



November 3rd, 2008

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-AMS-08-0083

Oregon Tilth thanks the National Organic Standards Board for the opportunity to comment on agenda items for the November 2008 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.

We offer comments on the following topics:

***Organic Pet Food***

Modifications to the pet food recommendation are needed.

The proposed regulatory language in § 204.237(c): 1) implies that all agricultural ingredients in the “made with” category must be organic; 2) does not provide an exception for ingredients listed on § 205.606; and 3) does not specify whether allowed substances under § 205.603 need to be nonsynthetic or more specifically nonagricultural and nonsynthetic.

Furthermore, § 205.301(g)(2) contains confusing language with respect to the use of non-synthetic processing aids. § 205.301(g)(2) states that any remaining product ingredients or processing aids must be organically produced (we assume this means any ***agricultural*** ingredients or processing aids), unless not commercially available in organic form and included on § 205.606, or must be nonsynthetic substances or synthetic substances in accordance with § 205.237(c). § 205.237(c) states that non-synthetic and synthetic substances allowed under § 205.603 and § 205.605 may be used as feed additives and supplements. It goes on to say that substances prohibited under § 205.301(f) may not be used, with the exception of nonsynthetic processing aids.

Given the above, Oregon Tilth requests that the language in the pet food standard clearly address the following two questions:

1. Do nonsynthetic feed additives and supplements allowed under § 205.603 need to be nonagricultural, or do they simply need to be nonsynthetic (agricultural or nonagricultural)?
2. Do nonsynthetic nonagricultural processing aids used during the manufacturing of an ***organic*** pet food product need to be on the National List at § 205.605 or § 205.606 or may they simply be nonsynthetic?

Question number one has been an ongoing point of confusion and debate with respect to the regulation of livestock feed. The NOP clarified that all agricultural products fed to livestock must be organic, including supplements and additives. The clarification posted on the Q & A section of their website is further supported by the language added to the NOP Access to Pasture (Livestock) Proposed Rule (Federal Register Vol.73, No. 207/Friday, October 24, page 63607):

§ 205.237(a). The producer of an organic livestock operation...Except, That, synthetic substances allowed under §205.603 and nonsynthetic substances may be used as feed additives and supplements, **Provided, That, all agricultural ingredients in such additives and supplements shall have been produced and handled organically.**

Question number two addresses whether § 205.301(f) relates to both processed human foods and livestock feed. If it relates to both, then processing aids used during the manufacturing of pet food labeled 100% organic would need to be organic and livestock feed labeled 'organic' would need to be processed using processing aids on § 205.603 or § 205.605. Our reading of the proposed regulation is that the Handling Committee is providing an exception to nonsynthetic nonagricultural processing aids; they may be used regardless of whether they are on the National list. Agricultural processing aids however must be organic.

Generally speaking, Oregon Tilth views the pet food regulations to be more akin to the regulations for human food vs. the livestock feed regulations. They largely follow the labeling and composition standards for human food, the major exception being additives and supplements in which § 205.603 is referenced. Combining pet food with livestock under the same heading is a recipe for confusion. We feel pet food would be best placed under its own section, namely § 205.240.

For better clarity, the following modifications are suggested (note that changes were made to the existing text in the recommendation under § 205.237; we simply gave this section a new heading):

#### **§ 205.240 Pet food.**

Pet food must be composed of agricultural products that are organically produced and, if applicable, organically handled: Except that, nonagricultural nonsynthetic substances, and synthetic substances allowed under §205.603, and § 205.605 may be used as feed additives and supplements provided they are allowed by the FDA in animal feed. Nonorganic agricultural ingredients allowed under § 205.606 may be used in products labeled organic provided they are commercially unavailable in organic form and allowed by the FDA in animal feed.

205.301(g)2. *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural ingredients. Any remaining agricultural ingredients or processing aids must be organically produced, unless not commercially available in organic form and included on § 205.606. Nonagricultural substances must be used nonsynthetic substances or synthetic substances in accordance with § 205.240. No products may be produced using prohibited practices or substances specified in § 205.301(f), except that nonsynthetic processing aids may be used. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

205.301(g)3. *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."*

Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. Nonorganic nonagricultural ingredients must be in accordance with § 205.240. No products may be produced using prohibited practices specified in paragraphs (1), (2), (3), (5), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.12.

***Petition to remove 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.

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 is no longer appropriate. To date there is **ONE** 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 common response is that operators need to use non-allergenic forms of lecithin. The only organic form of lecithin available is soy-based lecithin.

Additionally, we have on record the following correspondence that was sent in **September of 2008** from a Clarkson representative:

“I was at the plant last week for another round of bleached lecithin testing. We have ordered equipment and depending on it's delivery and installation will determine when samples/pricing are available. We are now targeting end of 4th quarter to roll out the bleached organic lecithin in the market place”.

The Clarkson petition dated in **June 2008** states the following:

“Since then, the supply of organic lecithin has evolved to the point that there are now certified organic lecithins available to replace the need for non-organic bleached Lecithin”.

The claim made in the petition does not agree with the information Oregon Tilth has on-hand.

Oregon Tilth strongly supports the commercial availability restrictions placed on substances listed on § 205.606. The existence of the commercial availability clause allows for our industry to grow and transition. The commercial availability concept enables manufacturers to develop and offer a wide-range of organic products in the absence of a reliable and consistent supply of minor ingredients while at the same time ensuring that organic forms are used when production and supply catch up with demand.

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 (form, quality, and quantity) left to the discretion of accredited certifiers.

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

***Clarification of Materials***

Oregon Tilth thanks the tireless efforts of the Material Working Group.

With respect to the MWG Discussion Paper, Oregon Tilth would like to reiterate key concepts that should remain central to the discussion as we move forward:

1. The definition of organic production is a production system that is managed in accordance with the ACT and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.
2. § 205.605 of the National List should be reserved for substances that are technically impossible to be organically produced. Technically *possible* candidates *include* anything extracted, isolated, or separated from agricultural material, or, anything composed at formulation of 95% agricultural material available in organic form.
3. The term synthetic should not include the effects of normal food processing activities. In other words the term “synthetic” should not be applied to an otherwise non-synthetic substance that is formulated or manufactured by processing, as processing is defined in the Act. In this respect, there is no such thing as a synthetic agricultural product, but rather a “processed agricultural product”.
4. The term organic is related to the process of production and handling, rather than the characteristics of the resulting product.

At this point in time we feel that Option #3 best captures the key concepts presented above. While Option #4 may involve significant rearrangement to the structure of § 205.605 and § 205.606, we feel it’s worth careful consideration as the suggested changes could harmonize nicely with the work the CAC committee is doing on guidance for use of the 100% organic label.

On the yeast front we would also like to reiterate the message we have stood by for many years. Yeasts are living organisms and their production relies primarily on agricultural material (greater than 95% at formulation) that is available in organic form. Yeast may not be “grown on a farm” but yeast products can be manufactured in accordance with the standards for a processed organic product. 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. In this respect, yeast should be eligible for organic certification and labeled as ‘organic’.

While Oregon Tilth strongly believes the handling requirements of § 205.270 provide adequate standards for certifying organic yeast, we accept that the larger community may feel more comfortable if organic yeast guidelines are further defined. The appropriate place to house such guidelines is in a guidance document that would be circulated by the NOSB for public comment, adopted by the NOP, and posted to the NOP website. Oregon Tilth offers our assistance in creating such guidelines.

With respect to the discussion on synthetic and non-synthetic, we encourage the Board to persevere with the NOSB Clarification documents of August 2005 and the NOP Recommended Framework to Further Clarify the Definition of Synthetic document of March of 2006. Clarification of synthetic and nonsynthetic is one crucial piece of the puzzle that will allow the work on agricultural vs. nonagricultural to be completed.

#### ***Petitioned items for § 205.606***

Oregon Tilth urges the NOSB Handling Committee to consider a few vital nuances to the petitions for Chlorella and Dumontiaceae algae. We understand that the petition for the Chlorella did not provide sufficient information about the organic chlorella on the market and the petition for the Dumontiaceae did not address obstacles preventing the materials from being produced in a certified form. Should this information be provided during the meeting, Oregon Tilth requests that the following also be considered:

- The handling committee states that Chlorella and Dumontiaceae are agricultural because they are photosynthesizing plants. However, they are also classified as a single celled algae, which can be categorized as a microorganism and potentially allowed under § 206.605(a). We also note that this photosynthesizing plant is being cultivated in hermetically sealed tanks. While we do not believe that such an environment should prevent a product from being classified as agricultural and/or organic, we recognize this to be an on-going debate surrounding hydroponics, yeast and other living organisms that are not cultivated in a soil-based system. We urge

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the NOSB to very specific and transparent with the guidelines and thought process used when classifying materials as agricultural.

- The Dumontiaceae algae are wild-harvested from the bottom of the Pacific Ocean. Oregon Tilth fails to see how this product could ever meet the NOP wild-crop harvesting practice standard with respect to contamination prevention. Ingredients that technically cannot be certified organic should not be placed on § 205.606.

Once again, thank you for receiving our comments.

Oregon Tilth, Inc.