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The following comments are in reference to USDA, Agricultural Marketing Service Docket Number TM-04-07 concerning 7 CFR Part 205, National Organic Program Sunset Review process.

CP Kelco, a Huber Company, thanks the United States Department of Agriculture and the National Organic Standards Board for the opportunity to comment on the Sunset Review of the 2002 National List. We ask for continuance of the following items as they are listed on the National List that we have provided for many years to our customers for their organic product formulations and would like to provide support the following materials:

CP Kelco recommends that the ingredients listed below of § 205.605 and § 205.606 remain on the list. As per the original evaluation by the NOSB that they are:

(1) Not harmful to human health or the environment.
(2) Necessary because of the unavailability of alternatives
(3) Consistent and compatible with organic practices.

Substantial safety and toxicology (mammal and eco-tox) data exists with JECFA and The US FDA that the above ingredients are not harmful to human health or the environment. They are used by formulators of organic products and have been reviewed for their unique applications in organic food and beverage formulations.

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food groups(s))” **(a) Nonsynthetics allowed.**

CARRAGEENAN:

Seaweed-derived hydrocolloids are carbohydrates obtained from different species of algae from various regions of the world. They are valuable for their gelling, thickening and stabilizing properties. Our carrageenan is obtained by extraction with water or alkaline water of certain species of seaweed. It is a hydrocolloid consisting mainly of the potassium, sodium, magnesium, and calcium sulfate esters of galactose and 3.6-anhydro-galactose copolymers. Carrageenans perform by providing uniform gelling and texturing agents. And are used in many food application such as milk systems (dairy) and water systems (deserts, etc.).

KAOLIN:

Our kaolin is from naturally occurring kaolin or china clay. Kaolin is generally recognized as safe ``as an indirect human food ingredient with no limitation other than current good manufacturing practice. Kaolin can be used directly in foods as an anticaking agent (up to 2.5%).

CALCIUM CARBONATE:

Our calcium carbonate is from naturally occurring ground limestone. Calcium Carbonate would be as a source for calcium in products such as breakfast cereal; nutritional bars; baked foods; fortified beverages; cookies & crackers; soups and sauces.

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food groups(s))” **(b) Synthetics allowed**

SILICON DIOXIDE:

Silicon Dioxide is used as a filler, carrier or free flow agent. Silicon Dioxide or synthetic amorphous precipitated silica is produced by the reaction of sodium silicate with a mineral acid.

For precipitated silicas reaction is carried out in neutral or alkaline media. Precipitated silica is non-toxic, odorless and chemically inert.

Silicates can be used for powder blends, spices and beverage mixes. It is an effective anti-caking material used in the manufacture of certain vegetable and fruit powders where brick-like cakes would be formed without the use of silicon dioxide. Alternative materials for anti-caking have not delivered the same functionality.

PECTINS (LOW-METHOXY):

Pectin is a natural component of all edible plant material and is a soluble dietary fiber. Pectin is a polymer of galacturonic acid and with that an acidic polysaccharide. Part of the acids is present as methyl ester. Pectin is a hydrocolloid and binds a lot of water resulting in thickening and gelling properties. In that pectin (low-methoxy) is a natural extracellular polysaccharide not only should it remain on the list, but also the NOP should consider reclassifying pectin (low-methoxy) to a non-synthetic as per § 205.605(a).

It is well known that high ester pectins, as extracted from citrus and apple fruit materials, do not produce a gel at sugar contents below a level of 60 - 65% total sugar solids as measured by refractive index. The exact limit depends both on the precise character of the pectin and on the nature of the sugars present, but neither of these variables, within the range of high ester pectins (degree of esterification 50% or greater) permits significant texture development below about 60% sugar solids.

However, if the degree of esterification is reduced to below 50% (typically but not exclusively 20 - 45%) the pectin can gel by a different mechanism, involving reaction with the calcium ions provided by the fruit in the product. Occasionally, but not normally, this may need to be supplemented by the addition of a suitable calcium compound.

In nature, de-esterification is carried out by pectin esterase enzymes, but this process is not readily controllable either in the fruit or on isolated pectins, and cannot easily be used at our present level of understanding to produce viable and reproducible commercial pectins. A reproducible degree of esterification can only currently be achieved in one of two ways, either by an extension of the acidic extraction process used to produce commercial high ester pectins, or by treatment with ammonia, yielding non-amidated and amidated low ester pectins respectively.

In order to produce low sugar fruit spreads and fruit bases, using organic fruit and sugars from suitable organic sources (including honey and fruit juice concentrates), it is essential to use low ester pectins produced by one of these processes, as neither the high ester pectin in the fruit, nor added commercial high ester pectin, will develop significant texture at low sugar contents. While all low ester pectins will thicken or gel low sugar products, amidated low ester pectins offer some advantages in the control of process and texture.

It should be realized that the distinction between high ester and low ester pectins is quite arbitrary, depending on whether the degree of esterification is above or below 50% of the total carboxylate groups. This distinction is not made in the current Food Chemicals Codex specification for pectins, or in the Codex Alimentarius specification. The current Codex Alimentarius draft standard permits pectins of all types in Organic products, based on this single specification.

However, if it is insisted that pectins which have been treated with ammonia to introduce amide groups must be classified as “synthetic” because of this modification, then they alone should be so classified, leaving all non-amidated pectins, whether high or low ester, as “agricultural products”. This would permit the production of low sugar “organic” products using non-amidated low ester pectins, to the benefit of consumer choice.

XANTHAN GUM:

Our xanthan gum is a polysaccharide produced via bacterial fermentation using naturally occurring nutrients sources. In that xanthan gum is a natural extracellular polysaccharide not only should it remain on the list, but also the NOP should consider reclassifying xanthan gum to a non-synthetic as per § 205.605(a).

Xanthan Gum is produced from natural sources, e.g., bacterial fermentation using naturally occurring nutrients. It is produced from natural constituents and contributes a unique

attribute to foods and beverages, thus allowing many more organic products to be formulated and marketed to the consumer. Xanthan gum is used in various food and beverage formulations such as batters, baked goods, bakery and pie filings, beverages, confectionary, dairy products, desserts, dietetic foods, dressings, dry mixes, flavor emulsions, frozen foods, icings and frostings, relish, retorted products, sauces and gravies, syrups and toppings.

The mode of action is as a thickener, stabilizer and emulsifier with texturizing attributes. The typical amounts of xanthan gum used is small (less than 1.0%) of the processed food because of the self-limiting nature, which is the concentration of substance above at which will result in an inedible or unusable product.

Xanthan gum may also be used personal care products, such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. Additional uses of the substances are found in consumer products, such as liquid detergents, cleaners, suspensions and films.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food group(s)).’’

PECTIN (HIGH-METHOXY):

Pectin is a natural component of all edible plant material. Pectin is located in the plant cell walls and in a layer between the cells called middle lamella. Pectin gives firmness to the plants and influences growth and water household. Pectin is a soluble dietary fibre. Pectin is a polymer of galacturonic acid and with that an acidic polysaccharide. Part of the acids is present as methyl ester. Pectin is a hydrocolloid and binds a lot of water resulting in thickening and gelling properties

Pectin is used in applications such as: Fruit applications (Jams, jellies, and desserts); Bakery fillings and toppings; Fruit preparations for dairy applications; Dairy applications (Acidified milk and protein drinks; Yogurts); Confectionery (Fruit jellies; Neutral jellies); Beverages; Nutritional and Health Products

Gums —water extracted only (arabic, guar, locust bean, carob bean):

GUM ARABIC:

A gum exuded by various African trees of the genus *Acacia,* especially *A. Senegal.* Gum Arabic *is* widely used in the food industry, as an emulsifier, thickener, flavor encapsulator, and thickening agent

LOCUST BEAN GUM/CAROB:

LBG is a textural ingredient is obtained from the kemels of the carob tree (Ceratonia Siliqua), which grows in Mediterranean countries. LBG is used in applications such as cream cheese, dairy desserts, ice cream, fruit preparations, baked goods, and dressings and sauces.

Specific reference to questions asked in FR (Appendix).

CATEGORY 1. No adverse impacts on humans or the environment

1. Substances listed above do not contribute any adverse impact to the environment or humans either during production or end-use. During manufacturing processes, any waste will be discharged to the municipal sewage treatment plant and will be present in only trace amounts.
2. There is no insignificant impact on the environment from these products. Polysaccharides are degraded by microorganisms found in the water and soil. Therefore, they do not persist in the environment. Minerals will naturally degrade. Any waste materials (e.g., finished products such as food or beverages) will be composted, sent to land fills or treated in wastewater treatment plants. These actions will not result in an adverse effect on the environment.
3. None of the above substances are on, nor do they contain, inerts from list 1, 2 or 3.
4. There is no potential for detrimental chemical interaction with other materials used.
5. There are no adverse biological and chemical interactions in agro-eco-systems.
6. There are no detrimental physiological effects on soil organisms, crops, or livestock.
7. There is no toxic or other adverse action of the material and there are no breakdown products.
8. There is no undesirable persistence or concentration of the material or breakdown products in the environment.
9. There are no harmful effects on human health.

Each of the above substances has a safe history of use as a food additive worldwide and is recognized by the World Health Organization Joint Expert Committee for Food Additives as safe. JECFA as well as the European Community Scientific Committee for Food have established an Acceptable Daily Intake (ADI) of 'not specified (NS),' the highest rating given to an ingredient for which no toxic effects were observed which show the ingredients to be safe for consumption in the human diet.

CATEGORY 2. Substances are essential for organic production.

Substances listed above are produced from natural sources, e.g., bacterial fermentation using naturally occurring nutrients or derived from mineral sources, agricultural sources, or aquatic plants. They are produced from natural constituents and each substance contributes a unique attribute to foods and beverages, thus allowing many more organic products to be formulated and marketed to the consumer. Substances are used in various food and beverage formulations such as aspics; frostings; brownies and bakery fillings; confectionery (fruit jellies; neutral jellies); gelatins and puddings; nonstandardized jams and jellies; dairy applications (dairy drinks, dairy desserts, beverages (fruit drinks, drinking jellies, novelty drinks, acidified milk drinks; yogurt, yogurt fruit and fruit sauces, sour cream and cheese where the standards of identity do not preclude its use); protein drinks; soy milks; nutritional products; pourable and spoonable dressings; nutritional and health Products
The mode of action is as a thickening or gelling agent with film-forming or texturizing attributes. The typical amounts of each hydrolloid used is small (less than 1.0%) of the processed food because of the self-limiting nature, which is the concentration of substance above at which will result in an inedible or unusable product.

These substances may also be used personal care products, such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. Additional uses of the substances are found in consumer products, such as liquid detergents, cleaners, suspensions and films.

CATEGORY 3. Substances are compatible with organic production practices.

Substances are listed at § 205.605 and § 205.606

CP Kelco, A Huber Company, has received a substantial number of requests from organic industry customers that use the above named products in their organic products asking that our company request that these ingredients remain on the NOP list.

We respectfully request that the above currently listed ingredients in the Code of Federal Regulations, Title 7, Part 205, under Sections 205.605 and 205.606 continue to be approved for use in products currently labeled "organic" and "made with organic" and appreciate your consideration of the comments provided above.

Sincerely,

Cheryl A. Van Dyne
Manager, Regulatory Affairs