7 July 2021

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Proposal P1028 Review of Infant Formula: Consultation Paper No.1/2021.*

Yours sincerely

Katherine Rich
Chief Executive

PROPOSAL P1028 REVIEW OF INFANT FORMULA: Consultation Paper No.1/2021

Submission by the New Zealand Food & Grocery Council

7 July 2021

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Proposal P1028 Review of Infant Formula: Consultation Paper No.1/2021.*

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

COMMENTS

3. NZFGC's first comment is that we support the Submission made by the Infant Nutrition Council on the *Proposal P1028 Review of Infant Formula: Consultation Paper No.1/2021 (*CP1). We want to highlight several aspects as follows.

Carryover

4. The most significant concern NZFGC highlights is the FSANZ proposal to change the carryover provisions.

5. FSANZ proposes alignment with Codex and EU regulations. FSANZ makes no apology for the fact that Codex and EU food additive permissions for infant formula and IFPSDU are not the same. Neither permits the general carry-over of food additives for infant formula and IFPSDU except where explicit food additive permissions already apply to them. The rationale from FSANZ is to ensure consistency between the Food Standards Code and relevant international infant formula and IFPSDU regulations. This does not offset cost.

6. The proposed carry-over changes add a significant degree of complexity to the assessment of carry-over compliance. Further, the changes proposed do not capture all the food additives permitted by the combined Codex and EU provisions in these products. This proposal introduces significant cost and these costs are unevenly spread across the market but mostly the burden will be on local manufacturers.

7. If the carryover is no longer permitted, there would be barriers for some nutrients which contain additives that are not listed in Schedule 15, category 13.1 or in Schedule 18 as a processing aid.

8. Taking an example, five nutrient carriers are listed in the Codex Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979 - Section D) which are not permitted food additives for use in infant formula under the proposed changes. FSANZ considers no changes to the Food Standards Code are needed to accommodate these as they can be considered as generally permitted processing aids in the regulation. This is a matter of interpretation.

9. In certain circumstances these five nutrient carriers may be considered to be food additives which would render them non-permitted under the proposed changes to carry-over provisions. This is due to the Food Standard Code's approach to additives which, if the proposed carry-over provisions are applied to infant formula, puts an undue emphasis on function, rather than simply level of presence of carry-over additives that are applied by Codex and the EU. From a food safety perspective, it is the <u>amount</u> of 'added substance' present that is relevant not its function (nutrient, food additive or processing aid) so regulation should be simplified to allow compliance to be easily ascertained.

10. In any case, we also note that these five additives (SIN 414, 551, 421, 1450, 301) are not listed in Schedule 18—2 (list of generally permitted processing aids). A clarification would be necessary. To ensure compliance of products with the proposed carryover provisions, all the additives authorised in the EU to be added in nutrients intended to be used in foodstuffs for infants and young children need to be authorised by the Food Standards Code. These additives are listed in regulation (EU) 1333/2008, annex III, part 5, section B.

11. FSANZ's interpretation cannot be relied upon on the face of the law and this is one of several reasons NZFGC recommends the retention of the status quo for carry-over. If this is not pursued, clarifying provisions in Standard 2.9.1 will be essential.

12. We also point out that there is a barrier to compliance in terms of the permissions of vitamins and minerals since there is no equivalent in the Food Standards Code to the Codex provision of explicit reference to advisory lists (CXG 10-1979). This leaves a gap between the Food Standards Code and the Codex carry-over permissions for infant formula. Our proposed solution is to add a food additive section to Standard 2.9.1 with text that addresses this particular problem. This will not address all the problems.

13. We also note that if an additive is permitted in the EU but not by the Food Standards Code, it will be nearly impossible for some manufacturers to produce a specific Infant formula for Special Dietary Uses (IFPSDU) for Australia and New Zealand only, due to low volumes. This is a very serious risk.

14. Retention of current carry-over provisions will avoid unwarranted time and resources being spent by industry and regulators on compliance verification checks due to the complexity that will apply if proposed changes to carry-over provisions are adopted. We encourage FSANZ hold a discussion with a small industry group on the issues to ensure it is well aware of the consequences especially to New Zealand and Australian manufacturers.

Additives

15. In relation to harmonisation of food additive permissions, NZFGC is largely supportive but we strongly recommend that food additives that contribute essential nutrients do not have maximum levels (MLs) specified, provided that there is no exceedance of nutrient compositional limits. It is the level of the substance present that determines safe use, not whether it is added as a nutrient or food additive.

16. We also note an oversight in the INC submission in relation to pectins, that the permission of pectins in infant formula limited to liquid infant formula containing hydrolysed protein with ML of 5000 (not 2000) mg/kg to align with Codex CXS 72-1981

Contaminants

17. In relation to contaminants, NZFGC is generally supportive but prefers MLs are stated on a powder basis.

18. In the EU, the limits for cadmium are being reviewed and a limit for cadmium in infant formula manufactured from plant protein isolates other than soya protein isolates is likely to be introduced, in addition to limits already existing for milk based and soya based formulas. This limit will be the same for infant formula manufactured from soya protein isolates: 0.02 mg/kg for powdered infant formula and 0.01 mg/kg for liquid infant formula. This update is not published yet. It is planned to apply from 1 January 2022.

19. We agree with INC's position but if an ML is introduced it would be preferable to not have tighter restrictions than the EU to avoid manufacturing barriers, especially for plant based formulas.

Lactic acid producing microorganisms

20. On lactic acid producing microorganisms, NZFGC considers it unnecessary to amend the current voluntary permission for the addition of L(+) lactic acid producing microorganisms due to the Food Standards Code overarching requirement for food to be safe and suitable. Codex refers to L(+) lactic acid producing cultures without further qualification and we do not consider it is necessary to insert 'non-pathogenic' as proposed.

Preparation, use and storage directions

21. In this area, NZFGC proposes clarification in application of the changes and stress the importance of maintaining the current flexibility in the wording applied for preparation instructions as companies also consider other important aspects for a particular formula.

22. This applies to the proposed inclusion of the word 'cooled'. NZFGC supports this inclusion, provided other similar terms could be used to indicate that boiling water should not be used directly (e.g. lukewarm). Other important aspects for a particular formula that might be considered and for which flexibility is important to include, but are not limited to, the impact of water temperature on specific, heat sensitive ingredients (e.g. probiotics) and the solubility of the powder.

23. For left-over formula, NZFGC agrees with the proposal that unfinished formula be discarded 'within 2 hours' but flexibility to use other non-contradictory terms is needed such as 'within one hour' or 'immediately after a feed'. This flexibility ensures that the statement can be changed to be consistent with both the Australian Infant Feeding Guidelines and the New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers. It also means the statement 'discard formula left in the bottle after a feed', as used in the consumer researched statement in the potentially improved instructions, could be used.

24. NZFGC supports proposed directions not applying to ready-to drink infant formula where they are not relevant and supports the continued flexibility in words and pictures for directions of use and on infant formula products. NZFGC recommends making it clear on the face of the law that the exact wording is not prescribed. This is particularly due to some statements including words such as 'must'.

25. In relation to date-marking, NZFGC supports retaining the existing provisions of permitting the use of 'best before' and 'use-by' dates under certain circumstances and supports the FSANZ proposal to maintain existing date marking requirements for infant formula products.

26. NZFGC does not support the extension of date marking requirements for IFPSDU. As raised previously, international alignment for date marking these specialty products is important to ensure consistent, affordable supply. This includes the use of 'expiry date' or other similar words instead.

27. NZFGC supports the proposal to maintain the existing requirements for storage instructions including the specific requirement for infant formula products, to cover the period after the package is opened. NZFGC also supports the proposal to maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used, without prescribing the exact wording for this direction and to not mandate a standard scoop volume.

Warning Statements

28. NZFGC does not support updating the warning statement. There are several compelling reasons for not requiring change that are set out in the submission.

29. If the proposed additional text must be required, it would be more appropriate to include the text in the preparation instructions since, according to FSANZ's own research, consumers read these more than the warning statement.

Age to offer foods

30. In relation to the statement about age to offer foods in addition to formula, NZFGC recommends updating the existing statement to include that infants from around the age of 6 months should be offered foods in addition to infant formula products. This would align with both the New Zealand and Australian dietary guidelines for infants and toddlers. As there may be some introduction of solids in the 5th month, the inclusion of 'around' would also help provide clarity for parents who may have been advised to start solids prior to 6 months by a healthcare professional.

Protein statement

31. NZFGC does not support the proposed clarification to the source of protein statement. Further limiting the statement as proposed will, in some cases, limit the information and clarity that can be provided to consumers and health professionals.

32. There is currently no evidence of consumer confusion or issues with the status quo. Limiting useful information on protein fractions such as 'partially hydrolysed', 'hydrolysed, 'amino acids' and 'a2', risks removing information that is relevant and important for both consumers and healthcare professionals.

Cost and Transition

33. NZFGC notes that the cost to change each product's label includes the cost for the development of a new label and the cost to dispose of the left-over quantities of the former version of the packaging, which is not negligible, in particular when the number of obsolete packaging units is important.

34. To ensure labels are updated as much as possible as part of normal business, NZFGC supports the proposal for a transition period of 5-years from manufacture date which also allows for stock in trade. This would accommodate composition and additive changes that may be required in addition to labelling changes.

35. If the label updates required due to changes to Standard 2.9.1 were part of other voluntary label changes to infant formula products, no extra cost would be incurred.

IFPSDU

36. NZFGC does not support prescribed warning statements and preparation instructions for IFPSDU. To do so unnecessarily constrains compliance of a category of products where the majority are imported in small, specialist quantities for use under medical supervision. Supply of IFPSDU is especially critical for these vulnerable populations. NZFGC does support regulating the intent for IFSPSDU. The approach of regulating intent rather than prescribed wording is consistent with the WHO Code, Codex Standard and EU Regulations.

Implementation

37. In terms of implementation, NZFGC strongly recommends avoiding misalignment between infant formula and follow-on formula requirements. Rather than raising a separate proposal which may experience the delays we have seen with P1028, we suggest consideration of either a consequential amendment or an amendment to the scope of proposal P1028 to accommodate consequential change to ensure timely alignment. The latter would not

preclude raising a proposal for follow-on formula in due course to consider the implications for the Food Standards Code of the current Codex review of the Codex follow-up formula standard.