

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: *May 24, 2010*
Subject: *Classification of Materials*
Chair: *Dan Giacomini*

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X
Guidance Statement: X
Other: _____

Summary Statement of the Recommendation (including Recount of Vote):

A joint committee of the Materials and Handling committee presented an addendum recommendation to complete the National Organic Standards Board recommendation on Classification of Materials made in November 2009. The key element of this recommendation was the definition of chemical change.

The joint committee, in its posted recommendation dated 3/1/10, recommended that the following underlined sentence be added to the NOSB's November 2009 recommendation for chemical change (shown here in italics):

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").*
Allowed processing, as defined in §205.2, that has only agricultural or nonsynthetic inputs, does not result in a substantive change in identity as it applies to the definition of this term.

Public comment was received in response to this posted 3/1/10 recommendation stating that the added, underlined, sentence was too expansive and would reclassify materials previously classified as synthetic to be non-synthetic. That was not the joint committee's intent. The joint committee had added the second sentence in response to public comment received at the November 2009 meeting that stated that the first sentence alone reclassified too many materials currently classified as non-synthetic to be synthetic. It has been the joint committee's intent to clarify the current definitions to best match current practice and to provide clarity for those few materials where classification has proved elusive.

Based on public comment received prior to and at the April 2010 meeting, the joint committee presented this definition of chemical change:

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").*
Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and §205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.

There were two no votes for this recommendation. One person voting against the addendum recommendation did so because they would not have supported the original November 2009 recommendation. The second person voting against this recommendation did so because they were unclear whether the added language would allow use of a synthetic "allowed" for use in handling to be used to produce a material that could then be used as an input for crops or livestock. It was not the intent of the joint committee or the NOSB during discussion to allow

a “back door” for “allowed” inputs from handling to be allowed in crops or livestock without being explicitly evaluated and listed on the National List.

The joint committee also added language to the recommendation indicating our desire to work closely with the National Organic Program to implement both this and the November 2009 recommendation. We specifically asked that where possible this recommendation be implemented as guidance.

The remaining work of the joint committee is development of a draft guidance document, in collaboration with the National Organic Program, based on the November 2009 recommendation and this, April 2010, addendum to that recommendation. That remaining work will be done by the NOSB Materials Committee.

NOSB Vote: **Motion:** *Katrina Heinze* **Second:** *Joe Smillie*

Board vote: Yes - 12 No- 2 Abstain- 0 Absent - 1

Summary Rationale Supporting Recommendation (including consistency with OFPA and NOP): *See accompanying recommendation*

Response by the NOP:

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Joint Materials and Handling Committee
Addendum to November 6, 2009 Recommendation on Classification of Materials
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I. Introduction

At the November 2009 National Organic Standards Board (NOSB) meeting, the NOSB passed a recommendation on Classification of Materials. The recommendation acknowledged that there were a few public comments that needed additional study and stated our intent to add clarifications to our recommendation to address these public comments. Since the November meeting, the Joint Materials and Handling committee has been reviewing these public comments. The recommendation offered below is in response to those comments and addresses the outstanding items in the November recommendation.

II. Recommendation & Discussion

Public comment asked the NOSB to clarify our support for “the principle that the terms “synthetic” and “chemical change” were intended to identify materials that are man-made synthesized compounds.” Similarly, we were asked to address “whether chemical changes generated during processing methods specifically allowed in the OFPA and/or allowed National List materials, would render an otherwise agricultural product “synthetic.”

There was a consistent concern, expressed in public comment, that our recommended definitions of *chemical change*, and its associated definition for *substance*, went too far and would result in a number of agricultural materials being classified as synthetic. A simple example to illustrate this point is toasted wheat kernels. Wheat kernels are clearly agricultural. When exposed to heat, the kernels toast resulting in chemical change. Public comment clearly indicated that classifying something like a toasted wheat kernel as synthetic was not the intent of OFPA.

The Joint Materials and Handling committee agrees. It is our belief that chemical changes that occur when an agricultural material is processed by itself, or in combination with other agricultural materials, the resulting material should continue to be classified as agricultural. Clearly chemical change happens in these cases, if looked at from a purely chemistry perspective, but from a consumer perspective these materials are agricultural.

The Joint committee discussed whether the same perspective applied when an agricultural material is processed with a nonsynthetic material. We decided that again consumers perceive these materials to be agricultural. As a result, the Joint Committee decided to include these cases, agricultural processed with nonsynthetic inputs, in this addendum to our recommendation and is interested in public comment on this topic.

As a result, we are proposing this addition to the definition of chemical change proposed in our November 2009 recommendation. The addition is underlined:

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”). Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and

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§205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.

III. Other Items

At the November 2009 NOSB meeting, we also received public comment asking the NOSB to modify our recommendation to “require organic preference for all ingredients in organic products, by applying the principle to all materials currently listed in sections 605 and 606 of the National List.” These comments supported a recommendation by the Material Working Group and other comments we have received in the past several years.

We neglected to address this topic in our November 2009 recommendation. Many members of the Joint Materials and Handling committee support requiring commercial availability materials listed on §205.605 in addition to those listed on §205.606. Unfortunately, it is our understanding from the National Organic Program that there does not appear to be a regulatory option for expanding commercial availability to §205.605. We request that the NOP continue to be aware of the public and NOSB’s desire to explore this topic.

IV. Update on Next Steps

The November 2009 NOSB recommendation included a number of steps needed to implement that recommendation. Below is an update to the public on the status of execution of these next steps:

Rule Change – In our November recommendation, we asked the NOP to begin the process for rule change when they received the recommendation from the NOSB. With this addendum, we are instead asking the NOP to begin the process of reviewing this recommendation for the purpose of facilitating a relevant rule change and/or developing industry guidance. Where possible, we would like this recommendation to be implemented in industry guidance for some period of time prior to rule change. The NOSB asks that the NOP provides feedback to the NOSB regarding its review and works collaboratively with its members to address any areas of concern. We ask the NOP to prioritize the review of and response to this recommendation, so that increased consistency in classification of materials can be implemented quickly.

Guidance Document – A draft Guidance Document based on the November 2009 recommendation is being presented at the April 2010 NOSB meeting. It is the intent of the members of the Joint Materials and Handling committee to solicit written feedback from the public on the clarity of the guidance document so that we can refine it in collaboration with the NOP.

Approval and Classification of Materials by Accredited Certifying Agents – We want to reiterate that it is critical that ACA’s and other industry stakeholders are consistent in how this recommendation is implemented. For that purpose, it is our intent that:

- ACA’s should approve use of materials as currently listed on the National List.

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- ACA's should begin using the classification of materials guidance document only when issued by the NOP as official guidance. Until then, classification of materials for the purposes of approving or prohibiting them for use should be done following current practices.

Changes to National List – The Crops, Handling and Livestock committees have added a review of materials on their respective sections of the National List for appropriate classification to their workplans. The committees are currently working through Sunset materials and will prioritize reclassification as appropriate given other workplan items.

Products from Naturally Occurring Biological Processes – The NOSB will review petitions for materials that fall into this category as we receive them. It continues to be our intent to use these petitions to expand our knowledge of this category so that additional guidance on classification of these materials can be made to the Guidance Document on Classification at a later date as appropriate.

The NOSB received a petition for the reclassification of yeast as agricultural in mid-February. The Handling committee will be reviewing the petition, requesting a technical review and intends to have a recommendation on the reclassification for our fall 2010 meeting.

NOSB Practices – The Joint Materials and Handling committee has asked the Policy committee to review the recommended practices and incorporate them into the NOSB Policy Manual as appropriate.

COMMITTEE VOTE:

The Joint Handling and Materials Committee moves to accept this document for full board consideration and vote:

Moved: Katrina Heinze Second: Joe Dickson

Yes: 9 No: 2 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Joint Materials and Handling Committee
Recommendation on Classification of Materials
November 4, 2009

I. Introduction

The proper classification of materials has been debated since the Organic Food Production Act was enacted. The National Organic Standards Board (NOSB) and the United States Department of Agriculture's (USDA) Accredited certifying agents (ACAs) often are confronted with decisions about the classification of materials according to current definitions under the National Organic Program (NOP) regulations. For both the NOSB and ACAs, this determination has significant impact on organic producers and processors.

For crops and livestock production, the synthetic/nonsynthetic classification determines whether a material is prohibited or allowed. For handling, all nonorganic materials used in certified organic products must be on the National List. However, for products that are labeled as "made with (organic ingredient)" nonorganic, agricultural ingredients can be used. In this case, the agricultural/nonagricultural classification can impact whether a particular material can be used as an ingredient without listing.

While the NOSB determines the classification of some materials when considering the material for inclusion on the National List of Allowed and Prohibited Materials (NL), most materials are classified by ACA's and outside technical groups (e.g., OMRI). There is general agreement on the vast majority of materials. However, a small number of materials have been problematic, and inconsistency in classification exists due to gaps in current definitions. Examples of these materials include gums (which are listed in multiple sections on the National List), products of naturally occurring biological processes, and natural flavors.

The need to provide additional clarity on the definition of materials for the National List has been recognized for several years. Since 2005, the National Organic Standards Board has been actively working to provide increased clarity on the "definition (or classification) of materials." A number of recommendations have been made, public comment has been heard and thoughtful debates have occurred. After the November 2007 NOSB meeting, a group of the organic community came together as the Material Working Group (MWG) to provide discussion and perspective for NOSB consideration. This group was open to anyone interested. Key documents are listed in Section VII References.

The joint Materials and Handling Committee has reviewed past recommendations, National Organic Program (NOP) responses, input of the Material Working Group and public comments received over the years. We acknowledge that there will always be areas of disagreement on the topic of materials classification and that not everyone will agree with our recommendation. The overwhelming majority of the input we have received has asked us to make a decisive recommendation that will bring clarity to this subject. This recommendation represents the majority view of the members of the joint Materials and Handling Committee.

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II. Scope

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.

III. Current Regulatory Framework

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.

1) The Organic Food Production Act of 1990

The Organic Food Production Act (OFPA) was passed by Congress in 1990 and signed by the President. One of the three defined purposes of the act was “to establish national standards governing the marketing of certain agricultural products as organically produced products” (§2102(1)).

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

The act defines **Organically Produced** as “*an agricultural product that is produced and handled in accordance with this title*” (§2103 (14)).

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 a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes*” (§2103 (21)).

The act defines **Processing** as a term meaning “*cooking, baking, heating, drying, mixing, grinding, churning, separating, extraction, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and included the packaging, canning, jarring, or otherwise enclosing food in a container*” (§2103 (17)).

OFPA did not define the terms “Agricultural”, “Nonagricultural”, or “Nonsynthetic”.

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2) The National Organic Program and the National Organic Standards Board

Under the authority of OFPA, the National Organic Program (NOP) was formed within the USDA. The Secretary of Agriculture appointed the original members of the NOSB in 1993. By 1994, the NOSB was working to develop the NL, a list of approved and prohibited substances (§2103 (12)) for use in certified organic food production as directed according to OFPA. At that time, the NOSB introduced the distinction between “agricultural products” and “nonagricultural substances”.

Final organic regulations, known as The Final Rule, were published in 2000.

The Final Rule defines **Nonagricultural substance** as “*a substance that is not a product of agriculture, such as a mineral or bacterial culture that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin that is extracted from, isolated from or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction*” (§205.2 Terms defined).

Nonsynthetic (natural) is defined as “*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*” (§205.2 Terms defined).

The Final Rule does not specifically define “process” or “synthetic process” and it further clarifies the definition of **Processing** by adding *curing, slaughtering, distilling and chilling* to the definition (§205.2 Terms defined).

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IV. Discussion

Our recommendation on classification of materials required debate and discussion on several aspects of the question. Each of these is discussed below.

1) Guiding Principles

The members of the joint Materials and Handling Committee have agreed to several overall principles to guide our recommendation. We agree that a material is defined both by the source of the inputs to the process and the process used to make the material. For example, tartaric acid can be sourced from grape wine or from malic acid. If sourced from grape wine then tartaric acid could be a non-synthetic material. Alternatively, tartaric acid sourced from DL-malic acid is synthetic. Pectin sourced from an agricultural source, either citrus peel or apple pomace, can be classified as either an agricultural product (pectin, high-methoxy) or synthetic (pectin, low-methoxy) depending on the process used to produce it ranging from extraction with acidified water (agricultural) to hexane extraction with ammonia chemical modification (synthetic).

Since a material is defined by both its source and the process used to make the material, we agree that a material, like pectin or tartaric acid, can have multiple classifications.

We have come to realize through the past several years of discussion on the topic of classification of materials that the historical approach of handling agricultural/nonagricultural and synthetic/non-synthetic as distinct questions of classification led to confusion. Specifically, confusion developed as to the degree of processing that an “agricultural product” could undergo to become “nonagricultural” versus the amount of processing for part of it to become “synthetic.”

There is general consensus that the questions of agricultural versus non-agricultural and synthetic versus non-synthetic must be linked in some fashion, and that the relationship should be codified and formalized. The committee recommends that the questions should be addressed together in sequence rather than addressed as two separate parallel questions. Generally we believe 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.

This leads to the widely debated classification of agricultural synthetics, or materials sourced from agriculture but processed in such a way that the final material would be classified as synthetic. We recognize that a material can exist, low-methoxy pectin for example, that clearly comes from an agricultural source but undergoes chemical change during manufacturing. There is strong consensus that this material should be classified as synthetic. We reject the idea of a new category of materials, the “agricultural synthetic” materials, as some have suggested. Instead, a material of this type would be classified as synthetic and 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.”

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Synthetic / Nonsynthetic

There are several parts of the definition of synthetic that have resulted in differences of opinion on how certain materials should be classified. These are “formulated and manufactured by a chemical process” and “chemically changed.” Questions that arise from these differences of opinion for “difficult to classify” materials include:

- What type chemical change is required for a material to be synthetic?
- Can synthetic solvents be used for extraction of nonsynthetic materials?
- What if the material, as available for use, includes minor, or inert, ingredients that are synthetic? Is the material then classified as synthetic?

The NOSB, NOP and MWG documents on these topics provide numerous examples where lack of consistency in interpretation exists. The 2005 NOSB recommendation on this topic, resulting 2006 NOP response and May 2009 MWG refinement were particularly helpful and provide the framework for our recommendation.

When reviewing the MWG recommendation two perspectives existed on the joint Materials and Handling Committee on the classification that results from the use of synthetics in a process. Some members felt that, consistent with the practice of the NOSB, NOP and ACA’s since the mid-1990’s, if the use of a synthetic in a process did not lead to chemical change and the synthetic was not present in the final material at significant levels then the resulting material was not synthetic. Others felt that any use of a synthetic not on the National List of approved synthetics should result in the material being classified as synthetic. These two perspectives reflect those discussed by the MWG and provided by the public in comments to the NOSB over the years. The majority of the joint committee agreed to proceed with definitions that aligned with current practice. The rationale was that we wanted our recommendation to be least disruptive to the National List and most consistent with past NOSB actions and historic organic industry practice.

Therefore we are recommending adoption of the definitions proposed by the MWG in their May 2009 recommendation, with the exception of the definitions for natural source and generic. The definitions that we are recommending for addition to §205.2 Terms Defined to clarify the classification of materials as synthetic are chemical change, extract, formulate, manufacture, naturally occurring biological process and substance. We did not include the definitions for natural source and generic in our recommendation because they were only used by the MWG in their proposed decision tree. We will review these definitions and include them as needed when we propose the guidance document listed in Section V Next Steps and Timing.

A full discussion of the MWG recommendation can be found in their recommendation. However, we want to highlight a few points here as well.

It is our intent through this recommendation that a material would be classified as synthetic when:

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- 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.

For our recommendation, 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 also include mechanical and physical separation in addition to solvent extraction. This is consistent with current classification practices.

Chemical change is defined by this recommendation as “*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. As discussed by the MWG in their recommendation, chemical change is “an event in which one substance becomes one or more difference substances.”* Chemical change would not necessarily include processes like ion-exchange or pH adjustment if the final material was not a different substance from the initial substance. For clarity, a definition of substance is included in the recommendation as well.

It is not our intent to reclassify as synthetic, products or ingredients that today can be certified organic in full compliance with the Final Rule. For example, certified organic soy lecithin exists today. It is manufactured from organic soybeans physically separated into oil and soybean meal. The soybean oil is then hydrated with water or steam and the lecithin gums are physically separated. Certified organic bleached soy lecithin can be manufactured by using less than 5% hydrogen peroxide which is a synthetic allowed for use in certified organic products (§205.605(b)).

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.

Finally, 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

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organic production or handling if the synthetic substance appears in the applicable section of 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, we recommend that the general type of materials commonly used in formulations be evaluated to determine whether any restrictions on source of these substances is warranted and expressed as an annotation. Otherwise, all possible formulations of such products would be considered acceptable.

At the November 3-5, 2009 NOSB meeting, public comment was heard on two topics related to classification of materials as either synthetic or nonsynthetic. The first was a concern that the use of CAS numbers as an example in the definition of substance was not clear. We have modified the proposed definition to address this concern. The proposed modifications to our recommended definition of “*Substance*”:

- NEW -- 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).
- ORIGINAL -- An element, molecular species, or chemical compound that possesses a distinct identity (e.g., having a separate Chemical Abstract Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

The second concern raised by public comment at the November 2009 NOSB meeting requested clarification on our recommended third guiding principle and related definition for chemical change. Public comments requested clarification as to how the third guiding principle would relate to a material from a source that is organic or to a material that undergoes a chemical change through the normal effects of food processing or the use of a synthetic allowed on §205.605(b). The joint Materials and Handling committee intends to further study these questions and address them if possible during development of our recommended Guidance Document with NOP. If not possible, we intend to have a further recommendation specific to this topic at the Spring 2010 NOSB meeting.

2) Agricultural / Nonagricultural

The NOSB has discussed recommendations on the classification of a material as either agricultural or nonagricultural on several occasions. Products of naturally occurring biological processes have been a major point of disagreement and confusion in these discussions. We believe that these discussions have also been confounded by discussions of “agricultural synthetics,” which are discussed above.

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When the classification of a material as synthetic or nonsynthetic is addressed first then materials from agricultural sources that are processed in such a way as to classify them as synthetic are removed from the question of classification of agricultural or nonagricultural. If we then determine that the products of naturally occurring biological processes need to be handled on a case-by-case basis, as we recommend below, these materials are also, for the time being, removed from the question of classification of agricultural or nonagricultural.

The materials that remain for classification are all nonsynthetic, either agricultural or nonagricultural and relatively easy to classify. Materials that are sourced from minerals or atmospheric gases are clearly not agricultural and should be classified as nonagricultural. The remaining materials are sourced from agriculture and processed in such a way that they are not synthetic. We are recommending that these materials be classified as agricultural. Therefore we are recommending that the definition of nonagricultural be simplified by deleting *“For the purposes of this part, a nonagricultural ingredient also includes any substances, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.”*

This recommendation will lead to the possible need to reclassify several materials currently on §205.605(a). Examples of these materials are egg white lysozyme, L-malic acid and agar-agar. Each of these will need to be reviewed to better understand source and process. Our recommended process for this review is described below in Section V Next Steps and Timing.

We recognize that for those materials that are reclassified from nonsynthetic to agricultural, resulting in the material being listed on 205.606, this requires that use of the material by a handler include demonstration by the handler that an organic version of the material is not commercially available. We believe this change will provide additional encouragement for market innovation to bring organic versions of these materials to market.

At the November 3-5, 2009 NOSB meeting, public comment was heard that questioned our recommended definition of nonagricultural. In reviewing this public comment, the joint Materials and Handling Committee realized that we had inadvertently included the wrong definition of nonagricultural in our recommendation. Below are the definitions that we considered:

- **CURRENT DEFINITION** = A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substances, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction
- **PROPOSED DEFINITION** = A product, such as a mineral or atmospheric gas that does not originate from an agricultural system

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- DEFINITION WE INTENDED TO PROPOSE = 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.

The public comment received at this meeting asked for better clarity on the definition of “agricultural system.” We believe that these comments are addressed through recommendation of the definition of “nonagricultural” that we intended to recommend.

3) Products of Naturally Occurring Biological Processes

The classification of products from naturally occurring biological processes has been a great source of differences of opinion and confusion. A variety of approaches and perspectives have been considered by the NOSB over the past several years. We believe that 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. Each of these sources may affect the classification of yeast. Similarly, the variety of processes and process inputs used to manufacture yeast may affect the classification of the material. Therefore, we believe that depending on source and process the product of a naturally occurring biological process could be either nonsynthetic or agricultural.

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.

At this time, the joint Materials and Handling Committee does not believe that we have sufficient understanding of the variety of sources and processes used to manufacture products of naturally occurring biological processes to issue a recommendation that would address all, or even most, of these materials. We are recommending that these materials remain classified as currently listed on the National List.

We are recommending that the term “*or bacterial culture*” be deleted from the definition of nonagricultural because we recognize that cultured microorganisms could possibly be classified as agricultural. In which case, certified organic versions would be required. We strongly support the development of certified organic versions of materials on the National List and want to, where practical, encourage that development.

Therefore, where a manufacturer believes that they can manufacture a product of a naturally occurring biological process from sources and using a process that would classify the material as agricultural, we would encourage the manufacturer to submit a petition to the NOP that clearly details the source and process and aids in our understanding of the breadth of sources and processes on the market. We will review the petitioned material, determine classification and list as appropriate.

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4) NOSB Practices Related to Classification of Materials

There are three practices that the NOSB should implement that would improve consistency in classification of materials by the NOSB. Since classification by the NOSB is typically used by others in the organic industry as a guide on classification, it follows that improved consistency in classification by the NOSB should lead to improved classification across the industry.

Originally the NOSB held two votes on all materials being considered for listing on the National List. A first vote was on the classification of a material. Once, the classification of the material was established, a second separate vote to decide to list the material was held. The separate votes separated the discussion into two parts. This practice better matches our intent that classification and whether a material should be allowed for use in organic production or handling are separate decisions. The joint Materials and Handling Committee recommends that this practice be re-implemented and that doing so would eliminate some of the confusion that has arisen in recent years.

Second, in recent years the NOSB has tried where possible to avoid the use of annotations. The rationale for this was that annotations pose an additional certification challenge. These materials are conventionally produced and information on their source and process can be difficult to obtain. We support this perspective but feel that in some cases, the use of annotations is warranted to provide further guidance for users of the material or certifiers on whether there are source or process limitations for a listed material. Annotations of this type exist today (e.g., citric acid). We recommend that future listing of materials include any source or process that is not included in the listing of the material. There are some current materials on the list that may need additional annotation. Our recommended process for this review is described below in Section V Next Steps and Timing.

Finally, the past several years of discussion on classification of materials has been a reminder that the source of inputs and the process to produce a certain material can be complicated and varied. A full understanding of these variations is needed to accurately make classification decisions and decisions on which variations may be compatible with organic production or handling. The members of the NOSB intend to refocus on fully understanding the technical aspects of a petitioned material and all the variations of source and process available in the marketplace to manufacture the material as we discuss classification and listing of a material. This will include broader use of technical reviews as appropriate.

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V. Recommendation

The recommendation includes 1) guiding principles for classification of materials, 2) future NOSB practices and 3) proposed changes and additions to regulatory language.

1) Guiding Principles

The members of the joint Materials and Handling Committee have agreed to 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.

2) NOSB Practices

Improved clarity on the classification of materials would result from enhancing current NOSB practices. The joint Materials and Handling Committee is recommending that these practices be implemented:

- Voting on the classification of a petitioned material before voting on whether a petitioned material should be listed on the National List.
- Increase, where appropriate, the NOSB’s use of annotations to properly list source or process where either are a determining factor for how a material is classified and placed on the National List.
- Refocus on fully understanding the technical aspects of a petitioned material and all the variations of source and process available in the marketplace to manufacture the material.

3) Proposed Regulatory Language

The joint Materials and Handling Committee recommends that the NOP implement rule change to clarify classification of materials. We recommend the following additions and changes to the regulation:

§205.2 Terms Defined.

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.

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.

Replaces the current definition, which is: *A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substances, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.*

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

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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VI. Next Steps & Timing

We recognize that implementation of this recommendation could be disruptive if coordination between the NOSB, NOP, and ACA's on timing does not occur. Therefore, we propose the following next steps and timing for implementation of this recommendation:

Rule Change – We ask the NOP to begin the process of rule change when this recommendation is made by the NOSB. We understand that the process for rule change takes time so we intend to proceed with guidance (see below) in collaboration with the NOP, so that increased consistency in classification of materials can be implemented quickly.

Guidance Document – We propose to work with the NOP staff to develop a guidance document to aid in classification of materials. The guidance document will include appropriate definitions, a discussion of each definition as appropriate, clarification that listing on 205.605(a) requires verification that source and process to produce the material are not synthetic, clarification that nonsynthetic versions of materials listed on 205.605(b) are allowed and classification examples for various materials. Additionally, if possible, it will include a decision tree. We propose to begin work immediately with the NOP on this guidance document. Once complete, the guidance document will be issued by the NOP for public comment and will be reviewed and issued per the NOP process for guidance (see “National Organic Program: Development, Issuance, and Use of Guidance Documents,” Federal Register, Vol. 70, No. 20, February 1, 2005). Anyone classifying materials should follow current practices until this guidance is issued by the NOP.

Based on public comment received at the November 3-5, 2009 NOSB meeting we intend in the Guidance Document to address questions raised about the scope of our third recommended guiding principle, questions about interpretation of §205.270(c)2 and provide better guidance for determining “significant level.”

Approval and Classification of Materials by Accredited Certifying Agents – It will be critical that ACA's and other industry stakeholders are consistent in how this recommendation is implemented. For that purpose, it is our intent that:

- ACA's should approve use of materials as currently listed on the National List.
- ACA's should begin using the classification of materials guidance document only when issued by the NOP as official guidance. Until then, classification of materials for the purposes of approving or prohibiting them for use should be done following current practices.

Changes to National List – This recommendation will require the review of the classification and/or annotation for several materials currently on the National List. The Materials Committee in collaboration with the Handling Committee will review materials on §205.605 and §205.606 to finalize those materials needing a classification or annotation review. The process for changing these listings is for a member of the NOSB to submit a petition to the NOP to change the listing for the material. It is our intention to submit a petition in time for the spring 2010 meeting and to address recommendations to change the listing of these materials at the fall 2010 and spring 2011

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meetings. This process will allow any necessary changes to the National List to occur following our normal process, including public input.

Products from Naturally Occurring Biological Processes – As discussed in Section III Discussion above, the members of the joint Materials and Handling Committee feel that a better understanding of the specific source and process used to produce a material that is the result of a naturally occurring biological process is needed in order for a review of the classification of the material to occur. 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.

Specifically, yeast has been the subject of much discussion and public comment for several years. Currently a petition to change the listing of yeast from §205.605 to §205.606 has been submitted but deferred for consideration by the petitioner. We ask the petitioner to revise the petition, as appropriate, to ensure that a detailed discussion of the source of inputs and the processes used to produce yeast is included. We will consider the petition when it is resubmitted, request a technical review if required and will recommend classification of yeast and the appropriate listing of this material.

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VII. Conclusion

The members of the joint Materials and Handling Committee are grateful for the input we have received from the public on this complicated topic. We want to particularly thank the members of the Material Working Group for their discussions, examples and recommendations. Their varied perspectives were critical in helping us understand where clarity was needed and the impact of our recommendation.

We acknowledge that this recommendation will not satisfy everyone and that there will be materials whose classification will, even with this recommendation, be the subject of debate. Where discussion will continue to elucidate this topic, we encourage on-going input and examples.

VIII. References

National Organic Standards Board Recommendations & other documents:

- 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
- Handling Committee, “Recommendations Relative to “Agricultural” and “Nonagricultural” Substances,” July 14, 2005
- Handling Committee and Materials Committee, “Recommendations Relative to “Agricultural” and “Nonagricultural” Substances for National List Consideration,” September 15, 2006
- Materials and Handling Committees, “Discussion Document on the Definition of Materials,” October 19, 2007

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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COMMITTEE VOTE:

The Joint Handling and Materials Committee moves to accept this document for full board consideration and vote:

Moved: Katrina Heinze Second: Joe Smillie

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