Calcium Sulfate

Identification

Chemical Name(s): calcium sulfate

CAS Number: 7778-18-9 (calcium sulfate)
10101-41-4 (calcium sulfate dihydrate)

Other Names:
alabaster, gypsum, plaster of paris, light spar, terra alba

Other Codes: INS 516,
RTECS: EW4150000

This TAP review is based on information available as of the date of this review.

Summary of Advised Recommendation

Synthetic / Non-Synthetic:	Allowed or Prohibited:	Suggested Annotation:
Non-synthetic (Dihydrate form, mechanically extrated and physically processed uncalcined from mined sources only). (reviewers unanimous)	*Allowed [Food grade (FCC) only] (reviewers unanimous)*	*None* (2 reviewers) *OR* *For use only as a coagulant in bean curd (tofu and similar products).* (1 reviewer)

Characterization

Composition:
$CaSO_4$ (anhydrous), $2CaSO_4 \cdot H_2O$ (hemihydrate), $CaSO_4 \cdot 2H_2O$ (dihydrate)

Properties:
A light, porous crystalline structure, 3.0-3.5 on Moh's hardness scale. Usually white, but some ores have a blue, gray, or reddish tinge. In some cases, the ores will be brick red (Budavari, 1996). Melting point: 1,450°C. (Lewis, 1989).

How Made:
Calcium sulfate may be obtained from natural sources or chemically synthesized, with mined gypsum being the primary natural source (Petersen, Kaleta, and Kingston, 1992). Gypsum is one of the most widely used minerals in the world, with the US being the largest producer of any country (Olson, 1999). The petition is regarding only the mined form, so the review will not consider the manufacture of other sources. Mined sources still account for most production of crude gypsum. According to the US Geological Survey, the number of producers and production level is increasing. In 1999, 35 companies that operated 60 mines in 20 states produced record levels of gypsum (Olson, 1999). In 1996, 30 companies operating 61 mines produced 73% of all domestic output (Balazik, 1998). Gypsum deposits occur in many parts of the US and Canada. The top producing states in 1999 were Oklahoma, Iowa, Texas, Michigan, California, Nevada, and Indiana—together they accounted for 72% of total output (USGS, 2000). Most mined sources are from gypsum ore in the dihydrate form, with some anhydrite deposits also naturally occurring (Petersen, Kaleta, and Kingston, 1992). Calcium sulfate dihydrate is obtained by grinding and separating gypsum that contains about 20% water of crystallization (Igoe, 1983).

Specific Uses:
The TAP review will focus on use as a tofu coagulant, as per the petition's example, but other uses will be discussed to illustrate some specific functions and other characteristics of the material relative to the OFPA and NOSB criteria.

Calcium sulfate has been used in China for over 2,000 years to coagulate soy milk to make tofu (Shurtleff and Aoyagi, 1975). FDA GRAS uses are listed in Table 1. One supplier estimated that there are over 100 uses as a direct food additive (Dichter, 2001). Other uses in food processing include: nutrient; dietary supplement; yeast food; dough conditioner; firming agent; sequestrant (Food Chemicals Codex, 1996); jelling ingredient (Ockerman, 1991); baking powder (Igoe, 1983); carrier; filler; pH buffer; and abrasive agent. The primary food processing use is in baked goods (Dichter, 2001). It is used as a firming agent with canned potatoes, tomatoes, carrots, lima beans, and peppers (Igoe, 1983). Calcium sulfate is an ingredient in confections, frostings, gelatins, soft-serve ice cream, and other frozen desserts (Lewis, 1989). It is used as a carrier, filler, or standardizing agent with many different minor ingredients. The TAP review does not extend to these

other ingredients. It is also used to process malt and increase the calcium content of water used for brewing beer (Ash and Ash, 1995). It is used as an abrasive in some scouring cleaning agents that are used on food contact surfaces. Calcium sulfate is also used in cosmetics and toothpaste (Winter, 1989).

Action:
Coagulation of soymilk is a complex interaction of several variables (Hou et al., 1997). The calcium and sulfate ions combine with the soluble proteins in soymilk to denature and take them out of solution.

Calcium sulfate helps fruits and vegetables retain firmness by binding with pectin and increasing the water-holding capacity. The calcium bonds to the negatively charged carboxylic groups in pectin (Gordon and Klimek, 2000). Flour that is low in calcium tends to produce dough that is soft and sticky (Igoe, 1983), so calcium sulfate is used to stiffen dough.

Combinations:
Food grade calcium sulfate is usually sold as pure terra alba. Impurities may include limestone (calcium carbonate) and various naturally occuring forms of silica. It may be combined with magnesium sulfate or calcium chloride as a tofu coagulant (Shurtleff and Aoyagi, 1975) and is also used in combination with carrageenan to produce a gelatinous tofu (Abd Karim, Sulebele, Azhar, and Ping, 1999). A product similar to tofu can be made from cooked field peas and calcium sulfate (Gebre-Egziabher and Sumner, 1983). It may also be used with rennet and cow's milk along with soymilk to make a soy-extended cheese food (Del Valle, et al., 1984).

Status

OFPA
The substance is used in handling and is non-synthetic but not organically produced [7 USC 6517(c)(1)(B)(3)].

Regulatory
FDA GRAS for human (21 CFR 184.1230) and livestock (21 CFR 582.5230). See table 1 for more information.
Bureau of Alcohol, Tobacco, and Firearms (BATF) 27 CFR 240.1051.

EPA/NIEHS/Other Appropriate Sources
EPA - No information on the Envirofacts Master Chemical Integrator (EMCI) or Toxics Release Inventory (TRI) as of January 12, 2001.

NIEHS - No information in the National Toxicology Program (NTP) database for either calcium sulfate or calcium sulfate dihydrate as of January 12, 2001.

Other sources -
Illinois Right-to-Know Toxic Substances List, Illinois Register, Section 205, Table A, Toxic Substances List (1991).
Massachusetts Substance List for Right-to Know Law (11 April 94); General Law C.111F, Chapter 30A (28 Jun 84); 105 CMR 670.000; Appendix A.
Pennsylvania Right-to-Know, Pennsylvania Department of Labor and Industry Hazardous Substance List (1989).

Status Among U.S. Certifiers
California Certified Organic Farmers – Allowed from non-synthetic sources only (CCOF, 2000).
Oregon Tilth Certified Organic – Allowed without restriction as to source or use (Coody, 1999).
OCIA International – calcium sulfate, natural is listed as Allowed as a non-organic ingredient (OCIA, 2000).
Texas Department of Agriculture – Listed as "Regulated: may be used to adjust pH for dyeing organic fiber products. Allowed as a non-organic ingredient in processing. Synthetic sources from chemical industrial byproducts, drywall rejects or sulfuric acid treatment anhydrite are prohibited" (February 2000).

International
CODEX – Allowed for cakes and biscuits, soy bean products, bakers yeast, and as a carrier (FAO/WHO, 1999).
EU 2092/91 – Allowed as a carrier and as a coagulation agent (EU 2092/91 Annex VI). This has been interpreted as prohibiting all direct uses other than as a coagulation agent for soymilk (Haccius and Schmidt, 1998).
IFOAM – Allowed for use in cakes and biscuits (baked goods) and soybean products (IFOAM, 2000).
Canada – Does not appear on the permitted substances list (CGSB, Appendix C1, 1999). Certified Organic Association of British Columbia (COABC) – Allowed as a non-organic ingredient (1999).
KRAV (Sweden) – Allowed for beer (KRAV, 1999).
Japan – Allowed, limited to use as a coagulant, or in confectionary, prepared products of beans, and baker's yeast (Woolsey, 2000).

OFPA 2119(m) Criteria

(1) *The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.* This is being considered as a processing material.
(2) *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.* See processor criteria 3, below.
(3) *The probability of environmental contamination during manufacture, use, misuse or disposal of such substance.* This is considered below under item 2.
(4) *The effect of the substance on human health.* This is considered in the context of the effect on nutrition in 3, below, as well as the consideration of GRAS and residues in 5, below.
(5) *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.* As this is not released into the agroecosystem, there is no direct effect.
(6) *The alternatives to using the substance in terms of practices or other available materials.* See discussion of alternatives in 1, below.
(7) *Its compatibility with a system of sustainable agriculture.* This is considered more specifically below in the context of organic handling in 6, below.

Criteria from the February 10, 1999 NOSB Meeting

A PROCESSING AID OR ADJUVANT may be used if;

1. It cannot be produced from a natural source and has no organic ingredients as substitutes.
Food-grade calcium sulfate dihydrate can be produced from natural sources and it can also be synthesized. The review is limited only to the natural mined source. Tofu can be prepared by a number of different recipes, but each has its own distinct flavor, texture, and functionality in various dishes and cuisines (Shurtleff, 1975). It is possible to coagulate tofu by the use of various acidic preparations, such as organic vinegar or organic lemon juice. However, this results in a tart or sour tofu that is generally used as an intermediate for other products and is seldom marketed retail by itself, instead it is primarily used in home recipes (Soyfoods Association, 1986). The NOSB has reviewed magnesium chloride and magnesium sulfate (these two ingredients make up nigari) as an alternative (NOSB, 1995 and 1999). The NOSB discussed various tofu coagulation agents, and issued Recommendation Addendum 16 regarding synthetic magnesium chloride. Calcium chloride is also on the National List. Calcium sulfate has been the traditional coagulation agent in Chinese-style tofu preparations (Shurtleff and Aoyagi, 1975).

Glucono delta lactone (GDL) was also petitioned for use in soy products in 1995, but the NOSB has not referred that substance to the TAP (NOSB, 1995). GDL is not considered appropriate by itself to make Chinese-style tofu (Tsai, Lan, Kao, and Chen, 1981). It is possible to obtain a tofu with somewhat similar characteristics by the addition of carageenan (Abd Karim, Sulebele, Azhar, and Ping, 1999). Industry standards for grades and quality of tofu are described in a publication from the Soyfoods Association (1986).

Calcium sulfate is essential for certain kinds of tofu. Tofu made from calcium sulfate will be softer and smoother with a mild, bland flavor profile (Shurtleff and Aoyagi, 1975). One can make tofu without calcium sulfate, but calcium sulfate is essential to make tofu with certain characteristics (Wang and Hesseltine, 1982; DeMan, DeMan, and Gupta, 1986).

2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA.
Food-grade calcium sulfate is produced from quarries or pit mines of high-grade gypsum deposits (Petersen, 1998). Drilling or blasting, with quarrying by heavy equipment, often opens these pits. Higher-grade veins are selected for food grade, and these deposits are taken to food grade facilities where the crude gypsum is crushed, screened, milled, graded, and packaged. All steps are mechanical for the dihydrate form. The anhydrous form is calcined at temperatures in excess of 115° C., with the highest temperatures used being 215°C. (Petersen, Kaleta, and Kingston, 1992).

The mining process produces dust, which causes air pollution and physical irritation (Material Safety Data Sheet). Persons handling and mixing products may also be exposed to dust.

Exposure Limits
Expressed as Time Weighted Averages (TWAs) over 8 hour working shifts.

NIOSH Recommended Exposure Limit (REL) (guideline)
Total dust: 10 mg/m^3
Respirable fraction: 5 mg/m^3
Source: NIOSH, 1992

OSHA Permissable Exposure Levels (PEL) (regulation)
Total Dust: 15 ppm
Respirable fraction: 5 mg/m^3
No limits on skin exposure
Source: 29 CFR 1910.1000 (2000)

It reacts violently with aluminum when heated; mixtures with phosphorous may ignite. When heated to decomposition it emits toxic fumes of SO_x. It reacts exothermically with the methylating agent diazomethane to the point of exploding (Lewis, 1989).

3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations.*
The nutritional profiles of tofu made from various coagulation agents compares favorably for some nutrients and has lower nutritional value for others. Tofu made from calcium sulfate as a coagulant will have a higher calcium content and a lower magnesium content than tofu made with nigari. As a rule of thumb, tofu made with calcium sulfate has 3.5 times as much dietary calcium as nigari tofu (Soyfoods Association, 1986). The difference may be as great as four times as much per serving (Toyo Shinpo, 1980). The protein quality of tofu produced by calcium sulfate precipitation is comparable to that produced by acid treatment (Schroder, Elliot, and Jackson, 1973). Tofu made with calcium sulfate consistently produces higher yields of tofu per pound of soybeans than nigari (Hou, Chang, and Shih, 1997).

Protein concentration and yield have both been shown to decrease as the amount of calcium sulfate increases. This response was found to be consistent across different varieties (Sun and Breene, 1991). Rats fed tofu made with calcium sulfate retained more calcium than rats fed non-fat dry milk. Nigari treated tofu has one-tenth the bioavailable calcium of calcium sulfate coagulated tofu (Poneros and Erdman, 1988).

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.*
The primary purpose used in tofu making is as a coagulant, and as such it is not used as a preservative. While it provides a distinctively different set of flavors and textures from other coagulants, coagulation is an essential step that defines tofu as different from soymilk. The addition of calcium sulfate increases the calcium content of tofu, but it is not used strictly as a nutritional supplement. Uses in products other than tofu may be used to recreate or improve flavors.

Calcium sulfate is used three ways in beer making: as a yeast food; to increase the yield in malt production from barley; and to add calcium to soft water used in brewing.

5. *Is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of FDA tolerances.*
Calcium sulfate is Generally Recognized As Safe under 21 CFR 184.1230.

The FDA permits the uses described in Table 1.

Table 1
FDA Approved Uses of Calcium Sulfate

Use	21 CFR
anti-caking agent	170.3(o)(1)
color and coloring adjunct	170.3(o)(4)
dough strengthener	170.3(o)(6)
drying agent	170.3(o)(7)
firming agent	170.3(o)(10)
flour treating agent	170.3(o)(13)
formulation aid	170.3(o)(14)
leavening agent	170.3(o)(17)
nutrient supplement	170.3(o)(20)
pH control agent	170.3(o)(23)
processing aid	170.3(o)(24)
stabilizer and thickener	170.3(o)(28)
synergist	170.3(o)(31)
texturizer	170.3(o)(32)
Source: 21 CFR 184.1230(c)	

Limits for Good Manufacturing Practices use of calcium sulfate are contained in Table 2.

Table 2
Maximum Levels of Calcium Sulfate Allowed Under Current Good Manufacturing Practices (As Served)

Product Category	Limit (%)	21 CFR
baked goods	1.3%	170.3(n)(1)
confections and frostings	3.0%	170.3(n)(9)
frozen dairy desserts and mixes	0.5%	170.3(n)(20)
gelatins and puddings	0.4%	170.3(n)(22)
grain products and pastas	0.5%	170.3(n)(23)
processed vegetables	0.35%	170.3(n)(36)
all other food categories	0.07%	184.1230(d)
Source: 21 CFR 184.1230(d)		

Table 3 Specific Food and Beverage References	
Food / Beverage	**Regulation**
Cheeses and related cheese products	21 CFR 133
Asiago fresh and Asiago soft	133.102(c)(2)
Blue	133.106(b)(3)(v)
Caciocavello siciliano	133.111(c)(2)
Gorgonzola	133.141(b)(3)(v)
Parmesan and reggiano	133.165(c)(2)
Provolone	133.181(b)(3)(v)
Romano	133.183(c)(2)
Swiss and emmentaler cheese	133.195(b)(3)(v)
Cereal flours and related products	21 CFR 137
Flour	21 CFR 137.105(a)(5)
Fruit butters, jellies, preserves, and related products	21 CFR 150
Artificially sweetened fruit jelly	150.141(a)(5)
Artificially sweetened fruit preserves and jams	150.161(a)(5)
Colorants for food-contact packaging	
Paper and cardboard	21 CFR 176.170(b)(2)
Polymers	21 CFR 178.3297(e)
Source: EAFUS, 2001	

BATF also permits it to lower pH in sherry wine, provided that the sulfate content of the finished wine does not exceed 2.0g/L, expressed as potassium sulfate (27 CFR 24.246). Use in alcoholic beverages is limited to 16.69 pounds per 1,000 gallons (Lewis, 1989).

The Food Chemicals Codex specifications for food grade calcium sulfate are:
Assay: Not less than 98% $CaSO_4$ calculated on a dry weight basis.
Fluoride: Not more than 0.003%.
Heavy metals: not less than 10 mg/kg expressed as lead (Pb).
Loss on Drying: $CaSO_4$ (anhydrous): not more than 1.5%;
$CaSO_4 \cdot 2H_2O$ (dihydrate): between 19.0% and 23.0%.
Selenium: Not more than 0.003%.

Lead content is a primary contaminant of concern (Shurtleff and Aoyagi, 1975).

6. *Its use is compatible with the principles of organic handling.*
The natural product is allowed and widely used in organic crop production, and used in organic livestock production. It has long been used by certified organic tofu makers. Organic food processors surveyed considered the use of 'mined minerals' as tofu coagulants to be more compatible than the use of 'acidic solutions' but less compatible with organic than the use of nigari (Raj, 1991). Some of its uses are not relevant to organic, e.g., use with artificial sweeteners. Use as a flour ingredient and as a dough conditioner has been questioned because of its historical linkage as a carrier and stabilizer with bleaching agents (Fennema, 1996), rodent control (Winter, 1989), and as an adulterant. Calcium sulfate, by itself, is not a bleaching agent. Its use as a coloring agent is generally restricted to use on packaging.

7. *There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.*
The petitioner states that calcium sulfate provides a qualitatively different product from that made by magnesium chloride and magnesium sulfate. Also see question 1, above. The amount used in most recipes amounts to 0.3% wet weight, and generally will not exceed 1% dry weight in most tofu preparations. (See Table 2.)

TAP Reviewer Discussion

TAP Reviewer Comments

OMRI's information is enclosed in square brackets in italics. Where a reviewer corrected a technical point (e.g., the word should be "intravenous" rather than "subcutaneous"), these corrections were made in this document and are not listed here in the Reviewer Comments. The rest of the TAP Reviewer's comments are listed here minus any identifying comments and with corrections of typos. The reviewers were asked the following questions; those reviewers who provided answers that could not be incorporated into the database above have their answers identified by 'A' and the question number (e.g. 'A1' for the answer to question 1).

1) What are the qualitative differences between tofu made from natural nigari, natural terra alba (calcium sulfate), (organic) vinegar, (organic) lemon juice, natural calcium chloride, synthetic (bleached) nigari, and synthetic calcium sulfate?

2) What are the nutritional differences?

3) It was claimed by several users and suppliers that all food-grade sources in the US are mined, or at least all food grade sources from their company. Is this easy to verify?

4) Are you aware of any synthetic steps used to purify or beneficiate mined gypsum to make it food grade?

5) Are the levels of lead, other heavy metals, and other contaminants set by Food Chemicals Codex appropriate for organic food?

6) Should the TAP review, recommendations, and annotations be unconditional and inclusive of all (otherwise FDA- or BATF-approved) uses, should they be limited to use in soy products, or are there other annotations that should be made? (e.g., not for use as a coloring agent, etc.).

7) How easy is it for certifiers and processors to distinguish the mined form of calcium sulfate from the synthetic form?

8) If you support an annotation that allows for additional uses, or no annotations (other than source) and no limitations on use, please provide a review that addresses the criteria for all requested or at least the major uses.

9) We have been asked specifically to address beer. Do you have any information on the use of calcium sulfate in the malting or brewing process? There appears to be more information on use as a yeast food, but I did not pull any references. Beer additives do not appear to be listed in 27 CFR. According to Lewis, it is at 27 CFR 240.1051, but that is a 1989 reference. Approved for wine & sherry uses are listed, but not beer.

Reviewer 1

[Consultant to organic certifiers]

Natural and Synthetic Forms

Calcium Sulfate may be obtained from natural, mined sources, as well as be synthesized from other materials. Thus, it can exist as both a synthetic and a non-synthetic material, under the definitions provided under OFPA and the NOP Final Rule (7 CFR 205).

This review will only consider the non-synthetic forms of calcium sulfate, per guidance given in the petition and the TAP database provided to this reviewer. As there are abundant non-synthetic supplies of calcium sulfate widely available to organic producers (USGS, 2000), there is no need to consider the synthetic forms, so the guidance of the petition and TAP database are appropriate in this regard. Thus, in any case, synthetic calcium sulfate should be prohibited in organic production systems.

Calcium sulfate as a dihydrate crystal may be obtained from mined sources using purely physical processes. While some sources claim to provide relatively pure supplies of the dihydrate form (US Gypsum, 1999) it is often found together with the anhydrous form, along with other impurities (Peterson, Kaleta, and Kingston, 1992). There are pertinent considerations for this review regarding impurities in the naturally mined material – see below under AFFECTS ON HUMAN HEALTH AND NUTRITION. For that part of the discussion, the dihydrate, anhydrate, and hemihydrate forms will not be considered as impurities, as long as they are results of the natural mining process, derived without chemical or heat processes.

Hydrated forms may be changed to the anhydrous form by subjecting them to heat to drive off the water portion of the original material. This latter step could technically be deemed to be a chemical alteration of the original material, thus making it closer to a synthetic material under the OFPA guidelines, although the functionality of the calcium sulfate is presumably not significantly affected by the calcination as such. Nonetheless, as the naturally occurring form is completely acceptable for the purposes petitioned, this reviewer concludes that the only acceptable form of calcium sulfate for addition to the National List should be the naturally mined form, derived solely by physical methods.

Environmental Considerations:

Non-synthetic calcium sulfate has long been recognized and used in organic crop production, with beneficial results.

The manufacture of the material can be by solely physical processes, where the crude gypsum is crushed, screened, milled, graded, and packaged.

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 affects 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.

It is the opinion of this reviewer that there is no particular reason to believe that use of non-synthetic calcium sulfate in organic systems would contribute undue adversity to the environment, particularly when compared to many other non-organic materials that are already approved for organic production systems.

USES, ESSENTIALITY:
Potential substitutes for calcium sulfate in processing systems depend on the specific purpose for using the material. There are a wide variety of uses known (see chart below for specifics) (Winter, 1994), and are listed in 21 CFR (EAFUS, 2001) and 27 CFR (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. . . . [See Table 4].

Effects on Human Health and Nutrition:
Calcium sulfate absorbs water and hardens quickly, and as such, when ingested in high concentration can result in intestinal obstruction (Winter, 1994).

Calcium sulfate added to foods can result in an increased dietary intake of calcium, and as such, can be considered a dietary supplement (Food Chemicals Codex, 1996). There is no evidence that ingestion as such does has deleterious affects on human health and nutrition, and may in fact have positive affects. Tofu made with calcium sulfate has been shown to have more than 3.5 times as much dietary calcium as tofu made with nigari (Soyfoods Association, 1986). However, there is a general pattern of decreasing protein yield in tofu with increasing concentration of calcium sulfate used as a coagulant (Sun and Breene, 1991). Nonetheless, overall protein yield is still comparable to tofu made with other coagulants, and total yield by weight of finished tofu is generally greater using calcium sulfate (Wang and Hesseltine, 1982; Hou, Chang, and Shih, 1997).

It is the opinion of this reviewer that these levels as set by the Food Chemicals Codex are appropriate for organic foods. The only alternative to such standards which occurs to this reviewer is to require synthetic calcium sulfate, which might, but not absolutely be guaranteed to be a more pure form. Given the conceptual inconsistency of using the synthetic rather than the naturally occurring material, this latter option does not seem as reasonable as relying on the FCC guidelines.

Organic certifiers should require that all handlers using calcium sulfate present documentation from the supplier (such as Certificates of Analysis, and other statements) which state that the purity of the product, as well as the source./method from which it was obtained.

SUMMARY AND RECOMMENDATION:
List calcium sulfate, as follows:

Synthetic / Non-synthetic	***Allowed / Prohibited***	***Annotation***
Non-synthetic	Allowed	For use only as a coagulant in bean curd (tofu and similar products). Mined sources only; must be derived and purified using only physical methods; must conform to the Food Chemicals Codex guidelines for impurities.

Reviewer 2

[Ph.D. Biochemistry with food industry experience]

TAP Reviewer Vote:

The material Calcium Sulfate, FCC, is NATURAL.
The material Calcium Sulfate, FCC, should be allowed without annotation.

General Comments

Specific Uses: Given the concerns of the organic community, one misstatement must be corrected to avoid generating an indelible bad impression. Calcium sulfate is **NOT** a "bleaching agent." It is a **carrier** for bleaching agents used to bleach flour and milk. Note that the Foods Chemical Codex description does **not** include "bleaching agent" among the purposes for calcium sulfate use in food. See the following sections in Title 21 CFR for details and corroboration.

133.102(c)(2)	Asiago fresh and Asiago soft cheese
133.106(b)(3)(v)	Blue cheese
133.111(c)(2)	Caciocavello siciliano cheese
133.141(b)(3)(v)	Gorgonzola cheese
133.165(c)(2)	Parmesan and reggiano cheeses
133.181(b)(3)(v)	Provolone cheese
133.183(c)(2)	Romano cheese
137.105(a)(5)	Flour

Similarly, calcium sulfate is used as a "gelling agent" to 'set' a pectin gel, but this usage is specifically allowed only in artificially sweetened fruit jelly [21CFR150.141(a)(5)] and in artificially sweetened fruit preserves and jams [21CFR150.161(a)(5)].

The fact is that artificially sweetened fruit products, cheese made with bleached milk and bleached flour have 'lost any organic integrity' they ever had. Consequently, universal acceptance of calcium sulfate as an ingredient in organic food will not create a problematic 'enablement' of these particular applications.

"The petitioner states that calcium sulfate provides a qualitatively different product from that made by magnesium chloride and magnesium sulfate."

This position is supported by the food science literature, in that calcium sulfate creates tofu with a unique soft, silky texture.

Production Method: The excerpt from the Kirk-Othmer Encyclopedia of Chemical Technology deals entirely with gypsum in its important role as a construction material (stucco, the mineral in wallboard, an ingredient in Portland cement) and does not describe the process for creating food grade calcium sulfate. The Quality procedure scheme for Terra Alba provided in the packet notes "outside piles" of the mineral, which is not reassuring. Overall, the evidence in the packet indicates that "terra alba" calcium sulfate used in food is natural gypsum of sufficient purity to satisfy Food Chemicals Codex quality standards. The enclosed description of the mining procedure for the food and pharmaceutical grade Terra Alba produced by Diamond K Gypsum supports this conclusion.

OFPA 2119(m) Criteria: Calcium sulfate is used as a soil conditioner to treat clay soils, so the small amounts of calcium sulfate used in foods would not represent a significant hazard to soil microorganisms or crops.

[Answers to Questions for TAP Reviewers]

A1a. Given the information provided (which appears reliable), synthetic calcium sulfate is not used to make Food Grade calcium sulfate. The synthetic material has too many impurities (and questions); the natural material is cheap enough so there is no incentive in the U.S. and most of the world to use anything else. One would expect no difference between synthetic calcium sulfate and native/mined calcium sulfate.

A1b. The literature citations, specifically DeMan, DeMan and Gupta (1986) and Wang and Hesseltine (1982), provide the answer to this question and make the point that each coagulant creates a organoleptically different product, thus confirming the petitioner's argument.

A2. The data provided in the report answer this question adequately. Coagulating with a calcium salt adds calcium; coagulating with nigari, a magnesium salt, adds magnesium; and so forth. The mineral elements in this case are all essential nutrients.

A3. . . . Information available on the internet supports the claim that all food grade calcium sulfate available in the U.S. is mined. . .

A5. The maximum levels of heavy metals, including lead, in substances allowed as direct food ingredients are established with safety margins to protect all consumers. These maxima are reviewed from time to time to ensure a safe food supply for the U.S. population. The Food Chemicals Codex standards are appropriate for all food. Note that "organic" does not mean "safer."

A6. The "organically unacceptable" uses of calcium sulfate are as a carrier or a diluent of undesirable "anti-organic" food ingredients, such as the bleaching agents used to bleach flour and milk, and as a gelling agent in fruit spreads (jelly, jam and preserves) artificially sweetened with an unnatural non-nutritive substance. The undesirable and organically unacceptable food ingredient would effectively prevent the use of the term "organic" on these foods containing calcium sulfate.

Consequently, the TAP review, recommendations, and annotations should be unconditional and inclusive of all (otherwise FDA- or BATF-approved) uses.

A7. In the United States, it appears that the synthetic form is not used for food. OMRI, an organic certifying organization, or the tofu processing industry itself should consider site visits and inspections to verify manufacturers' claims of a mined origin and no chemical benefication to remove impurities.

A8. Applications that technically allow interchangeable forms of calcium (yeast food, dough thickener, processed vegetables), for example, should not be restricted with respect to using a food ingredient such as calcium sulfate found acceptable for use in another organic food, such as tofu.

A9. [Attached are] excerpts from the Internet regarding calcium sulfate in the brewing process.

Reviewer 3

[Food Science and Nutrition Professor with inspection and certification experience]

Review of the Food Science literature is replete with the uses of calcium sulfate in foods. The primary use of calcium sulfate as a food additive is in the production of traditional forms of tofu. Sun and Breene (1991) indicate that calcium sulfate is the coagulant of choice among tofu makers. At concentrations of between 0.02 and 0.05 normal, optimum yields and textural quality were obtained using Minnesota grown soybeans. Generally tofu made with coagulants such as magnesium chloride or calcium chloride provide a coarse, granular and hard textured product much less in overall quality than tofu made with calcium sulfate. Historically calcium sulfate has been used for over 2,000 years to produce tofu that has been show to contain 3.5 to 4 times as much dietary calcium as tofu produced using other coagulants such as acid, glucono delta lactone, Nigari and magnesium chloride.

Calcium sulfate is readily obtained as a mined source and is purified by heating the hemihydrate form to the dihydrate by which 1.5 moles of water is removed as water vapor. The dihydrate form of calcium sulfate is then further heat treated to remove the 2 moles of water forming anhydrous calcium sulfate which generally contains approximately 98% $CaSO_4$ and less than 2% of calcium carbonate, calcium oxide, magnesium carbonate and silicon dioxide (United States Gypsum Company and Peterson et al). Generally all US supplies of calcium sulfate are mined in the US and North America. However, calcium sulfate can be manufactured as a by-product of various chemical processes especially in the scrubbing of gasses evolved in burning fuels that contain sulfur such as coal and the chemical industry where sulfuric acid is a by-product. However, the cost of processing and purifying calcium sulfate from these non-mined sources greatly exceeds the cost of the mined form of calcium sulfate. Additionally, I would suggest that calcium sulfate used for organic products processing specify that it is obtained from a mined source either on a certificate of analysis or in product information sheets. Additionally, due to cost considerations non-mined calcium sulfate simply may not be competitive.

With respect to the levels of heavy metals set by Food Chemical Codex, these levels are set by scientific studies that provide the FDA the recommended usage levels. Therefore, as a natural mined product, natural levels of heavy metals may be present with tolerances provided by the Food Chemical Codes. I do not see this as presenting any degree of difficulty or becoming problematic at the usage levels set by the FDA.

Overall. I would recommend on the basis of the scientific literature, that calcium sulfate be considered as non-synthetic and allowed for use in all organic foods as long as it be verified as obtained from a mined source. I would recommend an annotation that governed its use according to FDA approved uses and at the levels as mandated in 21CFR according to Tables 1 and 2 in the NOSB TAP review.

My reasoning is as follows. If calcium sulfate is allowed for use in only tofu processing and this determination is based on sound scientific and organic principles reasoning, then how could it be excluded for use in other foods as a functional, non-synthetic allowed ingredient? Obviously there is a cost benefit, functional and product quality considerations. I feel there is no compelling reason to exclude the use of mined calcium sulfate from organic baked goods, confectionery products, frozen deserts, puddings, grains and pasta, vegetables and other food categories such as beer if it is approved in 27CFR.

I am very much concerned about limiting the use of approved non-synthetic food ingredients since there is no strong scientific reasoning to support its inclusion only for tofu and exclusion for all other products.

It would be very simple for certifiers to determine whether calcium sulfate is from a mined source by mandating that a certificate of analysis or product information bulletin be provided or a letter from the supplier indicating its source. Also, I agree with the positions taken by CCOF, Oregon Tilth, OCIA and the Texas Department of Agriculture on the unconditional use of calcium sulfate but I would add “use be consistent with FDA approved uses at levels mandated by 21CFR.”

My position and recommendation regarding the use of calcium sulfate in beer brewing is allowed as documented in 27 CFR, since BATF has approved its usage to lower the pH of sherry wine. Use in beer fermentation may be as a component in a mineral mix to enhance or stabilize the rate of yeast cell growth and therefore the rate of the fermentation process.

In summary, I feel the use of mined calcium sulfate, which has been produced as a function of heat processing, is compatible with both the spirit and intent of organic integrity. Even though it may be deemed a food additive, it is really an ingredient because the calcium ions are the functional chemical components that govern its usage or the sulfate anions,

which are responsible for pH adjustment. Scientifically, I see no compelling justification to restrict its usage in organic foods or process operations.

Recommendations to OMRI

1. Non-synthetic
2. Allowed

Suggested Annotation

Mined sources only and use must be consistent with FDA approved uses at levels mandated by 21CFR.

Conclusion

Given the historical use and nutritional value of calcium sulfate used as a coagulant for tofu, it appears that the substance is compatible with organic principles. Similarly, its use in a variety of other applications appear to be compatible with organic principles, but a number may not be. These merit discussion in the overall context of the appropriate use of additives in organic food production. Two of the three TAP reviewers advise the NOSB to list Calcium Sulfate from Natural Mined Sources only as an Allowed Non-synthetic, Non-organic, Ingredient without any additional annotations.

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