



Brussels, 30th May 2016

Submission to P1028 Infant Formula Proposal of FSANZ (Food Standards Australia New Zealand) to revise and clarify standards relating to infant formula products

The European Natural Soy and Plant-based food Manufacturers Association (ENSA) and the European Vegetable Protein Association (EUVEPRO), as key stakeholders in soyfoods and soy protein products and as Codex Alimentarius Observers, would hereby like to submit comments on section 3.2. of the above consultation.

The comments concern the proposed change of the Nitrogen Conversion Factor (NCF) of soy protein to 5.71.

ENSA and EUVEPRO are concerned that the proposed change of the nitrogen to protein conversion factor for soy to 5.71 instead of the widely accepted 6.25 is in conflict with current Codex Standards, the guidance of globally recognised scientific organisations, national regulations, European Union legislation and published scientific literature which support NCF of 6.25:

- Codex Alimentarius STAN 175-1989 Codex general standard for soy protein products
- Codex Alimentarius CAC/GL 2-1985 Guidelines on nutrition labelling
- Codex Alimentarius STAN 234-1999 Recommended Methods of Analysis and Sampling
- European Union Regulation 1169/2011 on the provision of food information to consumers Annex I (which states that the labeling of protein should be defined as the protein content calculated using the formula 'protein= Kjeldahl nitrogen x 6.25');
- European Commission delegated Regulation (EU)2016/127 supplementing Regulation 609/2013 regarding compositional requirements of infant formula and follow-on formula Annex 2 ('protein content = nitrogen content x 6.25')
- recommendations from the Analytical Sciences Associations(AOAC),
- many national and regional governmental nutrition and labeling regulations

The 5.71 nitrogen conversion factor for soy protein would be calculated on the basis of only one storage protein present in soy i.e. glycinin, while a soybean contains several other proteins. As this calculation would disregard other major storage proteins present in soybeans, such as β -conglycinin, which constitutes approximately 35% of total storage proteins in soybeans, the NCF of 5.71 should be reevaluated.

β -conglycinin typically contains between 15.5%¹ - 15.9%² nitrogen, which translates to a nitrogen conversion factor of 6.45 – 6.29.

When both of the major storage proteins in soy beans are taken into consideration, a nitrogen conversion factor of 6.25 for soy proteins is the most accurate.

A nitrogen conversion factor of 6.25 for soy proteins is also supported both by (i) the calculation from the analytical determination of amino acid contents in various soy protein ingredients (FAO 2003 method³, industry data), and (ii) mass balance calculations measured by direct analysis whereby use of the 5.71 factor results in 8% “missing mass”¹. Since this “lost” 8% fraction cannot be properly classified as a nutrient by analytical methods, the proximate values do not add up to 100%.

Precise analytical determination faces numerous difficulties inherent to the methods used and lack of consistency, precision and accuracy.

FSANZ states in the consultation document that one of the objectives of the review is “*the promotion of consistency between domestic and international food standards*”, stating that “*The international standards of Codex and overseas regulations from the European Union, the United States of America and Asian countries are particularly relevant for the trade of products to and from Australia and New Zealand.*”

The Codex Committee for Methods of Analysis and Sampling (CCMAS) discussed the issue of NCF in February 2016 in Budapest and concluded that “... *it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors and to possibly update the report of the joint FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition (2002).*”

Against this background, changing the NCF for soy to 5.71 is not in line with a number of international standards. Also, it might appear premature for FSANZ to change the conversion factors at a time when the creation of an expert group at FAO level is being considered.

A change of the NCF for soy bean from 6.25 to 5.71 would have a significant impact on the recognition of soy protein as a nutritious and high-quality protein; it would also have economic repercussions, and impact international trade: It would result in an almost 10% reduction in the calculated protein content of soy without any change made to the formulation of the product. Such would put soy-based products and ingredients in an unfavorable and discriminated position triggering higher product cost, reformulation and adaptation of labeling.

For soy protein isolates as a food ingredient (European Union legislation on infant and follow on formula specifies that soy protein isolate is the only permitted vegetable protein source) this would mean:

- it would no longer meet certain product requirements,
- it might disappear from ingredients lists,

¹ **References:**



1. Morr, CV (1981) Nitrogen Conversion Factors for Several Soybean Protein Products. *Journal of Food Science* 46: 1362-67.
2. Roberts, RC and Briggs, DR (1965) Isolation and Characterization of the 7S Component of Soybean Globulins. *Cereal Chem* 42:71.
3. Food and Agriculture Organization of the United Nations (2003) Food energy – methods of analysis and conversion factors. Report of a technical workshop Rome, 3-6 December 2002.

For both soyfoods made from the whole soybean and for soy protein as ingredient

- it would result in expensive formula changes and
- it would incur high costs to manufacturers due to the resulting changes to food labels

For the above reasons, ENSA and EUVEPRO call upon FSANZ not to move away from the currently accepted NCF of 6.25 for soy protein.

For any questions, please contact:

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| ENSA Secretariat  Website: www.ensa-eu.org | EUVEPRO Secretariat  Website: www.euvepro.eu |
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About ENSA

Established in January 2003, the European Natural Soy and Plant-based food Manufacturers Association (ENSA) represents the interests of natural soy food manufacturers in Europe. The term “natural” refers to the production process used by ENSA members to produce food using whole soybeans. Soy food products from ENSA members are produced without any use of GM (genetically modified) material or GM beans.

ENSA is an association of internationally operating European companies, producing soy and other plant-based foods and beverages ranging from large corporations to small, family-owned businesses with an annual turnover of €0.8 billion. Since its establishment in 2003, ENSA has been raising awareness about the role of soy and a plant-based diet in moving towards more sustainable food production and consumption patterns.

About EUVEPRO

Founded in 1977, the European Vegetable Protein Association EUVEPRO represents the interests of manufacturers and distributors of vegetable proteins for human consumption (food) in the European Union. EUVEPRO monitors legislation that affects vegetable protein manufacturers, suppliers and users in Europe. It identifies potential problems specific to the sector, and delivers technical input and positions to EU decision makers as well as international bodies. EUVEPRO is a valued partner by the institutions and stakeholders of related industries, and promotes further recognition in European, national and international legislation, of vegetable protein products as foodstuffs and ingredients in their own right.