

**National Organic Standards Board –
Joint Materials and Handling Committee
Classification of Materials – DRAFT Guidance document
March 1, 2010**

Current Status & Request for Public Input

At the November 2009 National Organic Standards Board (NOSB) meeting, the NOSB passed a recommendation on Classification of Materials. The recommendation included several “Next Steps,” that the NOSB felt were required in order for the recommendation to be implemented. One of the “Next Steps” was development of a Guidance Document that the various stakeholders (e.g., Accredited Certifying Agents, committees of the NOSB, National Organic Program personnel) could use when classifying materials.

A *draft* version of this Guidance Document is proposed below. The joint Materials and Handling Committee is offering this draft as a discussion document for the Spring 2010 NOSB meeting. It is our desire to solicit public comments, preferably in writing, that identify how this draft could be improved. Particular areas where public comment would be useful include:

- Does the guidance document reflect the November NOSB recommendation?
- Do the example materials reflect the range of materials that currently pose classification difficulties?
- Are there materials whose classification would be unclear using this document?

We intend to use the input provided by the public to create a final draft of this document for NOP review and publication. Publication of the NOP Guidance Document would include another opportunity for public comment and input.

Note – This document does not include the Addendum to the November 2009 recommendation being offered for consideration by the NOSB at the April 2010 meeting. That recommendation will be incorporated at a later date if passed by the NOSB.

DRAFT Guidance Document on Classification of Materials – Presented for Public Comment

I. Introduction

Classification of materials, as either synthetic, nonsynthetic or agricultural, is the first, sometimes only, step towards determining whether a material is allowed or prohibited for use in production or handling of organic products as defined by the Organic Foods Production Act. Classification decisions are made by many stakeholders associated with the United States Department of Agriculture’s (USDA) National Organic Program (NOP) including accredited certifying agents (ACAs), NOP personnel and the National Organic Standards Board (NOSB). Consistency in classification of materials underpins implementation of the act and is one factor in ensuring that consumers can have confidence in the certified organic products that they eat.

However, classification decisions are not always straight forward. This guidance document is intended to provide clarity and further detail on how the NOSB and NOP interpret the definitions in the final rule and make classification decisions.

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At the November 2009 NOSB meeting, the NOSB passed a recommendation on classification of materials. This recommendation identified several overall principles that should guide the classification of materials. These are:

- The classification of a material is determined by both the source of the inputs and the process used to make the material.
- The same material can be agricultural, non-synthetic or synthetic depending on source and process.
- If a material is processed such that it is classified as synthetic then the material is classified as synthetic regardless of source. A material of this type would most correctly be referred to as an “agriculturally sourced material which has been processed in such a way as to classify the material synthetic.” Materials that are manufactured in full compliance with the final rule are outside the scope of this principle; their status with regards to use in organic is not affected by this recommendation.

Finally, it is important to remember that classification of a material, while an important part of determining whether a material is allowed or prohibited for use in organic production or handling, is a separate decision from certifying a material as organic. To be certified organic, a material must be produced in full compliance with the Final Rule. As an example, mint extract made from certified organic mint and extracted with hexane would be classified as agricultural but clearly could NOT be certified organic.

II. Regulation Background

In crop production, nonsynthetic substances are allowed unless listed on the NL §205.602, while synthetic substances are prohibited unless listed on the NL §205.601.

In livestock production, nonsynthetic substances are allowed unless included on the NL §205.604, while synthetic substances are prohibited unless included on the NL §205.603.

For handling, nonorganic agricultural substances to be used in certified “organic” products for human consumption must be listed on the NL §205.606. Nonagricultural substances must be listed on the NL §205.605 with nonsynthetics listed on §205.605(a) and synthetics listed on §205.605(b). “Made with” products can contain non-organic agricultural products not included on NL §205.606. Materials listed on the NL §205.606 may only be used when the organic version is not available in the form, quality, or quantity needed.

Definitions from the final rule that are applicable to classification of materials decisions are:

Agricultural Products Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketing in the United States for human or livestock consumption” (§2103(1)).

Chemical Change An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

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Extract To separate, withdraw, or obtain one or more essential constituents of an organism, substance or mixture by use of solvents, mechanical or physical methods.

Formulate To combine different materials according to a recipe or formula to prepare the product being evaluated.

Manufacture To make a crop, livestock or handling input from raw materials.

Naturally Occurring Biological Process Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.

Nonagricultural Substance A product, such as a mineral or atmospheric gas, that does not originate from agriculture. For the purposes of this part agricultural refers to the production or handling of crops or livestock.

Nonsynthetic (natural) A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term used in the Act

Organically Produced An agricultural product that is produced and handled in accordance with this title” (§2103 (14)).

Processing Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing food in a container

Substance An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

Synthetic A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes

III. Worksheet Discussion

This section provides further discussion and background for each question on the classification of materials worksheet found in Appendix A. Appendix B contains completed worksheets for several example materials.

The November 2009 NOSB recommendation should be referred to for a full discussion of the options considered for classification and the history of debate on classification of materials. Briefly, the NOSB recommendation was that the relationship between the questions of agricultural versus non-agricultural and synthetic versus non-synthetic be codified and formalized. The recommendation was that these questions be addressed together in sequence rather than addressed

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as two separate parallel questions. Further the NOSB recommended that if a material, either due to its source or the process by which it is made, is determined to be synthetic, that this determination comes first. Then, of those nonsynthetic remaining materials, those with a source that is not agricultural would be classified as nonsynthetic. The remaining materials, from agricultural sources would be classified as agricultural.

The NOSB, through its recommendation, intended that a material would be classified as synthetic when:

- The source of the material is not “from mineral, plant, or animal matter” (from the definition of nonsynthetic) and is not a “substance created by naturally occurring biological processes” (from the definition of synthetic) or;
- The process used to manufacture the material is synthetic (per the definition of synthetic and clarifying definitions in our recommendation) or;
- The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics.

When classifying a material it is critical that a good understanding of how the material is manufactured exists including how the manufacturing process or source may vary across the industry. Where the source of the material or manufacturing process is not fully understood, the precautionary principle would dictate that the material be classified as synthetic until a full review determines it to be nonsynthetic or agricultural.

Question #1 Is the substance a product of a naturally occurring biological process (for example, a microbiological organism, a fermentation by-product, an enzyme)?”

Materials that are biological in source or process (e.g., yeast, enzymes, fermentation by-products) have been the most difficult to classify and the materials on which the most differences of opinion on classification exist. These different perspectives arise from the great variety of sources and processes used to manufacture these materials. For example, yeast can be sourced from certified organic grapes or from a yeast strain whose original source is unknown because it only exists in purified form in a “bottle.”

In the NOSB’s November 6, 2009 recommendation, the NOSB recommended that depending on source and process the product of a naturally occurring biological process could be either nonsynthetic or agricultural. Further, the NOSB determined that, as a board, they did not have a sufficient understanding of the variety of sources and processes used to manufacture products of naturally occurring biological processes to issue a classification recommendation that would address all, or even most, of these materials. The NOSB recommended that materials already on the National List remain classified as currently listed and that all new materials being considered for use in organic production or handling be petitioned to the NOSB for full evaluation and classification. It is the hope of the NOSB that evaluation of these petitions will provide further insight that will allow a further revision of this guidance document to aid in classification of these biological organisms and their by-products.

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It is our intention that these materials continue to be approved or prohibited based on their current listing on the National List. We believe that some of these materials could be reclassified, including classification as agricultural, depending on source and process and that these materials need to be considered on a case-by-case basis. Therefore, if there are materials whose classification is unclear, we believe that a petition should be submitted to the NOSB for a review of classification and listing. The NOSB will determine the classification of the material. It is our belief that, at some future time once source and process is better understood, additional rule changes and guidance could occur to address the classification of products from naturally occurring biological processes.

Proper terminology for the products of naturally occurring biological processes and the microorganisms that lie at the heart of these biological processes has been elusive. For the purposes of this document, the term “products of naturally occurring biological processes” includes the microbiological organisms (e.g., yeast, bacteria) used in the process.

Question #2 Is the substance certified organic or certified “made with (organic ingredients)?

Classification of materials is required in association with the Final Rule because classification forms the foundation of whether a material is allowed or prohibited, for crops and livestock, or whether organic versions have to be used when available (aka commercial availability), for handling. Additionally, classification determines where the material is listed on the National List of Allowed and Prohibited Substances. Products that are certified organic, or “made with (organic ingredients)” are allowed for use in production and handling as described in the Final Rule. These materials are not listed on the National List. Therefore, classification of these materials is not necessary. More specifically, classification of the material is not applicable because they are materials that would never be listed on the National List.

For the above reason, the NOSB’s November 2009 recommendation stated that “this recommendation applies to the inputs and ingredients used in crop production, livestock production and handling. Products that are being reviewed for certification as organic or “made with (organic ingredients)” are addressed broadly by all portions of the Final Rule and are outside the scope of this document.”

Question 2 specifically identifies these certified organic, or “made with (organic ingredients),” materials and pulls them out of the classification process.

Question #3 Is the substance chemically changed as a result of the process by which the substance is manufactured?

This question is the one most debated when classification of materials is considered. After much debate, public input and work by the Material Working Group, all of which is listed in the Section VI References, the NOSB recommended the following definitions be added to the Final Rule to clarify chemical change:

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Chemical Change An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

Substance An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

Lack of consistency on classification of materials has arisen from materials which are changed temporarily during the manufacturing process but identical to the original sourced material at the end of process or where a synthetic chemical is used in a process but does not change the material. The definitions above are intended to clarify the situation such that if a material is substantially changed in function or identity between the source of the material and the end of the process by which the material is manufactured then chemical change has occurred. Additionally if a synthetic chemical used in the process is not removed from the final material, then the material is classified as synthetic; this topic is addressed in Question 4.

For example, certain botanicals are extracted with hexane to process botanical pesticides used in organic crops. The hexane is removed and not present at a significant level in the final material. The extracted material, pyrethrin for example, is identical in the source botanical and in the final material. Therefore, there is no chemical change and the answer to this question would be “No.”

For extraction, extraction with a synthetic not on the National List would not result in a material being classified as synthetic unless either the extraction resulted in chemical change or the synthetic remained in the final material at a significant level. Also, extraction is broadly defined to include mechanical and physical separation in addition to solvent extraction.

Another example is soy protein isolate for which the manufacturing process includes an acidification step with hydrogen chloride. This step precipitates the soy protein. Once the precipitate is purified by washing, sodium hydroxide is added to neutralize the soy protein and make it soluble. The material is then spray dried. In this case, the soy protein at the end of the process has the same identity as the soy proteins in the source soybeans; there is no chemical change as a result of the acidification and neutralization steps. Therefore, the answer to this question would be “No.”

Conversely if acid is added to a source material to break a chemical bond, the resulting substance is different than the starting substance and chemical change has occurred. Ion-exchange is another process that has been discussed in detail. Similar to acidification, ion-exchange may or may not result in chemical change depending on whether the final substance has the same identity as the source substance.

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Question #4 Is a significant amount/level of any synthetic input to the process remaining in the final substance?

The joint Materials and Handling committee has begun discussions on how to provide more clarity on a “significant level” of synthetic input. We did not reach a conclusion in time to include it in this draft Guidance Document. Our November 2009 recommendation stated that “The MWG spent considerable time discussing the terms insignificant and significant level. We concur with their conclusion that a significant level should be determined with reference to the applicable regulatory limits for the type of substance, in addition to technical and functional effects produced by the residual level of the synthetic.”

We intend to continue our discussion to provide more clarity and to get public comment on the guidance.

Question #5 Is the substance formulated to commercially produce the generic substance? If so, are all components of the formulation non-synthetic?

There are materials on the National List or used as allowed nonsynthetics in crops or livestock that are available as ingredients only as a formulated product, a combination of materials in a recipe or formula. In this case, all the materials are present at significant levels and must all be nonsynthetic for the material to be classified as nonsynthetic. The presence of any synthetic, including those on the National List of allowed synthetics, would result in classification of the formulated material as synthetic. Also, if the act of formulation leads to a chemical change, with the exception of chemical change resulting from a naturally occurring biological process, then the material is classified as synthetic. A formulated product that contains greater than insignificant levels of a synthetic substance may be approved for use in organic production or handling if the synthetic substance appears in the applicable section of the National List.

When approving a specific material for use in organic, formulation must be considered if applicable. For example, if a soil supplement is to be evaluated for use on a farm, all components of the supplement must be non-synthetic if the supplement is to be classified as non-synthetic. This includes, as examples, stabilizers, preservatives and dispersing agents.

For consideration of materials for listing on the National List, formulation is not typically relevant to classification of single materials. Rather formulation needs to be considered when a broad category of materials (e.g., natural flavors, enzymes, dairy cultures) are classified. In these cases, it is important for the NOSB to carefully consider the types of materials commonly used in formulations to determine whether any restrictions on these substances are warranted. In some cases, use of annotations may be necessary to restrict formulations to those considered during review of the material. Otherwise, all possible formulations of such products would be considered acceptable.

Question #6 Does the substance originate from agriculture?

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Questions 1 and 2 in this worksheet remove certain materials from consideration for classification. Questions 3, 4 and five determine whether a material should be classified as synthetic. All remaining materials are non-synthetic. A subset of non-synthetic is agricultural materials. Question 6 determines which of the non-synthetic materials is also agricultural. This determination is made using the definition of “Nonagricultural Substance” which is, as recommended in the November 2009 recommendation, “a product, such as a mineral or atmospheric gas, that does not originate from agriculture. For the purposes of this part agricultural refers to the production or handling of crops or livestock.”

If the answer to this question is “no,” then the material is a non-synthetic which does not originate from agriculture and is therefore classified as non-synthetic.

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IV. Additional Guidance Items

There are several topics related to classification of materials that are not specifically addressed in the Appendix A Worksheet. These topics are discussed below to provide additional clarification.

Crude Oil and materials sourced from crude oil – Using the worksheet in Appendix A crude oil and some by-products of crude oil would be classified as non-synthetic. The joint Materials and Handling committee acknowledges that this classification might be uncomfortable for some in the organic industry. Clearly use of crude oil and most of its by-products, beyond use in vehicles and motors, is not compatible with organic production or handling. It is the intent of the joint Materials and Handling committee to work with the Crops and Livestock committees to have, where appropriate, crude oil and its by-products listed as prohibited non-synthetics.

Synthetic Solvents and their use in non-organic ingredients used in Handling – The NOSB has received public comment from ACA's over the last several years asking for clarification on whether a synthetic solvent or processing aid used during the manufacturing of a nonorganic ingredient intended for use in an organic product, needs to be on the National List as indicated by § 205.270(c)(2).

§ 205.270(c)(2) states that (c) “the handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic: (2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: Except, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.”

It is the opinion of the NOSB that synthetic solvents may be used in manufacturing materials listed on §205.606 unless during the review and listing of these items on §205.606 the NOSB has included an annotation restricting use of synthetic solvents.

Use of non-synthetic, agricultural or organic versions of materials listed as approved synthetic materials for handling as listed on § 205.605(b) – Some materials can be manufactured in several ways from either different sources or using different processes. When a material is listed on the National List of Allowed or Prohibited Substances as a synthetic allowed for use in handling (§ 205.605(b)), it is the opinion of the NOSB that a non-synthetic or agricultural version of the material is also allowed for use in handling. In this case, the non-synthetic or agricultural version may be used but is not required to be used.

The converse is not true. If a material is listed as a non-synthetic allowed for use in handling (§ 205.605(a)) or a non-organic agricultural allowed for use in handling (§ 205.606), then the synthetic version is not allowed for use in handling.

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V. Conclusion

We acknowledge that this Guidance Document and Worksheet will not resolve classification for all materials. Certainly the classification of products of naturally occurring biological processes will require further study by the NOSB. It is the intention of the NOSB to review petitions for products of naturally occurring biological processes and to at some future time provide an addendum to this Guidance Document and Worksheet to address the products of naturally occurring biological processes.

Other materials may also elude classification. In those cases, the material should be petitioned for listing on the National List of Allowed and Prohibited Substances. The NOSB's review of the material will include a vote to classify the material.

VI. References

National Organic Standards Board Recommendations & other documents:

- Materials and Handling Committee, "Classification of Materials," November 6, 2010
- Materials and Handling Committees, "Discussion Document on the Definition of Materials," October 19, 2007
- Handling Committee and Materials Committee, "Recommendations Relative to "Agricultural" and "Nonagricultural" Substances for National List Consideration," September 15, 2006
- Handling Committee, "Recommendations Relative to "Agricultural" and "Nonagricultural" Substances," July 14, 2005
- Materials and Handling Committee, "Clarification of the definition of Synthetic as it is applied to Substances Petitioned for Addition or Prohibition to the National List(s)," June 23, 2005

Material Working Group

- May 2008 presentation at National Organic Standards Board meeting titled "Clarification of Definitions -- Agricultural vs. Non-agricultural"
- November 2008 presentation at National Organic Standards Board meeting titled "Clarification of Definitions -- Agricultural vs. Non-agricultural"
- May 2009 presentation at National Organic Standards Board meeting titled "Clarification of Definition of Synthetic Substance"

National Organic Program

- "Evaluation of the NOSB Recommendation on the Definition of Synthetic," March 9, 2006

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Appendix A -- CLASSIFICATION OF MATERIALS WORKSHEET

SUBSTANCE:

USE, APPLICATION, OR FUNCTION:

DESCRIPTION OF MANUFACTURING PROCESS INCLUDING SOURCE, ALL INPUTS AND PROCESSES:

-
1. Is the substance a product of a naturally occurring biological process (for example, a microbiological organism, a fermentation by-product, an enzyme)?

Explain:

If YES, Stop -- Substance should be petitioned to NOSB for review and classification.

If NO, proceed to #2

-
2. Is the substance certified organic or certified “made with (organic ingredients)?”

Explain:

If YES, Stop -- Classification of substance is not required (or, alternatively) substance is agricultural.

If NO, proceed to #3

-
3. Is the substance chemically changed as a result of the process by which the substance is manufactured?

Explain:

If YES, Stop -- Substance is SYNTHETIC.

If NO, proceed to #4

-
4. Is a significant amount/level of any synthetic input to the process remaining in the final substance?

Explain:

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If YES, Stop -- Substance is classified as SYNTHETIC.

If NO, proceed to #5

-
5. Is the substance formulated to commercially produce the generic substance? If so, are all components of the formulation non-synthetic?

Explain:

If not formulated or all components are non-synthetic, proceed to #6

If formulated and any component is synthetic, Stop – substance is SYNTHETIC

-
6. Does the substance originate from agriculture?

Explain:

If YES, Stop – substance is AGRICULTURAL

If NO, Stop – substance is NON-SYNTHETIC

CONCLUSION: SYNTHETIC ☐
AGRICULTURAL ☐

NON-SYNTHETIC ☐

Explain:

DEFINITIONS:

Chemical Change An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

Extract To separate, withdraw, or obtain one or more essential constituents of an organism, substance or mixture by use of solvents, mechanical or physical methods.

Formulate To combine different materials according to a recipe or formula to prepare the product being evaluated.

Manufacture To make a crop, livestock or handling input from raw materials.

Synthetic A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes

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Naturally Occurring Biological Process Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.

Nonagricultural Substance A product, such as a mineral or atmospheric gas, that does not originate from agriculture. For the purposes of this part agricultural refers to the production or handling of crops or livestock.

Nonsynthetic (natural) A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term used in the Act

Processing Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing food in a container

Substance An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

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Appendix B – EXAMPLES -- Classification of Materials Worksheet

SUBSTANCE: *Lecithin – variety as described below*

USE, APPLICATION, OR FUNCTION:

	<i>Lecithin, bleached -- Sourced from Certified Organic Soybeans</i>	<i>Lecithin, de-oiled and unbleached</i>	<i>Lecithin, de-oiled(with acetone) and bleached</i>
DESCRIPTION OF MANUFACTURING PROCESS INCLUDING SOURCE, ALL INPUTS AND PROCESSES:	Certified organic soybeans are physically separated into oil and soybean meal. The soybean oil is then hydrated with water or steam and the lecithin gums are physically separated. The lecithin gums are bleached with less than 5% hydrogen peroxide which is a synthetic allowed for use in certified organic products (§205.605(b)).	Soybeans are physically separated into oil and soybean meal. The soybean oil is then hydrated with water or steam and the lecithin gums are physically separated. The lecithin gums are de-oiled using acetone extraction. <u>Note:</u> This material could be certified organic if the lecithin gums were de-oiled using physical separation.	Soybeans are physically separated into oil and soybean meal. The soybean oil is then hydrated with water or steam and the lecithin gums are physically separated. The lecithin gums are de-oiled using acetone extraction. This de-oiled lecithin is then bleached with less than 5% hydrogen peroxide which is a synthetic allowed for use in certified organic products (§205.605(b)).
<u>Question #1</u> -- Is the substance a product of a naturally occurring biological process (for example, a microbiological organism, a fermentation by-product, an enzyme)? <i>If YES, Stop -- Substance should be petitioned to NOSB for review and classification.</i> <i>If NO, proceed to #2</i>	NO -- Proceed to #2	NO -- Proceed to #2	NO -- Proceed to #2
<u>Question #2</u> -- Is the substance certified organic or certified “made with (organic ingredients)?” <i>If YES, Stop -- Classification of substance is not required (or, alternatively) substance is agricultural.</i> <i>If NO, proceed to #3</i>	YES – Stop <u>Note</u> – If the lecithin in this example were de-oiled AND the de-oiling process was physical separation (i.e., an impeller), this material would still be certified organic.	NO -- Proceed to #3 <u>Note</u> -- Use of acetone in the process means that this material cannot be certified organic.	NO -- Proceed to #3 <u>Note</u> -- Use of acetone in the process means that this material cannot be certified organic.
<u>Question #3</u> -- Is the substance chemically		NO – Proceed to #4	YES – Stop, substance is SYNTHETIC

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	<i>Lecithin, bleached -- Sourced from Certified Organic Soybeans</i>	<i>Lecithin, de-oiled and unbleached</i>	<i>Lecithin, de-oiled(with acetone) and bleached</i>
changed as a result of the process by which the substance is manufactured? <i>If YES, Stop -- Substance is SYNTHETIC.</i> <i>If NO, proceed to #4</i>		Lecithin is an original component of soybeans. Extraction with water or steam does not change identify of lecithin. De-oiling of the resulting lecithin gums also does not change the identity of lecithin.	Lecithin is an original component of soybeans. Extraction with water or steam does not change identify of lecithin. De-oiling of the resulting lecithin gums also does not change the identity of lecithin. Bleaching of the de-oiled lecithin DOES chemically change the lecithin.
Question #4 -- Is a significant amount/level of any synthetic input to the process remaining in the final substance? <i>If YES, Stop -- Substance is classified as SYNTHETIC.</i> <i>If NO, proceed to #5</i>		NO – Proceed to #5 The acetone used to de-oil the lecithin gums is evaporated and does not remain in the final material at a significant level.	
Question #5 -- Is the substance formulated to commercially produce the generic substance? If so, are all components of the formulation non-synthetic? <i>If not formulated or all components are non-synthetic, proceed to #6</i> <i>If formulated and any component is synthetic, Stop – substance is SYNTHETIC</i>		NO – Proceed to #6 Material is not formulated	
Question #6 -- Does the substance originate from agriculture? <i>If YES, Stop – substance is AGRICULTURAL</i> <i>If NO, Stop – substance is NON-SYNTHETIC</i>		YES – Stop, substance is AGRICULTURAL Substance originates from soybeans which are agricultural	
CONCLUSION – Classification of Material	CERTIFIED ORGANIC According To Final Rule	AGRICULTURAL	SYNTHETIC

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SUBSTANCE: *Gellan Gum*

USE, APPLICATION, OR FUNCTION:

	<i>Gellan Gum</i>
DESCRIPTION OF MANUFACTURING PROCESS INCLUDING SOURCE, ALL INPUTS AND PROCESSES:	Gellan gum is produced by a microbial culture and then further processed for commercial applications. Gellan gum is produced from <i>S. elodea</i> by a pure-culture fermentation process. It is recovered from the fermentation culture with isopropyl alcohol (Doner and Douds, 1995). The thickness and hardness of the gellan gum is determined by acetyl groups present in the gellan gum obtained from the microbial culture. With acetyl groups present, the gel is soft and elastic. Firmer gels are obtained by removing the acetyl groups to some extent by adding potassium, magnesium, calcium, and/or sodium salts). Thus, gellan gum is produced by a naturally-occurring biological process, and a chemical process is used to extract the gellan gum from the fermentation medium and to formulate the desired thickness of the gum. The extraction and formulation steps do not alter the identity of the gellan gum produced by the microbial culture, but they do manipulate functional properties (i.e., the thickness and hardness) of the substance.
Question #1 -- Is the substance a product of a naturally occurring biological process (for example, a microbiological organism, a fermentation by-product, an enzyme)? <i>If YES, Stop -- Substance should be petitioned to NOSB for review and classification.</i> <i>If NO, proceed to #2</i>	NO – true, it is originally produced from <i>S. elodea</i> by a pure culture fermentation process BUT, it is recovered from the fermentation culture with isopropyl alcohol – a naturally occurring biological process with a chemical process used to extract the gellan gum from the fermentation medium and the addition of chemicals to remove acetyl groups and manipulate viscosity, formulating the desired thickness of the gum.
Question #2 -- Is the substance certified organic or certified “made with (organic ingredients)?” <i>If YES, Stop -- Classification of substance is not required (or, alternatively) substance is agricultural.</i> <i>If NO, proceed to #3</i>	NO – Proceed to # 3
Question #3 -- Is the substance chemically changed as a result of the process by which the substance is manufactured? <i>If YES, Stop -- Substance is SYNTHETIC.</i> <i>If NO, proceed to #4</i>	YES – Substance is synthetic
Question #4 -- Is a significant amount/level of any	

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	<i>Gellan Gum</i>
synthetic input to the process remaining in the final substance? <i>If YES, Stop -- Substance is classified as SYNTHETIC.</i> <i>If NO, proceed to #5</i>	
Question #5 -- Is the substance formulated to commercially produce the generic substance? If so, are all components of the formulation non-synthetic? <i>If not formulated or all components are non-synthetic, proceed to #6</i> <i>If formulated and any component is synthetic, Stop – substance is SYNTHETIC</i>	
Question #6 -- Does the substance originate from agriculture? <i>If YES, Stop – substance is AGRICULTURAL</i> <i>If NO, Stop – substance is NON-SYNTHETIC</i>	
CONCLUSION – Classification of Material	SYNTHETIC

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COMMITTEE VOTE:

The Joint Handling and Materials Committee moves to accept this draft Guidance Document and to request input from the public and rest of the National Organic Standards Board to aid in further development of the document:

Moved: Heinze Second: Demuri

Yes: 9 No: 1 Abstain: 0 Absent: 1 Recuse: 0