

Date: January, 2004

To:

National Organic Standards Board, c/o Robert Pooler, Agricultural Marketing Specialist,
USDA/AMS/TM/NOP, Room 4008-So., 1400 Independence Ave SW, Washington, D.C.
20250-0020. Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov

Dear Mr. Pooler.

The enclosed petition for Lecithin is being submitted by the following
company.

(insert company name)

**Petition for Amending the National List of the USDA's
National Organic Program**

Lecithin - change listing

Petitioners are required to provide the following information as applicable:

Category for inclusion on or removal from the National List:

Remove unbleached lecithin from § 205.606 *Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" or "made with organic..."*

Common name

Lecithin, unbleached.

Manufacturers name, address and telephone number

List of uses, rates and applications for crops and livestock uses, mode of action for handling uses

Lecithin is utilized in a wide variety of food and industrial applications. It is common in baked goods, chocolates, salad dressings, nut butters, candies, protein drinks, instant soups and prepared foods. It is available as a supplement in capsules. It is also used in animal feed and in industry in cosmetics, paints, and metal tape.

There are several functional effects from lecithin. It is an emulsifier which keeps oils from separating and keeps fat molecules evenly dispersed in food products. Because of that property it can be used to lower the fat content of some foods while enabling them to still taste good. It is an anti-caking agent and releasing agent which keeps foods from sticking to each other or cooking surfaces. It can serve as a wetting agent to help dry ingredients mix easily.

Sources and detailed description of manufacturing procedures:

The following description is for organic lecithin manufacture:

Organic soybeans are crushed using certified organic methods extracting the oil by cold press or (expeller press methods). The crude oil is cleaned by mechanical means and the gums from the oil are extracted by adding city water. The gums are then placed into a lecithin dryer which removes the water and extracts the lecithin. The lecithin can then be adjusted to meet individual customers specs. by carefully adding different quantities of organic RBD (Refined, Bleached, and Degummed Soy Oil). The resulting organic product is in liquid form.

Conventional lecithin uses conventionally grown soybeans which may or may not be from genetically engineered crops. The basic steps of crushing and extracting may be the same, although solvents may be used in the purification and removal of water from the lecithin. Then the crude lecithin may be bleached using hydrogen peroxide or benzoyl peroxide. This lecithin is either available as liquid or dried in a variety of products for differing uses.

Summary of any previous reviews by state or private certification agencies:

The Soil Association of the UK did a very interesting review in 1999 which is attached. It studied the issue of GMO contamination of lecithin from conventional soybeans. It found that the lecithin may be tested for GMOs, but the test will identify absence of GM protein or genetic material, but it cannot necessarily guarantee that the beans used to produce the lecithin were non-GM. Therefore they were “upholding the right of producers and consumers to grow and purchase GM-free food” by insisting that their clients source lecithin from segregated non-GM sources (including organic).

Regulatory status with EPA, FDA or state authorities

Lecithin is considered to be GRAS under CFR 21, PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE-- Subpart B--Listing of Specific Substances Affirmed as GRAS, Sec. 184.1400 Lecithin.

Chemical Abstract Service (CAS) number or other product #, samples of labels:

CAS # 008002-43-5, EINECS Number 232-307-2, Harmonizing Export Reference 2923.20.00006

Physical properties of the substance and chemical mode of action: including environmental impacts, interactions with other materials, toxicity and persistence, effects on human health, effects of soil organisms, crops or livestock

Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. Vital organs such as the liver and reproductive tract, and muscles contain high concentration of phospholipids. Phospholipids are also among the primary building blocks of all cellular membranes. Membrane functions include cellular transport of nutrients and wastes, internal cellular pressure regulation, and ion exchange.

It appears as an amber to brownish viscous material with a specific gravity of 1.03. As a natural component of most cell membranes, it is readily broken down in nature and

the manufacture results in minimal environmental impact or waste. It has beneficial effects on human health and soil organisms.

The substance was reviewed by the NOSB in a prior TAP review in Orlando, FL in 1995. That prior TAP review contains details about the criteria in OFPA.

Safety information, including a MSDS (Material Safety Data Sheet) and report from National Institute of Environmental Health Studies (NIEHS):

One MSDS for a formulated lecithin product is attached. Another one can be found at this URL – http://www.kedia.com/soya_msd.htm. Lecithin is completely safe.

Research information, including research reviews and bibliographies:

American Lecithin Company, Alcolec™ - S Materials Safety Data Sheet (enclosed)

Buchanan, C., 1989. Lecithin supplements: A source of help or hype? Environmental nutrition. June 1989. v. 12 (6) Pages: p. 1, 6-7. charts. NAL CALL NO: TX341 E5

Canty, D.J. 1994. Lecithin and choline in human health and disease. Nutrition reviews. Oct 1994. v. 52 (10) Pages: p. 327-339. NAL CALL NO: 389.8 N953

Cherry, J.P. 1981. A review of lecithin chemistry and glandless cottonseed as a potential commercial source. Journal of the American Oil Chemists' Society. Oct 1981. v. 58 (10) Pages: p. 903-913. ill. NAL CALL NO: 307.8 J82

Dashiell, G.L., 1988. Characterization and use of soybean lecithin. Soybean utilization alternatives : February 16-18, 1988, a symposium / sponsored by the Center for Alternative Crops and Products ; organizing committee, Leland Hardman [et al.]; publication editor, Laura McCann. Pages: p. 355-366. NAL CALL NO: SB205 S7S693

Miller, D.L. 2002. Health benefits of lecithin and choline. Cereal foods world. May 2002. v. 47 (5) Pages: p. 178-184. NAL CALL NO: 59.8 C333

Riceland Foods website, www.lecithin.com

Soil Association 1999, GMOs, Lecithin and Organic Standards, June 1999 - A Briefing Paper.
http://www.soilassociation.org/web/sa/saweb.nsf/librarytitles/Briefing_Sheets02071999 (enclosed)

Petition justification statement - why the synthetic substance is necessary, alternatives that could be used, beneficial effects to the environment, etc:

§ 205.606 states, “Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.” At the time of the initial review by the NOSB in 1995, lecithin was not commercially available in organic form. As of 2003 there is now liquid lecithin made from organic soybeans and it is readily available.

The prevalence of genetically engineered soybeans in commercial production has made it more critical than ever for organic processors to seek out organic sources of substances derived from soybeans that are free of genetic engineering. This is almost impossible to do with conventionally produced lecithin, but is easily achieved from organic lecithin. Companies that may export products are particularly in need of assurance that there are no genetically engineered ingredients in them.

Lecithin is a more beneficial ingredient than most of the alternatives to it in emulsifying products. This was determined by the NOSB when they initially added it to the National List. At a future time it may be possible to also remove bleached lecithin from the synthetic portion of the list in §205.605, but right now there are situations where even the organically derived lecithin might need to be bleached to make it work in certain functions, and the bleaching process was considered synthetic by the NOSB in 1995.

However the unbleached lecithin is now abundant, and as such it does not need to be on the list in §205.606 anymore, just as most other foods are not on the National List.

Commercial Confidential Information Statement - describing information that is considered to be confidential business or commercial information