II. Sunset Materials

We have one general comment about the committee's approach to the sunset review. In some of the recommendations, we have seen wording like:

> Review of the original recommendation, the 2001 TAP review, historical documents, the 2007 sunset recommendation, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list and again re-list this material.

How can the committee conclude that there is "no new information contradicting the original recommendation when they have not looked?

We sent separately comments on agar-agar and carrageenan.

A. Calcium Sulfate

1. Is there a need?

Calcium sulfate has been used as a coagulant for tofu for over 2000 years in China. Although there are other coagulants that may be used, calcium sulfate is essential for traditional Chinese tofu. Other uses are allowed under this listing, and the need for them has not been established. They include: nutrient, yeast food, dough conditioner, firming agent, sequestrant, jelling agent, baking powder ingredient, carrier, pH buffer, and abrasive agent. One of the three TAP reviewers in 2001 recommended that calcium sulfate be approved only for use in making tofu.

2. What are the human health and ecological impacts?

As stated by one TAP reviewer,

> Calcium sulfate derived from natural sources impacts the environment in that mining operations are needed to obtain it. This involves quarrying or blasting, and the use of heavy equipment. In addition to the direct impact of the mining operations on the Earth, there is a negative impact caused by the generation of gypsum dust in the process. This dust can affect air quality, and can be a potential exposure hazard to humans and other animals. There are no other known negative effects of toxicity and/or persistence in the environment caused by production of calcium sulfate from these methods, as long as standard regulations for proper mining activities are followed.

Calcium sulfate is an irritant to eyes and skin, and when inhaled. We have not seen any reports indicating that problems associated with Chinese gypsum in drywall are problems for food-grade calcium sulfate.

3. Is it consistent with principles of organic production and handling?

We ask you to consider Table 4 from the TAP review, reproduced as an attachment to these comments. We agree that the use of calcium sulfate as a coagulant in tofu production is compatible with organic principles, but other uses should be considered individually. The information in this table might support the use of calcium sulfate in brewing, but not in other possible uses.

4. Conclusion

We have not seen sufficient evidence to support the use of calcium sulfate for all food uses. Therefore we support renewing the listing of calcium sulfate with the annotation, *"For use only as a coagulant in bean curd (tofu and similar products)."*

B. Glucono Delta-Lactone

1. Is there a need?

Glucono delta-lactone (GDL) does not have the long history as a coagulant for tofu that nigari and calcium sulfate do. Its use dates back to the 1950's, and it has been used to make silken tofu. There seems to be some disagreement about how essential GDL is to making silken tofu. One TAP reviewer cites a study indicating that calcium sulfate should do as well:

> According to the 1986 paper by J.M. deMan et. al., a comparative study of assessment of five coagulants on the texture of tofu showed that minimal textural difference was obtained in producing a tofu product of high bulk weight and smooth (silky) texture for a 0.75% $CaSO_4$ solution in comparison to a 0.4% solution of glucono delta lactone. The authors concluded that there were minimal texture differences in peak force, compression, and firmness in tofu made with 0.5 to 1.0% concentrations of calcium sulfate vs. 0.3-0.4% concentrations of glucono delta lactone. This evidence seems to suggest that there are minimal textural differences between tofu coagulated with $CaSO_4$ or glucono delta lactone.

On the other hand, the pudding-like silken tofu developed in the 1950's, was only developed with the discovery of GDL. According to the "History of Tofu" on the SoyInfo Center website,

> The 1950s saw the development of two new types of tofu: bagged lactone silken tofu (*fukuroiri-dofu*) and pressed silken tofu (*softo-dofu*). The former type, which used glucono delta-lactone (GDL) as a coagulant, was patented in the mid-1950s and started to become popular in about 1958-59…. Bagged lactone silken tofu is made by mixing a little GDL into cold soymilk, then running the mixture into sausage-shaped plastic bags, each typically 2 inches in diameter, 5-7 inches long, and of 300-350 ml capacity. After the bag is sealed, it is immersed in hot water at about 85*C (185*F) for 50 minutes until the tofu sets like a pudding and its simultaneously pasteurized. Prior to 1960 most of Japan's tofu made with GDL was produced in small neighborhood tofu shops. The second type of new tofu was pressed silken tofu; it is not known exactly when or by

> second type of new tofu was pressed silken tofu; it is not known exactly when or by whom it was developed??. It was made by coagulating rich soymilk in a curding vat with calcium sulfate until it set like a pudding (without separation of curds and whey), carefully scooping large slices of the curd into a perforated, cloth-lined forming box, then pressing them under a heavily-weighted lid until they fused. This tofu was firmer, more cohesive, and less delicate than regular silken tofu made with calcium sulfate, but softer, smoother textured, and higher yielding than regular tofu.

So, GDL may be essential to the production of at least the pudding-like silken tofu. No other need has been supported by the TAP or the committee, so we recommend that the use be limited to use only as a coagulant in bean curd (tofu and similar products).

2. What are the human health and ecological impacts?

According to the TAP review, three kinds of processes may be used for making GDL, by the oxidation of D-glucose with:

1. bromine water;
2. microorganisms that are nonpathogenic and nontoxicogenic to man or other animals; or
3. enzymes derived from these microorganisms.

One of the reviewers pointed out that other oxidizing agents besides bromine water might be used, including sodium hypochlorite, and that metallic catalysts have also been studied for making GDL. All of these methods are synthetic and would not produce a nonsynthetic product. The current annotation, "production by the oxidation of D-glucose with bromine water is prohibited," is therefore insufficient. We don't know where the current annotation came from, however, since the NOSB motion in 2002 was to add "GDL produced by microbial fermentation of carbohydrate substances," and the vote in 2007 was a straightforward relisting.

We have not identified any potential health or environmental impacts other than those associated with oxidizing agents.

3. Is it consistent with principles of organic production and handling?

One of the TAP reviewers pointed out, "The crystallization process of GDL from gluconic acid should be investigated. Crystallization processes may involve prohibited solvents." Other potential problems that were raised that were not incorporated into the original recommendation concerned the avoidance of genetically modified micoorganisms or substrate materials.

4. Conclusion

We support the relisting of glucono delta-lactone with the following annotation: *"For use only as a coagulant in bean curd (tofu and similar products); when produced by oxidation of D-glucose by non-genetically-modified, nonpathogenic, and nontoxicogenic microorganisms or by* *enzymes derived from these organisms. No volatile synthetic solvents may be used in the crystallization process. "*

C. Cellulose

1. Is there a need?

The listing allows synthetic cellulose to be used for three uses: regenerative casings, microcrystalline cellulose as an anti-caking agent (non-chlorine bleached), and powdered cellulose as a filtering aid.

In the 2001 Technical Advisory Panel (TAP) review, reviewers found that there were not natural alternatives to cellulose for peelable hot dog casings. These casings are removed from the sausage before sale, resulting in skinless hot dogs.

Powdered cellulose as a filtration aid is used with diatomaceous earth. One of the three reviewers supported this use. The following alternatives were identified (TAP, lines 428-431)

> One source lists alternatives for juice that include activated carbon, diatomaceous earth, isinglass finings, paper shavings, rice hulls, silica compounds, carrageenans. (Branen, 1990) As described under Specific Uses, cellulose when combined with diatomaceous earth is the preferred filtering method for apple juice and for certain types of filtration equipment. Another alternative would be to market un-clarified juice forms only.

None of the reviewers supported adding microcrystalline cellulose to food as an anti-caking agent. They pointed to alternatives (414-426):

> Potato starches or other starches and also rice or corn flours may be used in shredded cheese products. According to a cellulose supplier (Benbold, 2001) potato starch is cheaper but does not absorb as much moisture and is not as effective a flowing agent as powdered cellulose. The petitioner also noted problems with mold contamination of potato and other starch products. FDA GRAS listed anti-caking agents including several silicates, such as aluminum calcium silicate and calcium silicate magnesium silicate. These are not included on the National List at 7CFR 205.605 and would need to be petitioned.
>
> Silicon dioxide is listed as GRAS at 7 CFR 172.480 when less than 2% for use "in only those foods in which the additive has been demonstrated to have an anti-caking effect." Silicon dioxide is included on the National list, and is used currently as an anti-caking agent for spices. According to a supplier, the silicates are used only in very limited amounts for shredded cheese, and silicates are more hazardous to formulate due to

> particulates and OSHA requirements for worker exposure. (Ang, 2001) Silicates or silicon dioxide may not be as desirable an anti-caking agent in some products, such as spices due to the abrasive qualities that can affect product structure or texture.

The reviewers also recommended that the board investigate natural forms of cellulose (317-321):

> Cellulose is a widely abundant natural material, however the processing of fiber sources to remove other natural constituents results in a purified material that can be considered synthetic. As stated under description of manufacturing, it is possible to extract cellulose from agricultural commodities, including fibers such as cotton, hemp, ramie, linen, and jute as well as sugar cane, corn stalks and cobs, straw, soybean hulls, among others. Cellulose is commercially available from cotton linters and could be produced and processed organically. No known organic source has been identified at this time.

2. What are the human health and ecological impacts?

The 2001 TAP review did not identify any human health concerns with the food impacts of cellulose casings, powdered cellulose in filtration, or microcrystalline cellulose as an anti-caking agent. Although no health impacts were associated with it, a World Health Organization paper pointed out that the assumption that microcrystalline cellulose (MCC) particles are too large to be absorbed by the body is not true:

> Rats, pigs and dogs were used to study the persorption of microcrystalline cellulose. The animals were not fed for 12 hours prior to oral administration of the test compound. Rats, dogs and pigs were given 0.5, 140 and 200 g, respectively, of the test compound. Venous blood was taken from the animals 1-2 hours after administration of the test compound, and examined for particles. Persorbed particles were demonstrated in the blood of all three species. The average maximum diameter for persorbed particles was greater in rats than in dogs or pigs (Pahlke & Friedrich, 1974).[6]

The main concerns are associated with the production of wood pulp, which involves treatment with sulfites, caustic soda, or sodium sulfate, or steam explosion for delignification; purification and bleaching, usually involving chlorine compounds, sodium hydroxide, sulfuric acid, and chelating agents. (107-134)

As stated in the TAP review (326-331),

> Cellulose pulp manufactured from wood products historically has many environmental concerns. Recovery of waste chemicals, such as caustics, sulfites, and bleaching agents

[6] World Health Organization, 1998. Food Safety Additives Series 40. http://www.inchem.org/documents/jecfa/jecmono/v040je03.htm

> are important to avoid water pollution. The organic waste liquor substances may be disposed of by combustion, resulting in odors and air pollution (Kirk-Othmer, 1993). Conventional production of microcrystalline cellulose results in production of acid wastes due to the use of hydrochloric and other acids (Hanna, 2001). The use and disposal of cellulose powder itself is not reported to have any adverse environmental effects as synthetic cellulose is similar to that found naturally in the environment.

In addition, the TR states (149-154),

> MCC production uses an additional step involving hydrolysis of the purified wood pulp, using hydrochloric acid to reduce the degree of polymerization. This leaves only the tiny, acid-resistant crystalline regions. It can be spray-dried, and is then termed "powdered MCC." This produces average particle sizes ranging from about 20-90 µm. Another form is colloidal MCC, which is water dispersible and has properties similar to water soluble gums. It requires the use of mechanical energy after hydrolysis to tear apart microfibrils and provides a major proportion of colloidal sized aggregates (less than 0.2µm in diameter) (Kirk- Othmer, 1993; Whistler, 1990).

Note that the colloidal sized particles mentioned in the above quote fall within the range of the definition of engineered nanomaterials adopted by the board at its Fall 2010 meeting and should therefore be excluded from use in organic production and handling. TAP reviewers also recommended that the NOSB examine the possibility that nonsynthetic forms of cellulose might be available for the uses considered.

3. Is it consistent with principles of organic production and handling?

We agree with the TAP review (405-408):

> A basic principle of organic handling is to minimize the use of additives. The use of a non-organic additive to replace fat or provide texture characteristics not present in the natural food is not compatible with criteria 1 and 4[7]. Reviewers believe that natural sources such as bacterial cellulose (non GMO source) or cellulose derived from cotton using a less synthetic process would be more compatible with organic principles for this type of direct additive use.

In addition (21-22), "All reviewers considered microcrystalline cellulose to be a highly processed material not compatible with organic handling systems."

[7] 1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
4. Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law.

4. Conclusion

We urge the committee to update its review to examine the availability of nonsynthetic, possibly even organic, forms of cellulose for these uses. The board has received a petition to remove silicon dioxide for some of these uses because of the existence of an organic rice concentrate alternative, which should be considered. We also urge the board to delist microcrystalline cellulose as an anticaking agent because it is a highly processed synthetic material, and nonsynthetic alternatives are available.

Thank you for this opportunity to comment on petitions and sunset recommendations for handling materials.

Sincerely,

Teresa Ann Shistar

Terry Shistar, Ph.D.
Board of Directors

Attachment

The uses and potential substitutes for calcium sulfate in processing systems depend on the specific purpose for using the material. Calcium sulfate has a wide variety of food uses, with the main functions and products summarized in Table 4. (EAFUS, 2001 and 27 CFR 24.246). Of the uses mentioned, calcium sulfate should only be considered for some, as the others would be disqualified under criteria used by the TAP. Each of these uses/functions will be considered individually in this section, as its necessity/essentiality and compatibility in organic production, and potential alternatives (organic or otherwise):

Table 4
Reviewer 1 Commentary on Uses

Use/function	Products	Reviewer 1 Comments:	Alternatives
Firming agent	mainly canned fruits and vegetables	Not compatible, as the calcium sulfate would only be used to recreate texture lost during processing, or "improve" texture not had in the first place.	Grape leaves, cherry leaves, other fruit or oak leaves, for certain applications such as pickling. Salts already included on the National List.
Dough conditioner	Breads, crackers, other baked items	Not compatible or essential, as calcium sulfate is being used to improve a texture that could be otherwise achieved via alternative baking techniques. Not a necessary ingredient for any baked goods formulation.	Salt; skillful baking techniques.
Yeast food	Beer and other fermentation products	Not necessary, as there are a variety of organic ingredients which can be substrates for this purpose.	Organic foodstuffs as substrates
pH adjuster, flocculating agent, calcium source	Beer brewing, winemaking	1) As an aid in beer brewing, use of calcium sulfate purportedly increases yield when it is added to the mash tun. Supposedly it also increases yield by promoting proper gelatinization of the starch in the cooker mash, as well as protein degradation and starch conversion. Although the increase in yield is favorable to the brewer, it is not essential to the process. 2) Water adjustment is said by some brewers to often be necessary to provide a flavor and finish that is needed, particularly with top-fermented yeast. Calcium stimulates enzyme activity and improves protein digestion, stabilizes the alpha amylase, helps gelatinize starch and improves lauter runoff. While sulfates can impart off-flavors, so can chloride (salty) and carbonate (chalky). Calcium also extracts fine bittering principles of the hop and reduces wort color.	Various, depending on the process and product.
Coloring/ bleaching agent	Cheeses, flours	Not compatible, as calcium sulfate is being used to alter a color without any other purpose. Not a necessary ingredient.	Food without colorants
Carrier for bleaching agent	Cereal flours	Not compatible, as color alteration is not a valid use for organic.	Unbleached flour
Jelling agent	fruit jellies	Not compatible, as other more suitable alternatives exist., and it is most often used with artificially sweetened jellies and preserves.	Pectins
Abrasive	Toothpaste, tooth powders	Not really applicable at this time for organic considerations. Alternatives exist.	Calcium carbonate