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March 19, 2013

Ms. Michelle Arsenault

National Organic Standards Board

USDA-AMS-NOP

1400 Independence Avenue, SW

Room 2648-So, Ag Stop 0268

Washington, DC 20250-0268

Docket: AMS-NOP-12-0070

RE: Handling Subcommittee Proposal– Other Ingredients

Dear Ms. Arsenault,

Thank you for this opportunity to comment on the Handling Subcommittee's proposal for the assessment of other ingredients used in ingredients allowed on the National List.

Stonyfield supports the proposal of the Handling Subcommittee on this issue. We thank the Handling Subcommittee for developing a proposal that allows for a transparent and thorough review of other ingredients, without creating a new burden for the petition and sunset review processes. Stonyfield submitted comments on the Handling Subcommittee's Other Ingredients Discussion Document at the Fall 2012 NOSB meeting; those comments are attached for your reference.

Stonyfield, now in its 30th year, is the world's leading organic yogurt company. Its certified organic yogurt, smoothies, milk, cultured soy, frozen yogurt and ice cream are distributed nationally. The company advocates that healthy food can only come from a healthy planet. Its use of organic ingredients helps keep over 200,000 farm acres free of toxic, persistent

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pesticides and chemical fertilizers known to contaminate soil, drinking water and food.

Stonyfield would like to emphasize our support for the comments submitted by the Organic Trade Association on this topic, including the changes and clarifications suggested in those comments. We agree with the Handling Subcommittee's assessment that while the overall ingredient review process is already quite rigorous, improvement and harmonization of this process would be beneficial. The NOSB has had a history of consistently reviewing other ingredients in the substance petition and sunset processes, however the establishment of a more clear and consistent process will achieve several goals that are beneficial to all participants in the organic supply chain, from producer to processor to consumer:

- **Transparency:** By ensuring that the NOSB identifies and reviews other ingredients, either individually or categorically, in the initial or sunset review process, this will clearly show that all components of a substance have been reviewed as part of the substance review.
- **Consistency and predictability:** The Handling Subcommittee's proposal outlines steps that will be taken each and every time a substance that contains other ingredients is reviewed. A checklist of questions that address the role, essentiality, and viability of alternatives to other ingredients will ensure that other ingredients are always evaluated in the same way. As OTA stated in their comments, this checklist should be developed in accordance with OFPA and 7 CFR 205 and the checklist should be available for public comment before it goes into use. We agree with OTA that this checklist should serve as background information for NOSB only, and final guidance about other ingredients should be published by NOP. By establishing a standardized process for evaluating other ingredients, processors such as Stonyfield who rely on substances on the National List that contain other ingredients, like dairy cultures, will know what to expect for the review of any other ingredients in substances we use that are on the National List.
- **Integrity:** By setting up a process that ensures that all other ingredients are evaluated: (1) in the same way, (2) in accordance with the guidelines set out in OFPA and 7 CFR 205, and (3) in a way that anyone can easily find out what types of other ingredients are allowed in a substance by consulting NOP guidance, the NOSB and

NOP can codify a more transparent, consistent review process that fosters and strengthens the integrity of the organic standard.

We agree that the NOSB has the authority to set restrictions on the use of other ingredients, either categorically or individually, or a combination of both. As OTA states, it is important that restrictions and/or prohibitions are recommended, formally adopted by the National Organic Program (NOP) and explicitly communicated through one or more of the following mechanisms: 1) a National List annotation; 2) the Permitted Substance Database; and/or 3) NOP Guidance or Policy.

It is also important that final guidance documents from the NOP state whether agricultural other ingredients must be organically produced, and whether there are specific restrictions on synthetic vs. non-synthetic other ingredients. On the subject of agricultural other ingredients, we support the recommendation to decide whether these agricultural other ingredients should be organic on a case by case basis. It is important to remember that other ingredients are only present in the final substance at the incidental level, and thus requiring agricultural other ingredients to be organic is not likely to have much impact either on the volume of demand for organic products or on the purity of the final product. There are also practical obstacles to using agricultural other ingredients, especially when the substance they are used in is not itself certified organic. Nonetheless, we are supportive of the general goal of requiring agricultural ingredients to be organic wherever possible. The NOSB should carefully weigh all these considerations and stakeholder input on feasibility when determining whether an agricultural other ingredient should be certified organic.

We appreciate the work of the NOSB and specifically the Handling Subcommittee to address this issue in a way that effectively ensures the integrity of all organic ingredients without adding unnecessary steps to the process. Continued growth of the organic sector depends in part on continued growth of processed organic products, and these products often contain substances that are on the national list. Previous options explored by the Handling Subcommittee for evaluating other ingredients had the potential to create many additional layers of process and review, without adding any value in terms of improved product integrity. The framework set up in the Handling Subcommittee's proposal provides

an opportunity for the NOSB, processors, certifiers, scientists, and consumers to work together to help the entire organic sector thrive.

Thank you for this opportunity to comment.

Sincerely,

Britt Lundgren
Director of Organic and Sustainable Agriculture
Stonyfield

Attachment: Stonyfield comments on Other Ingredients Discussion Document, September 2012



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September 24, 2012

Ms. Michelle Arsenault

National Organic Standards Board

USDA-AMS-NOP

1400 Independence Avenue, SW

Room 2648-So, Ag Stop 0268

Washington, DC 20250-0268

Docket: AMS-NOP-12-0040

RE: Handling Subcommittee – Other Ingredients Discussion Document

Dear Ms. Arsenault,

Thank you for this opportunity to comment on the Handling Subcommittee's proposal for the assessment of other ingredients used in ingredients allowed on the National List. We appreciate that the NOSB has decided to look more closely at the use of other ingredients in substances allowed on the National List, and to develop a more clear and consistent process for evaluating these ingredients.

Stonyfield, now in its 28th year, is the world's leading organic yogurt company. Its certified organic yogurt, smoothies, milk, cultured soy, frozen yogurt and ice cream are distributed nationally. The company advocates that healthy food can only come from a healthy planet. Its use of organic ingredients helps keep over 200,000 farm acres free of toxic, persistent pesticides and chemical fertilizers known to contaminate soil, drinking water and food.

We appreciate that the organic standard sets forth the most rigorous ingredient evaluation criteria of any food production standard. This criteria ensures us all that any ingredients in

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organic have been thoroughly evaluated to ensure the safety of that ingredient.

In their comments, the Organic Trade Association provides some detail about the history of ingredient evaluation by the NOSB. They observe that historical records show that NOSB has reviewed other ingredients when evaluating multi-ingredient substances for inclusion on that National List. The Handling Subcommittee's proposal to codify the method for evaluating other ingredients is consistent with past NOSB work and also consistent with the goal of continual improvement within the standard.

We agree with the Handling Subcommittee's assessment that while the overall ingredient review process is already quite rigorous, improvement and harmonization of this process would be beneficial. We support the establishment of a more clear and consistent process to review other ingredients contained within ingredients allowed on the national list. The codification of a process for reviewing other ingredients will promote even greater transparency within the standard. It will also provide greater certainty for processors such as ourselves, by establishing a standard process that will be followed each time an ingredient is reviewed.

For the purposes of this discussion, we are using the definition of other ingredients used in the Handling Subcommittee's discussion document, which is ingredients that are used in the processing of an ingredient that remain in the final product in very small amounts; these other ingredients are referred to as incidental additives by FDA.

Preferred Policy Options

We support a combination of the elements of the policy options A and B described in the Handling Subcommittee's memo. We believe that this is the best way for the NOP to ensure that all other ingredients are evaluated in the process of evaluating ingredients for inclusion on the National List, while not creating an onerous new set of requirements that does nothing to advance the actual integrity of organic products but could create a regulatory bottleneck for the agency and thus hinder further growth of the organic industry.

Before NOSB settles on a policy for evaluating other ingredients, though, we think the first step is to have a better understanding of the other ingredients that are in use in substances already on the National List. In many cases these other ingredients have already been reviewed as part of the approval and sunset processes for substances on the list, while in some cases we may not be aware of all the other ingredients that are in use. Without first defining the scope of the issue, NOSB risks establishing a policy that is inappropriate for the problem at hand. The first step the NOSB should take in improving their evaluation of other ingredients is to conduct a more thorough assessment of which substances on the National List have other ingredients. This review should identify both the substances that

have other ingredients and the function of the other ingredients in these substances. This review can serve to inform the development of a comprehensive policy on other ingredients, and also help the industry understand exactly how the substances they use would fit into this policy.

For some substances, it may be appropriate to specify the allowance or prohibition of individual other ingredients. In other cases, it may be appropriate to allow or prohibit functional classes of other ingredients. In other cases, it may be appropriate to allow other ingredients based on a regulatory reference under another government agency. The point is that a one-size-fits-all policy for evaluating other ingredients does not take into account the variety of other ingredients in use, nor does it account for differences between synthetic, non-synthetic, and agricultural other ingredients. A one-size-fits-all approach may be inadvertently restrictive if the NOSB is not fully aware of the variety of formulations of a substance, or it could result in NOSB having to review many individual other ingredients when a simple annotation to approve a functional class of ingredients would suffice. By first conducting a more thorough review of the universe of other ingredients currently in use, the NOSB can then develop a policy that accomplishes the goal of ensuring organic integrity without creating unnecessary layers of regulation.

In some instances, because of the proprietary formulation of some substances, it may not be possible for the board to have full access to a complete list of other ingredients used in some substances. In this case, it should be up to the certifying agency to evaluate the other ingredients listed on product spec sheets for allowed substances. By first reviewing all allowed substances to determine which are likely to have other ingredients, and which of these are likely to be of a proprietary nature, the NOSB can be in a better position to provide appropriate guidance to certifying agencies about how to evaluate these other ingredients, as they have done in the case of natural flavors.

Once the review of other ingredients used in substances on the National List is complete, then the NOSB should propose a policy for evaluating other ingredients. This policy should foster more transparency within the standard by requiring the Technical Evaluation Report and any other review done by the NOSB to always note any presence of other ingredients, and establish either specific allowances or restrictions as appropriate. NOSB should also develop guidance for ACAs and MROs on how to evaluate other ingredients in proprietary formulations of substances.

OFPA sets out rigorous criteria for evaluating substances for inclusion on the National List. However, it is clear that OFPA never intended to require the separate listing of other ingredients/incidental additives on the National List. Rather, OFPA clearly states that other ingredients should be evaluated as part and parcel of the consideration of substances for inclusion on the list. In establishing the criteria for what should be included on the national list and how items on the National List should be evaluated, OFPA uses the term

“substance” to describe these items. It does not use terms like “single ingredient” or even “ingredient” in Sections 2118 or 2119, and it does not state that substances with more than one ingredient must be evaluated individually. Indeed, Sec. 2119 (l)(2) makes it clear that it was understood that substances might contain multiple ingredients where it says:

“Sec. 2119 (l)(2) work with manufacturers of substances considered for inclusion on the National List *to obtain a complete list of ingredients* and determine whether such substances contain inert materials that are synthetically produced;” {emphasis added}

It is clear that OFPA gives the NOSB the authority to determine what constitutes a substance when deciding what can go on the National List. It is equally clear that OFPA requires the NOSB to thoroughly evaluate these substances, including their manufacturing and components, to make sure that the substances are consistent with the organic standard. This is not a loophole in the standard that would allow for incidental additives that are incompatible with organic agriculture to be used. Rather, it is a mechanism to allow a substance to be thoroughly evaluated through one petition and evaluation process, rather than requiring multiple petitions and reviews for each item on the National List. As we saw in 2011 and 2012 with the recent tranche of sunset reviews, this process is already quite intensive and time consuming. If each substance that contains incidental additives must be broken out into individual petitions for each incidental additive, the workload for NOSB and NOP would increase substantially.

Synthetic vs Non-synthetic Other Ingredients

The policy options suggested by the Handling Subcommittee consider whether non-synthetic and synthetic other ingredients should be treated differently. Provided there is final guidance issued by NOP on the classification of materials, so we have more clarity about how the determination between synthetics and non-synthetics is made, we support treating these categories separately in the evaluation of other ingredients. We support the treatment of non-synthetics outlined in Option B, where non-synthetic other ingredients are allowed unless specifically prohibited. We suggest that in the process of reviewing a substance for the National List, if the NOSB identifies synthetic or non-synthetic other ingredients that should not be used, they should restrict their use with an annotation.

Organic Preference

The principle of continuous improvement is an important part of the national organic standards. The establishment of a consistent review process for other ingredients is well aligned with this goal. The concept of continual improvement is also relevant when considering the question of whether there should be a requirement that agricultural other ingredients be organic where possible. While we are supportive of the standard moving in this direction over time, we are concerned that an immediate imposition of this requirement

could be severely disruptive to the production and availability of many of the ingredients on the national list.

Many of the ingredients allowed on the National List are manufactured by companies whose primary customers are not certified organic. These manufacturers are not set up to produce certified organic products, and they would have to develop new procedures to segregate ingredients manufactured with certified organic agricultural other ingredients from those that were manufactured using non-organic agricultural other ingredients. It is important to remember that non-organic ingredients allowed for use in organic products are not certified, so it would be difficult if not impossible to enforce the preference for organic agricultural other ingredients. If the standard were to require the use of certified organic agricultural ingredients as incidental additives, it is likely that many manufacturers would simply walk away from this market, rather than going through the effort to segregate their ingredient production – there are not enough organic processors buying these ingredients to make it worth their while to produce a separate line of organic-compliant ingredients.

The requirement that all agricultural other ingredients be organic is also not likely to have any near term benefit for organic markets. Because other ingredients are such a minor component of the allowed ingredients on the national list, the volume of organic purchases that could be driven by such a new requirement would not even be noticeable in the general market for these organic ingredients.

We believe our focus should be to first scale up the organic production of major and minor agricultural ingredients before moving on to “other ingredients” contained within non-agricultural ingredients.

Cleaners and Sanitizers

We support moving cleaners and sanitizers to their own section of the National List, because they are not ingredients in food and thus should be considered separately from ingredients. Listing cleaners and sanitizers separately could also provide more clarity to processors about permissible cleaners and sanitizers.

Other ingredients contained in sanitizers or cleaners or other similar non-food inputs that are used in direct contact with certified product must be on the National List, or their allowance must be specified through an annotation via a CAS # or reference to another agency’s regulation, (e.g., peracetic acid), or their use must be mandated by law or specifically allowed through NOP Policy.

In line with current practice and as accepted by the National Organic Program, cleaners, sanitizers, disinfectants and other secondary indirect additives (aka not used in direct contact with certified product) may be used by certified handlers without regard to “other

ingredients” provided the operator has clear intervention/contamination prevention measures detailed in its OSP (e.g., a sanitizer is used on food contact surfaces and completely removed prior to organic production).

In conclusion, Stonyfield would like to thank the NOSB and the USDA NOP for this opportunity to comment, and for their work in developing these policy options for other ingredients. The principle of continual improvement is an important part of the organic standard, and this effort to standardize and clarify the assessment of other ingredients used in allowed substances on the National List is an important step in the continual improvement process.

Sincerely,

Britt Lundgren

Director of Organic and Sustainable Agriculture

Stonyfield