SUMMARY OF TAP REVIEWERS' ANALYSES[1]

Soy protein isolate is being petitioned for use as a fertilizer in organic crop production in order to ensure sufficient available nitrogen for crop health and development. Since soy protein is produced by and stored in the soybean, it is considered a non-synthetic substance. Due to the significant amount of processing required to separate, or "isolate," soy protein from other soybean constituents, soy protein isolate could be considered a synthetic substance. Soy protein isolate is commonly added to commercial food products and is found as an ingredient in industrial compounds. However, not much information concerning the chemical properties or the manufacturing process of soy protein isolate is available in the scientific or popular literature. Most published information concerning soy protein isolate discusses its role in human health. No information concerning its use as either a conventional (non-organic) or organic plant fertilizer was found.

All three reviewers concluded that soy protein isolate, as petitioned, is a synthetic substance. Two of the reviewers recommended that soy protein isolate should not be included on the National List since no information concerning its production could be obtained from the manufacturer and since a wide variety of other organic fertilizer options are available. The other reviewer recommended that soy protein isolate should be included on the National List since it is innocuous and is very unlikely to cause any environmental concerns. However, this reviewer also expressed some apprehension about the lack of production information for soy protein isolate.

Synthetic or Non-synthetic?	***Allow without restrictions?***	***Allow only with restrictions? (See reviewers' comments for restrictions)***
Synthetic (3) **Non-synthetic (0)**	**Yes (1)** **No (2)**	**Yes (0)** **No (0)**

IDENTIFICATION

Common Name: Soy Protein Isolate

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[1] *This Technical Advisory Panel (TAP) report was based upon the information available at the time this report was generated. This report addressed the requirements of the Organic Foods Production Act of 1990, as amended, to the best of the investigator's ability and was reviewed by experts on the petitioned substance. The substance was evaluated according to the criteria found in Section 2118 (7 U.S.C. 6517) and in Section 2119 (7 U.S.C. 6518) of the OFPA. Any recommendation(s) presented to the National Organic Standards Board (NOSB) was based on the information contained within the TAP report and the evaluation of that information relative to these criteria. The TAP report does not incorporate commercial availability, socioeconomic impact, or other factors related to the petitioned substance, which NOSB and USDA may want to consider in their decision process.*

CAS Registry Number: 9010-10-0

CHARACTERIZATION

Composition: Off-white to light brown powder
Properties:
Molecular Formula: Not Available
Molecular Weight: Not Available
Melting Point: Not Available
Boiling point: Not Applicable
Density: Not Available
Water Solubility: Insoluble
[MSDS, 1998]

PRODUCTION

Archer Daniels Midland Company (ADM), the manufacturer and primary supplier of soy protein isolate to the petitioner, is bound by all local and national regulations with respect to environmental contamination and is fully committed to compliance. Several attempts were made to obtain additional information concerning soy protein isolate production, but ADM never responded to these inquiries. Therefore, the specific procedures for the production of soy protein isolate are not available. However, generic production information for soy protein isolate is shown below in *Figure 1: Typical Commercial Soy Protein Isolate Production Process.*

HISTORY OF USE

Non-Organic Growers and Producers: Up until 1894-95, China localized all soybean production until the Japanese began importing soybean oil for fertilizer use. The earliest written reference to soybeans in the United States occurred in 1804. Soybeans were notably well adapted to Pennsylvania soil. Soybeans grown in the U.S. were originally utilized as a forage crop versus harvesting them for grain. After WWII, the majority of soybean production occurred in Iowa, Illinois, Minnesota, Indiana, Ohio, Missouri, and Nebraska, which accounted for 72% of the total U.S. soybean production in 2000. In 1941, the U.S. soybean acreage dedicated to grain production exceeded that grown for foraging and other purposes [Gibson, 2002]. Currently, soybeans are processed for human and animal consumption as well as for industrial use. Soy protein isolate is commonly used as an additive to various commercially-available food products in order to increase their protein content. Industrial products, such as spackling paste and adhesives, may also contain soy protein isolate.

Organic Growers and Producers: Soybeans are a relatively easy crop to produce organically and comprise the largest segment of organic legume production by volume in the United States [Hansen, 2003]. Due to its nitrogen-fixing ability, the soybean is a moderate consumer of nutrients and is able to furnish most of the nitrogen it requires for crop production [Kuepper, 2003]. Soy protein isolate is not currently used by either

organic growers or producers since it is not included on the National List of Allowed and Prohibited Substances.

CURRENT STATUS

U.S Regulatory Agencies:

National List in the Final Rule: Soy protein isolate is not listed as a plant or soil amendment allowed for use in organic crop production according to the National List of Allowed and Prohibited Substances [§205.601(j)]. Aquatic plant extracts (other than hydrolyzed) are allowed as a plant or soil amendment. Therefore, depending upon the amount of sodium hydroxide (NaOH) used to extract soy protein from soybeans, soy protein isolate may be appropriate as a plant or soil amendment in organic farming. [USDA/NOP, 2003]

Organic Foods Production Act of 1990: According to the OFPA [§6508(b)(1)], for a farm to be certified organic, producers on such farm shall not use any fertilizers containing synthetic ingredients or any commercially blended fertilizers containing materials prohibited under this chapter or under the applicable state organic certification program [USDA/NOP, 1990].

FDA: "In October 1999, FDA approved a health claim that can be used on labels of soy-based foods to tout their heart-healthy benefits. The agency reviewed research from 27 studies that showed soy protein's value in lowering levels of total cholesterol and low-density lipoprotein (LDL, or "bad" cholesterol).

Food marketers can now use the following claim, or a reasonable variation, on their products: 'Diets low in saturated fat and cholesterol that includes 25 grams of soy protein a day may reduce the risk of heart disease. One serving of (name of food) provides __ grams of soy protein.' To qualify for the claim, foods must contain per serving:

- 6.25 grams of soy protein
- low fat (less than 3 grams)
- low saturated fat (less than 1 gram)
- low cholesterol (less than 20 milligrams)
- sodium value of less than 480 milligrams for individual foods, less than 720 milligrams if considered a main dish, and less than 960 milligrams if considered a meal

Foods made with the whole soybean, such as tofu, may qualify for the claim if they have no fat other than that naturally present in the whole bean." [Henkel, 2000]

EPA: The U.S. Environmental Protection Agency (EPA) does not include soy protein isolate as an inert pesticide ingredient on List 1, 2, or 3. However, similar soybean products are included on List 3 as inert pesticide ingredients. Inert

pesticide ingredients on List 3 are currently of unknown potential toxicological concern. They have also not been determined to be of minimal concern (List 4). List 3 inert pesticide ingredients will continue to be evaluated to determine if they merit reclassification to List 1, 2, or 4 [EPA, 2004].

OSHA: Soy protein isolate dust levels must remain below 15 mg/m^3.

Other U.S. Sources: The state of Utah follows all organic standards set forth by USDA/NOP. The Texas Department of Agriculture (TDA) certifies producers, processors, distributors, and retailers of organic food and fiber within the state. TDA certifies a host of Texas-grown crops and products made from grains (wheat, corn, and rice), beans (soybeans, mungbeans, pintos, and many other peas and beans), sesame, peanuts, fruits (blackberries, blueberries, strawberries, citrus, peaches, apples, and melons), vegetables, herbs, aloe vera, mushrooms, sprouts, and wildflower and grass seeds.

International Certifiers:

European Union: Soy protein isolate is not currently listed as an approved food additive in the European Union. [FSA, 2004]

Japan: Soy protein isolate is not currently listed as an approved substance in the Japanese Standards of Organic Processed Foods. [JMAFF, 2000]

Codex: Soy protein isolate is not currently listed as an approved substance in the production of organic foods (Annex II). [FAO/WHO, 2001]

Canada: Soybean meal is permitted in Canadian organic crop production provided that the soybeans have not been genetically engineered. [COABC, 2003]

APPLICATION

Soy protein isolate is being petitioned for use as a fertilizer for organic crop production as well as for turf, landscape, and other horticulture applications. Soy protein isolate will be applied either as a spray to foliage or as pellets to soil.

INCOMPATIBILITIES

Soy protein isolate is a stable compound and is non-hazardous. Hazardous polymerization will not occur and there are no specific conditions to avoid. [MSDS, 1998]

SECTION 2118 (7 U.S.C. 6517) AND SECTION 2119 (7 U.S.C. 6518) OFPA CRITERIA

Category 1: Impact of the Substance on Humans and the Environment

1. *What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance [§6518(m)(3)]?*

   ADM, the manufacturer and primary supplier of soy protein isolate to the petitioner, is bound by all local and national regulations with respect to environmental contamination and is fully committed to compliance. Several attempts were made to obtain additional information concerning soy protein isolate production, but ADM never responded to these inquiries. Therefore, the specific procedures for the production of soy protein isolate are not available.

2. *Is the substance harmful to the environment [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i)]?*

   The U. S. Environmental Protection Agency (EPA) has not included soy protein isolate as a List 1, 2, or 3 inert pesticide ingredient. EPA does include similar soybean products as List 3 inert ingredients. Therefore, EPA does not fully know the toxicity levels of the similar soybean products. These similar soybean products have also not been determined to be of minimal concern (List 4). List 3 substances will continue to be evaluated to determine if they merit reclassification to List 1, 2 or 4 [USEPA, 2004].

3. *Does the substance contain List 1, 2, or 3 inert pesticide ingredients identified by U.S. EPA's Office of Pesticide Programs [§6517(c)(1)(B)(ii); §205.601(m)(2)]?*

   Soy protein isolate is not included as a List 1, 2, or 3 inert pesticide ingredient. However, the following soybean products were included as List 3 inert ingredients [USEPA, 2004]:

   - 68122-64-5: Soybean oil polymerized
   - 67762-12-3: Soybean oil, polymer with glycerol, maleic acid, pentaerythritol and phthalic anhydride
   - 70131-70-3: Soybean oil, polymer with benzoic acid, pentaerythritol, phthalic anhydride, TDI and trimethylolpropane
   - 67700-73-6: Soybean oil, polymer with ethylene glycol, linseed oil, pentaerythritol and phthalic anhydride 3
   - 67700-76-9: Soybean oil, polymer with ethylene glycol, pentaerythritol and phthalic anhydride 3

- 67762-11-2: Soybean oil, polymer with fumaric acid, pentaerythritol and phthalic anhydride 3
- 66070-61-9: Soybean oil, polymer with glycerol and pentaerythritol 3
- 66070-65-3: Soybean oil, polymer with glycerol, linseed oil, pentaerythritol and phthalic anhydride 3
- 66071-86-1: Soybean oil, polymer with isophthalic acid and pentaerythritol 3
- 67762-15-6: Soybean oil, polymer with maleic anhydride, pentaerythritol and phthalic anhydride 3
- 66070-60-8: Soybean oil, polymer with pentaerythritol and phthalic anhydride 3
- 67989-28-0: Soybean oil, polymer with pentaerythritol, toluenediisocyanate and tung oil

4. *What is the potential of the substance for detrimental chemical interactions with other materials used in organic farming systems [§6518(m)(1)]?*

   There is no record that soybean protein isolate, a readily biodegradable organic material, has shown any potential for detrimental chemical interactions with organic farming systems. The maximum residual sodium, as a result of the manufacturing neutralization process, amounts to no more than 900-1200 mg/100g of the final product. This is an inconsequential concentration in soil systems where the application rate is typically between 1-1.5 lbs/1000 square feet.

5. *Does the substance cause adverse biological and chemical interactions in the agroecosystem [§6518(m)(5)]?*

   No information was available.

6. *Does the substance cause detrimental physiological effects on soil organisms (including the salt index and soil solubility), crops, or livestock [§6518(m)(5)]?*

   An epidemiological study included feeding different diets to two groups of monkeys. One of the diets contained casein, and the other diet contained soy protein isolate. Positive effects on the monkeys were reported. After soy protein isolate was substituted for casein in their diet, the monkeys consuming the diet high in soy protein isolate had significantly higher levels of high-density lipoprotein (HDL) and significantly lower levels of low-density lipoprotein (LDL) than the monkeys who continued to consume the diet high in casein. [Endres, 2001]

Contrary to the abundance of studies on the positive effect of soy consumption on human health, two FDA scientists have vehemently challenged the FDA soy health claim. They claim that safety issues concerning soy protein products are still unanswered. The two FDA scientists, Dr. Daniel Doerge and Dr. Daniel Sheehan, have pointed to research that links soy with animal fertility problems. The animal data eludes to possible adverse human health effects. In the doctors' opinion, it is the chemical in soy mimicking estrogen that leads to the potential alteration of an animal's sexual development. [Ross, 2003]

7. *Do either the substance or its breakdown products/contaminants cause a toxic or other adverse action in the environment [§6518(m)(2)]?*

   Iowa State University researchers are continually working to develop soybean protein plastics. These products are biodegradable and could replace current non-biodegradable plastics. The lead researcher, Dr. Jay-Lin Jane, has stated that the soy-based plastics could benefit the soil because soy proteins may act as a soil conditioner after degradation. Preliminary studies have shown plants utilizing soy protein, in powder form, from the soil to aid in the growth process. [Jane, 1996] The research alludes to a positive effect of the degradation of soy protein products in the environment.

8. *What is the probability of an undesirable persistence or concentration of the substance or its breakdown products/contaminants in the environment [§6518(m)(2)]?*

   Refer to Category 1: Question 7.

9. *Is the substance harmful to human health [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)]?*

   Epidemiological studies have shown an inverse relationship between diets high in vegetable protein and either plasma cholesterol levels or the development of coronary heart disease (CHD). A 1982 study in Italy and Switzerland confirmed that in patients whose cholesterol levels exceeded 300 mg/dl, a 20-22% drop in total cholesterol and low-density lipoprotein (LDL) cholesterol was evident after the patients completely replaced animal protein with soy protein in their diets. This study demonstrates the positive effect soy protein has on human health. [Endres, 2001]

   Contrary to the abundance of studies on the positive effects of soy consumption on human health, two FDA scientists have vehemently challenged the FDA soy health claim. They state that safety issues concerning soy protein products are still unanswered. The two FDA scientists, Dr. Daniel Doerge and Dr. Daniel Sheehan, have pointed to research that links soy with animal fertility problems. The animal data eludes to possible adverse human health effects. In the doctors'

opinion, it is the chemical in soy mimicking estrogen that leads to the potential alteration of an animal's sexual development. Various other studies have suggested a link between soy consumption and the development of estrogen-feeding breast cancer. A thirty year study performed by the National Institutes of Health (NIH) showed a potential connection between soy tofu and accelerated brain aging and shrinkage, particularly among elderly men. [Ross, 2003]

Category 2: Importance of the Substance for Organic Production

1. *Is the substance necessary to the production or handling of an agricultural product due to the unavailability of wholly natural substitute materials [§6517(c)(1)(A)(ii)]?*

   Various other organic fertilizers are available for use in "organic crops as well as for turf, landscape, and other horticulture applications." These organic options include cottonseed meal, blood meal, fish emulsion, and manure. Cottonseed meal is an organic fertilizer that causes an acid-producing reaction. This option is desirable for acid-loving plants, including azaleas, camellias, and rhododendrons. Cottonseed meal normally contains 7, 3, and 2 percent nitrogen, phosphorus, and potash, respectively. Blood meal consists of powdered blood collected from cattle slaughterhouses. This is a nitrogen-rich fertilizer and may burn plants if used in excess. Fish emulsion contains a partially decomposed blend of finely minced fish. Fish emulsion contains high levels of nitrogen and trace elements. Although manure is a complete fertilizer, it lacks vital nutrients. The nutrient content of manure is dependent upon the diet and species of the animal that produced it. Fresh manure contains the highest level of nutrients needed for plant growth. Manure is better suited as a soil conditioner than as a fertilizer. [Relf, 1997]

2. *Is the substance non-synthetic, but not produced organically, and used in handling [§6517(c)(1)(B)(iii)]?*

   The most common procedure for the production of soy protein isolate utilizes defatted soybean flakes (Figure 1). This process results in a >90% protein composition. The soybeans are cleaned, cracked, and dehulled to obtain the meats. The meats are then flaked and extracted to remove excess oil. The flakes are desolventized (without denaturing the protein) and mixed with water to produce a slurry. The slurry is then extracted to separate the flakes from the slurry solution. An acid, typically hydrochloric acid (HCl), is added to the resulting protein solution to precipitate out the protein. The protein is then washed with water and neutralized with a base, typically sodium hydroxide (NaOH), to reach a pH of 7. The resulting solution is spray-dried to produce the final product, soy protein isolate. [Trank, 1989]

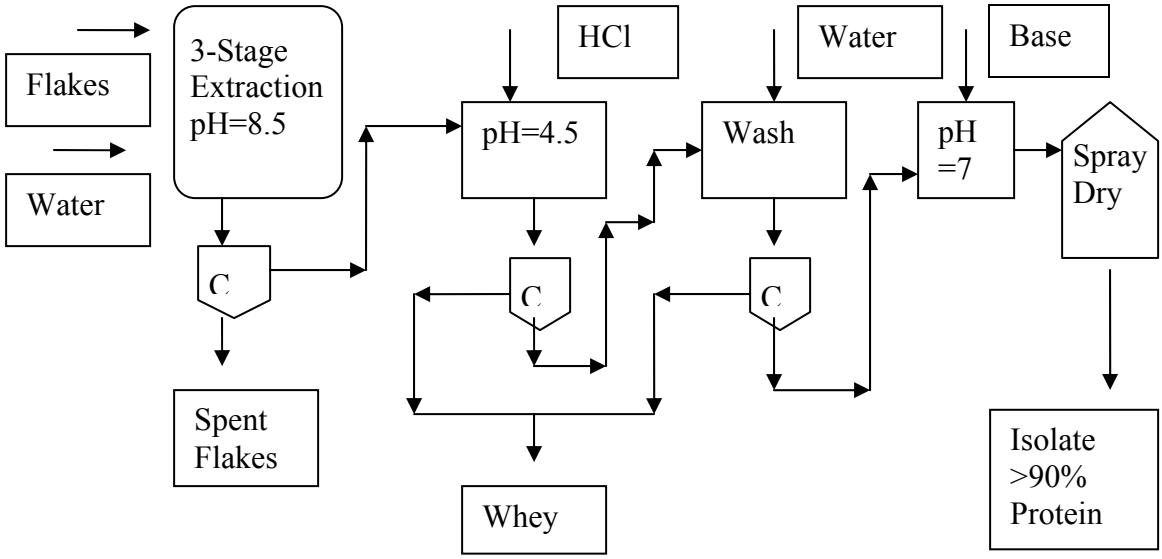

Figure 1. Typical Commercial Soy Protein Isolate Process

An alternative to the traditional method of soy protein isolate (SPI) production involves using temperature-sensitive gels (Figure 2). The focus of this method is on the gel, polyisopropylacrylamide, because its swelling properties are so highly temperature dependent. In this SPI production process, the protein solution is produced by a three stage extractor (Figure 1). Upon exiting the extractor, the protein solution passes through three gel extraction stages. Pure water is used to wash the protein solution in stage three, and the resulting effluent from stage three is used to wash the protein solution in stage two. The resulting effluent from stage two is then used to wash the protein solution in stage one. Advantages of the gel process over the conventional process include the limitation/inhibition of microbial growth since the protein can be extracted at temperatures as low as 5 degrees Celsius and the elimination of acid for protein precipitation. [Trank, 1989]

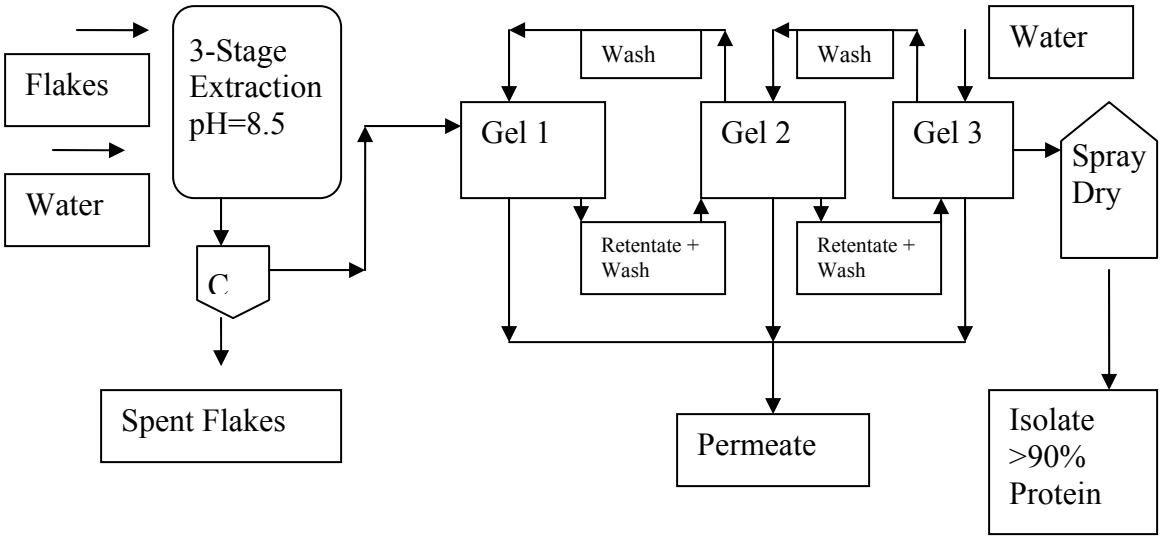

Figure 2. Soy Protein Isolate Process with Temperature Sensitive Gels

3. *Would other available materials be suitable alternatives to using the substance [§6518(m)(6)]?*

   Refer to Category 2: Question 1.

4. *Would other practices either reduce or eliminate the requirement for the substance [§6518(m)(6)]?*

   Refer to Category 2: Question 1.

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REVIEWER 1

Ph.D., Research Associate Professor of Chemistry, Gulf Coast, USA

A. Comments on Database

The database is incomplete. More data is needed from the manufacturer.

B. Evaluation of OFPA Criteria

1. *What is the potential of the substance for detrimental interactions with other materials used in organic farming?*

   There are no detrimental interactions.

2. *What are the toxicity and mode of action of the substance and its breakdown products/contaminants and their persistence in the environment?*

   Generally, soy is totally harmless.

3. *What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance?*

   This is unknown according to the database. However, looking at the details on manufacture, there are some nasty substances involved here. So it is possible that there would be environmental contamination during production.

4. *What are the effects of the substance on human health?*

   With the one debate in the literature notwithstanding, there are no adverse effects on human health.

5. *What are 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 soil solubility), crops, and livestock?*

   There are no interactions.

6. *What are the alternatives to using the substance, including other practices or available materials?*

   Many alternatives are available.

7. *Is the substance compatible with a system of sustainable agriculture?*

It is absolutely compatible.

C. Conclusion--Summarize Why This Substance Should Be Allowed or Prohibited for Use in Organic Crop or Livestock Production

Soy is sufficiently innocuous and beneficial.

D. Recommendation Advised to NOSB

Soy protein isolate is synthetic and should be allowed.

REVIEWER 2

M.S. in Biochemistry and Chemistry with Forensic Drug Testing Experience, Adjunct Instructor for Mid-Atlantic Academy, East Coast, USA

A. Comments on Database

Incomplete database provided.

B. Evaluation of OFPA Criteria

1. *What is the potential of the substance for detrimental interactions with other materials used in organic farming?*

   Soy protein readily decomposes and should have no detrimental interactions with other materials used in organic farming.

2. *What are the toxicity and mode of action of the substance and its breakdown products/contaminants and their persistence in the environment?*

   Soybean protein is a readily biodegradable organic material. The acid neutralization process yields a residual sodium concentration of about 1 g/100 g of final product, but would also leave a chloride residue of about 1.5 g/100 g of final product. This would probably yield an inconsequential soil concentration at the described application rate of 1-1.5 lbs/1000 square feet, but there is no data presented that supports this.

3. *What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance?*

   This is difficult to assess without more data on the actual manufacturing process. The primary manufacturer of soy protein isolate is, of course, bound by local and national environmental regulations, and one would hope they are fully committed to its compliance.

4. *What are the effects of the substance on human health?*

   There is a sizable body of evidence supporting the health benefits of greater use of vegetable protein in the human diet. The presence of an estrogen-like molecule in soy protein products that may adversely affect sexual development in animals is possible, but the report and attached references are insufficient to conclude that there are adverse effects on human health. In any event, the petitioned use of soy protein isolate is for organic crop production applications.

5. *What are 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 soil solubility), crops, and livestock?*

   No evidence is presented that would indicate adverse effects on biological and chemical interactions in the agroecosystem. I would estimate that the salt index would be extremely low since only a residual amount of NaCl (about 3% by mass based on the data provided in the report) would remain in the dried soy protein isolate after neutralization with NaOH coupled with a low soil application rate.

6. *What are the alternatives to using the substance, including other practices or available materials?*

   I agree with the report summary. A number of organic fertilizers are available containing various amounts of nitrogen, phosphorus and potassium along with trace nutrients. The relative amounts of these elements can be controlled by the particular choice of organic fertilizer and its application rate.

7. *Is the substance compatible with a system of sustainable agriculture?*

   Soy protein isolate could be compatible with a system of sustainable agriculture. It is, in essence, a mixture of denatured protein readily biodegradable, not unlike blood meal or cottonseed meal. The pertinent issue is whether it is a fertilizer containing synthetic ingredients and prohibited under OFPA 6508(b)(1).

C. <u>Conclusion</u>--Summarize Why This Substance Should Be Allowed or Prohibited for Use in Organic Crop or Livestock Production

In my opinion, soy protein isolate should be prohibited for use in organic systems. OFPA 6508(b)(1) restricts the use of any fertilizers containing synthetic ingredients. While not described in detail, the primary processing method for soybeans requires an organic (presumably a synthetic hexane) extraction step to separate the soybean oil, followed by HCl(aq) precipitation and NaOH neutralization, leaving NaCl residue. Even the suggested alternative commercial processing requires the same synthetic extraction prior to protein separation on the temperature sensitive gels.

The National List 205.601(j)(1) allows aquatic plant extracts, but restricts the solvents to minimal use of aqueous KOH or NaOH. Section 205.601(j)(6) restricts micronutrients to those not made from nitrates or chlorides and only where a soil deficiency is documented. Fish product soil amendments are allowed if they are not pH adjusted with HCl(aq) [205.601(j)(7)].

Section 205.600(b)(1) permits additions to the National List when a substance can not be produced from a natural source and there are no organic substitutes. There is no evidence that soy protein isolate can not be prepared by a non-synthetic

method. Mechanical or CO_2-based extraction methods may be feasible. In place of HCl(aq), precipitating acids, such as sulfuric or phosphoric acid, are available and are permitted as pH adjusters with liquid fish emulsion. Several alternative organic fertilizers are available. There is nothing in the report to support the conclusion that soy protein isolate is uniquely necessary for the petitioned use.

The general theme behind the inclusion of alternative protein fertilizers to the National List is that naturally-occurring protein substances are acceptable if they have been subjected to minimal synthetic processing. In my opinion, the use of soy protein isolate prepared as described would be inconsistent with the letter and spirit of the OFPA.

D. Recommendation Advised to NOSB

Soy protein isolate manufactured as described is synthetic. It should not be allowed for use in organic systems.

REVIEWER 3

USDA Accredited Certifier, Midwest, USA

A. Comments on Database

This TAP does not mention if the substance is compatible with a system of sustainable agriculture. The TAP does not address this question directly. However, the section on "Current Status" shows that soy protein isolate has not historically been allowed in U.S. organic production and that allowing it may make the U.S. standard inconsistent with Codex, EU, and Japanese standards. Since a large amount of U.S. organic products are exported to these areas, this would affect the sustainability of organic farms as well as their recognition as "organic" in the marketplace. Therefore, this reviewer feels that soy protein isolate is not consistent with sustainable agriculture and organic farming and handling practices. [OFPA 2118(c)(iii)] In this reviewer's opinion there is insufficient information in this TAP to evaluate most of these questions.

B. Evaluation of OFPA Criteria

Category 1: Impact of the Substance on Humans and the Environment

1. *What is the probability of environmental contamination during manufacture, use, misuse, or disposal of the substance [§6518(m)(3)]?*

   From the TAP, "ADM, the manufacturer and primary supplier of soy protein isolate to the petitioner, is bound by all local and national regulations with respect to environmental contamination and is fully committed to compliance. Several attempts were made to obtain additional information concerning soy protein isolate production, but ADM never responded to these inquiries. Therefore, the specific procedures for the production of soy protein isolate are not available."

   There is insufficient information to answer this question. An adequate TAP review can not be done without information on how the material is manufactured. There should be concern about GMO contamination unless the soy used is identity preserved GMO free. The fact that ADM is bound by local and national regulations does not prove lack of environmental contamination during manufacture, use, misuse, or disposal.

2. *Is the substance harmful to the environment [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i)]?*

   From the TAP, "Therefore, EPA does not fully know the toxicity levels of the similar soybean products. These similar soybean products have also not been determined to be of minimal concern (List 4). List 3 substances will continue to

be evaluated to determine if they merit reclassification to List 1, 2 or 4 [USEPA, 2004]."

There is insufficient information to answer this question.

3. *Does the substance contain List 1, 2, or 3 inert pesticide ingredients as designated by USEPA's Office of Pesticide Programs [§6517(c)(1)(B)(ii); §205.601(m)(2)]?*

   There is insufficient information to answer this question.

4. *What is the potential of the substance for detrimental chemical interactions with other materials used in organic farming systems [§6518(m)(1)]?*

   This is not possible to determine since we do not know how it is to be used in organics.

5. *What are the effects of the substance on biological and chemical interactions in the agroecosystem [§6518(m)(5)]?*

   From the TAP, "No information was available."

   There is insufficient information to answer this question.

6. *What are the physiological effects of the substance on soil organisms (including the salt index and soil solubility), crops, and livestock [§6518(m)(5)]?*

   From the TAP, "An epidemiological study included feeding different diets to two groups of monkeys. One of the diets contained casein, and the other diet contained soy protein isolate. Positive effects on the monkeys were reported. After soy protein isolate was substituted for casein in their diet, the monkeys consuming the diet high in soy protein isolate had significantly higher levels of high-density lipoprotein (HDL) and significantly lower levels of low-density lipoprotein (LDL) than the monkeys who continued to consume the diet high in casein. [Endres, 2001]"

   "Contrary to the abundance of studies on the positive effect of soy consumption on human health, two FDA scientists have vehemently challenged the FDA soy health claim. They claim that safety issues concerning soy protein products are still unanswered. The two FDA scientists, Dr. Daniel Doerge and Dr. Daniel Sheehan, have pointed to research that links soy with animal fertility problems. The animal data eludes to possible adverse human health effects. In the doctors' opinion, it is the chemical in soy mimicking estrogen that leads to the potential alteration of an animal's sexual development. [Ross, 2003]"

There is insufficient information to answer this question, unless the material is to be used in feed or food.

7. *What are the toxicity and mode of action of the substance and its breakdown products/contaminants in the environment [§6518(m)(2)]?*

   From the TAP, "Iowa State University researchers are continually working to develop soybean protein plastics. These products are biodegradable and could replace current non-biodegradable plastics. The lead researcher, Dr. Jay-Lin Jane, has stated that the soy-based plastics could benefit the soil because soy proteins may act as a soil conditioner after degradation. Preliminary studies have shown plants utilizing soy protein, in powder form, from the soil to aid in the growth process. [Jane, 1996] The research alludes to a positive effect of the degradation of soy protein products in the environment."

   There is insufficient information to answer this question.

8. *What is the persistence of the substance and its breakdown products/contaminants in the environment [§6518(m)(2)]?*

   There is insufficient information to answer this question.

9. *Is the substance harmful to human health [§6517(c)(1)(A)(i); §6517(c)(2)(A)(i); §6518(m)(4)]?*

   From the TAP, "Epidemiological studies have shown an inverse relationship between diets high in vegetable protein and either plasma cholesterol levels or the development of coronary heart disease (CHD). A 1982 study in Italy and Switzerland confirmed that in patients whose cholesterol levels exceeded 300 mg/dl, a 20-22% drop in total cholesterol and low-density lipoprotein (LDL) cholesterol was evident after the patients completely replaced animal protein with soy protein in their diets. This study demonstrates the positive effect soy protein has on human health. [Endres, 2001]"

   "Contrary to the abundance of studies on the positive effects of soy consumption on human health, two FDA scientists have vehemently challenged the FDA soy health claim. They state that safety issues concerning soy protein products are still unanswered. The two FDA scientists, Dr. Daniel Doerge and Dr. Daniel Sheehan, have pointed to research that links soy with animal fertility problems. The animal data eludes to possible adverse human health effects. In the doctors' opinion, it is the chemical in soy mimicking estrogen that leads to the potential alteration of an animal's sexual development. Various other studies have suggested a link between soy consumption and the development of estrogen-feeding breast cancer. A thirty year study performed by the National Institutes of Health (NIH) showed a potential connection between soy tofu and accelerated brain aging and shrinkage, particularly among elderly men. [Ross, 2003]"

There is insufficient information to answer this question, unless the use is for human food. Without more information on the process by which this is manufactured, I have concerns that the use of soy protein isolate as a foliar feed may cause contamination of the crops with monosodium glutamate (MSG) or glutamic acid, both of which may cause serious reactions in people who are sensitive to these substances. I am looking into more information on this issue since I feel this possibility merits exploration. I will report my findings back to you on this matter as I feel it is critical to the evaluation of this material for this application.

Category 2: Importance of the Substance for Organic Production

1. *Is the substance necessary to the production or handling of an agricultural product due to the unavailability of wholly natural substitute materials [§6517(c)(1)(A)(ii)]?*

   From the TAP, "Various other organic fertilizers are available for use in "organic crops as well as for turf, landscape, and other horticulture applications." These organic options include cottonseed meal, blood meal, fish emulsion, and manure. Cottonseed meal is an organic fertilizer that causes an acid-producing reaction. This option is desirable for acid-loving plants, including azaleas, camellias, and rhododendrons. Cottonseed meal normally contains 7, 3, and 2 percent nitrogen, phosphorus, and potash, respectively. Blood meal consists of powdered blood collected from cattle slaughterhouses. This is a nitrogen-rich fertilizer and may burn plants if used in excess. Fish emulsion contains a partially decomposed blend of finely minced fish. Fish emulsion contains high levels of nitrogen and trace elements. Although manure is a complete fertilizer, it lacks vital nutrients. The nutrient content of manure is dependent upon the diet and species of the animal that produced it. Fresh manure contains the highest level of nutrients needed for plant growth. Manure is better suited as a soil conditioner than as a fertilizer. [Relf, 1997]"

   This section indicates that the use of soy protein isolate may be for fertilizer and/or as a fertilizing foliar feed. If that is the case, then there are many natural alternatives that are already allowed and have historically been used with great success by organic producers.

2. *Is the substance non-synthetic, but not produced organically, and used in handling [§6517(c)(1)(B)(iii)]?*

   From the TAP, "The most common procedure for the production of soy protein isolate utilizes…" and "An alternative to the traditional method of soy protein isolate (SPI) production involves using…"

The TAP report did not answer this question. Rather, it talks about "The most common procedure for the production of soy protein isolate," which may not apply in this case. In order to review this, I need to know more about the intended use and the details of the manufacturing process, although it appears that the material is not being petitioned for use in handling.

3. *Would other available materials be suitable alternatives to using the substance [§6518(m)(6)]?*

   If this is being considered as a fertilizer, then there are so many alternatives. Fish, seaweed, legume-based rotation, soy meal, blended natural fertilizers, manure, compost, etc. So far, organic producers seem to have been doing pretty well with natural materials.

4. *Would other practices either reduce or eliminate the requirement for the substance [§6518(m)(6)]?*

   Yes, there are. See 1 and 3 above.

C. <u>Conclusion</u>--Summarize Why This Substance Should Be Allowed or Prohibited for Use in Organic Crop or Livestock Production

The TAP does not contain information on the actual manufacturing process of the petitioned product. It only contains information on the generic production of soy protein isolate. This is not sufficient information for a proper review.

D. <u>Recommendation Advised to NOSB</u>

The process by which soy protein isolate is made indicates it to be synthetic, although there is no real information on exactly how this particular soy protein isolate is manufactured. Soy protein isolate should not be allowed on the National List.