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April 10th, 2010

The National Organic Standards Board  
c/o Valerie Frances, Executive Director, NOSB  
1400 Independence Avenue, SW  
Room 4008 – South Building, Ag Stop 0268  
Washington D.C. 20250-0200

RE: Docket Number AMS–NOP–10–0021.

Oregon Tilth thanks the National Organic Standards Board for the opportunity to comment on agenda items for the April 2010 meeting. Oregon Tilth, Inc. is a non-profit 501(c)(3) organization that supports and promotes biologically sound and socially equitable agriculture through education, research, advocacy, and product certification. We represent over 700 members and 1200 certified operators.

## **RECOMMENDATION ON THE CLARIFICATION OF MATERIALS**

Oregon Tilth appreciates the Joint Materials and Handling Committee’s continued efforts on an incredibly difficult and often frustrating topic that the industry has been grappling with for years. Oregon Tilth presented the challenges of making agricultural and nonagricultural determinations using existing regulatory definitions in October 2004. In our comments we made several suggestions that the Board has been considering since that time. We appreciate the perseverance spent on this issue over the years and we appreciate the thorough response included with this April recommended addendum and guidance document.

Oregon Tilth engages in the review of crop, livestock, and handling materials daily. In addition to the material review decisions made by the NOSB twice a year, we are one of 99 certifiers in the world reviewing and making material determinations everyday. We also recognize the Organic Materials Review Institute (OMRI) as a leader and major stakeholder in the development of industry guidance on the classification of materials. We consider their comments and collaboration on this process to be paramount.

With our long-time experience and support we offer the following suggested improvements to the recommendation:

### **Summary**

The recommendation continues to improve, but more work is needed. The overall shortcoming of the committee recommendation is that it’s “processing centric”. This is primarily reflected in the suggested change to the definition of ‘chemical change’ and the draft guidance document classification of materials worksheet. The other major points covered in our very lengthy comments are:

- The proposed definition of chemical change is taken out of context and could be applied to the processing of nonagricultural inputs. We have provided an alternative revision that we feel accurately addresses the concerns expressed in public comment.
- The definition of nonagricultural needs to include wild harvest crops, and the definitions of ‘crop’ and ‘livestock’ will need revisions and/or further clarification.
- The classification of crop, livestock and handling materials should not be combined into one series of questions. Agricultural and nonagricultural considerations are not applicable to crop and certain livestock materials. While a synthetic determination is integral to all materials reviewed for approval, we feel that guidance and decision worksheets should be separated into crop, livestock, and handling material review.
- As recognized by the committee, the terms ‘significant’ and ‘insignificant’ need to be qualified as they apply to crop, livestock and handling materials. Oregon Tilth supports this effort.
- The term and definition of ‘natural source’ should be included with the proposed new definitions, and the term and definition of ‘generic’ should at least be included with the guidance document.
- In the worksheet example of Gellan Gum, the justification for classifying as synthetic appears to be in conflict with the proposed definition of ‘chemical change’. Clarification is requested.
- Commercial availability should be assigned to select materials listed on § 205.605 via annotations. We would like to see the NOSB and NOP continue to explore this option.

## **Addendum to November 6, 2009 Recommendation**

### ***Revision to the Definition of Chemical Change***

Oregon Tilth does not support the revision to the definition of **chemical change**.

The definition in the NOSB Recommendation has been revised to include the following:

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.

We feel that this change is taken out of context, or could be taken out of context. Public comment requested that the Board address the chemical changes that may occur during the processing of an agricultural product. The example given was toasted wheat kernels. The topic discussed by previous Boards relates to the processing of agricultural products, namely food back in the day, and the chemical changes that food may undergo during processing. Those chemical changes are allowed under OFPA 2103(21) and the NOP rule (§ 205.270). This concept however, generally built into the definition of chemical change, could have unintended consequences on the outcome of several non-organic nonagricultural crop, livestock and handling inputs.

#### **Example #1 – Crop Input: Potassium Nitrate**

**Nonsynthetic sodium nitrate** could be *mixed* with **nonsynthetic potassium chloride** and a chemical reaction would result in **potassium nitrate**, which has historically been classified and recognized as a synthetic fertilizer. Given the revised definition, and the fact that the definition

of processing includes “mixing”, the resulting compound could be classified as nonsynthetic. We’re confident that the revision to the definition of ‘chemical change’ was not intended to apply to the reaction of two nonagricultural minerals. However the intent will not be expressed in the plain language of the regulation therefore its application could be misinterpreted.

**Example #2 – Handling Input: Ethyl Citrate**

**Nonsynthetic ethanol** (fermentation and distillation) could be *mixed* with **nonsynthetic citric acid** and the resulting product would be **ethyl citrate**.

Historically the chemical reaction between two substances resulting in a 3<sup>rd</sup> new compound would be considered synthetic. As a result, ethyl citrate could be reviewed and approved for use in handling, and placed on the National List as a nonagricultural synthetic. However, in this situation the raw materials include an agricultural product (ethanol) available in organic form and an allowed § 205.605(a) National List material (citric acid). A certified organic form is possible; therefore ethyl citrate from the described source and process is most appropriately categorized as *agricultural* if it were to be reviewed for handling.

In order to capture the exception provided to the processing of agricultural products utilizing allowed NL materials, Oregon Tilth suggests the following definition for 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 of agricultural products as defined in § 205.270(a) using allowed § 205.605 or § 205.606 National List materials as minor ingredients or processing aids are not considered chemically changed.**

Incorporating this language into the definition of chemical change would do the following:

- In general non-organic crop, livestock and handling materials would be classified as synthetic if they undergo a chemical change as defined by the definition of synthetic.
- Nonorganic ***agricultural products*** processed using mechanical or biological methods, and minor ingredients or processing aids allowed under § 205.605 or § 205.606 would not be classified as synthetic. Accordingly a material classification as synthetic (nonagricultural) would not conflict with organic alternatives that may be available thus preventing preference for the certification and use of the organic form.
- The exception provided to agricultural products made using compliant materials, would align with the National Organic Program standard created for a processed organic product, and accordingly would not conflict with a mutually existing synthetic classification.

We would also like to point out that the proposed change to the definition of ‘Chemical Change’ was not incorporated into the definitions on page 15 of 19 in the Addendum to November 6, 2009 Recommendation.

## ***Proposed definition of Nonagricultural***

The Joint Committee recommends the following definition of nonagricultural:

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**.

Oregon Tilth generally supports this definition because it uses existing terms in the regulation such as crop, livestock, production, and handling. Therefore classification of agricultural products should stay within the context of OFPA and the Rule. It also allows the NOSB and program to clearly identify the types of organisms and systems that can be considered agricultural within the context of ‘crops’ and ‘livestock’ and in response to public comment and consumer demand. In order to provide better guidance, the definitions of ‘crop’ and ‘livestock’ may need additional clarification or revision, in order to adequately address commodities such as aquatic plants (algae, kelp etc.), fungi, yeast, and other organisms consumed by humans or livestock.

The NOP definition of ‘crop’ as written in the Final Rule effective June 17, 2010 specifically references “plant and parts of a plant”.

*Crop.* Pastures, cover crops, green manure crops, catch crops, or **any plant or part of a plant** intended to be marketed as an agricultural product, fed to livestock, or used in the field to manage nutrients and soil fertility.

Plants are living organisms belonging to the kingdom Plantae. Algae and Fungi however, both of which are managed and utilized by humans for food and livestock feed, are no longer members of the Plant Kingdom. Technically they are then without a home unless they are categorized as non-plant life under livestock. This poses problems because the large majority of the algae and fungi organisms utilized for food are more appropriately certified to the crop standard, the wild-crop harvesting standard, or the processing standards. This problem could be addressed by either revising the definition of ‘crop’ or by clarifying in the Guidance Document that ‘crop’ refers to any plant, part of a plant, or other “non-animal life” intended for human or livestock consumption. Additionally, the definition of ‘nonagricultural’ should be revised to reference wild-crop harvest in order to be clear and consistent with the scope of the NOP regulations. **Oregon Tilth proposes the following:**

**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 wild or domesticated crops or livestock.*

The NOP definition of ‘livestock’ as written in the NOP Final Rule effective June 17<sup>th</sup>, 2010 excludes aquatic animals:

**Livestock.** *Any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, **except such term shall not include aquatic animals** for the production of food, fiber, feed, or other agricultural-based consumer products.*

Oregon Tilth recognizes however that the NOSB Recommendation for the Aquaculture Standard addresses the exclusion of aquatic animals in the following revised definition consistent with the OFPA definition of livestock:

**Livestock** – *The term “livestock” means any cattle, sheep, goats, swine, poultry, equine animals used for food or*

*in the production of food, **fish used for food**, wild or domesticated game, or other non-plant life.*

Furthermore the definition of aquaculture encompasses the domestic production of **aquatic plants**:

***Aquaculture product.*** Any product of aquaculture, including but not limited to whole alive or dead aquatic animals, gutted fish, fillets and other forms of raw or processed meat, eggs for human consumption, eggs for reproduction, skin and other animal parts, and alive, **fresh and dehydrated aquatic plants**, either whole or processed. By-products from aquatic animals grown in aquaculture, such as fish meal, oil, silage, and hydrolyzed offal, are included.

**Oregon Tilth proposes the following definition of livestock (combined from the Access to Pasture Final Rule definition and the Aquaculture Recommendation definition):**

***Livestock.*** Any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; **fish used for food**; wild or domesticated game; or other nonplant life.

We believe that all definitions once completed and added up will account for the various types of food systems we are working with today and the innovations that may develop in the future. Terms such as non-plant life and non-animal life remain vague, but such terms seem necessary to accommodate the forgotten or not yet identified. Conclusively, the definitions of ‘agricultural product’ and ‘nonagricultural substance’ will accommodate *any* living organism and its appropriate production setting. Eligibility for certification depends on whether it can meet the NOP standards and the development of standards will be dictated by public comment and consumer demand.

### **Draft Guidance Document on Classification of Materials**

As proposed in our comments submitted in October 2004, Oregon Tilth strongly supports the creation of a Guidance Document to assist the NOP, NOSB, Accredited Certifying Agents and other industry stakeholders such as OMRI with material classification decisions. We agree that clear definitions, a Decision Tree and/or Decision Worksheet, and a narrative explaining the steps or questions in the Decision Worksheet are all necessary aspects to such a document.

Our concern with the Draft Guidance Document relates to the NOSB’s position that a relationship between the questions of agricultural versus nonagricultural and synthetic versus nonsynthetic are linked in some fashion, and therefore should be codified and formalized. While we agree that a relationship does exist between agricultural and synthetic, linking the questions together as a connected series and then applying those questions during the review of crop and livestock materials is confusing and often not applicable. During the review of allowed non-organic crop inputs for example, agricultural and nonagricultural determinations are not applicable. The same is generally the case when reviewing livestock inputs, with the exception of livestock feed ingredients where agricultural determinations become relevant.

The material review process for crop, livestock and handling, as supported by their separate sections within the regulation, is best broken down into their own unique set of questions. Examples are provided below and suggested alternatives are provided in the OTCO Material Classification Worksheets attached to our comments.

The draft guidance worksheet as written, tends to be “processing-centric” and will pose several difficulties to the crop and livestock sector. Additionally, the examples provided (gellan gum and lecithin) raise questions and present conflicting information.

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

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

*If NO, proceed to #2*

- **Crop Material** - This first question and subsequent answer **will not work for crop inputs and most livestock inputs**. This is a primary example of where the worksheet is designed for handling materials. If a crop material is under review and the answer is “YES” to this first question, then the crop material should be allowed as a nonsynthetic, provided it’s not rendered synthetic through further processing or formulation. A “YES” answer however, as provided in the NOSB worksheet, states that the substance should be petitioned to NOSB for review and classification. In actuality, if the answer is “YES”, the reviewer should proceed to Question #3. We believe that a worksheet specific to synthetic and nonsynthetic (crop and health care livestock materials) should be used (**See attached Synthetic / Nonsynthetic Determination Worksheet**).
- **Fermentation By-Products** – This class of products can range from beer or ethanol, to citric acid or acetone. We’re assuming, as stated in the recommendation, that the classification worksheet would only be used for materials whose classification is unclear. As a result, hopefully fermented foods that are generally recognized as agricultural would not need to be petitioned. However, we strongly encourage the NOSB to distinguish between fermented foods and beverages that are wholly consumed (agricultural), fermentation by-products such as microbial metabolites (further review needed) and the organisms that carry out a biological process (further review needed). **We have captured this distinction in the attached worksheet for Agricultural / Nonagricultural Determinations.**
- **Gellan Gum** – We’re unclear why gellan gum is not considered a product of a naturally occurring biological process. The example states that it’s a chemically processed biological product. Clarification is needed on when human intervention would nullify the classification as a naturally occurring biological product. It’s Oregon Tilth’s opinion that Gellan Gum is a product of a naturally occurring biological process, and subsequent questions are needed to determine the synthetic/nonsynthetic status. With the answer of “YES” however, we would need to turn the review over to the Board.

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

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

*If NO, proceed to #3*

Once again, this question is geared towards processing and is intended to address certified organic products that may have undergone chemical changes during processing. For example:

- **Lecithin, bleached** - We agree that NOP organic products are outside the scope of this review and do not need to be listed on the National List. **The question that needs to be asked when reviewing a nonorganic material for classification is whether the source and process could be certified?** If the only obstacle between an organic or nonorganic form is the use of organic agricultural material, then the substance should not be listed on § 205.605. Three lecithin examples were provided in the example worksheet, however none of the three included a nonorganic bleached lecithin produced using non-organic soybeans and hydrogen peroxide. If

this example were used, the results would have been as follows:

#1 – No it's not a product of a naturally occurring biological process. Go to #2.

#2 – No, it's not certified organic. Go to #3.

#3 – Yes, the bleaching chemically changes the lecithin. According to the recommended definition of 'chemical change' the identity change would be "substantive" because the agricultural material was processed with a synthetic. Stop – Substance is Synthetic.

Herein lies the problem. The bleached lecithin would be classified as synthetic (nonagricultural) under § 205.605 where commercial availability cannot be applied, according to the NOP. Although an organic form could be made using organic soybeans, there would be no regulatory incentive to create it or use it under a listing where commercial availability does not apply. This problem could be remedied by adopting Oregon Tilth's proposed definition of 'Chemical Change' as it appears on pg. 3 of our comments.

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

*If YES, Stop -- Substance is SYNTHETIC.*

*If NO, proceed to #4*

This question is relevant to crops, livestock and handling and should be a central question included in all classification worksheets. While we have separated out the agricultural/nonagricultural decision worksheet from the synthetic/nonsynthetic worksheet, we have retained this question and applied it as criteria that would result in a substance losing its agricultural or nonsynthetic status. Oregon Tilth notes the definition of 'chemical change' provided in the Appendix A Worksheet and strongly encourages the definition to include our suggested revision.

Additionally, we are requesting clarification on the synthetic determination of **Gellan gum**. In the worksheet example, the substance is classified as synthetic because the extraction process manipulates functional properties. The example explicitly states that the extraction and formulation steps do not **alter the identity** of the gellan gum. The synthetic determination appears to be in conflict with the proposed definition of 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").

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

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

*If NO, proceed to #5*

Oregon Tilth agrees that guidance is greatly needed if a reference to "significant amount/level" is going to be used.

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

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

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

This question is relevant to crops, livestock and handling and should be a question included in all worksheets. The narrative provided however refers to the **evaluation of significant or insignificant**

**levels.** Again, this will need clarification.

**Question #6** *Does the substance originate from agriculture?*

*If YES, Stop – substance is AGRICULTURAL*

*If NO, Stop – substance is NON-SYNTHETIC*

This last question relates to agricultural and nonagricultural determinations, and brings us back to the core question of this discussion – What is agricultural? Questions #1 - #5 were arranged to weed out anything that is synthetic, or unclear and in need of NOSB review. The remaining substances would either be agricultural or nonsynthetic nonagricultural. However, a crop input does not need to originate from agriculture. If it's not on the National List it needs to be nonsynthetic, so this last question will create confusion. Again, this is an example of the impracticality of combining crop, livestock and handling material review into a single series of questions.

### **Suggested Decision Tree Worksheets**

Oregon Tilth strongly encourages the Board to distinguish between crop, livestock and handling inputs and reserve agricultural and nonagricultural considerations for handling materials and livestock feed only. We have created decision tree worksheets that we feel would best serve the industry in a Classification of Materials Guidance Document. They are largely based off of the work of the MWG while combining the work of the NOSB April Recommendation with new ideas of our own. The OTCO Decision Tree Worksheets incorporate the following:

- A Substance Evaluation Overview as was suggested by the MWG in the March 2008 presentation. The overview provides a map to the decision worksheets to be used. The first question asked is whether agricultural or nonagricultural determinations are relevant. If they are not, the only determinations that need to be made are synthetic and nonsynthetic.
- The term and definition 'natural source' as was suggested by the NOP and the MWG. This term is used rather than "products of naturally occurring biological processes". We have also provided for microorganisms and isolated fermentation byproducts. Fermented foods are distinguished from fermentation by-products and from the organisms that carry out a naturally occurring biological process.
- The term and definition 'generic', as was suggested by the MWG. Oregon Tilth would like to see this added back into the Guidance Decision Tree we are suggesting because the term 'generic' is used within the worksheets and it's widely recognized as an OMRI term the industry refers to. We acknowledge that the NOSB has not recommended this term to be added to the regulation, but feel it should at least be added to the Guidance Document.

### **Conclusion**

The organic industry needs clear guidance on material review and classification. Clear definitions and evaluation criteria needs to be made available as soon as possible and used consistently by the NOP, NOSB, ACAs and all other NOP material review organizations. We recognize that synthetic and nonsynthetic determinations may continue to be unclear for some materials, but that the recommended definitions and worksheets included with our comments will considerably increase the consistency by which determinations are being made. The guidance documents can be improved and refined with time, and the best way to do this is by putting them to work. With respect to synthetic and nonsynthetic determinations, Oregon Tilth supports the basic approach that was taken by the NOSB and NOP in the March 9, 2006 Recommended Framework to Further Clarify the Definition of Synthetic, and the work that was furthered by the MWG. We believe the

current committee decision worksheet has strayed too far from the work accomplished by previous Boards and by the MWG.

With respect to agricultural and nonagricultural determinations, there are clearly some materials where classification is not clear, or agreement can't be met, and/or classification as agricultural will create a significant disruption to organic livestock production. We see that organic certification is possible for inputs that have historically been viewed as nonagricultural, yet a reclassification as agricultural will conflict with traditional practices and/or conflict with certain sections of the regulation. ***The crux of the matter is that a commercial availability clause does not exist for agricultural products used in livestock feed.*** We also do not believe that the requirement to organic agricultural feed was intended to apply to nonsynthetic feed additives and supplements. This is creating serious challenges for the classification and certification of yeast and microorganisms, kelp, and fishmeal. In some cases the supply of organic doesn't even begin to match the demand, and in other cases certification standards do not exist.

There is also the problem of broad category listings such as natural flavors. There are thousands of different natural flavors available, and over 1500 organic flavors on the market. Trying to parse out the agricultural from the nonagricultural in order to retain certain ones on § 205.605 while moving hundreds to § 205.606 individually is a complete nightmare if not impossible. The annotation requires that flavors be derived from nonsynthetic sources therefore organic certification is inherently possible although they are listed as 'nonagricultural'. Additionally, the NOSB Recommendation included a stepwise organic preference approach.

Oregon Tilth strongly believes that the most immediate solution is to identify the few items on § 205.605 of the National List that are creating a roadblock to industry guidance, and apply commercial availability as appropriate through the use of an annotation. This would address yeast/microorganisms and natural flavors. § 205.270(b)(1) already states that nonagricultural substances allowed under § 205.605 may be used in an organic product when an organic form is not commercially available. In addition § 205.301(f)(6) states that all products labeled as organic must not be produced using nonorganic ingredients when organic ingredients are available. And to seal the deal, the NOP has specifically affirmed the organic production and certification of both yeast and natural flavors listed on § 205.605. If the International Astronomical Union can decide that Pluto is not a planet, we believe that that the NOP can assign commercial availability to agriculturally derived substances listed on § 205.605.

Alternatively, or in addition to, Oregon Tilth strongly encourages the NOSB and NOP to explore the possibility of creating a commercial availability clause for minor supplemental livestock ingredients that are agricultural yet commercially unavailable in organic form. Examples include yeast, kelp and fishmeal, and any other organism where organic certification has only recently become possible due to finalization of standards, or the substance is classified as agricultural after years of classification as nonagricultural. In these situations organic supply will not meet the immediate demand. We have tried to work these considerations into our Decision Worksheets acknowledging this as an area where additional thought and exploration is needed.

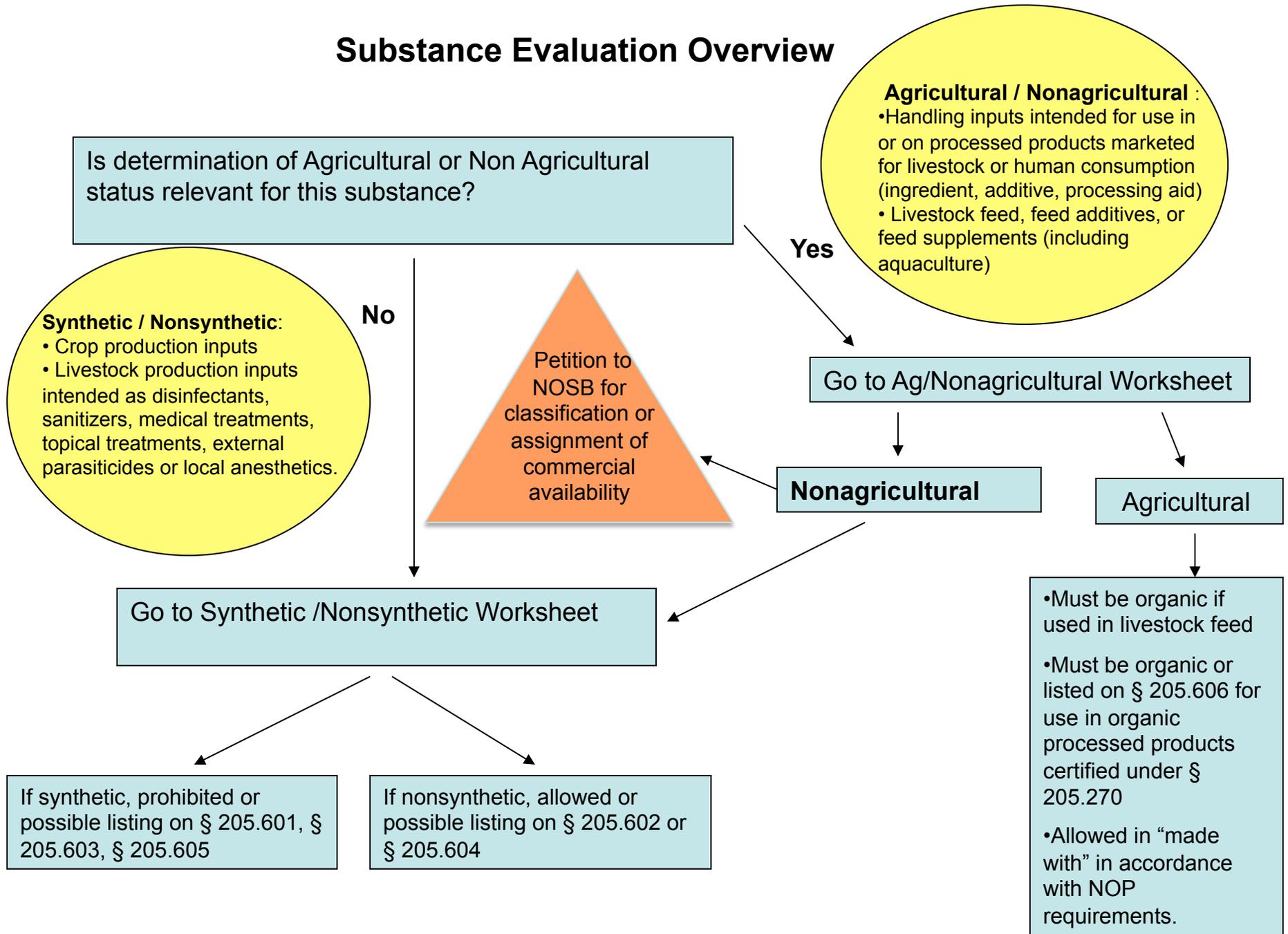
Once again, thank you for your close consideration of our comments.

Oregon Tilth, Inc.

Attached:

- A. Substance Evaluation Overview and Definitions
- B. Synthetic / Nonsynthetic Decision Tree Worksheet
- C. Agricultural / Nonagricultural Decision Tree Worksheet.

# Substance Evaluation Overview



Is determination of Agricultural or Non Agricultural status relevant for this substance?

**Agricultural / Nonagricultural :**  
 • Handling inputs intended for use in or on processed products marketed for livestock or human consumption (ingredient, additive, processing aid)  
 • Livestock feed, feed additives, or feed supplements (including aquaculture)

**Synthetic / Nonsynthetic:**  
 • Crop production inputs  
 • Livestock production inputs intended as disinfectants, sanitizers, medical treatments, topical treatments, external parasiticides or local anesthetics.

Petition to NOSB for classification or assignment of commercial availability

Go to Ag/Nonagricultural Worksheet

Nonagricultural

Agricultural

Go to Synthetic /Nonsynthetic Worksheet

If synthetic, prohibited or possible listing on § 205.601, § 205.603, § 205.605

If nonsynthetic, allowed or possible listing on § 205.602 or § 205.604

• Must be organic if used in livestock feed  
 • Must be organic or listed on § 205.606 for use in organic processed products certified under § 205.270  
 • Allowed in “made with” in accordance with NOP requirements.

## Proposed Decision Tree to Distinguish Synthetic and Nonsynthetic Substances, cont'd.

### **Underlined items are defined here:**

**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 of agricultural products as defined in §205.270(a) using allowed § 205.605 or § 205.606 National List materials as minor ingredients or processing aids, are not considered chemically changed.**

**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.

**Generic:** The common and familiar non-proprietary name of a substance.

**Livestock:** Any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; fish used for food; wild or domesticated game; or other nonplant life.

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

**Natural source:** Naturally occurring mineral, plant, or animal matter used to obtain non-synthetic inputs for organic production or handling.

**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 wild or domesticated crops or livestock**.

**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).

## Synthetic / Non-synthetic Determination Worksheet

**SUBSTANCE:**

**USE, APPLICATION, OR FUNCTION:**

**(1). Is the substance manufactured or extracted from a natural source?**

*If Yes, proceed to (3). If No – proceed to (2).*

**(2). Is the substance created by a naturally occurring biological process?**

*If Yes, proceed to (3). If No, Stop – Substance is Synthetic.*

**(3). Is the substance chemically changed as a result of the process by which the substance is manufactured or extracted from its source?**

*If Yes, proceed to (4). If No, Stop - Substance is Synthetic*

**(4). If synthetic inputs are used during processing, do they remain in the final substance at a significant level?**

*If Yes, Stop – Substance is \*Synthetic. If No, proceed to (5).*

**(5). Is the substance formulated to commercially produce the generic substance?**

*If Yes, proceed to (6). If No, Substance is NON - Synthetic*

**(6). Are all of the *components present* in the formulation non-synthetic?**

*If Yes, Stop - substance is NON-synthetic. If No, Stop, the substance is \*Synthetic. If **unknown**: Repeat step 1 for that component.*

**Conclusion:**

Non-synthetic

Synthetic

**Explain:**

*\* Unless synthetic component(s) are allowed on the National List for the intended use of the product.*

General description of manufacturing

*References:*

## Agricultural / Nonagricultural Determination Worksheet Handling Inputs and Livestock Feed

**SUBSTANCE:**

**USE, APPLICATION, OR FUNCTION:**

**(1). Is the substance a microorganism, a microbial metabolite or an \*isolated fermentation by-product?**

*If No, proceed to (2). If Yes, Stop, substance is defaulted to NONAGRICULTURAL – proceed to Synthetic / Nonsynthetic Decision Tree Form, or if commercially available as organic, petition to NOSB for consideration, reclassification, or assignment of commercial availability.*

**(2). Does the substance/product originate from agriculture (see definitions of agricultural product and nonagricultural substance)?**

*If Yes, proceed (3). If No, product is NONAGRICULTURAL - proceed to Synthetic / Nonsynthetic Decision Tree Form.*

**(3). Is the substance chemically changed as a result of the process by which the substance is manufactured or extracted from its source?**

*If No, proceed to (4). If Yes, Stop - Substance is Synthetic*

**(4). Is the substance formulated to commercially produce the generic substance?**

*If Yes, proceed to (5). If No, Stop –substance is AGRICULTURAL.*

**(5). Are all of the *components present in the formulation* non-synthetic?**

*If Yes, Stop - substance is Agricultural. If No, evaluate synthetics for allowance and allow or prohibit accordingly. If synthetic status is **unknown**: Refer to Synthetic / Nonsynthetic Decision Worksheet.*

*\*Isolated fermentation by-products do not include fermented foods or beverages that are wholly consumed. Fermented foods and beverages such as beer, sauerkraut, Koji, and miso originate from agriculture and are fermented into the finished and consumed product.*

**Conclusion:**

Non-synthetic

Synthetic

**Explain:**

General description of manufacturing

*References:*

**Underlined items are defined here:**

**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 of agricultural products as defined in §205.270(a) using allowed § 205.605 or § 205.606 National List materials as minor ingredients or processing aids, are not considered chemically changed.

**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.

**Generic:** The common and familiar non-proprietary name of a substance.

**Livestock:** Any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; fish used for food; wild or domesticated game; or other nonplant life.

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

**Natural source:** Naturally occurring mineral or biological matter used to obtain non-synthetic inputs for organic production or handling.

**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 wild or domesticated crops or livestock.

**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).