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Aug. 16, 2005

Mr. Arthur Neal
Director, Program Administration
National Organic Program
USDA – AMS-TMP-NOP
1400 Independence Ave., SW
Room 4008 So. AgStop 0268
Washington DC 20250
Sent via email: National.List@usda.gov

**Re: Docket Number TM-04-07, National Organic Program Sunset Review**

Dear Mr. Neal:

Stonyfield Farm, Inc. is a certified organic handler and processor of yogurt and other dairy and soy products. We recognize the importance of the National List and the 5 year "sunset" review, and appreciate the opportunity to comment. Stonyfield Farm supports the process that the NOP and NOSB have utilized in carefully reviewing substances that have been included on the National List. The Sunset Review process is an important piece of the integrity that is built into the USDA's National Organic Program regulations.

Stonyfield Farm is committed to testing alternatives and formulations in search of organic options for *all* non-organic ingredients used in our products. We have performed an extensive review of all ingredients used in our products, including all non-organic substances used in certified organic ingredients purchased from our suppliers. We find all the following substances to have important technical functions to produce high quality organic products and support their continuation on the National List.

| Name | Use | Comments, relevant information |
|---|---|---|
| **205.605(a) Nonsynthetics allowed** | | |
| Acid, citric | Used as pH control, to buffer acidity, and as flavor enhancer; and for preserving color. | Produced from microbial fermentation of carbohydrates, non-GMO source forms are used |
| Acid, lactic | Used to ferment juice concentrate (for color), also as acidifier. | Produced by lactic acid bacteria grown on carbohydrate substrate, non GMO source forms are required. |
| Agar | As a gelling and stabilization agent. | A natural substance derived from seaweed. |

| Name | Use | Comments, relevant information |
|---|---|---|
| Calcium carbonate | As calcium source for fortification. | A natural mined mineral, FDA GRAS at 21 CFR 582.1191, and as a nutrient or dietary supplement at 21CFR 582.519 |
| Calcium chloride | 1) To precipitate protein and aid in separation/removal in the process of making some syrups<br><br>2) Used for texture and stabilization | A natural mined mineral, considered GRAS by FDA, 21 CFR 582.1193 |
| Carageenan | For thickening stability and freeze thaw control (prevents liquid separation). | A natural substance derived from algae. |
| Dairy cultures | Includes bacterial sources plus substrate. | Non-GMO sources are required for strains of bacteria. Substrate is consumed by the growing cells during fermentation. |
| Diatomaceous earth | Filter aid in juices and syrup | 1) Used as a processing aid to clarify the syrup, acts like a porous face to filter so filter does not clog. Any sugar sand is picked up by the filter aid and filter. Use rate is .001% and is filtered back out of the syrup. This is standard for all maple producers.<br>2) Similar use in juice filtering, typically on screens to remove sediment.<br>In both cases, this processing aid does not appear in the final product. |
| Enzymes | | Non-GMO sources are required.<br><br>This processing aid does not appear in the final product. |
| Natural colors | | Certified organic entities are required to document for their certification that they are routinely seeking organic alternatives for non-organic natural colors. One of the challenges is that some organic forms are only available in powder or spice form, which are not suitable in some applications. |

| Name | Use | Comments, relevant information |
|---|---|---|
| Natural flavors, non synthetic sources produced without synthetic solvents and carrier systems or artificial preservatives | | Stonyfield continually evaluates organic flavors, and works with suppliers to develop organic versions of non-organic natural flavors. Since there is currently an extremely limited number of organic flavors, it is frequently difficult to achieve the desired flavor profile in an organic form. |
| Nitrogen, oil free grades | Used in packaging of juices to protect freshness | |
| Oxygen, oil free grades | Used in manufacture of juice concentrates to increase pressure during processing | This processing aid does not appear in the final product |
| Sodium bicarbonate | Used for pH control and leavening | Baking soda, considered GRAS at 21 CFR 582.1736 |
| **205.605(b) Synthetics allowed** | | |
| Ascorbic acid | For preserving color and freshness | Non-GMO source forms must be used.<br>Also considered a nutrient (Vitamin C) and desirable for replacing vitamins lost in processing. |
| Calcium hydroxide | Filtering and clarifying aid for organic sugar production. Sugar cane is crushed, and a suspension of calcium hydroxide (milk of lime) is added to neutralize the syrup and causes the organic solids to precipitate, so they can be removed as “mud.” | Organic sugar is used in the majority of SF products. Calcium hydroxide is a processing aid, not found in the final product. It is the one essential synthetic used in organic sugar production, while conventional sugar uses soluble phosphoric acid, polymer flocculation aids and other clarification aids.<br><br>Calcium hydroxide is produced by combustion of natural calcium carbonate (limestone) at high temperatures, producing calcium oxide and carbon dioxide, and has a long history of use. Calcium oxide reacts with water to form calcium hydroxide. It is considered GRAS, 21 CFR 582.1205and also permitted as a nutrient source in organic livestock feed. |
| Chlorine materials | | A cleaning aid, does not appear in the final product |

| Name | Use | Comments, relevant information |
|---|---|---|
| Calcium phosphate, tribasic | 1) As a flow agent used in the drying process for organic soy milk powder<br>2) Buffers in dairy cultures | GRAS at 21 CFR 182.1217 |
| Ferrous gluconate | | For iron fortification, recommended in cereal products for young children. |
| Glycerin | As a carrier/solvent used in natural flavors | Glycerin is a better solvent for certain compounds than ethyl alcohol. It is also used to dilute the concentration of ethyl alcohol in some cases so that it is still called a 'flavor' and is not classified as an 'alcoholic beverage'. Glycerin also aids in preserving flavor over shelf life<br><br>It is produced by hydrolysis of natural fats and oil, using heat steam and pressure to split the glycerin from the oil. |
| Hydrogen peroxide | Sanitizing agent | Does not appear in the final product |
| Nutrient vitamins and minerals | | Consumer preference for fortified products. |
| Ozone | For water treatment, sanitation, used in post harvest produce handling | Approved by EPA as water disinfectant, leaves no undesirable by-products in treated water. |
| Pectin, Low methoxy | Stabilization and texturant | LM pectin has a functionality not offered by HM pectin: HM works better for low pH and high soluble solids applications. For many applications that have lower sugar content or high pH, LM pectin is required in order to achieve desired function.<br>More information on pectin types and function is available at http://www.cpkelco.com/pectin/applications.html. |
| Phosphoric acid | Cleaning aid | Does not appear in the final product. |
| Potassium hydroxide | As peeling agent for peaches<br>As a boiler additive | As a peeling agent for peaches, it is a processing aid not found in the final product. |
| Silicon dioxide | | Produced from sand, and is processed by either a vapor phase hydrolysis process, which yields fumed (colloidal) silica, or by a wet process that yields precipitated silica, silica gel or hydrous silica. (Food Chemicals Codex) |

| Name | Use | Comments, relevant information |
|---|---|---|
| Sodium citrate | pH control, stabilization, and buffering agent | Sodium salt of citric acid, citric acid is produced by fermentation. Prepared by neutralizing citric acid with sodium carbonate or sodium hydroxide. GRAS at 21CFR184.1751 |
| Sodium hydroxide | As a cleaning agent. | A cleaning aid, does not appear in the final product |
| Xanthan gum | Stabilizer | A polysaccharide gum derived from a bacterium, *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol, and is manufactured as the sodium, potassium, or calcium salt. |
| 205.606 Nonorganic agricultural items | | |
| Gum, arabic | Also called acacia gum, stabilizer | |
| Gum, locust bean | For texture and as a thickener | Water extracted sources |
| Gum, guar | Thickener and stabilizer | |
| Lecithin, unbleached | Binder and release agent in baked goods, emulsifier, and as a component of anti foam agents | Although some organic lecithin does exist, its functionality is different than its non-organic counterpart and thus it can not be used for all applications |
| Pectin- High methoxy | Stabilization and texturant | HM pectin provides unique product characteristics that are not viable with other texturants, namely LM pectin. |

**Stonyfield Farm supports the <u>removal</u> of the following substances from the National List:**
**Oxytocin**
Consumers have made it clear that any supplemental hormone use is undesirable and incompatible with organic agriculture.

**Ivermectin**
Ivermectin should be replaced with Moxidectin, which has been approved by the NOSB, but not yet added to the National List.

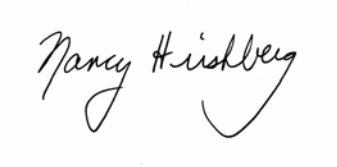
**Additional comments:**
The sunset process is an important part of the Organic Food Production Act, and aids in updating the National List so that it remains appropriate and compatible with organic principles. In order to facilitate this process of review and renewal, it would be helpful in the future if the USDA could provide documentation of all Technical Advisory Panel reviews on a publicly accessible website. There is limited access at present to the majority of reviews conducted in 1994-1996 by the NOSB of substances that make up the bulk of the National List. We would appreciate it if these documents could be scanned and included on the petitioned substance database, so that the public can have access to this information. In addition, for the next round of sunset review, a minimum of a 90 day comment period would be appreciated to permit the technical comments requested on these specific substances.

We also hope that despite the workload generated by this Sunset review, that NOP can proceed promptly with additional Federal Register dockets on processing and livestock materials previously recommended by the NOSB, in some cases as long as five years ago. This includes important materials such as natural microorganisms used in food production (lactic acid bacteria, for example), activated carbon as a filter aid, and peracetic acid used as an environmentally benign sanitizing agent. In addition, livestock producers should be able to use the health care materials recommended for organic livestock by the NOSB, in order to provide humane animal care as required by OFPA.

If you would like more information on any of the ingredients mentioned, or their potential use, please feel free to contact us.

Thank you for your consideration.

Sincerely,



Nancy Hirshberg
Vice President of Natural Resources