21 March 2025

NSW Submission

Proposal P1064 – Australian only Infant Formula Product Standard

Minor Procedure – 1st Call for Submissions

Summary

NSW Food Authority appreciates the opportunity to comment on Proposal P1064 (P1064) – Australian only Infant Formula Product Standard the 1st Call for Submissions (CFS). The submission does not represent a NSW Government position, which will be a matter for the NSW Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

NSW Food Authority notes the New Zealand Government formally notified the Food Ministers' Meeting (FMM) in August 2024 that New Zealand would opt out of '*the amended infant formula product standard developed under Proposal P1028*'[1]. While the 5-year transition period is currently in force for Proposal P1028 – Infant Formula[2], it is understood that New Zealand will apply the infant formula standard as it was the day before the gazettal of Proposal P 1028. This will create separate and different infant formula product regulations between the two countries as the transition period continues. More significant divergence is expected 3 years from gazettal of Proposal P1028 amendments (estimate September 2027). NSW Food Authority understands the purpose of Proposal P1064 is to clarify parts of the Code that New Zealand has opted out of, by inserting a Note stating 'Applies in Australia only' in relevant parts of the Code.

NSW Food Authority supports the intent of P1064, however, is concerned that effects of the operation of Schedules in the Code are not clearly expressed in the proposed Code amendments put forward in P1064. This creates ambiguity in the application of specific content in the Schedules decided after the gazettal of Proposal P1028 (September 2024).

Code amendments through Proposal P1028 range across multiple Standards and Schedules. FSANZ's proposal to clarify that only Standard 2.9.1 would apply to Australia only leaves ambiguity if the Proposal P1028 amendments to other standards and schedules apply to New Zealand. These issues are explained in detail below.

NSW Food Authority requests clarity from FSANZ in the Approval report to resolve the ambiguity and potential undesirable consequences as described above through P1064.

[1] https://www.foodregulation.gov.au/resources/publications/new-zealand-notice-opt-out-proposal-p1028-infant-formula-standard

[2] https://www.foodstandards.gov.au/food-standards-code/proposals/P1028

P1028 amended multiple Standards and Schedules

Proposal P1028 resulted in amendments to eight standards and five schedules in the Code. In P1064, FSANZ is only proposing to provide clarification (through insertion of a note) about application of Standard 2.9.1. P1064 is silent about the other seven standards and five schedules (i.e. Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3 and 2.9.5 and Schedules 8, 15, 19, 25 and 29) amended through Proposal P1028. NSW Food Authority requests clarity from FSANZ as to whether these amendments through Proposal P1028 should apply to New Zealand.

A note stating 'Applies in Australia only' in the relevant parts of the seven standards and five schedules would allow readers to interpret parts of the Code that could continue to apply to New Zealand compared to amendments to the Code made after the gazettal of Proposal P1028. An example is Application A1307, this application proposed to add a new nutritive substance to infant formula products. Nowhere in the proposed amendments for Application A1307 does it inform that the amendments would apply in Australia only.

Inconsistency between Australia and New Zealand

Only clarifying that Standard 2.9.1 would apply in Australia only may cause confusion in the applicability (or not) of other standards and schedules associated with Proposal P1028 amendments that may/may not apply in New Zealand.

For example, labelling requirements updated through Proposal P1028 (e.g. section 2.9.1—28 prohibited representations) would not apply, whereas updated food additive permissions (Standard 1.3.1 and Schedule 8 and 15) and novel food permissions (Standard 1.5.1 and Schedule 25) to add to infant formula products could apply in New Zealand (as there is no specific notes on these Schedules indicating non-applicability of certain content within these Schedules in New Zealand). This is inconsistent with the arrangement during the P1028 transition period in Australia, that is, until 13 September 2029, infant formula products need to comply with either all the current (post-P1028) Code requirements or all the Code requirements that had been in force immediately prior to the P1028 gazettal (pre-P1028). This gap may result in the need to review how product manufactured in New Zealand complies (or not) with Australian food standards. The only way to address the gap would be making all the P1028 Code amendments (i.e. to eight standards and five schedules) not applicable to New Zealand. This would ensure that infant formula products sold in New Zealand would comply with all the pre-P1028 Code requirements, that would also be compliant in Australia until 13 September 2029.

NSW notes FSANZ commentary concerning other Standards in the Code where New Zealand has opted out (e.g. Standard 1.4.2. and Standard 1.6.2) however suggests that Standard 2.9.1 operates differently to these two standards as Standard 2.9.1 has numerous other Code interdependencies (novel foods, nutritive substances) that the other 2 mentioned standards do not.

Ambiguity in applying post-P1028 standards and schedules without Standard 2.9.1

NSW Food Authority seeks clarity from FSANZ on the following standard/schedule-specific issues:

Schedule 29

- Given that all provisions in Schedule 29 relevant to infant formula products have reference to Standard 2.9.1, clarity is sought if the current (post-P1028) Schedule 29 applies to New Zealand, even though post-Proposal P1028 Standard 2.9.1 itself does not apply (as proposed in P1064).
- If FSANZ's understanding '*Standard 2.9.1 as it was in force immediately prior to the gazettal of the variations made by Proposal P1028 remains in force in New Zealand as a part of New Zealand law*' stated in CFS page 6 is correct, clarity is sought what is applicable to New Zealand as the Schedule 29 referenced in pre-Proposal P1028 Standard 2.9.1.

Standard 1.1.2

- For the update of key definitions such as 'infant formula product', 'infant formula' and 'follow-on formula', clarity is sought if the updated definitions apply to New Zealand as these terms are used throughout the Code.
- For the addition of the new definition of special medical purpose product for infants (SMPPi), clarity is sought if the SMPPi definition applies to New Zealand. If the FSANZ's understanding that '*Standard 2.9.1 as it was in force immediately prior to the gazettal of the variations made by Proposal P1028 remains in force in New Zealand as a part of New Zealand law*' (CFS page 6) is correct, the SMPPi subcategory does not exist in New Zealand.

Standard 1.2.3

- P1028 amendment in paragraph 1.2.3—6(4)(b) replaced the specific listings of infant formula products for special dietary use with the term SMPPi. Assuming there is no SMPPi and infant formula products for special dietary use (IFPSDU) remains current in New Zealand, the P1028 amendment in paragraph 1.2.3—6(4)(b) may cease to take effect on IFPSDU in New Zealand. Clarity is sought if it is the intent.

Standard 1.5.1

- For the update of the definition of 'novel food' in subsection 1.5.1—2(2) (note the same update in section 1.1.2—8 as well), clarity is sought that use of a food as a SMPPi does not constitute a history of human consumption in Australia or New Zealand. This makes it clear that use of an unapproved novel food in SMPPi (as explicitly permitted in the post-Proposal P1028 section 2.9.1—35) does not negate pre-market safety assessment should a manufacturer consider adding the same food to standard infant formula products.
- Clarity is sought if the general prohibition to add novel food to infant formula products unless explicitly permitted (section 1.5.1—3) applies to New Zealand based on the current (i.e. post-Proposal P1028) infant formula product definition in Standard 1.1.2.

Schedule 15

- Clarity is sought if the updated food additive permissions apply to New Zealand based on the current (i.e. post-Proposal P1028) definitions in Standard 1.1.2, despite the absence of the SMPPi subcategory in New Zealand.

Schedule 19

- Clarity is sought if the new entry of aluminium and the amended maximum level for lead applies to New Zealand based on the current (i.e. post-Proposal P1028) definitions in Standard 1.1.2, despite the absence of the SMPPi subcategory in New Zealand.

Schedule 25

- Clarity is sought if the post-Proposal P1028 conditions of use for Dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695), Oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA) and Oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA) apply to New Zealand, as the conditions state 'in accordance with Standard 2.9.1'. If they apply to New Zealand, further clarification is sought as to which version of Standard 2.9.1 applies in New Zealand.
- Clarity is sought if the added conditions of use for Trehalose applies to New Zealand based on the current (i.e. post-Proposal P1028) infant formula product definition in Standard 1.1.2.

Post-P1028 Code amendments

NSW Food Authority anticipates further amendments in the infant formula product regulation after the gazettal of Proposal P1028. NSW Food Authority raises the following issues as implications of New Zealand's opt-out to future amendments in the Code:

Applications for adding new substances to infant formula products

Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products[3] and Application A1308 – 2′-FL from GM *Escherichia coli* W in infant formula products[4] are currently on the FSANZ workplan[5]. Both applications if approved by the FSANZ Board and gazetted into the Code will affect the operation of Standard 2.9.1 of the Code.

FSANZ states in the CFS documents for both A1307 and A1308 that the permission for addition of the 2′-FL (A1308)/ MFGM-WPC (A1307), '*if approved, would apply in Australia only as per the Code as*

[3] https://www.foodstandards.gov.au/food-standards-code/applications/a1307-milk-fat-globule-membrane-nutritive-substance-infant-formula

[4] https://www.foodstandards.gov.au/food-standards-code/applications/a1308-2-fl-gm-escherichia-coli-w-infant-formula-products

[5] https://www.foodstandards.gov.au/sites/default/files/2025-01/Work%20Plan%20Jan%202025.pdf

currently in force' (A1307 CFS document[6] pages 2 and 4, and A1308 CFS document[7] pages 3). However, the proposed Code amendments to the relevant schedules (i.e. Schedule 3, 26 and 29) do not include clarification that the provisions would apply in Australia only. NSW Food Authority requests clarity from FSANZ as to if FSANZ intends to insert a Note stating 'Applies in Australia only' in the new listings in the relevant schedules as part of A1307 and A1308 so their application does not rely on referring to CFS and approval reports associated with various applications.

Proposal P1055 is proposing to transfer HiMO permissions to Schedule 29

Proposal P1055 – Definitions for gene technology and new breeding techniques[8] the 2nd CFS is proposing to transfer existing permissions for human identical milk oligosaccharides (HiMOs) from Schedule 26 to Schedule 29 due to FSANZ's proposed approach to regulate them as not GM food but as permitted nutritive substances used in infant formula products.

It is clear that Schedule 26 applies to New Zealand as no provisions in Schedule 26 were amended through Proposal P1028. Although P1064 is not proposing to insert the Note stating 'Applies in Australia only' to Schedule 29, provisions relevant to infant formula products in Schedule 29 have reference to Standard 2.9.1 which, P1064 is proposing, would not apply to New Zealand. Therefore ambiguity would arise if the existing HiMO permissions may cease with effect in New Zealand, if the proposed transfer in P1055 takes place. Clarity is required in the Code to address this ambiguity and to prevent unintended consequences.

Ends

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

Dated as 21 March 2025

[6] https://www.foodstandards.gov.au/sites/default/files/2024-12/A1307%20CFS%20%284%29.pdf

[7] https://www.foodstandards.gov.au/sites/default/files/2024-11/A1308%20CFS.pdf

[8] https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques