

Docket No. 2007N-0464

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## SECTION A:

### PRELIMINARY REQUIREMENTS: INELIGIBILITY OF SOY PROTEIN FOR A HEALTH CLAIM

Soy protein isolate has never received GRAS (Generally Recognized As safe) status as an additive to food. Unlike other GRAS substances in use prior to 1958, soy protein isolate was not originally developed as a food but as an industrial product to bind and seal paper products. It therefore does not qualify as a product having a long history of safe use in the food supply.

Soy protein isolate contains a number of toxins and carcinogens introduced into the product by the high temperatures, high pressures and chemicals used in its manufacture. In 1979, the Select Committee of GRAS Substances (SCOGS) examined safety issues pertaining to the manufacture of soy protein isolate and recommended the establishment of acceptable levels of the carcinogens nitrite and nitrosamines and the toxic amino acid lysinoalanine in order to avoid future problems. To this date, the FDA has not established safe levels of these toxins and no agency is monitoring levels of these substances in edible food. The SCOGS committee determined that 150 mg per day of soy protein was the maximum safe dose, an amount is far less than the 25 grams per day of soy protein recommended in the currently allowed soy/heart disease health claim.<sup>1</sup>

The approval of the soy/heart health claim in 1999 helped establish the image of soy as heart healthy and increased consumption of soy protein in the United States from an average of 0.78 g per day in 1999 to 2.23 grams per day in 2004. As a direct result of the health claim, many people who would not otherwise choose soy have consciously added more soy foods carrying the heart disease health claim to their diets. Many of these people consume amounts well in excess of the average. Populations at greatest risk are infants on soy formula, vegetarians and vegans who consume soy as both meat and dairy replacements and adults self medicating with soy foods because of their trust in the FDA-approved claim that, in so doing, they will prevent heart disease.

In its Final Ruling on the 1999 soy protein/heart health claim, the FDA chose to disregard the SCOGS's committee's warning and dismiss the dangers of nitrites, nitrosamines and lysinalanines, merely stating that good manufacturing practices are and should be employed. The fact is that good manufacturing processes are not subject to oversight and today's soy products do contain dangerous levels of these toxic and carcinogenic substances.

Scientists have known since 1937 that nitrosamines damage the liver; and since 1956 that nitrosamines are mutagens and carcinogens.<sup>2,3</sup> Nitrates occur naturally in vegetables, water and many foods and beverages, including those containing soy. Nitrate is harmless until reduced to nitrite, which occurs through the processing methods used to manufacture soy protein isolate (SPI), casein and other fractionated food products. Nitrites are very reactive chemically and lead to nitrosamine formation in processed foods. Preformed nitrosamines are especially likely to be found in soy protein isolates and other soy products that have undergone acid washes, flame drying or other high temperature spray-drying processes. USDA studies from the 1980s showed that soy protein isolate contained almost twice the nitrite levels contained in other soy protein products. They also found in soy protein levels of 1.5 parts per billion of a potent nitrosamine known as N-nitrosodimethylamine (NDMA).<sup>4</sup>

The California Environmental Protection Agency Office of Environmental Health Hazard Assessment has established safe levels for nitrosamines ranging from 40 ng per day for NDMA to 80 ug per day for the relatively weak nitrosamine N-nitrosodiphenylamine. The soy industry has stated that intakes of soy protein at the level of 25 grams per day and higher are reasonable, prudent and present no safety concerns. Indeed, in the petition to the FDA that led to the currently allowed soy/heart disease health claim, Protein Technologies International (PTI) promoted 100 grams per day of soy protein as healthful. Levels of nitrosamines vary from batch to batch, but if we accept the USDA finding of 1.4 parts per billion, people eating 100 grams per day of soy protein clearly could easily exceed safe limits. Furthermore, the safe levels have been defined for a 70 kg adult male, levels that might be toxic for adult women, teenagers, children and infants.<sup>5</sup>

Lysinoalanine is a cross-linked amino acid that is produced when the essential amino acid lysine is subjected to strong alkaline treatments. Soyfood processors use alkali because it helps them transform soybeans into soy milk, tofu, textured vegetable protein, soy protein isolate, soy protein concentrate and other products quickly and profitably. Only old-fashioned, fermented soy products or precipitated tofu made at home or in small, cottage-type industries can claim to be lysinoalanine-free."<sup>6,7</sup>

Ghulam Sarvar, PhD, of the Nutrition Research Division of the Banting Research Centre in Ottawa, writes: The data suggested that LAL (lysinoalanine), an unnatural amino acid derivative formed during processing of foods, may produce adverse effects on growth, protein digestibility, protein quality and mineral bioavailability and utilization. The antinutritional effects of LAL may be

more pronounced in sole-source foods such as infant formulas and formulated liquid diets which have been reported to contain significant amounts (up to 2400 ppm of LAL in the protein) of LAL"<sup>8</sup>

The highest levels of lysinoalanines occur in soy protein isolates manufactured for use as sizing and coating adhesives for paper and paper-bound products. Such products are produced at high alkaline pH levels. Rats fed soy proteins processed using similar high alkali baths have suffered kidney damage, specifically increased organ weights, lesions and kidney stones. The industry claims that soy proteins intended for human consumption are safer because they are extracted at a pH level below 9, but a look at new processes receiving patents reveals that keeping alkaline levels low is not a high priority for much of the food-processing industry.<sup>9-11</sup> A recently patented process invented to deflavor soy milk, flour, concentrates and isolates involves adjusting the pH to levels ranging from 9 to 12.<sup>12</sup> A high pH makes it possible to dissolve the soy proteins and release the beany flavors through a special ultrafiltrated membranous exhaust system. Soy industry publications and processing manuals have repeatedly stated that soy's beanness is a major deterrent to consumer acceptance and profitability and that it must find failproof and economically feasible ways to turn beany tasting soybeans into bland soy ingredients.

Clearly these facts do not support the assertion in FDA's Final Rule that good manufacturing practices are and should be employed. Furthermore, we would like to remind the FDA of the language it used regarding GRAS status in the Proposed Rule, Food Labeling: Health Claims: Soy protein and Coronary Heart Disease (63 FR 62977). FDA tentatively concludes that the petitioner has provided evidence that satisfies the requirement in §101.14 (b)(3)(ii) that use of soy protein at the levels necessary to justify the claim is safe and lawful. We believe that the word tentatively indicates that the FDA recognizes the fact that the GRAS issue has not been resolved. Nearly 30 years after the Select Committee on GRAS substances (SCOGS) voiced concerns about lysinoalanine, nitrites and nitrosamines, needed safety studies remain to be carried out.

It is evident that the soy industry knows that soy protein isolate ingredients would not be legitimately eligible for GRAS status. Protein Technologies International's original petition to the FDA -- submitted May 4, 1998 -- proposed defining soy protein concentrate and soy protein isolate as soy flour because the procedures used to convert vegetable flours to vegetable protein concentrates and isolates were commonplace in various sectors of the grain industry, such as corn processing, well before 1958. PTI therefore concluded that soy protein isolate and soy protein concentrate should be considered no different from soy flour.

Although FDA did not take issue with this self-determination of GRAS status in 1999, we submit that FDA should reconsider this decision. Soy flour is very different from the soy protein isolates and concentrates now penetrating the market. Soy flour is a low-tech product with a comparatively long -- though minor -- history of use in the food supply. Soy flour has been most heavily consumed as part of wartime rations, vegetarian fare and to stave off hunger caused by poverty, famine or natural disasters. It has no standard of identity as the industry uses natural, full-fat soy flours, raw enzyme active flours used as bleaching agents and crumb color enhancers, toasted soy flours and defatted and low-fat soy flours.<sup>13-15</sup>

In contrast, soy protein concentrate and soy protein isolate are high tech products that are precisely manufactured under industrial conditions in chemical factories, not kitchens. Soy protein concentrate (SPC) comes from defatted soy flakes, consists of 70 percent protein and retains most of the soybean's fiber. It is made by precipitating the solids with aqueous acid, aqueous alcohol, moist heat and/or organic solvents. These immobilize the protein, which is then removed along with some of the soy carbohydrates, isoflavones and salt residue. Different processing methods favored by different manufacturers affect the quality of the protein, the levels of the antinutrients and toxic residues, solubility, emulsifying ability and texture. Two types of SPC are in general use. Textured soy concentrate a subtype of textured soy protein (TSP) is put through an extruder and turned into the flakes, chunks and granules of ersatz meat. Functional soy protein is used by food processors in the binding phase of production to guarantee firmness, cohesion and juiciness. Food processors often combine forms of SPC to form soy protein products.<sup>16-18</sup>

Soy protein isolates are a component of numerous products sold in today's stores, including energy bars, shake powders, pasta sauces, burgers and hot dogs. SPI is also the major ingredient in most of today's soy infant formulas. Consisting of 90 to 92 percent protein, SPI is a highly refined product processed to remove off flavors, beany tastes and flatulence producing compounds and to improve digestibility. The manufacture of SPI is a complicated, high-tech procedure in which vitamin, mineral and protein quality are sacrificed. Indeed soy isolates increase the body's requirements for vitamins E, K, D and B12. Among the minerals, phosphorous is poorly utilized, and calcium, magnesium, manganese, molybdenum, copper, iron and especially zinc deficiencies appear in animals fed SPI as the primary source of protein in their diets. Soy protein isolates are also more deficient in sulfur-containing amino acids than other soy protein products.<sup>19-21</sup>

Both soy protein isolate and soy protein concentrate contain glutamate, a potent excitatory neurotransmitter, although the FDA has no requirement to disclose its actual concentration."<sup>22, 23</sup>

Although the manufacturing process varies and some companies hold patents on key elements of the process, the basic procedure begins with defatted soybean meal, which is mixed with a caustic alkaline solution to remove the fiber, then washed in an acid solution to coagulate the protein. The protein curds are then dipped into yet another alkaline solution and spray dried at high temperatures.<sup>24,25</sup>

Toxicologists, endocrinologists and other expert scientists have questioned the safety of soy protein because of the known presence of antinutrients (protease inhibitors, phytates, lectins, saponins and oxalates) as well as the plant hormones known as phytoestrogens. A large body of research exists documenting these hazards, refuting industry claims that there are no known safety hazards associated with soy protein. Specific issues related to protease inhibitors and the development of heart disease will be discussed in depth later in this petition. Given the numerous reports of antinutrients, toxins and carcinogens in modern soy products, they cannot be assumed safe. We therefore conclude that the FDA is not authorized to allow a health claim for soy and heart disease.

Finally, the FDA-approved soy/heart health claim has indirectly served to put men, women and children with soy allergies at risk. Soy is now one of the top eight allergens, a fact acknowledged by the Food Allergen Labeling and Consumer Protection Act (S. 741) that went into effect January 2006. In fact, soy allergies are increasing, may already be in the top six and some experts predict they will soon be in the top four. Many allergy experts believe that the increased use of soy protein ingredients in food products -- encouraged in part by the positive image given to soy by the FDA-approved soy/heart health claim -- has increased exposure and the potential for sensitization. Soy proteins are now incorporated into more than 60 percent of the commercial recipes for baked goods, canned, packaged and other processed foods. This hidden soy poses a clear danger to allergy sufferers, who may experience symptoms that range from mild to life threatening, involving, the gastrointestinal, cutaneous and respiratory systems.<sup>26-32</sup>

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## ENDNOTES

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