



1st September 2021

FSANZ Proposal P1028 - Infant Formula Consultation paper 2 - Nutrient Composition

Comments from EUVEPRO and ENSA

The European Vegetable Protein Association (EUVEPRO) and the European Plant-based Foods Association (ENSA) appreciate the opportunity to provide comments on the Food Standards Australia New Zealand (FSANZ) Consultation Paper 2 under Proposal P1028 - Infant formula. EUVEPRO & ENSA are key stakeholders in the area of plant-based proteins and foods respectively and have Codex Alimentarius Observer status.

Section 4.1 Protein calculation: appropriate nitrogen conversion factors (NCF)

EUVEPRO and ENSA **support** the proposal to adopt 6.25 in the Standard 2.9.1 as the NCF for all protein sources, as presented in option 1 of the consultation paper. This is the generally accepted protein conversion factor used by regulatory authorities for infant formula and follow-on formula, for example in EU Regulation 2016/127 and in the Codex Standard for Infant formula, as well as in the draft revised Codex Standard for Follow-up Formula. Moreover, deviating from this NCF would have other regulatory and market implications. For example, the use of different NCFs in different markets would result in multiple labels and required label changes and product reformulations as well as unfair trade advantages for other plant-based proteins should the NCF for soy be changed.

In addition, we would like to comment on a few elements presented in this section.

When referring to a scientific basis for an NCF of 5.71 for soy protein in the consultation, a publication by Maubois & Lorient (2016) is quoted. Although these two scientists used a scientific method for determining their NCF value, it has been pointed out by other academics, notably by E. Krul (2019)¹ reviewing the NCFs for soy, that there were several assumptions made by Maubois and Lorient that biased their data considerably, and that using similar logic for determining the NCF for soy (i.e. from amino acid sequence data) could ultimately result in a calculation of a NCF from 5.92 to 6.65 due to the significant variation in the protein subunit composition among different soy genotypes. Therefore, it would be extremely difficult to accurately determine a specific, universal NCF for soy using their methods.

¹ Krul, E. S. (2019). Calculation of nitrogen-to-protein conversion factors: A review with a focus on soy protein. *Journal of the American Oil Chemists' Society*, 96(4), 339-364.

Secondly, it is inaccurately stated that nitrogen levels in soy are reduced by glycosylation. The presence of N-glycoylation in proteins does not lower the nitrogen content; it stays the same. The nitrogen group is what the sugar is attached to in this case. If glycosylation were to have a reducing effect, then milk proteins would also have lower nitrogen levels since some of these are also glycosylated.

Furthermore, the paper states that soy proteins contain trypsin inhibitors as anti-nutritionals. While it is true that two very well-known trypsin inhibitors are present in soybeans (Kunitz trypsin inhibitor and Bowman-Berk Inhibitor), both are removed during processing. This is one of the main reasons why protein processing companies use an acid precipitation step for soy protein isolate used in infant formula.

Section 4.3 Protein: source

EUVEPRO and ENSA consider that protein sources of infant formula should be safe to support the healthy development of this age group and be high in quality, as determined by the PDCAAS method, the globally approved method for assessing the ability of a protein to meet needs of the human population.

Section 4.4 Protein: quality and use of protein scoring methods

EUVEPRO and ENSA **support** the proposal to maintain the use of amino acid composition of human milk as the reference for protein quality in infant formula. One of the protein scoring methods considered by FAO (2018) as alternative to ensure protein quality, DIAAS, has not been validated for regulatory purposes as an accurate determination of needs of the growing infant.

As regards the Questions for submitters listed in section 9 of the Consultation paper, EUVEPRO and ENSA have no further comments.

[EUVEPRO](#) - European Vegetable Protein Association
[ENSA](#) - European Plant-based Foods Association