crop. There are fly and beetle species that might provide control, however, the supply is not consistent. Predatory snails can destroy pest snails. However, these snails are not native and their use is restricted.” A predatory nematode is available in Europe and Britain but is not currently sold in the US ([http://ucanr.edu/sites/CalSnailsandSlugs/Management/Natural\\_enemies/](http://ucanr.edu/sites/CalSnailsandSlugs/Management/Natural_enemies/)).

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]  
Yes.



**National List Motion:**

Motion to add sulfur, as petitioned, at §205.601(h) of the National List of Allowed and Prohibited Substances.

Motion by: Asa Bradman

Seconded by: Harriet Behar

Yes: 7 No: 0 Abstain: 0 Absent: 2 Recuse: 0

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**National Organic Standards Board**  
**Materials Subcommittee Discussion Document**  
**Protecting the Genetic Integrity of Seed Grown on Organic Land**  
**February 22, 2018**

## **I INTRODUCTION**

The USDA National Organic Program regulations do not allow the use of “excluded methods” in certified organic production. The term “excluded methods” refers specifically to genetically modified organisms (GMO). In the U.S., 94% of soybeans, 92% of corn, 94% of cotton (cottonseed oil is a foodstuff derived from cotton), 75% of Hawaiian papaya, 90% of sugar beets and 90% of canola crops are genetically engineered. By contrast, less than 1% of crops grown in Europe are genetically modified and that production is limited to a handful of countries in southern Europe. Planting stock can also be genetically engineered, with a GMO non-browning apple poised to be in the marketplace in a few years, as well as fish, pigs, and a wide variety of vegetables and fruits. Various traits are engineered into these patented crops, with herbicide resistance being the main trait, and insecticides incorporated into the DNA of those plants the second main trait.

## **II BACKGROUND**

Currently, in the U.S., no testing is required for presence of foreign genetically engineered materials to meet the requirements of the federal organic label. While so-called process-based standards are in place (buffer distances from GMO crops, temporal separation of when crops are planted etc.) farmers and consumers have no verified Genetically Engineered (GE) free quantitative tests in place even when it’s clear such contamination is increasingly likely. For many years farmers who purchase and plant non-organic seed due to the commercial unavailability of organic seed have needed to obtain non-GE affidavits if their seed is a type that has a genetically engineered equivalent in the marketplace that is a cultivar with and without the transformed GMO trait. These affidavits have been accepted as proof by their organic certifiers that the seed is non-GMO. Even if a seed or crop has been found to be “contaminated” with the genome of traceable GMO traits, technically it does not lose its organic certification status. Depending on the requirements of the end buyer, and the integrity of the seller, some of these known contaminated seeds and crops are likely to make it into the organic production stream and ultimately the organic market.

In the raw crop marketplace, buyers respond differently to the risk of genetic contamination: some buyers are performing extensive and expensive testing to determine if there is contamination, while others perform more inexpensive tests only periodically, or perform none at all. Some buyers do testing of grower supplied samples, of deliveries unloaded at the facility, and/or of cleaned product before it is shipped out to the next customer, while others do not. This inconsistency both for seed and for the final crop, leaves organic growers vulnerable to the varied demands of buyers as well as to genetic contamination that occurred from no fault of their own in the field, during transport, or at the cleaning facility. The European Union, as well as other international and domestic buyers, have set a tolerance limit, allowing some GE contamination (0.9%), while still accepting the product as organic. There are no prescribed or consistent GE tolerance levels for U.S. domestic organic production.

Most organic seed producers take protection of genetic integrity quite seriously. They monitor their custom growers, or their own facilities, when planning location, planting dates, pollination times for their crops, and carefully monitor the integrity of their handling and transport chain. We have heard from a number of organic seed breeder/producers that they elect to drop promising cultivars after investing much in their selection and germplasm evaluation when those cultivars inadvertently become contaminated with GMO genetic material. This has become increasingly problematic with outcrossing crops like maize and canola. Even with this careful oversight, some corn seed breeders report almost 20% contamination of their organic corn seed with foreign GMO germplasm. These seed breeders destroy specific lots of contaminated seed, a loss which they need to compensate for by raising the price of the remaining organic corn seed, resulting in higher prices to organic farmers and ultimately consumers.

### **III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS**

NOP standards adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibit the use of GMOs in the production and handling of organic products certified to national organic standards. The terminology used for GMOs in the NOP Regulation, “excluded methods,” is specified under section 205.2 (Terms Defined) as:

***Excluded methods.** A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.*

At its October 2016 meeting, the NOSB passed a recommendation to update and clarify the definition of Excluded Methods. The proposal (dated August 30, 2016) allows the NOP to be more flexible in addressing new technologies as they are developed. Numerous specific methods have been reviewed under this terminology, using transparent criteria, principles and descriptions. The NOSB has determined some new technologies should be excluded from organic production, and others are still under review.

**Detection and Testing Requirements:** Under the residue testing requirements of NOP, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods. This requirement is specified in Subpart G (Administrative) of the regulations:

**§ 205.670 Inspection and testing of agricultural product to be sold or labeled “organic.”**

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as “100 percent organic,” “organic,” or

“made with organic (specified ingredients or food group(s))” when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

**NOP Policy:** The NOP finalized a Policy Memo on July 22, 2011 (Policy Memo 11-13) on GMOs. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answers questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard and the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

#### **IV DISCUSSION and PUBLIC COMMENT**

The NOSB put forth discussion documents on this subject in 2013, 2014, 2015, 2016 and 2017. Public comment has clearly shown this to be an important issue for organic producers, food processors and consumers. Organic stakeholders would like to see consistency in the organic certification process as it relates to excluded methods and to protect organic integrity overall in order to maintain consumer trust. The genetic integrity of seed used on organic land continues to be at risk, and the risk appears to grow each year. The questions at the end of this document are intended to continue this conversation and inform possible next steps.

Since there is an allowance for the use of non-organic seed when organic seed of an equivalent variety in the quality and quantity desired cannot be found, this increases the risk of GMO contamination of organic crops. If a farmer starts out with GMO contaminated seed, then many of their defensive management tactics are entirely ineffective. The very contaminated seed they plant will freely cross fertilize other cultivars of that crop on their farm greatly compounding the contamination problem. In most cases, non-organic seed producers do not perform the same due diligence in testing and oversight to protect against GMO contamination as organic seed breeders. Some may state in their non-GMO affidavits that their assessment of non-GMO presence is “to the best of their ability”, since they are not actually testing to prove this statement as true.

The issue of maintaining the genetic integrity of organic and non-organic seed and planting stock grown on organic land and sold in the organic marketplace is complex, but not an insurmountable task. The respective interests of organic seed and planting stock growers and the farmers who buy their products can be at odds, even though they are both seeking the same ultimate outcome of avoidance of GMO contamination whenever possible. Non-GMO labeling such as the Non-GMO Project does not guarantee 100% GMO free products, with a 0.9% tolerance level allowed in foods for human consumption and a 5% allowance of GMO contamination in livestock feeds whose final product would then be labeled as non-GMO. The Non-GMO Project has a tolerance of 0.25% for seed.

Tolerance levels can also present problems. How are these seeds and products to be tested, and by whom, and where in the supply chain? Would a 100% GMO free standard in organic result in large regions of the United States not being able to grow organic crops, preventing the growth of organic acreage and commercial activity in the US? Could those businesses that sell or buy the GMO crops that

are causing the contamination be assessed a fee to cover the losses caused by GMO contamination? If so, how could this be implemented in an efficient and fair way?

The question of solving GMO contamination in organic seed and crops does not have clear answers, and might result in the unintended consequence of causing damage to the growth and integrity of organic agriculture, as well as negatively impacting organic growers and seed breeders. However, both growers and consumers feel contamination of organic seed and crops by GMOs negatively affects the integrity of organic foods.

## **V DISCUSSION QUESTIONS**

The following list of questions is by no means comprehensive, but is a starting point for discussion on possible options to address GMO contamination. This is a big topic, and we welcome all types of ideas and proposed solutions.

- a. Should we move to quantify the extent of GMO contamination in order to better understand the scope of the problem? How could this be accomplished?
- b. Should a requirement be in place establishing a seed purity threshold for purchased seed (either organic or nonorganic, or both) planted on organic land? If so, what should the threshold be? How will that threshold vary with crop?
- c. Should there be an approved list of tests, and/or testing laboratories, for tracking the presence of GMO in seed and/or crops?
- d. Should there be an approved method of sampling for GMO traits? How much of a seed or crop should be tested to provide confidence that the entire lot is likely to be GMO free?
- e. Would a seed label statement indicating the percentage of GMO traits detected by an approved testing regime, be sufficient in providing the information needed by the purchaser of the seed? No detectable level of GMO traits, .1% or other levels are examples that could be provided.

## **VI Subcommittee vote**

Motion to approve the discussion document on Protecting the Genetic Integrity of Seed Grown on Organic Land

Motion by: Dan Seitz

Seconded by: Dave Mortensen

Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Harriet Behar, Subcommittee Chair to transmit to NOSB, February 27, 2018**