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April 20th, 2009

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-TM-09-0014

- Petitioned Materials
- Clarification of Materials
- 100% Organic Label
- Status of Various Recommendations

Oregon Tilth thanks the National Organic Standards Board for the opportunity to comment on agenda items for the May 2009 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.

Petitioned Materials for Handling (§ 205.605 and § 205.606)

Oregon Tilth supports the addition of Sodium Chlorite and Myrrh Essential oil to the National List. We also agree with the committee recommendation to not add Propionic Acid, Propane, Chicory root, and Red Corn Color. We disagree with the committee's recommendation on the removal of all fluid lecithin. We offer the following elaborations on Red Corn Color and Lecithin:

Petition and review for Red Corn Color

We understand the petition for the Red Corn Color did not provide sufficient information on the availability of organic alternatives. Should this information be provided during the meeting, Oregon Tilth once again strongly encourages the NOSB to consider the joint comments submitted by OTCO and PCO at the last two NOSB meetings (comments are attached as an addendum). The initial request for clarification was sent to the NOP in May 2007. We have received ZERO response, yet decisions are being made everyday and to the best of our knowledge inconsistently. In summary, the majority if not all of the colors currently on the National List are manufactured or formulated using nonorganic agricultural and nonagricultural carriers, standardizing agents and processing aids. The NOSB recommendations have not addressed whether the use of such substances must be organic and/or on the National List. The NOSB Recommendations focus on

source material and extraction process but they do not address the commonly used carriers and additives. Certifiers have been waiting for a response to this issue for two years. We respectfully request that the NOSB and/or the NOP address this issue immediately.

Removal of lecithin from the National List

Oregon Tilth does not support the removal of bleached or unbleached lecithin from the National List. We believe that bleached lecithin should be moved from § 205.605 to § 205.606 and unbleached lecithin (all forms regulated under 21 CFR 184.1400) retained on § 205.606. Complete removal of one or all forms is premature of stable market availability in quantity, quality and form.

Bleached lecithin is derived from an agricultural product and can be processed using materials allowed on the National List. It is reportedly available in organic form therefore its listing as a non-agricultural substance on § 205.605 is no longer appropriate. However, based on the information we diligently collect from our clients, the supply of organic lecithin (bleached, unbleached, liquid, powdered, and granular) is **fragile** therefore lecithin, bleached and unbleached, should be listed at § 205.606 and the status of its commercial availability left to the discretion of accredited certifiers.

To date Oregon Tilth is aware of ONE NOP supplier of organic lecithin, and as reported from our clients the products offered are still in the testing phase, not consistently available, or available in a form that is not suitable. For example, the organic liquid lecithin is reportedly very viscous and has created significant equipment operating (pumping) difficulties. New heating devices, tank systems, flow meters, and pumps offer potential solutions but these types of changes do not happen overnight. Another extremely important consideration is the availability of non-allergenic forms of lecithin. The only organic form of fluid lecithin available is soy-based. Many operators are in need of sunflower or safflower based lecithin.

Oregon Tilth strongly supports the commercial availability restrictions placed on substances listed on § 205.606. The improvement on the ability to enforce the requirements of § 205.606 were addressed by the NOSB in the guidance document titled 'Further Guidance on the Establishment of Commercial Availability Criteria' dated 11-30-07.

In order for this guidance document to better serve the organic community we ask that it be approved by the NOP and posted on the NOSB and NOP website as official guidance. Circulation and use of this document we believe will address many of the concerns surrounding lecithin and the effectiveness of the commercial availability clause.

Clarification of Materials

Oregon Tilth thanks the Joint Materials and Handling Committee for their continued efforts on this very difficult subject matter. The lack of clear criteria is causing inconsistent decision making throughout the industry. This leads to certifier shopping, embarrassment, lawsuits, headaches, disenchanted organic consumers and constant complaining. More than anything, certifiers and NOSB members and the NOP need to be making consistent and transparent decisions. Clarification of definitions and decision-making tools such as decision trees will allow for a documented process and uniform outcome. Even if the clarification is not perfect, at least there will be uniform imperfection encouraging a level playing field.

Prior to addressing microorganisms and products of microbial fermentation, we want to address the committee's current thinking on the concept of "agricultural synthetic". Page 2 of the Committee Discussion Document states:

"We reject the idea of an agricultural synthetic classification".

We are concerned by the dismissal of this concept. There are agricultural products currently certified "organic" to the NOP processing regulations that could be classified as "synthetic" if they were evaluated against the NOP definition of "synthetic". The NOP definition of processing and the allowed materials on § 205.605 and § 205.606 can and will continue to bring about chemical changes when applied to raw agricultural material. The definition of synthetic does not account for chemical changes brought about by physical or mechanical methods or by allowed handling inputs. For example, during the production of maltodextrin, the wet milling process causes the agricultural material to undergo protein configuration changes. Similarly, glycerin derived from vegetable oil will undergo chemical changes under the conditions of heat and water. The current handling regulations allow for such processes and accordingly the resulting chemical change is also allowed.

This consideration dates back to the early 90s and was embraced by subsequent Boards and captured in the 2005 NOSB guidance on the clarification of synthetic. Rejecting this idea will therefore ignore history and reject allowances found in our current handling regulations.

From the 6/14/93 Handling Committee Working Draft on the National List:

The first question is whether the normal effects of processing food by processing methods specifically allowed in the OFPA, such effects being known to generate chemical changes in the food, thereby render the food "synthetic".

The committee's consideration and thus interpretation of the term synthetic led to the following statement:

"The "term" synthetic shall not be applied to an otherwise non-synthetic substance that is formulated or manufactured by processing, as processing is defined in the Act".

From the NOSB August 16th, 2005 Clarification Document on Synthetic vs. Nonsynthetic

The definition of synthetic as defined in the regulation is clarified in this document as it applies to adding substances to the National List (205. 601-606). Processing of an agricultural product by a handling operation or food may involve synthetic and nonsynthetic substances on the list and these substances along with the agricultural component(s) may undergo chemical changes as they are processed. These chemical changes are allowed under OFPA 2103(21) and the NOP rule (205.270).

Oregon Tilth agrees that the concept or rather the terminology of "agricultural synthetic" is problematic. Instead the concept of a **processed agricultural product** must be embraced. **IMPORTANT** – the context of such idea occurs **only in a certified handling facility**. It does not apply to non-certified

operators manufacturing non-organic crop, livestock or handling inputs. The exception granted to materials or products undergoing a chemical change is one that applies only to a certified handling operation under the allowances provided by OFPA and the NOP Rule.

205.1 Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Oregon Tilth asks that the NOSB reconsider this topic as an important point of clarification. The following question must be answered: If something is synthetic under one condition (non-certified manufacturer of an input) can it also be organic if produced in a certified handling facility in accordance with the applicable sections of the regulation? Oregon Tilth believes the answer is yes.

Agreement with the above circumstances is important because it will help encourage the production of organic products and allow the petition process to take its course. For example, minor ingredients derived from agricultural material may be evaluated by the NOSB and placed on the National List as a nonagricultural synthetic. However, it is entirely feasible that the same ingredient could be produced in a certified handling facility using organic agricultural material and compliant minor non-organic ingredients. The product will have undergone chemical changes but they are allowed under the definition of processing. At that time the NOSB should expect a petition for removal from §205.605 due to the availability in organic form.

Microbes and Microbiological Fermentation and the two proposed NOSB Options:

The NOSB needs to be more specific with their terminology. The document refers to “microbiological materials” and the “products of microbiological fermentation”. What are *microbiological materials*?

There are microorganisms and there are products of microbial fermentation. They should not be discussed as one in the same. And “products of microbiological fermentation” needs to be further defined. Products of microbiological fermentation for example include but certainly are not limited to the following: tempeh, beer, wine, ethanol, Sake, yogurt, citric acid, erythritol, kefir, xanthan gum, and lactic acid. We can’t imagine that the NOSB intended to call beer or yogurt nonagricultural? We suggest that the NOSB identify the materials and the processes that would result in a nonagricultural fermentation by-product. Otherwise, products of microbial fermentation consumed by humans and livestock should generally be considered agricultural.

Option #1 – Define microorganisms as nonagricultural and use annotations to provide direction.

Oregon Tilth does not support this option and we do not think this approach would clean up the debate. Annotations are difficult to interpret and enforce, and the verification process is generally based on declarations/affidavits vs. inspection/3rd party certification. Additionally, yeast manufactures, for example, would invest significant resources into the use of organic substrate and compliant materials (essentially meet the requirements for an organic product), without having the benefits of marketing their products as organic.

Option #2 – Define microorganisms as agricultural but no certification until standards are developed.

While Oregon Tilth cannot positively point to yeast as being “agricultural” in a traditional sense, we can say yeast are living organisms and their production relies primarily on agricultural material (greater than 95% at formulation) that is available in organic form. We see no reason why they can’t be viewed as “non-plant life”. We recognize that yeast production has definite agricultural and environmental implications and we feel that these should and can be addressed by applying organic principles to yeast used in organic food. We also recognize that the difference in composition requirements under § 205.237(a) and § 205.606 creates an unlevel playing field that would create undue burden on certain sectors of the industry (namely livestock) if yeast and other microorganisms were classified as agricultural and livestock producers were required to use organic forms only without any transition period or commercial availability clause.

We believe the problem can be addressed by the following approach:

1. Continue to list microorganisms and yeast as nonagricultural while standards are developed specific to organic production practices. Once standards are developed, microorganisms can be classified as agricultural. This will allow a transition period for the entire industry.
2. In the interim, the NOP should clarify that yeast and other microorganisms ***can currently be certified*** based on the product composition requirements of § 205.301 (b or c) and the handling requirements of § 205.270. This is consistent with the allowance to certify “natural flavors” currently listed as nonagricultural. The NOP describes this situation as the “imperfect world” we live in. If flavors can be listed as nonagricultural AND be certified as organic, yeast should also be granted this exception. This approach would also facilitate recognition for organic yeast produced under the EU regulations. If the industry is unclear on the standards that should be followed when producing and certifying yeast, a guidance document could be developed. Oregon Tilth currently has such a document and is willing to support such an effort.
3. Clarify the term “organic” must not be used to modify the term “yeast”. In other words, the labeling of yeast should reflect an organic “product”, but the yeast itself cannot be represented as organic. During the interim of standard development, this would make a clear distinction between the yeast cell itself, and the formulation used to reproduce the yeast cell. Example labeling options are as follows:
 - A. Yeast – “made with organic (specified organic substrate/ingredients)”. Ingredients statements can list: Yeast (grown on organic (specified substrate)).
 - B. Organic Super Y – Yeast Extract Powder. Ingredients statements can list: Yeast (grown on organic (specified substrate)).

100% Organic Label Claim

Oregon Tilth does not believe the use of inert atmospheric gases ***for packaging applications*** should disqualify a product from making a 100% organic claim. The gases do come in contact with product, but they do not become incorporated into the food and are no longer present by the time the food is consumed. Nitrogen is used as an example below; the same concept can be applied to carbon dioxide and argon.

Nitrogen Example

Nitrogen is regulated as a direct food substance under 21 CFR 184.1540. It is not regulated as an additive, it does not need to be labeled as per FDA labeling regulations, and it's not "added to a food during processing" as described in the NOP definition of a processing aid. The CFR listed use is as follows:

Nitrogen is a relatively inert gas and helps to enhance product stability by displacing oxygen and thus reducing oxidation. Under pressure, it is a superior propellant without ozone-depleting properties.

The use of nitrogen in this application is reducing the amount of oxygen in contact with the food in packaging rather than having a technical effect on the product during processing. In support of this reasoning, the FDA defines the technical functional effect of oxygen displacement under 21 CFR 170(3)(25) whereas the technical functional effect of a processing aid is described under 21 CFR 170(3)(24).

As supported by the regulatory language in § 205.301, loss of the 100% organic label occurs when a non-organic substance listed under § 205.605 or § 205.606 is used during **processing** and functions as a **ingredient** or as a processing aid.

Inert atmospheric gases used for packaging applications do not meet the NOP definitions of "ingredient" or "processing aid", therefore they should not impact the 100% Organic labeling claim.

Status of Various Recommendations

Oregon Tilth is concerned about the status of several NOSB Recommendations that provide greatly needed industry guidance. It would be very beneficial to the industry if the NOP website contained a home for officially approved NOSB Guidance Documents. We urge the NOP to address the work of the NOSB and if approved, post the following guidance documents prominently on the NOP website:

- November of 2007 - Commercial Availability Guidance Document
- October 2006 – Listing of Certifying Agent's Name on Packaged Products
- November 2006 - Use of Compost, Vermicompost, Processed Manure and Compost Tea.

Oregon Tilth encourages the NOP to complete their process and looks forward to further clarification to ensure the uniform implementation of this standard.

Once again, Oregon Tilth would like to thank the NOSB for their ongoing work and commitment to the organic industry. We offer our support.

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Oregon Tilth, Inc.