Question Number One[1]:

- At what stage in the manufacturing process does the soy protein change from a natural to a **“synthetic”** based on the definition of **“synthetic"** that is contained in the Organic Foods Production Act and 7 CFR 205? **(BLUE)**

§205.2 Terms Defined – Definition of “Synthetic”

- **“Synthetic” (§205.2 Terms Defined):** “A substance that is **formulated or manufactured by a chemical process** ***(emphasis added)*** or by a process that **chemically changes a substance** ***(emphasis added)*** extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.”

Answer Number One:

- The soy protein in the final product soy protein isolate (SPI) is not chemically changed by the conventional manufacturing process. However, the final product SPI is conventionally manufactured by a chemical process that early includes an organic extraction followed by solubilization by adding an acid – and later, neutralization by adding a base. **(BLUE)**

- The primary processing method for soybeans of using an organic extraction to separate the soybean oil from the soy protein is a chemical process that uses the physical properties of the respective different solubilities of soy protein and soybean oil. Here, the soybean oil is more soluble in the organic phase than the aqueous phase which facilitates a physical separation from the soy protein which is more soluble in the aqueous phase than the organic phase. Therefore, use of the organic solvent in the organic extraction process makes the final product SPI **“synthetic”** as per **§205.2 Terms Defined** because the solvent extraction is part of the chemical process used to conventionally manufacture final product SPI. **(BLUE)**

- Adding an acid and later a base both change the electric charge of the SPI. (This is a change in a physical property and not a chemical change.) The final product SPI is therefore **“synthetic”** as per **§205.2 Terms Defined** because it is manufactured using a chemical process – and not because the soy protein is chemically changed to a **“synthetic”** at any given stage of the chemical process used to conventionally manufacture the final product SPI. **(BLUE)**

[1] The “answer” and “analysis” for Question Number One are in blue color throughout this document with **(BLUE)** at the end of each paragraph or sentence for assistance when reading black-and-white copies.

Question Number Two [2]:

- During the **neutralization process** of the soy protein, does **neutralization** chemically change the original nature of the soy protein? **(RED)**

Answer Number Two:

- **Neutralization** does not chemically change the original nature of the soy protein. **Neutralization** has minimal impact on the soy protein in the final product SPI during manufacture and it only directly changes the final product SPI electric charge (a physical change – not a chemical change) and indirectly adds ~3% NaCl physically mixed with – and not chemically incorporated into – the final product SPI. **(RED)**

Analysis [3]

Basic Principles of Final Product SPI Production[4]:

"The basic principles of SPI production are simple.

1. Using an organic extraction, the soy bean oil is physically separated from the soy protein.
2. Using defatted soy flour or flakes as the starting material, the protein is first solubilized in water.
3. The solution is separated from the solid residue.
4. Finally, the protein is precipitated from the solution, separated and dried.

►The Association of American Feed Control Officials, Inc. (AAFCO)[5] defines SPI:

- *"**Soy Protein Isolate** is the major proteinaceous fraction of soybeans prepared from dehulled soybeans by removing the majority of non-protein*

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[2] The "answer" and "analysis" for Question Two are in red color throughout this document with **(RED)** at the end of each paragraph or sentence for assistance when reading black-and-white copies.

[3] The "analysis" that applies to both Question Number One and Question Number Two is in black color throughout this document when reading either color or black-and-white copies.

[4] *Technology of Production of Edible Flours and Protein Products from Soybeans.* Zeki Berk, Technion, Israel Institute of Technology, Haifa, Israel. FAO Agricultural Services Bulletin No. 97. Food and Agriculture Organization of the United Nations Rome 1992. This extensive footnote material is taken primarily verbatim from the reference and is therefore enclosed in quotation marks.

[5] Association of American Feed Control Officials, Inc. (AAFCO) http://www.aafco.org

components and must contain not less than 90% protein on a moisture-free basis." (From '90 Soya Bluebook).

There are no official standard definitions or specifications for the various types of soy protein isolates. Final product SPI is bought and sold on the basis of specifications formulated by the manufacturer or the user.

Table: Typical composition of SPI
(Moisture-Free Basis)

COMPONENT	WEIGHT PERCENT
Protein	90
Fat	0.5
Ash	4.5
Total carbohydrate	0.3

The conventional procedure for final product SPI production is based on protein solubilization at neutral or slightly alkaline pH followed by precipitation by acidification to the isoelectric region near pH 4.5. The resulting product is "isoelectric SPI". It has low solubility in water and limited functional activity. Different "proteinates" can be produced by resuspending isoelectric SPI in water, neutralizing with different bases and spray-drying the resulting solution or suspension. According to the base used for neutralization – sodium, potassium, ammonium or calcium "proteinates" are produced. The first three are highly soluble in water, producing solutions with very high viscosities, foaming, emulsification, and gel forming properties. Calcium proteinate has low solubility. Low-solubility (inert) SPIs are used where the formulation calls for a high level of protein incorporation without excessive viscosity of other functional contributions.

Because spray-drying is the common drying method in the production of final product SPI, the primary physical form of final product SPI in commerce is that of fine powders.

Production Processes

►The Conventional Process

This is the process commonly described in the literature and suggested by suppliers of equipment and complete plants. Exact processing conditions and the type of equipment used may vary from plant to plant.

An outline of the process is given in the figure below.

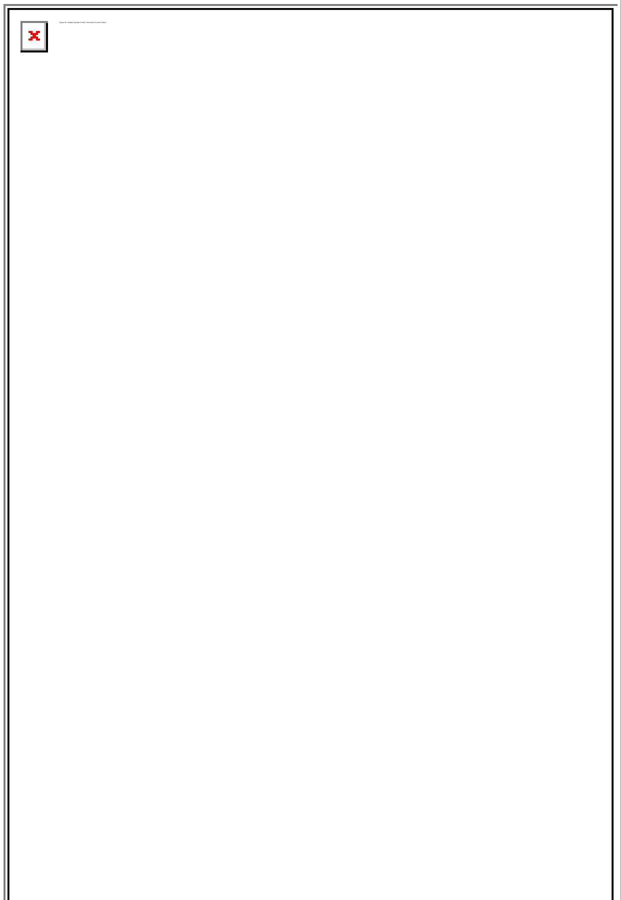

Figure: Isolated Soybean Protein.
Production Process Outline

►Starting Material

Dehulled, defatted, edible-grade white flakes or meal with the highest possible protein solubility index are used. [*Note: It is a manufacturer's conscious choice to use GMO soybeans or not.*] Although the rate of protein extraction from finely ground flour would be faster, flakes permit easier separation after extraction. In batch extraction, particle size has no effect on protein extraction yield with an extraction time greater than 30 minutes.

►Protein Extraction

The flakes are mixed with the extraction medium in agitated, heated vessels. The extraction medium is water to which an alkali – such as sodium hydroxide (NaOH), lime, ammonia, or tri-basic sodium phosphate – has been added to bring the pH to neutral or slightly alkaline. The majority of the proteins go into solution under these conditions. The sugars and other soluble substances are also dissolved.

►Alkalinity

More protein can be extracted at a higher pH. However, the extracted proteins may undergo undesirable chemical modifications in strongly alkaline solutions. These include protein denaturation and chemical changes in amino acids. Excessively high pH also favors protein-carbohydrate interaction (Maillard Reaction[6]) which results in the formation of dark pigments and in loss of nutritive value. Furthermore, proteins precipitated from highly alkaline media tend to retain too much water and do not settle well. In practice, the alkaline range between pH 7.5 and pH 9.0 is commonly preferred.

One of the chemical reactions of amino acids in alkaline media has attracted particular attention – the destruction of the amino acid cystine with the formation of dehydroalanine. In addition to the nutritional implications resulting from the loss of cystine, there might be also a toxicological aspect to consider. Dehydroalanine can react with free epsilon-amino groups of lysine to produce lysinoalanine. This compound has been found to cause kidney lesions in rats under certain experimental conditions. The toxicity of lysinoalanine for man is still an open question. [None of these minimal side products are of concern here where the final product SPI is to be used as a fertilizer.]

►Extraction Time

The course of nitrogen extraction from white flakes, using 0.03 molar calcium hydroxide as extractant is shown in the figure below. The amount of nitrogen extracted under these conditions increased steadily during the first 30 minutes and reached a nearly constant level after 45 minutes. The extraction time in industrial operation is probably in the order of one hour.

►Temperature

Protein extraction yield is considerably increased by increasing the temperature to as much as 80°C.

►Solid / Liquid Ratio

Protein extraction yield is improved as the quantity of liquid medium used to extract a given weight of flakes is increased. After extraction and separation by filtration or centrifugation, the extracted flakes retain a considerable proportion of extract – about 2.5 times the weight of the solid. In single-stage batch extraction, the more liquid used

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[6] Maillard reaction is a non-enzymatic browning reaction caused by the condensation of an amino group and a reducing compound that causes complex changes in biological and food systems. This reaction was described for the first time by Louis Maillard in 1912. Maillard reaction occurs when virtually all foods are heated – and during storage. Most of the of Maillard reaction effects are desirable, including the caramel aromas and golden brown colors. Nevertheless, some of the Maillard reaction effects are undesirable including foods darkness and off-flavor development.

for extraction results in a lower protein concentration in the extract, and a smaller quantity of protein associated with the retained portion of the extract. On the other hand, larger volumes of liquid have to be handled per unit weight of protein produced. This means larger extraction vessels, centrifuges, etc. – plus a larger volume of "whey" for disposal.

The choice of a solid/liquid ratio for extraction is a matter of economical optimization. The ratios used in industry range apparently between 1:10 and 1:20.

In industrial scale operation, it may prove convenient to carry out the extract clarification process in two steps: screening (vibrating screen, rotary screen, or the like) to separate most of the solids and then centrifugal clarification of the extract. The wet solids can be pressed to remove as much entrapped extract as possible. All these operations can also be carried out in one step by using decanter centrifuges. A flow diagram of a decanter-based process for the production of final product SPI is shown in the figure below.

SPI Production Using Decanter Centrifuges

►**Precipitation**

The protein is precipitated from the extract by bringing the pH down to the isoelectric region. The type of acid used or the temperature of precipitation does not affect the yield or purity of precipitated protein.

The curd is the precipitate obtained by acidification of the extract. After washing and drying, it becomes the final product: isoelectric ISP. It contains 75% of the protein of the starting material.

Nearly three tons of defatted soybeans are needed to produce one ton of final product SPI.

►Quality

SPI obtained by the conventional manufacturing process contains several types of impurities (e.g. phytates and phenolic substances) which may somewhat impair its functional, sensory, and nutritional qualities when used as a foodstuff. More complete dehulling of the beans, thorough extract clarification, and repeated washing of the curd reduce the impurities but does not eliminate them completely.

►Alternative SPI Production Processes

Several alternative processes for the isolation of soy protein have been reported in the literature. These include:

1. Solubilization of the soy proteins in the salt solutions (salting-in) followed by precipitation by dilution with water.

2. Precipitation from the extract at near-boiling temperature using calcium salts (as used in the Tofu production).

3. Ultrafiltration of the extract to remove the low molecular weight components of the whey, leaving a concentrated solution of protein which may be spray-dried.

4. Physical separation of the intact protein from very finely ground soy flour by density fractionation (flotation).

5. Purification of the extract by ultrafiltration, filtration through activated carbon, and ion exchange in order to increase curd purity."[7]

►Multiple Areas of Unacceptable Subjectivity in the Organic Foods Production Act of 1990 as Amended

Whether the final product SPI is **"… a chemically changed substance …"** as per **§205.2 Terms Defined** because its electric charge(s) have been changed – and its final chemical composition also changed with the physical addition of ~3% NaCl – are but two areas of potential contention open to different interpretations that can only be remedied by formally gathering a sufficient number of credentialed subject matter experts to precisely define **"… chemically changes a substance …"** in **§205.2 Terms Defined**.

[7] *Technology of Production of Edible Flours and Protein Products from Soybeans.* Zeki Berk, Technion, Israel Institute of Technology, Haifa, Israel. FAO Agricultural Services Bulletin No. 97. Food and Agriculture Organization of the United Nations Rome 1992

There are many other vague areas and terms throughout the **Organic Foods Production Act of 1990 as Amended** that must sooner-than-later be precisely defined in order to not keep revisiting these same intellectual pitfalls that will continue to be encountered given the current formal understanding of the vague verbiage found in the **OFPA of 1990 as Amended**.

►Vagueness in "§205.2 Terms Defined" – "Synthetic"

- It is not open to interpretation that the electric charge of the final product SPI is changed by adding HCL (or another acid) and later NaOH (or another base).

- It is also not open to interpretation that ~3% NaCl is physically added to the final product SPI when NaCl is formed by the chemical reaction **HCl + NaOH → NaCl + HOH** as a result of adding HCl to the soy protein that later reacts with the added NaOH leaving the final product SPI chemical composition to physically include the ~3% NaCl that otherwise would not be there.

- What is open to interpretation(s) (and/or legitimate intellectual challenge(s)) is/are whether one and/or both changes to/of the final product SPI meets the undefined threshold of **"… chemically changes a substance …"** of **§205.2 Terms Defined**.

- Does changing the electric charge (i.e., a physical property) on what would otherwise be a natural soy protein product that retains the same atomic configuration change the natural soy product to **"synthetic"** as per **§205.2 Terms Defined**?

- Does physically adding ~3% NaCl (that is formed by the chemical reaction **HCl + NaOH → NaCl + HOH** during the manufacture of the final product SPI) to the final product SPI with artificially adjusted electric charge **chemically change** the final product SPI?

Finally, if the specific final product SPI in this petition intended to be used as an organic fertilizer will solely be that produced by Archer Daniel Midland (ADM) using its closely-guarded, presumptively-proprietary manufacturing process, then further data cannot not be reviewed to determine if the final product SPI is **"synthetic"** or a natural product by any interpretation of the **OFPA of 1990 as amended**. This includes whether the ADM final product SPI is manufactured using a chemical process **or** if the ADM final product SPI is a chemically changed substance – because ADM has exercised its prerogative to not share the details of their final product SPI manufacturing process(es).

We may hypothesize that ADM is manufacturing its final product SPI using a chemical process – and therefore we may also- hypothesize that the ADM final product SPI is **"synthetic"** as per §**205.2 Terms Defined. (BLUE)**