



Submission to FSANZ in response to Consultation Paper – Proposal P1028

Infant Formula

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I. Executive Summary

In Supporting Document 1 (SD1) to P1028, FSANZ have proposed to adopt a nitrogen conversion factor of 5.71 for soy protein, and retain a factor of 6.25 for protein for mammalian milk and other plant sources. DuPont hereby submits that using the 6.25 nitrogen conversion factor for soy protein is also supported by international consensus of the following scientific and regulatory experts and organisations:

- Codex Alimentarius
 - Codex Standard 175-1989 Codex General Standard for Soy Protein Products
 - Codex Standard 174-1989 Codex General Standard for Vegetable Protein Products (VPP)
 - Codex CAC/GL 2-1985 Guidelines on Nutrition Labelling (as amended by the 29th Session of the Commission, 2006)
 - Codex Standard 234-1999 Recommended Methods of Analysis and Sampling (as amended by the 30th Session of the Commission, 2007)
- National and Regional Government Nutrition Labeling Regulations
 - Argentina
 - Brazil
 - China
 - European Union
 - India
 - Japan
 - Korea
 - United States
- Globally Recognised Analytical Sciences Associations
 - American Oil Chemists Society (AOCS)
 - AOAC International (AOAC)
 - AACC International (AACC)
 - International Organisation for Standardization (ISO)

FSANZ have stated in P1028 the factor of 5.71 can be supported by scientific evidence for soy protein. DuPont maintains that this idea is based on outdated and inaccurate data from analyses conducted in 1931. These data have since been discredited with improvements in analytical methods and technology, as well as an increased understanding of the chemical composition of proteins and the effects of amino acids and protein on human health:

- Analytical data of amino acids for over 50 samples of various soy products conducted by the United States Department of Agriculture, independent laboratories, and an independent university researcher show a nitrogen conversion factor in a range of 6.24-6.37

Changing the nitrogen conversion factor for soy protein from 6.25 to 5.71 will represent a departure from internationally recognised analytical methods, established nutrition clinical research procedures, as well as widely embraced trade and regulatory practices.

Changing the nitrogen conversion factor for soy protein from 6.25 to 5.71 will result in an approximately 9% reduction in the calculated protein content of soy formulas without any change to the product itself. Potential impacts include:

- Elimination of isolated soy protein as a food ingredient as it will be impossible to meet the CODEX product standard 90% protein minimum using a 5.71 nitrogen to protein conversion factor
- Revision of the definition for 'soy-based formula' in Standard 1.1.2 Definitions used throughout the Code, to replace 'soy protein isolate' with 'soy protein concentrate'.
- Significant costs to formula manufacturers due to requirement for label changes
 - "Isolated soy protein" would have to be removed from product ingredient lists
 - Nutrition information panels
 - Potential requirement for product formula changes
- Confusion for food manufacturers seeking to make products containing isolated soy protein who also supply into countries that recognise 6.25 as the nitrogen conversion factor for soy.
- Confusion for consumers (parents) seeking soy based formula products for dairy intolerant and allergic infants
- Impacts on presentation and interpretation of data from nutritional research for both scientific and lay audiences (which generally use 6.25)

DuPont therefore, supports the continued use of the 6.25 nitrogen conversion factor for the measurement of protein in soy-protein formula.

II. Introduction

DuPont acknowledges that we come late into this forum with our comments to the adoption by FSANZ of a nitrogen conversion factor for soy protein of 5.71 under P1028. Our position, there is significant scientific justification to challenge the decision by FSANZ to adopt a separate conversion factor of 5.71 for soy protein in infant formula as outlined in Supporting Document 1 of P1028.

We hereby submit that the 6.25 nitrogen conversion factor for soy protein is supported by international consensus of scientific and regulatory experts and organisations. The World Health Organisation (WHO) and the Food & Agriculture Organisation of the United Nations (FAO)¹⁻⁵, as well as several national and regional governments recognise the 6.25 nitrogen conversion factor for soy protein for purposes of trade, nutritional labeling, and the promotion of public health. The proposed 5.71 conversion factor is based on outdated and inaccurate data from analyses conducted in 1931 by D.B. Jones, a USDA researcher⁶. These data have since been discredited with improvements in analytical methods and technology, as well as an increased understanding of the chemical composition of proteins⁷⁻¹⁰ and the effects of amino acids and protein on human health. Changing the conversion factor for soy protein from 6.25 to 5.71 will represent a departure from internationally recognised analytical methods, established nutrition clinical research procedures, as well as widely embraced trade and regulatory practices. This submission document will briefly cover three important viewpoints that support a 6.25 nitrogen conversion factor, namely: the current regulatory environment, the scientific analytical environment, and analytical data on a variety of soy ingredients based on a direct method of analysis recommended by the FAO (2003) for the measurement of protein⁵.

III. Regulatory Environment

International Product Standards and Nutrition Labeling Recommendations and Regulations

Use of the 6.25 nitrogen conversion factor for soy protein is widely recognised as the appropriate method to determine compliance with product standards and nutritional labeling regulations by international organisations, such as Codex Alimentarius, and government regulatory agencies in India, Japan, Korea, the European Union, the United States, Argentina, and Brazil (Table 1). Although an exhaustive list of regulations from around the globe is not provided in this document, the data provided represent the nutrition labeling regulations for a significant portion of the world's population¹¹.

The most current Codex standards specifically state the 6.25 conversion factor should be applied to calculate protein values for soy and vegetable protein products. Namely:

- 175-1989 “Codex General Standard for Soy Protein Products”¹
- 174-1989 “Codex General Standard for Vegetable Protein Products (VPP)”²
- CAC/GL 2-1985 “Guidelines on Nutrition Labelling” (as amended by the 29th Session of the Commission, 2006)³

Standard 1.1.2 identifies soy based formula as ‘an infant formula product in which soy protein isolate is the sole source of protein’. Codex Standard 175-1989¹ is widely accepted and followed by the isolated soy protein industry. Additionally, the 90% minimum protein level stated in Codex

Standard 175-1989¹ serves as an important product standard to help identify high value isolated soy protein.

The nutrition labeling regulations of many major trading blocs list the 6.25 nitrogen conversion factor. For example, Argentina¹², Brazil¹³, the European Union¹⁴, India¹⁵, Japan¹⁶, Korea¹⁷, and the United States¹⁸ all require a 6.25 nitrogen conversion factor for soy protein ingredients. In addition, these nations recognise the Codex General Standard for Soy Protein Products STAN 175-1989¹, which requires a minimum 90% protein content.

Table 1. Current Soy Protein Conversion Factors from Around the Globe

<i>Organisation/Country/Region</i>	<i>Standard/Regulation</i>	<i>N Conversion Factor</i>
Codex	Codex General Standard for Soy Protein Products STAN 175-1989 ¹	6.25
Codex	Codex General Standard for Vegetable Protein Products (VPP) STAN 174-1989 ²	6.25
Codex	Guidelines on Nutrition Labelling CAC/GL 2-1985 ³	6.25
Argentina	Laws for the Labeling and Advertising of Food: Resolution in Conjunction with SPRyRS 149/2005 y SAGPyA 683/2005 ¹²	6.25
Brazil	Brazil National Health Surveillance Agency (ANVISA). Resolution - RDC No. 268, September 22, 2005 ¹³	6.25
European Union	Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs ¹⁴	6.25
India	Lab. Manual 3, Manual of Methods of Analysis of Foods, Cereal and Cereal Products, Directorate General of Health Services Ministry of Health and Family Welfare, Government of India 2005 ¹⁵	6.25
Japan	Japanese Agricultural Standard for Vegetable Protein and Seasoned Vegetable Protein ¹⁶	6.25
Korea	Nitrogen Conversion Factors for Protein Calculation, Korea Food Code ¹⁷	6.25
United States	Title 21 Code of Federal Regulations Part 101.9 ¹⁸	6.25

DuPont acknowledges the Codex Standard 72-1981 currently lists a single nitrogen conversion factor of 6.25 with a footnote indicating that different factor for soy of 5.71 may be applied. This footnote creates a global confusion in infant formula nutrition when so many countries support 6.25. We feel it is pertinent too, that the 5.71 reference is currently under debate within CCNFSDU, and as noted in SD1,

CCNFSDU (2015) has sought advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on the validity of 5.71 as the nitrogen conversion factor for soy isolates (REP16/NFSDU). At the latest CCMAS 37th meeting, February 2016, CCMAS recognised that there is an issue, but declared this to be beyond their scope and competence. Hence, CCMAS has called on FAO to establish an expert panel to investigate further. With this in mind, DuPont suggests that the FSANZ have been premature in adopting nitrogen conversion factor 5.71 in the recent draft to Standard 2.9.1.

IV. Scientific/Analytical Methodological Environment

Analytical Methods Support a 6.25 Conversion Factor

The Kjeldahl method, the modified Kjeldahl method, and the combustion method (known as the Dumas method) are commonly used for analytical measurement of protein. These methods measure protein in foods indirectly by assessing the quantity of nitrogen that can be released from a protein and captured as ammonia. Nitrogen from all nitrogenous compounds, including proteins and non-protein material, are typically included in this total. In the early 1880s, when the Kjeldahl method was invented, proteins readily available for testing (serum albumin and globulin from blood, casein from milk) contained about 16% nitrogen. Dividing 100 by 16% gave a nitrogen conversion factor of 6.25 and it was believed that this factor applied to all proteins. Although it has since been discovered through further scientific research that few foods contain precisely 16% nitrogen, use of the 6.25 conversion factor for measurement of protein sources has been maintained to allow for a measure of international harmonization in the expression of protein levels.

Application of the 6.25 nitrogen conversion factor to measure soy protein analysed by Kjeldahl, modified Kjeldahl, and combustion methods is widely recognised by international organisations, such as Codex Alimentarius and FAO^{4,5}, and technical associations, such as the American Oil Chemists Society (AOCS), AOAC International (AOAC), AACC International (AACC), and the International Organisation for Standardization (ISO).

The Codex Standard 234-1999 “Recommended Methods of Analysis and Sampling” (as amended by the 30th Session of the Commission, 2007)⁴ lists method AOAC 955.04D, that recognises 6.25 as the recommended protein measurement method for soy and vegetable protein products. Furthermore, Codex Standard 234-1994 specifically states the 6.25 conversion factor should be applied to nitrogen values for soy and vegetable protein products obtained using AOAC 955.04D.

AOCS, AOAC, AACC, and ISO analytical methods are widely recognised by regulatory agencies in enforcement of national regulations, as well as by university and government researchers. The current protein analysis methods approved by membership consensus in these technical associations list 6.25 as the nitrogen conversion factor for soy protein (Table 2).

Table 2. Official AOCS, AOAC, AACC, and ISO Soy Protein Analytical Methods

<i>Current Protein Analytical Method</i>	<i>Recommended Nitrogen Conversion Factor</i>
AOCS Ac 4-9119(revised 2011)	6.25
AOCS Ba 4d-9020 (reapproved 2009)	6.25
AOCS Ba 4e-9321 (reapproved 2009)	6.25
AOCS Ba 4f-0022 (reapproved 2009)	6.25
AOCS Ba 4a-3823 (reapproved 2009)	6.25
AOCS Ba 10-6524 (reprinted 2009)	6.25
AOAC 992.2325 (revised 2005)	6.25
AACC 46-10.0126 (reapproved 1999)	6.25
AACC 46-11.0227 (reapproved 1999)	6.25
AACC 46-16.0128 (reapproved 1999)	6.25
AACC 46-30.0129 (reapproved 1999)	6.25
ISO 16634-1:200830	6.25

Newer Protein Analysis Methods Provide More Accurate Protein Data and Prove 5.71 Conversion Factor for Soy is Incorrect

The 5.71 nitrogen conversion factor for soy protein is based on analytical data generated by D.B. Jones, Principal Chemist of the United States Department of Agriculture (USDA) in a Circular (1931)⁶. In this Circular⁶, Jones hypothesized that not all nitrogen in foodstuffs was protein nitrogen and not all proteins contained 16% nitrogen; therefore, a universal conversion factor of 6.25 was not always appropriate. In support of his theory, Jones reported nitrogen contents for several plant and animal proteins from a variety of sources. He also reported a wide variation in the nitrogen content across these protein sources. Jones justified the 5.71 factor for soybeans by stating the major protein in soybeans is glycinin, a globulin composed of 17.5% nitrogen. From these data, he designated a conversion factor for soy protein of 5.71 (100 divided by 17.5 results in a factor of 5.71).

This 5.71 conversion factor for soy protein, based on Jones' logic, is false.

Research^{7, 9, 10} has shown, however, that there can be wide variations in the levels of the major proteins in soybeans, glycinin and β -conglycinin, which could result in widely different nitrogen conversion factors if Jones' logic were carried out. Murphy and Resurreccion (1984)⁷ found glycinin/ β -conglycinin ratios varied significantly, depending on the soybean variety and differences in seasonal growing conditions. Roberts and Briggs (1965)⁹ and Koshiyama (1968)¹⁰ found that soy proteins typically consist of about 35% β -conglycinin and contain between 15.5% - 15.9%¹⁰ nitrogen, respectively, translating to a conversion factor of 6.45 – 6.29.

In recognition of the inconsistencies and inaccuracies inherent in analytical methods that measure protein indirectly through nitrogen content, other methods for measuring protein have been developed. In December of 2002, FAO convened the "Technical Workshop on Food Energy: Methods of Analysis and Conversion Factors". Outcomes of this workshop were published in FAO Food and Nutrition Paper 775.

One of the significant outcomes of this workshop was the recommendation by the expert panel for a superior and more accurate method using the sum of the anhydrous amino acids to measure protein. That is:

To measure protein as the sum of individual anhydrous amino acids, rather than the measurement of nitrogen by the Kjeldahl and other indirect methods.

Further, the workshop participants recommended that food composition tables should express protein content by the sum of anhydrous amino acids whenever possible, so these data may be used globally⁵. Using this recommended method, analytical product data supports a 6.25 nitrogen conversion factor as discussed below.

V. Analytical Product Data Using FAO's 2003 Recommendation

Analytical Product Data Supporting 6.25 Nitrogen Conversion Factor

Application of the FAO (2003) recommended protein measurement method cited in the Food and Nutrition Paper 775 yields nitrogen conversion factors for defatted soybean meal, soy protein concentrate, and isolated soy protein that range from 6.24 – 6.37 (Figure 1 and Tables 3-5). The amino acid content of various soy ingredients produced from 1993-2007 were measured using a modification of the method described in Mosse (1990)³¹. The anhydrous amino acid content was calculated as the amino acid molecular minus the molecular weight of water.

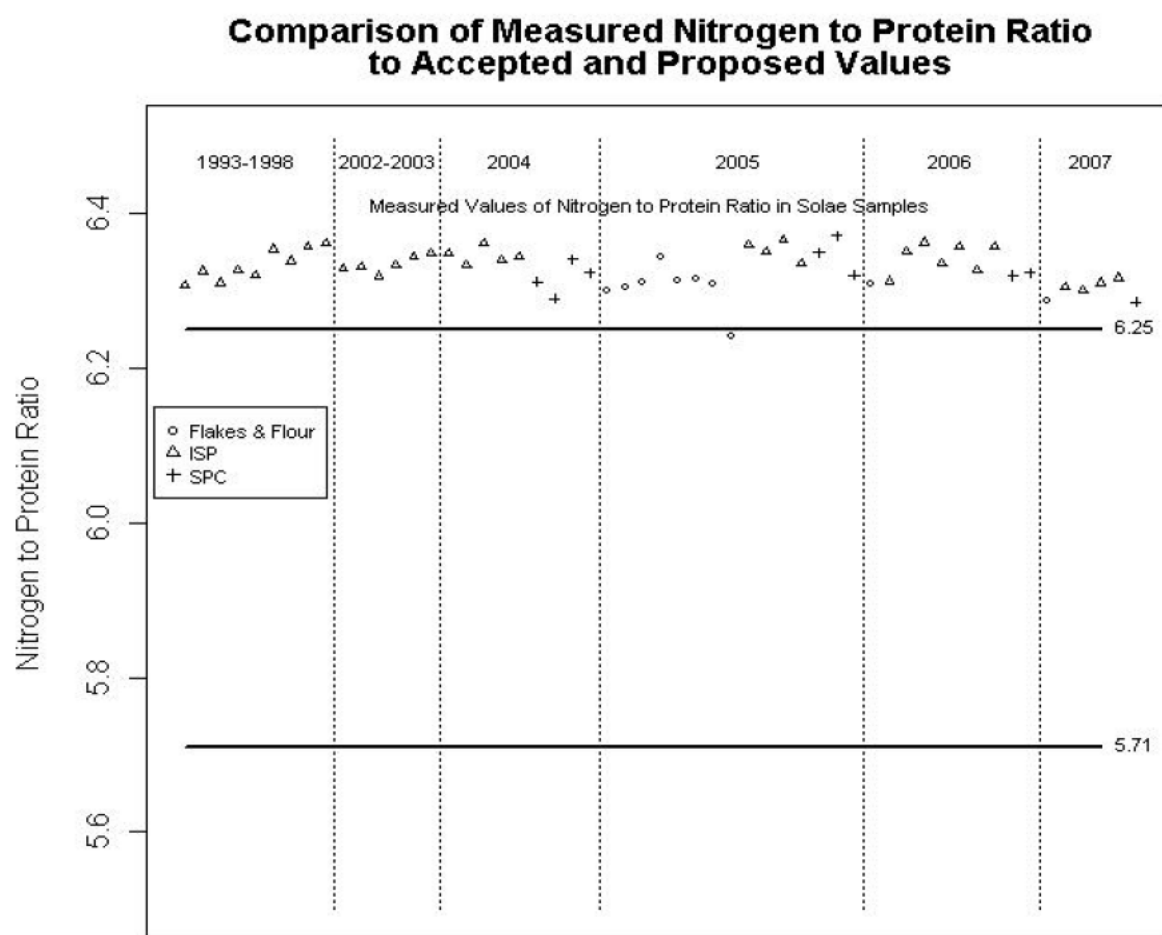
In addition, application of the FAO method to isolated soy protein amino acid data from 1982, isolated soy protein data currently available on the USDA National Nutrient Database for Standard Reference^{32,33}, and to amino acid data independently published in the scientific literature by Morr (1981)⁸ yield a 6.30-6.31 conversion factor for soy protein. Application of the FAO method to amino acid values to commonly consumed foods, like soymilk³⁴ and tofu³⁵, published in the USDA National Nutrient Database for Standard Reference yields a 6.30 conversion factor.

The nitrogen conversion factors calculated from fifteen years of amino acid data demonstrate an overall average value of 6.33 (Figure 1). With the exception of one data point at 6.24 for one lot of defatted soy meal, the remaining nitrogen conversion factor values vary from 6.29 – 6.37. It is well recognised by experts in the field that plant products exhibit natural year-to-year differences and product-to-product differences, which are to be expected due to different growing conditions and variations in manufacturing processes. The data for isolated soy protein ingredients presented in this document demonstrate stability of the protein nitrogen conversion factor over a 15 year period of time (Figure 1). The time resolution here is one year so any apparent trends within a year are an artifact of plotting the data in this order.

The data in Figure 1 are based on analytical data from daily production samples analysed by a single independent laboratory and show nitrogen to protein ratio that is greater than the value, 6.25.

Very importantly, it is noteworthy that these data are much more consistent with a nitrogen conversion factor of 6.25 than 5.71. The probability that these data are consistent with a nitrogen-to-protein ratio of 5.71 is essentially zero.

Figure 1.*



*Analytical data

Use of the 5.71 Conversion Factor Conflicts with Mass Balance Calculations

As part of a quality assurance program, soy protein ingredient manufacturers generally analyse protein, moisture, fat, and ash for each lot of product. These proximates are all measured by direct analysis. Carbohydrates are not directly analysed. Carbohydrate values are calculated by difference: 100 minus the sum of protein, moisture, fat, and ash. Therefore, proximates must always add up to 100%. Isolated soy protein typically contains <1% carbohydrate, as determined by calculation. Direct total dietary fibre analysis of isolated soy protein has confirmed that the <1% carbohydrate value is composed almost entirely of dietary fibre³⁶. Typical proximate values (on dry matter basis) for isolated soy protein using 6.25 as the conversion factor generate proximate data that can be supported by direct analysis (Table 6). Typical values for isolated soy protein using 5.71 as the conversion factor, however, generate proximate data that cannot be supported by direct analysis (Table 7). Use of the 5.71 factor results in 8% “missing mass”. This 8% fraction cannot be properly classified as a nutrient by analytical methods, as the proximate values do not add up to 100% (Figure 2).

Table 3. 6.25 Factor: Typical Macronutrient Data for Isolated Soy Protein

<i>Macronutrient</i>	<i>Typical Value</i>
Protein (dry matter basis)	91%
Fat	4%
Ash	4%
Carbohydrate	1%

Table 4. 5.71 Factor: Typical Macronutrient Data for Isolated Soy Protein

<i>Macronutrient</i>	<i>Typical Value</i>
Protein (dry matter basis)	83%
Fat	4%
Ash	4%
Carbohydrate	1%
Missing Mass	8%

Figure 2.

VI. Implications of the Change from 6.25 to 5.71 Nitrogen Conversion Factor

Changing the nitrogen conversion factor for soy protein from the widely accepted 6.25 to 5.71 could have significant implications:

- Elimination of isolated soy protein as a food ingredient as it will be impossible to meet the CODEX product standard 90% protein minimum using a 5.71 nitrogen to protein conversion factor
- Revision of the definition for 'soy-based formula' in Standard 1.1.2 Definitions used throughout the Code, to replace 'soy protein isolate' with 'soy protein concentrate'.
- Significant costs to formula manufacturers due to requirement for label changes
 - "Isolated soy protein" would have to be removed from product ingredient lists
 - Nutrition information panels
 - Potential requirement for product formula changes
- Confusion for food manufacturers seeking to make products containing isolated soy protein who also supply into countries that recognise 6.25 nitrogen conversion factor for soy.
- Confusion for consumers (parents) seeking soy based formula products for dairy intolerant and allergic infants
- Impacts on presentation and interpretation of data from nutritional research for both scientific and lay audiences (which generally use 6.25)

Current isolated soy protein production methods generate product with a typical protein range of 90-92%, using 6.25 as the conversion factor. Occasionally, protein levels can reach 93-94%. Use of the 5.71 conversion factor for soy protein would artificially eliminate the isolated soy protein category, as protein levels will not reach the 90% minimum for the product standard. Product that is currently labeled as "isolated soy protein" would now be identified as "soy protein concentrate" (Codex STAN 175-1989 defines protein levels for soy protein concentrate as <90%, but ≥65%¹). When the factor 5.71 is applied,

typical protein values would change to 82-84%, with occasional levels of 85-85.9%. Resulting replacement of the terminology “isolated soy protein” with “soy protein concentrate” in the ingredient list as a result of the use of a 5.71 conversion factor would require costly label changes for any infant formula currently containing isolated soy protein. This would also require an amendment to Standard 1.1.2 Definitions used throughout the Code, which references soy protein isolate in the definition of soy based formula.

In addition, products containing soy protein based formulas imported from countries utilising the 6.25 conversion factor would require significant label changes. These significant label changes could generate confusion amongst consumers seeking formulae made with isolated soy protein.

Soy protein has long been recognised for its beneficial health effects. As a result, soy protein has been extensively used in pre-clinical and clinical infant nutrition research. An important aspect of reporting data from nutrition studies for publication in international scientific research journals is the quantification of dietary protein intake. If the 5.71 factor is utilised to assess dietary soy protein intake while other countries use 6.25, the data may reflect artificially, yet significantly lower protein intakes studies that utilise soy protein and the incorrect 5.71 factor. These artificially lower protein intakes in studies could conflict with soy research data generated from dietary intervention trials from other parts of the globe, making comparability of results across studies a challenge.

Finally, if the 5.71 conversion factor were to be applied to soy protein based on the 1931 research conducted by Jones⁶, it should follow that the nitrogen conversion factors should be revisited for ALL major food proteins. Jones cited several nitrogen conversion factors for various proteins. As is the case with soy protein, it is likely that several of the nitrogen conversion factors reported by Jones are potentially wrong, due to the lack of sophisticated analytical techniques in 1931, compared to what we have available today. Application of these unique conversion factors to all of the different proteins that may be found in the food supply could be confusing and complicated for all members of the supply chain.

VII. Conclusions

In conclusion, this submission has carefully documented both regulatory and scientific support for the validity of 6.25 as the soy protein nitrogen conversion factor. To this effect, credible and valid analytical data on a variety of ingredients has been included that further support 6.25 as the soy protein nitrogen conversion factor. We therefore, respectfully request the continued use of the 6.25 nitrogen conversion factor for the measurement of protein in soy-based infant formulae in Australia and New Zealand. Continued use of the 6.25 factor for soy protein will also very importantly ensure harmonised nutrition labeling and products standards with international organisation standards and national/regional government regulations.

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