Most of the concerns expressed by NOSB when they deferred the original SPI TAP report in April 2004 have been addressed. However, the following questions could not be answered:

- What percent of soy is genetically modified?
- What is the genetic modification?
- If some soy is genetically modified, how is cross-contamination handled?
- If soy is genetically modified, could the protein from the genetic modification be concentrated during processing into soy protein isolate?

General information concerning agricultural production of genetically modified soybeans was provided in the revised SPI TAP report. However, specific information regarding the use and handling of genetically modified soybeans in the petitioned substance must be obtained from the manufacturer (Archer Daniels Midland Company).

CFNP's previous attempts to obtain missing SPI production information from the manufacturer were unsuccessful. Therefore, CFNP recommends that the petitioner obtain the missing information requested by NOSB before any other action is taken. According to 7 CFR Part 205: Final Rule with Request for Comments, "[w]hen a retail operation contracts for the production, packaging, or labeling of organic product, it is the certified production or handling operation that is responsible for complying with the applicable organic production or handling regulations."[1] Since the petitioner and the manufacturer probably have an established business relationship, the manufacturer may be more responsive to the petitioner's requests for additional information. It is also to the petitioner's benefit to obtain the missing information.

Any additional information concerning the use of hydrochloric acid (HCl) and sodium hydroxide (NaOH) in the production of SPI should be requested from the manufacturer. Although the revised SPI TAP report does provide some general information about these substances, only the manufacturer will be able to answer more specific questions, such as quantities used and disposal procedures.

In addition, the comment "FDA information needed (do not need information on use as a food); address its use as a soil amendment" is inappropriate since FDA does not regulate soil amendments. In this section, the GRAS status of SPI was addressed to demonstrate that FDA does not consider SPI a threat to human health.

Please let me know if you have any questions concerning the revised SPI TAP report. Although the revised SPI TAP report has not been re-evaluated by the original reviewers, I strongly doubt that the revised information would change their original determinations. In addition, all of the product-specific information requested by NOSB should be included in the revised SPI TAP prior to its re-evaluation by the reviewers.

[1] U.S. Department of Agriculture/Agricultural Marketing Service. "Applicability—Clarifications: Private Label Products." *7 CFR Part 205: Subpart B—Applicability* 2000; http://www.ams.usda.gov/nop/NOP/standards/FullText.pdf.

SUMMARY OF TAP REVIEWERS' ANALYSES[†]

Soy protein isolate is being petitioned for use as a fertilizer for organic crop production as well as for turf, landscape, and other horticultural applications. Soy protein isolate, the most highly refined soy protein, would ensure sufficient available nitrogen for plant health and development. Due to the significant amount of processing required to extract soy protein from whole soybeans, soy protein isolate should be classified as a synthetic substance. Information concerning the production of soy protein isolate supplied by the petitioner was incomplete. Attempts to obtain additional production information from the manufacturer (Archer Daniels Midland Company) were unsuccessful. Despite the widespread use of soy protein isolate in food and industrial products, information concerning its use as a fertilizer is either nonexistent or not publicly available.

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 detailed information concerning its production could not 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 detailed 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[1,2]

Common Name: Soy Protein Isolate
CAS Registry Number: 9010-10-0
Other Names: Isolated Soy Protein; Soya Protein Isolate; Isolated Soya Protein

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[†] *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 (OFPA), 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.*

CHARACTERIZATION[3]

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

PRODUCTION

Two methods of soy protein isolate (SPI) production were described in the scientific literature:

- Precipitation with Hydrochloric Acid[4,5]—whole soybeans are cleaned, cracked, and dehulled; the resulting soy meats are then flaked; these full-fat soy flakes undergo hexane extraction to remove the soybean oil and are then desolventized under conditions that prevent denaturing the soy protein; the defatted soy flakes are slurried in water that has been pH-adjusted to 8.5-9.0 with sodium hydroxide (NaOH) in order to disperse the soy protein and to dissolve the water-soluble constituents (carbohydrates); this slurry is centrifuged to separate the solid and liquid portions; the liquid is then removed and stored for further processing; the solid portion is similarly re-extracted two more times; each time the solid portion is re-extracted, the resulting liquid is removed and combined with the stored liquid; the aggregate liquid is mixed with hydrochloric acid (HCl) to a pH of about 4.5 in order to precipitate most of the soy protein; the precipitated protein is then washed with water, neutralized (pH=7) with NaOH, and spray dried.

- Separation with Polyisopropylacrylamide Gel[6]—whole soybeans are cleaned, cracked, and dehulled; the resulting soy meats are then flaked; these full-fat soy flakes undergo hexane extraction to remove the soybean oil and are then desolventized under conditions that prevent denaturing the soy protein; the defatted soy flakes are slurried in water that has been pH-adjusted to 8.5-9.0 with sodium hydroxide (NaOH) in order to disperse the soy protein and to dissolve the water-soluble constituents (carbohydrates); this slurry is centrifuged to separate the solid and liquid portions; the liquid is then removed and stored for further processing; the solid portion is similarly re-extracted two more times; each time the solid portion is re-extracted, the resulting liquid is removed and combined with the stored liquid; the aggregate liquid is added to collapsed polyisopropylacrylamide gel and cooled to about 5^{o}C, causing the gel to swell; the swollen gel absorbs water and other small solutes; the gel does not absorb solutes of high molecular weight, such as proteins; the swollen gel and the unabsorbed liquid (retentate) are separated; the retentate is similarly re-extracted with

collapsed polyisopropylacrilamide gel until the desired protein concentration and purity is reached; the final retentate is then spray dried.

Advantages of obtaining soy protein isolate via separation with polyisopropylacrylamide gel versus precipitation with HCl include:

- Limitation/Inhibition of Microbial Growth—soy protein isolate is extracted at temperatures as low as 5°C.

- Partial Elimination of Corrosive Chemicals—soy protein isolate is extracted without the use of HCl.

Soy protein isolate is typically produced via precipitation with HCl, and the limited information provided by the petitioner suggests that this is the production method that will be used. However, the complete production method for the petitioned substance was not supplied by the petitioner. The manufacturer and primary supplier of soy protein isolate to the petitioner—Archer Daniels Midland Company—was unresponsive to several requests for additional production information.

HISTORY OF USE

Non-Organic Growers: Prior to the Chinese-Japanese war of 1894-95, all soybean production was localized in China. After the war, the Japanese began importing soybean oil cake for fertilizer use. The earliest written reference to soybeans in the United States occurred in 1804. Soybeans grown in the U.S. were originally utilized as a forage crop rather than harvested for seed. By 1941, the U.S. soybean acreage dedicated to seed production exceeded that grown for foraging and other purposes.[7] Genetically modified soybeans are now commonly grown in the U.S. In 2000, 60% of domestic farms were growing herbicide-resistant soybeans.[8] By 2003, 81% of all soybeans planted in the U.S. were genetically engineered, totaling 59.7 million acres.[9] Despite the widespread use of soy protein isolate in food and industry products, soy protein isolate is either not currently used as a crop or horticultural fertilizer, or information concerning its use as such is not publicly available.

Organic Growers: Soybeans are a relatively easy crop to produce organically and comprise the largest segment of organic legume production by volume in the United States.[10] 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.[11] Soy protein isolate is not currently used by organic growers as an organic crop and horticultural fertilizer since it is not included on the National List of Allowed and Prohibited Substances.

CURRENT STATUS

U.S. Regulatory Agencies:

EPA: According to 40 CFR Part 180 (§180.1001), residues of isolated soy protein—when used as an adhesive—"...are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest..." In addition, residues of isolated soy protein—when used as an adhesive—"...are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals..." Both of these pesticide tolerance exemptions expire on May 24, 2005 and are scheduled for reassessment during 2005.[12]

FDA: According to 21 CFR Part 101 (§101.82), a food product that meets specific content and labeling requirements may make a health claim concerning soy protein consumption and a possible reduction of coronary heart disease.[13] According to the Final Rule for 21 CFR Part 101 (§101.82), FDA states that "although soy protein is not listed as GRAS or prior sanctioned in Title 21 of the CFR, FDA has noted that these lists 'do not include all substances generally recognized as safe for their intended use' and, as stated at 21 CFR 182.1, '[i]t is impracticable [for FDA] to list all substances that are GRAS for their intended use'...FDA does not take issue with the petitioner's self-determination of GRAS status...Although FDA has not ruled formally on the GRAS status of soy protein ingredients, it has not challenged determinations that soy's use as dietary protein is GRAS. Food ingredients whose use is generally recognized as safe by qualified experts are not required by law to receive FDA approval."[14]

OSHA: According to the Occupational Safety and Health Administration, soy protein isolate dust levels must remain below 15 mg/m^3.[15]

International Certifiers:

EU: Soy protein isolate is not currently listed as a permitted 'non-organic' fertilizer or soil improver for organic crop production in the European Union.[16] However, soya beans (whole, meal, and cake obtained by pressure) are permitted as 'non-organic' feedstuffs for organic animal production.[17]

Japan: Soy protein isolate is not specifically listed as an approved substance for organic agricultural production in Japan. However, soybean cake and its powder are allowed as fertilizers and soil improvement substances for organic agricultural production as long as chemosynthetic substances have not been added.[18]

Canada: Soy protein isolate is not specifically listed as an approved organic crop production material in Canada. However, soybean meal is allowed as an organic fertilizer/plant food/soil amendment provided that the soybean meal was not derived from genetically engineered soybeans.[19]

Codex Alimentarius: Soy protein isolate is not currently listed as a permitted soil fertilizing or conditioning substance for the production of organic foods in the Codex Alimentarius.[20]

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 either be applied to the soil as pellets or to foliage as a spray. According to the petitioner, the rate of application will be dependent upon crop requirements proportional to the nitrogen content.

INCOMPATIBILITIES

Soy protein isolate is a stable compound and is considered non-hazardous. Soy protein isolate has no incompatibilities with other materials, and hazardous polymerization will not occur.[21]

ORGANIC FOODS PRODUCTION ACT OF 1990 (OFPA), AS AMENDED

7 USC 6517. NATIONAL LIST.

"(a) *In General.* The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this chapter in order for such products to be sold or labeled as organically produced under this chapter.

(b) *Content of List.* The list established under subsection (a) of this section shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c) (1) of this section or each natural substance prohibited under subsection (c) (2) of this section.

(c) *Guidelines for Prohibitions or Exemptions.*

(1) *Exemption for Prohibited Substances.* The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if

(A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

(B) the substance

(i) is used in production and contains an active synthetic ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock paraciticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;

(ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern; or

(iii) is used in handling and is non-synthetic but is not organically produced; and

(C) the specific exemption is developed using the procedures described in subsection (d) of this section."

Therefore, under 7 USC 6517 of the OFPA, as amended, it must be determined if the use of soy protein isolate as a fertilizer for organic crop production as well as for turf, landscape, and other horticultural applications is consistent with subsection (c)(1) of 7 USC 6517. If so, then soy protein isolate should be allowed an exemption as a synthetic substance and be included on the National List.

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)]?*

   According to the petitioner, 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.

   In general, spillage and disposal procedures for soy protein isolate include:

   - "Spillage—[Soy protein isolate] is non-hazardous. If dusting occurs in confined area, a dust mask should be worn.

- Disposal—Non-contaminated waste material can be disposed of as non-hazardous solid waste."[22]

The information provided by the petitioner suggests that soy protein isolate will be produced via extraction with NaOH, followed by precipitation with HCL and neutralization with NaOH.

Some characteristics of HCL and NaOH are:

- HCL—colorless or slightly yellow liquid with pungent odor; extremely corrosive; inhalation of vapor or contact with skin or eyes can cause serious injury; ingestion may be fatal; lethal to fish at concentrations of 25 mg/L; toxic to aquatic organisms due to pH shift.[23]

- NaOH—odorless white solid; very corrosive; inhalation of dust or contact with skin or eyes can cause serious injury; very harmful if ingested; can have harmful environmental effects due to pH shift.[24]

Since the petitioner provided incomplete information concerning the production of soy protein isolate, several attempts were made to obtain the missing information from ADM. However, ADM did not respond to these requests for additional production information. Therefore, the probability of environmental contamination during manufacture, use, misuse, or disposal of soy protein isolate can not be completely ascertained.

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

   Soy protein isolate is not expected to have any negative environmental impacts due to its stability, insolubility in water, and compatibility with other substances.[25]

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 does not contain any List 1, 2, or 3 inert pesticide ingredients identified by U.S. EPA's Office of Pesticide Programs since all the soybean oil is extracted from the soy protein isolate during processing. Soy protein isolate itself is also not included as a List 1, 2, or 3 inert pesticide ingredient.[26]

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

   Soy protein isolate is unlikely to produce detrimental chemical interactions with other materials used in organic farming systems since soy protein isolate has no known incompatibilities with other substances.

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

   Soy protein isolate is unlikely to cause adverse biological or chemical interactions in the agroecosystem. Soy protein is readily metabolized by soil microorganisms into ammonium and nitrate ions. These ions are an excellent source of nitrogen for the growth and development of plants. In fact, research is being conducted to develop biodegradable products made with soybean protein, such as plastic films.

   "Polyethylene films are used to make agricultural mulch films, garbage bags, paper coatings, laminating materials and other products...Because [polyethylene films] don't degrade in the environment, they can cause severe pollution problems...Bags litter beaches and streets. Plastics can harm wildlife, especially aquatic animals. Mulch films can block underground water circulation and hurt soil quality.

   Soy-based biodegradable films have some attractive properties...As agricultural mulch films, soy-based plastics may even help improve soil quality. After they degrade, they may act as a soil conditioner...Preliminary studies show ground soy powder can be utilized by plants, helping them grow."[27]

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

   Soy protein isolate, a readily biodegradable material, has not shown any detrimental physiological effects to soil organisms. The maximum residual sodium in soy protein isolate, due to the manufacturing neutralization process, amounts to no more than 900-1200 mg Na/100g of final product. This causes an inconsequential amount of sodium to be added to soil systems since the soy protein isolate application rate is typically between 1-1.5 lbs/1000 ft^2.

   Soy protein isolate, which has a protein content of 90% or more,[28] is unlikely to cause detrimental physiological effects to crops or livestock. Soybean meal, another rich source of protein, is a recommended fertilizer for plants. Soybean meal is also consumed in feed by pigs, cows, and chickens.[29]

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

   Soy protein isolate will not cause a toxic or other adverse action in the environment due to its stability and lack of reactivity with other materials. The breakdown products of soy protein isolate—amino acids, ammonium ions, and nitrate ions—are similarly non-hazardous. These breakdown products, which result from the actions of microorganisms in soil, are readily absorbed by plants to meet their nitrogen requirements for growth.[30]

According to the petitioner, soy protein isolate fertilizer contains such low levels of heavy metals that no toxic or other adverse action in the environment from these contaminants would be expected.

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)]?*

   Soy protein isolate is readily metabolized by soil microorganisms into amino acids, ammonium ions, and nitrate ions. All remaining amino acids are also converted to either ammonium or nitrate ions. Ammonium and nitrate ions are the two forms of nitrogen that are most palatable to plants.[31] Consequently, neither soy protein isolate nor its breakdown products will result in an undesirable persistence or concentration in the environment.

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

   Sufficient data have been generated to suggest a link between soy protein consumption and several positive health benefits, such as decreased risk of coronary heart disease, diseases of the lower gastrointestinal tract, and certain cancers.[32]

   Some researchers claim that isoflavones found in many soy products may be associated with negative health effects. Isoflavones are phytoestrogens, a weak form of estrogen, which some studies have shown to contribute to an increased risk of cancer, especially breast cancer.[33]

   However, it is unlikely that soy protein isolate—when used as a fertilizer—would pose any health risk to humans. After soy protein is precipitated from defatted soy flakes, the percentage of total isoflavones remaining in the soy protein isolate is only about 26%.[34] Using soy protein isolate as a fertilizer—not as a food additive—further reduces the likelihood of any remaining isoflavones causing harmful effects to humans.

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)]?*

   Although soy protein isolate is an excellent source of nitrogen for plants, other soy-based sources are available. Soybean meal, the product remaining after extracting most of the oil from whole soybeans, is usually sold as animal feed. Due to the high protein content of soybean meal, it also makes an effective soil fertilizer.[35] A product known as Clean Green™ is being sold as a slow-release,

soy-based fertilizer without the negative environmental impacts of excess phosphorus.[36] However, information concerning the soybean components included in Clean Green™ was not publicly available. In addition, no data concerning the commercial or private usage of either soybean meal or Clean Green™ could be located.

According to Section 205.601 [§205.601(j)(1)] of the National List of Allowed and Prohibited Substances, aquatic plant extracts (other than hydrolyzed) are synthetic substances that may be used as plant or soil amendments in organic crop production. However, the extraction process is limited to the use of potassium hydroxide (KOH) or sodium hydroxide (NaOH). The amount of KOH or NaOH used must also be limited to only the amount necessary for extraction.

After whole soybeans are processed into defatted soy flakes, both methods of soy protein isolate production (precipitation with HCl versus separation with polyisopropylacrylamide gel) limit the extraction process to the use of NaOH. The limited production information provided by the petitioner suggests that precipitation with HCl is the method that will be used. Unfortunately, no information concerning the amount of NaOH required during soy protein isolate extraction was provided. Information concerning the amount of HCl required for precipitating soy protein isolate was also missing.

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

   Soy protein isolate is being petitioned as a fertilizer for organic crop production as well as turf, landscape, and other horticultural applications only. Since soy protein isolate is not being petitioned for use in organic handling, this question is not applicable.

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

   Suitable alternatives to using soy protein isolate as a fertilizer for organic crop production as well as turf, landscape, and other horticultural applications include:

   - Cottonseed Meal—by-product of cotton manufacturing that produces a slightly acidic reaction in soil; desirable for acid-loving plants, such as azaleas, camellias, and rhododendrons; generally contains 7% nitrogen, 3% phosphorus, and 2% potash.

   - Blood Meal—dried, powdered blood collected from cattle slaughterhouses; a very nitrogen-rich fertilizer; may burn plants if used in excess.

- Fish Emulsion—partially decomposed blend of finely pulverized fish; high in nitrogen and may burn plants; strong odor usually dissipates within two days.

- Manure—nutrient content depends upon species and diet of animal; nutrient content highest when fresh, but also more likely to burn plants; better used as soil conditioner than fertilizer due to overall low nutrient content.[37]

- Compost—decomposed remnants of materials with plant and/or animal origins; nutrient content depends upon plant and animal materials used.

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

   Other practices that could reduce or eliminate the requirement for soy protein isolate as a fertilizer for organic crop production include:

   - Crop Rotation—the sequence of crops grown on a specific field; confers benefits to long- and short-term soil fertility; incorporating forage legumes, such as soybeans, into the rotation schedule provides the vast majority of the nitrogen required by subsequent crops.

   - Cover Cropping—growing a crop for the specific purpose of soil and nutrient conservation.

   - Green Manuring—incorporating into the soil a crop grown for the specific purpose of soil improvement.

   - Tillage/Cultivation—conserving crop residues and added manures in the upper, biologically active zones of the soil; not leaving soils completely bare and vulnerable to erosion; eliminating excessive tillage/cultivation to minimize soil compaction and the destruction of earthworms and their tunneling.[38]

   Any of the practices listed above can be combined to further improve organic crop production.

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