Nestlé Submission

Consultation Paper 1 2021

Proposal P1028 - Infant Formula

07 July 2021

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This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Limited.

Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula and other foods. Nestlé currently imports and markets infant formula products which are regulated in section 2.9.1 of the Australia New Zealand Food Standards Code ('the Code').

Nestlé welcomes the opportunity to consider the issues and preliminary views proposed in the consultation paper for Proposal 1028 (P1028), and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Consultation paper on the Regulation of Infant Formula. We thank FSANZ for its consideration of the comments, issues and views raised in this submission.

Introduction:

Breast milk is the best nutrition for infants. Nestlé fully supports this and optimal breastfeeding for optimal health outcomes for infants. We welcome the consultative effort of FSANZ to determine the best nutrition advice and outcomes for Australian and New Zealand infants.

In situations where the infant cannot receive breast milk, an infant formula is the only suitable and safe alternative, as a sole source of nutrition. Nestlé advocates a science–based approach to formulating products for the health and well-being of infants and young children. It is important that health recommendations and regulations focus on the best interests of the child and are based on the latest body of scientific evidence.

Comments and Responses to Questions

Section 2: Food Additives

2.2 Food class system for food additive permissions

In Section 2.2.4, FSANZ proposes three options for the future food classification system for food additive permissions for infant formula:

Option 1 - status quo

Option 2 - additional subclasses

Option 3 - simplified approach

Nestlé agrees with the simplified approach in Option 3. It is consistent with international approaches.

The principles relating to food additive use are generally technological (e.g. manufacturing process, ingredients, stability, food matrix, nutrient delivery). Whereas the label of an IFPSDU will align to the purpose of the product rather than the ingredients. The use of sub-categories that do not exist in other jurisdictions could limit the access of this population to appropriate nutrition.

We note there are some variations on the conditions/qualifications for IFPSDU containing hydrolysed proteins, peptides or amino acid e.g. 'For use in…', 'From birth onwards…'. We suggest that these are consistent.

2.3 Carry-over principle for food additives and infant formula

Nestlé supports the carry-over principle, where safe and technologically necessary.

Nestlé agrees that the Codex Standard and EU Regulations both restrict carry-over for food additives from ingredients used in the manufacture of infant formula unless there is explicit permission. However, we note that the EU and Codex carry-over permissions are not identical. We suggest that if FSANZ progresses amending the Code in regard to the carry-over principle then further harmonisation of food additives with both EU and Codex may be required, particularly in regard to permission of additives for addition to nutrient preparations and additive preparations, would be required.

Question 10. What would be the practical steps involved in ensuring compliance of your products with the carry over provisions proposed in this paper?

Nestlé notes that the final carry-over provisions and harmonisation with Codex and EU food additive permissions will be required to determine whether reformulation can be avoided.

Where reformulation is required, manufacturers will need to identify substitutes, undertake product reformulation and storage stability trials. It should be noted that some infant formula products have a three-year shelf-life. Also, suppliers may have to complete stability studies on the ingredients. Alternatively, manufacturers will need to make an application for approval of the additive for use in infant formula products.

Question 11: Do you have any more information on how much ensuring compliance would cost per effected product?

The cost of compliance would depend upon the individual manufacturer and their approach.

Research and development costs to find an alternative solution would need to consider the technological application, ingredient and final product trials and stability trials.

The cost of compliance could be greater if the route required included an application to change the Code.

Question 12: Would different sized businesses be generally equally impacted from our proposed changes to the carry-over principle?

Businesses are unlikely to be impacted equally since it will depend on the number of their product formulations impacted by the proposed changes to the carry-over principles, harmonisation and the cost of steps needed in order to comply with amended requirements.

2.4 Harmonisation of food additive permissions

Nestlé notes that CP1 does not reflect the 2020 amendment to Codex Standard CXS 72-1981 which has been updated to permit the use of pectins and xanthan gum in some infant formula products.

Section 2 refers to particular descriptions of IFPSDUs used in relation to the dietary management of a specific disease, disorder or medical condition for which the product is intended. Codex Standard CXS 72-1981 and EU regulations do not have sub-divisions of IFPSDU and if any such sub-divisions are retained by FSANZ they should not be contrary to the additive permissions from Codex or EU.

2.4.2 Acidity Regulators

Nestlé suggests that a condition of use is applied to sodium, potassium, calcium and phosphate salts that they should be in conformity with the compositional requirements set out in the Code. This would be consistent with the Codex and EU approaches and avoid potential confusion or duplication of effort should additive MLs be applied.

Nestlé generally agrees with the proposal to permit calcium hydroxide as a food additive in all infant formula and calcium carbonates and calcium citrates as food additives in IFPSDU.

In the EU, calcium citrate and tricalcium phosphate are permitted additives for addition to nutrient preparations used in all infant formula[1]. These permissions should be taken into consideration if FSANZ amends the carry-over principles.

2.4.3 Citric acid and fatty acid esters of glycerol (CITREM (INS 472c)

Nestlé supports the FSANZ proposal to harmonise permissions for CITREM with the Codex and EU - 9000 mg/L for liquid infant formula and 7500 mg/L for powdered formula.

2.4.4 Starch sodium octenylsuccinate (INS 1450)

Nestlé supports the FSANZ proposal to permit the use of starch sodium octenylsuccinate in IFPSDU however consider that this use should not be restricted to only products containing hydrolysed protein and/or amino acids. This would be consistent with the EU permission.

In addition, we note that starch sodium octenylsuccinate is permitted as a food additive for addition to nutrient preparations intended to be used in all infant formula in the EU. These permissions should be taken into consideration if FSANZ amends the carry-over principles.

2.4.5 Locust bean (carob bean) gum (INS 410)

Nestlé supports the FSANZ proposal to retain the current permission for use in infant formula to 1000 mg/kg. In addition, to permit locust bean gum for use only in IFPSDU 'products for reduction of gastro-oesophageal reflux' with an MPL of 10000 mg/kg to align with EU.

2.4.6 Pectins (INS 440)

Nestlé notes that FSANZ did not consider the recent Codex permission for use of pectins as a food additive in liquid infant formula containing hydrolysed protein[2]

We suggest that FSANZ align with Codex and permit pectins in liquid infant formula containing hydrolysed protein with an ML 2000 mg/kg. Also, to permit pectins in IFPSDU limited to products for gastro-intestinal disorders with ML 10,000 mg/kg to align with EU.

2.4.7 Xanthan gum (INS 415)

Nestlé notes that FSANZ did not consider the recent Codex permission for use of xanthan gum as a food additive in liquid infant formula containing hydrolysed protein[2]

Nestlé suggests that xanthan gum be permitted in IFPSDU products based on amino acids or peptides for use with patients who have problems with impairment of the gastrointestinal tract, protein mal-absorption or inborn errors of metabolism at a ML of 1200 mg/kg in line with the EU.

In addition, Nestlé suggests that xanthan gum be permitted in powdered hydrolysed protein and/or amino acid based infant formula to align with Codex.

2.4.8 Guar gum (INS 412)

Nestlé understand that the current permission for guar gum in infant formula products with an ML of 1000 mg/L would be retained.

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[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (as amended)

[2] CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS72-1981 (amended 2020)

2.4.9 Sodium alginate (INS 401)

Nestlé supports the FSANZ proposal to align with the EU permission in IFPSDU from four months onwards required for metabolic disorders and for general tube-feeding with an ML of 1000 mg/kg.

We note that the requirement to state “from 4 months” does not align with the mandatory statement to label all infant formula as “suitable from birth”.

2.4.10 Sodium carboxymethylcellulose (INS 466)

Nestlé supports the INC response.

2.4.11 Sucrose esters of fatty acids (INS 473)

Nestlé supports the FSANZ proposal to permit the use of sucrose esters of fatty acids in IFPSDU only in products containing hydrolysed proteins, peptides or amino acids with an ML 120 mg/kg to align with EU.

The food additive is not currently permitted for direct addition by the Code. Nestlé is not aware of any current use.

2.4.12 Diacyltartaric and fatty acid esters (472e)

Nestlé refers to the INC response.

Question 2. Table 2.17 lists the proposed approach for food additives. It includes some food additives where it is proposed to align with EU regulations but FSANZ has noted that there is a lack of safety information and therefore, it is not possible to draw a conclusion on the safety of these substances at the proposed levels in the target population. In these cases (all relate to IFPSDU which are generally imported into the Australian and New Zealand market), we request further information from health professionals about the need to permit addition of these food additives to IFPSDU and information from manufacturers about industry use of these food additives in Australian and New Zealand. The food additives that this question pertains to are:

- *Locust bean gum*
- *Pectins*
- *Xanthan gum*
- *Sodium alginate*
- *Sodium carboxymethylcellulose*
- *Sucrose esters of fatty acids*

Comments on specific food additive permissions are noted in the earlier sections.

Question 6: Would there be any practical barriers to complying with new permissions and limits as proposed in this document for any formula products that have not yet been identified? How might such barriers be overcome?

Nestlé appreciates the work that FSANZ has completed on harmonisation, however notes that there are some further considerations particularly related to carry-over.

Complying with new provisions for carry-over is likely add extra complexity. In particular, it would be less complex to ensure continued permission for additives permitted at GMP to additionally be permitted for carry-over from nutrient preparations and additive preparations.

We note that new permissions in Codex or EU would be subject to a FSANZ application and welcomes the work ongoing in the review of the FSANZ Act which may simplify such applications.

Question 7: What (if any) implications might overcoming any practical barriers have for production costs per product line? Please quantify where possible.

See above.

Question 8: Might smaller or else larger businesses be disproportionately impacted if a new permission does not align with international regulations or standards? If so can you specify how by providing quantitative evidence where possible?

As previously noted, businesses are unlikely to be impacted equally since it will depend on the number of their product formulations impacted by the proposed changes to the carry-over principles, harmonisation and the cost of steps needed in order to comply with amended requirements.

Question 9: Are any food additive preparations (food category 0 in Schedule 15) used in infant formula products? If so, how?

Nestlé notes that there are some food additives e.g. with an antioxidant function, from the list of additives permitted at GMP which are used in additive preparations then used in infant formula.

Section 3: Contaminants

3.3.1 – 3.3.3 Acrylonitrile, Aluminium, Arsenic

Nestlé supports the INC response.

3.3.4 Cadmium

Question 1: FSANZ has proposed two options in relation to the ML for cadmium (Section 3.3.4). FSANZ ask stakeholders for views on these options.

Nestlé supports option 1 – do not establish an ML for infant formula in the Code.

FSANZ risk assessment has determined that dietary exposures to cadmium in infant formula are not considered likely to be of health concern, noting that no data is available for soy-based infant formula. Nestlé supports maintaining this risk-based approach to establishing MLs.

3.3.5 Lead

Nestlé supports the FSANZ proposal to reduce the ML for lead to 0.01 mg/kg on a ready to feed basis, consistent with Codex General Standard for Contaminants 193-1995 (revised 2019).

3.3.6 Melamine

Nestlé agrees with the FSANZ proposal that it is not necessary to set an ML for melamine.

3.3.7, 3.3.8 Tin and inorganic tin compounds, Vinyl chloride

Nestlé supports the INC response.

3.3.9 – 3.3.14 Mycotoxins: aflatoxins B1and M1, Mycotoxins: Ochratoxin A, Polycyclic aromatic hydrocarbons Perchlorate, Chloropropanol, glycidol and their esters

Nestlé agrees with the FSANZ proposal that it is not necessary to set an ML for mycotoxins: aflatoxins B1and M1; Ochratoxin A; polycyclic aromatic hydrocarbons; perchlorate; chloropropanol, glycidol and their esters.

Section 4: L(+) lactic acid producing microorganisms

Question 13: Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic. Do these need to be explicitly excluded (or non-pathogenic specifically permitted) or is the base 'safe and suitable' requirement considered sufficient to manage this risk?

Nestlé considers that it is not necessary to amend the current voluntary permission for addition of L (+) lactic acid producing microorganisms. The Food Standards Code requires food to be safe and suitable hence any L(+) lactic acid producing microorganisms would need to be non-pathogenic and non-toxic. We note that Codex Standard 72-1981 refers to L(+) lactic acid producing cultures without further qualification.

In addition, there should not be internal inconsistencies within the Code, for example with permissions for use of microorganisms Standard 2.5.3.

Section 5: Labelling

Question 14: Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach?

5.3 Preparation, use and storage directions to manage microbiological hazards

5.3.1 Directions for preparation and use

Nestlé supports the FSANZ proposal to maintain the current approach not to prescribe the exact wording or pictures. This flexibility is important to allow companies to provide instructions for preparation, storage and use particular to their formula.

- Nestlé supports the continued labelling requirement for an instruction that each bottle should be prepared individually.
- Nestlé supports the amended labelling requirement for directions for the use of cooled previously boiled water.
- Nestlé agrees that it is safe to store prepared formula for up to 24 hours when cooled rapidly and stored at 4°C or less. Also, that any lesser period of storage time at 4°C or less is also safe.
- Nestlé supports that formula left in the bottle after a feed must be discarded and considers that it is helpful to provide a timeframe. Nestlé receives consumer questions regarding this timeframe from time to time.

  The WHO PIF guidelines indicate prepared feed should be discarded after two hours unless stored in the refrigerator, and leftover feed should never be saved for later or added to freshly prepared feed (WHO 2007). This is consistent with the New Zealand Guidelines. Nestlé agrees with the proposed addition of "within 2 hours" noting that this is within 2 hours of preparation of the formula.

5.4 Other safe preparation and storage issues

5.4.1 Date Marking

Nestlé supports the FSANZ proposal to maintain existing date marking requirements for infant formula. However, for IFPSDU we recommend the format of date marking is not prescribed. This would allow the use of, for example, expiry date or other similar words as well. This will contribute to ensuring the ongoing supply of these products to Australia and New Zealand.

5.5 Warning statements

5.5.2 Warning statements about following instructions exactly

Nestlé does not support the FSANZ proposal to amend the warning statement for infant formula products. We note that FSANZ observed that there is limited evidence of adding other foods to formula and therefore limited food safety issues to address. Also, the warning statement may not be the most effective way of communicating this information. The eye-tracking data from FSANZ consumer research highlighted that the preparation instructions received more attention than the warning statement by participants. The research also found the improved preparation instructions with a statement on not adding food [to the infant formula] significantly improved understanding.

If needed, it would be better to include this additional text in the preparation instructions.

5.6 Product identification

5.6.4 Source of protein statement

Nestlé's does not support the clarification of the 'source' of protein in section 2.9.1—23 to refer to the origin of the protein but not the protein fractions.

Whilst protein quality and quantity are regulated, there are additional differences in protein source which are relevant to consumers and healthcare professionals and may not be listed elsewhere on the label. For example, whey dominance may be recommended by healthcare professionals as whey is more readily digested than casein[3], and breastmilk is whey dominant. We note the EU explicitly permits the declaration of whey protein/casein ratio[4].

Guidance for healthcare professionals for formula-fed infants often includes guidance on protein source in infant formula, such as The Academy of Breastfeeding Medicine's protocol[5]. Information beyond the protein origin in the protein source statement will allow healthcare professionals to help their patients to identify the appropriate infant formula without recommending a brand.

Nestlé does not consider the protein source statement to be the primary source of allergen information for caregivers. This statement does not contain sufficient information to make safe choices of allergenic infants as allergens may be present from other ingredients. Declaration of allergens is regulated by Standard 1.2.3, which has been recently amended to ensure clarity and consistency in the declaration of this information.

Nestlé supports the retention of the requirement for the co-location of the protein source statement and the name of the product. Also, we support clarification of the 'name of product' and that the protein source adjacent to the prescribed name is not required every time the prescribed name occurs on the label.

Question 15: Are you aware of any further data on infant illnesses that can be attributed to incorrect preparation as a result of unclear labelling or warning statements on products?

Nestlé is not aware of any additional data.

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[3] Dupont C. Protein requirements during the first year of life. Am J Clin Nutr. 2003 Jun;77(6):1544S-1549S. doi: 10.1093/ajcn/77.6.1544S. PMID: 12812152.

[4] Regulation (EU) 2016/127 COMMISSION DELEGATED REGULATION (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

[5] Kellams, Ann & Harrel, Cadey & Omage, Stephanie & Gregory, Carrie & Rosen-Carole, Casey. (2017). ABM Clinical Protocol #3: Supplementary Feedings in the Healthy Term Breastfed Neonate, Revised 2017. Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine. 12. 10.1089/bfm.2017.29038.ajk

Question 16: How often do you change labels on your products voluntarily for marketing or other purposes?

The frequency of voluntarily labelling updates varies considerably between products, and consumers are sensitive to these changes. Labels, particularly for IFPSDU, would usually be changed less frequently since they are used in small quantities and label changes may require notification.

Question 17: If the proposed changes were made at the same time as a voluntary label change, how much extra would it cost to change each product's labels (on average)?

If the proposed changes to the label were made at the same time as voluntary label changes then additional cost would be minimal.

Question 18: If the proposed changes could not be made at the same time as a voluntary change, how much extra would it cost to change each product's labels (on average)?

The overall costs of changing a label would include internal resource to make the amendments, external design costs, communication of change to consumers and any packaging write off costs at the time of change. Additional costs would also be incurred amending off label representations e.g. websites.

Question 19: Apart from any costs, would there be any other practical challenges of changing your products' labels as proposed?

Nestlé suggests further consideration is given to potential confusion as a result of the preparation instructions for infant formula and follow-on formula being different.

Nestlé supports the need to regulate labelling for IFPSDU but requests consideration not to prescribe wording for warning statements and date marking for IFPSDU and to give sufficient flexibility in wording for preparation instructions.

To do so would unnecessarily constrain compliance of a category of products where the majority are imported in small, specialist quantities for use under medical supervision. This adds cost for the consumer or healthcare provider and can constrain supply.

General question related to the Consultation paper

Question 20: In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence and quantify impacts where possible.

FSANZ will need to consider how changes such as those proposed for food additives and labelling requirements will be implemented. Some infant formula products have a 3-year shelf-life. In addition, some products may be listed in the Australian Pharmaceutical Benefits Scheme (PBS) or New Zealand Pharmac Pharmaceuticals Schedules which require notification of changes.

Also, consideration needs to be given to potential misalignment between infant formula and follow-on formula.