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Introduction

DGC is very pleased to see progress on P1028 with the release of this consultation paper and advice that this is to be followed soon by two more. The length of time that has elapsed since the start of P1028 has perpetuated issues relating to non-alignment with aspects of the Codex infant formula standard and resulted in decreased harmonization with requirements for infant formula products in export markets. We hope progress can be more rapid from here on.

We appreciate the opportunity provided by this Consultation Paper to make comments on the safety and technology related proposals put forward. DGC is an associate member of the Infant Nutrition Council (INC) and has participated in the preparation of the INC submission to this consultation paper. Consequently this submission focuses on the issues of key importance and relevance to DGC. In the interest of future efficiency and cost effectiveness, for industry and regulators alike, we seek for requirements in standard 2.9.1 and associated schedule(s) post-revision to be clear and free from unnecessary and unwarranted requirements.

Key issues of concern

Proposed change to carry-over provisions for food additives in infant formula

This is our key area of concern and we strongly recommend that further consideration is given to this topic.

It is proposed to apply carry-over provisions for infant formula that vary from the general carry-over provisions in Standard 1.3.1-3 (2) to follow the approach applied by EU and Codex of prohibiting the carry-over of food additives into infant formula unless explicit food additive permissions exist for use of such food additives in infant formula and IFPSDU. We support the general principle of minimization of food additives in infant formula but the changes proposed to the carry-over provisions are not supported because:

- Alignment with Codex carry-over provisions for infant formula is not achieved.
- Similarly, alignment with EU carry-over provisions is not achieved (the carryover provisions applied to infant formula by EU and Codex are not the same even though they both follow the same high-level approach).
- Differing interpretations about the primary function of additives carried over will result in significant challenges to determine compliance; and subsequently to verify compliance to the satisfaction of auditors and regulators.

The key issue identified is an undue emphasis on function. Under the Food Standards Code the primary function performed by an additive determines whether it is considered to be used as a processing aid, as a food additive or as a nutritive substance. This, in turn, determines eligibility for carry-over. From a safety perspective it is the amount of 'additive' present that is relevant not its function (nutrient, food additive or processing aid). Regulation of additive carry-over should be straight forward and not complicated by undue emphasis on function(s) performed.

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A key contributing factor to complexity for proposed changes arises because of the differentiation in the Food Standards Code between processing aids and food additives. By contrast Codex takes the approach that use as a processing aid is one justification for use of a food additive (STAN 192-1995 3.2). This differentiation between processing aids and food additives within the Food Standards Code causes challenges as is without exacerbating this further by introducing the carry-over changes proposed for infant formula.

It is our understanding from CP1 that food additives that can be used at GMP, as listed in schedule 16-2, will not be permitted as food additives for use in infant formula except if explicitly permitted for infant formula products in S15. For example, calcium citrate is permitted for use at GMP within schedule 16-2 but not specifically permitted as a food additive in infant formula in Schedule 15. It is being proposed within the consultation paper for calcium citrate to be explicitly permitted for use in IFPSDU at GMP. Under the proposed carry over provisions for infant formula calcium citrate will not be permitted for use as a food additive in infant formula other than IFPSDU and therefore will not be able to be carried over from raw materials used in these products where it is used as a food additive. This seems nonsensical given that calcium citrate may be used as a calcium source in infant formula (refer to S29-7).

Table 1: Compounds specifically listed in Section D of CAC/GL 10-1979 entitled Advisory List of Food Additives for Special Nutrient Forms

INS n.°	Additive/carrier	Maximum level in Ready-to use Food for Infants and Young children (mg/kg)	
414	Gum Arabic (gum acacia)	10	*All are listed in Schedule 16-2 of the FSC. None are listed in Schedule 15 or schedule 18.*
551	Silicon dioxide	10	
421	Mannitol (for vitamin B_{12} dry rubbing, 0.1% only)	10	
1450	Starch sodium octenyl succinate	100	
301	Sodium-L-ascorbate (in coating nutrient preparations containing polyunsaturated fatty acids)	75	

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Further, based on the comments within the consultation paper on the five additives specifically listed in Section D of CAC/GL 10-1979 (entitled Advisory List of Food Additives for Special Nutrient Forms), it appears that the 'additives' listed in S16-2 may continue to be used as processing aids in infant formula. As such they will not be subject to the carry over provisions proposed. In the consultation paper the additives specifically listed in Section D of CAC/GL 10-1979 are referred to as 'nutrient carriers' which are considered to be 'used as processing aids.' On this basis it is concluded that their use in nutrient preparations used in infant formula will be accommodated without change to the Food Standards Code if the proposed carry over provisions for infant formula are instigated. Refer to table 1 above.

From our perspective neither of the interpretations that these additives are 'nutrient carriers' and that they are 'used as processing aids' can be relied upon on the face of the law. For example, silicon dioxide is most commonly considered to be used as an anti-caking food additive and sodium-L-ascorbate is very commonly considered to be used as an anti-oxidant food additive. If a powdered form of long chain polyunsaturated fatty acids (LCPUFAs) containing sodium-L-ascorbate is dry-blended into an infant formula end product, many formulators, auditors and regulators would conclude that the sodium-L-ascorbate in the LCPUFA preparation is used as an antioxidant and arguably continues to perform this function in the end product. With this interpretation it would not be permitted under the proposed carry-over provisions for infant formula.

Other key points to note:

1. Codex permits the carry-over of food additives listed in this Section or in the *Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children* (CAC/GL 10-1979). This makes sense as the mineral salts and vitamins listed are permitted for use in infant formula and, with respect to the safety of the end products it is irrelevant if these are added to the raw material concerned for a technological or nutritive function. This has not been identified in the proposal put forward in the consultation paper.
2. Section D of CAC/GL 10-1979 has two parts. Under this provision:
    a. For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used.
    b. *In addition*, the food additives as listed in Table 1 may be used as "nutrient carriers":

    Again, the first of these provisions has not been identified int the proposal put forward in the consultation paper.
3. EU permits a wider range of additives in nutrient preparations used in infant formula than those permitted by Codex as per Table 1[1]. To achieve alignment with the EU broader carry

[1] EC Regulation 1333/2008 of the European Parliament and of the Council on Food additives, Annex III, Part 5, section B.

over provisions are needed for infant formula than those being proposed in the consultation paper.

Proposed solutions:

Preferred solution: Retain the current general carry-over provisions. As far as we are aware there has been no market failure associated with the current carry-over provisions. Retaining the status quo avoids the over complication of requirements inherent in the proposal to amend the carryover provisions for infant formula.

Alternatively, if proposed changes to carry-over provisions for infant formula continue are to be pursued, the carry-over provision added to 2.9.1 for infant formula products should make it clear that this provision:

a. Relates to food additives only and not processing aids
b. Further to a., permits additives at GMP listed in Schedule 16-2 to be carried over irrespective of whether they are used as a processing aid or a food additive. *This approach will significantly reduce misalignment with EU permissions as well as overcoming the issues identified above in practically achieving alignment with Codex carry over provisions for infant formula.*
c. Permits carry-over of permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes listed in Schedule 29-7 into infant formula products, providing the infant formula end products comply with the specified maximums for nutrients concerned.
d. Permits carry-over of food additives necessary in nutrient preparations used in infant *formula i.e. a provision that replicates the following overarching provision in section D of CAC/GL 10-1979:*

   "For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations, e.g. gum arabic coated products, dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used."

   This approach would help to provide some future proofing.

We reiterate that from a food safety perspective, it is the amount of 'added substance' carried over that is relevant not its function (nutrient, food additive or processing aid). Regulation of carry-over therefore should be straightforward so compliance can be easily ascertained. Overly complicating the requirements results in poor regulation which in turn results in increased time (and therefore cost) needing to be spent on determining compliance without delivering any food safety benefit.

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MPLs for food additives

A number of the food additive permissions proposed for infant formula contribute essential nutrients. For a number of these, for example calcium hydroxide, MPLs are proposed which are above the maximum levels specified for the nutrients concerned within the compositional requirements. We strongly recommend that the use of these additives is permitted providing the compositional maximum levels for the nutrients concerned are not exceeded. It is the level of the substance present that determines safe use not whether it is added as a nutrient or food additive.

MPLs specified for food additives that provide essential nutrients above compositional maximum levels are redundant given the levels of use are already constrained below the MPLs specified. Inclusion of such redundant requirements adds prescription for no benefit and results in resources being wasted on unnecessary additional compliance checks.

Responses to questions for submitters

Questions for submitters
Questions about food additives and contaminants (Section 2, Section 3)
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. Option #1 is preferred: Do not establish an ML. As described in the paper, if the available data demonstrates intake is unlikely to pose a concern to the population there is no need to establish a limit, as described in the paper. 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 N/A to DGC as does not currently manufacture IFPSDU.

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Questions for submitters
For health professionals, please provide information to the following questions: 3. In addition to the above list, what new evidence (if any) do you have for the potential health impacts for infants of changing any of the current permissions for any other food additives, discussed in this paper? 4. In addition to the list above, can you provide any further examples of lack of alignment with EU regulations delaying important formula from reaching vulnerable infants? 5. To what extent would proposed changes to current permissions and limits for Special formula address any perceived delays to vulnerable infants accessing the imported formula that they need? Please provide evidence where possible. Questions 3-5 are for health professional so N/A to DGC. For industry, please provide information to the following questions: 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? Please refer to comments provided under key issues identified above. The change to carry-over provisions for infant formula, as proposed, will create significant challenges to firstly determine formula compliance and subsequently to verify compliance to the satisfaction of auditors and regulators. The change proposed needs further consideration due to the complexity added for compliance and gaps with regard to alignment sought with Codex/EU. If implemented some nutrient preparations currently used in infant formula manufacture may no longer be permitted, in some cases due to function(s) performed by additives rather than presence per se. Further, if implemented as proposed, Australia and New Zealand could prove to be less desirable as countries to manufacture infant formula products for companies that have flexibility to produce their products in other countries. Some of the food additives permissions proposed include MPLs that are effectively redundant. In the interest of efficiency and minimum prescription these MPLs should not be included in the Food Standards Code. 7. What (if any) implications might overcoming any practical barriers have for production costs per product line? Please quantify where possible. Production costs for product lines will be impacted if any currently used raw materials are no longer able to be used. More certainty is needed about changes that will be implemented before cost implications can be considered. 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? The cost impact to businesses will not be governed by business size. The impact will be more influenced by the number of product formulations impacted by the proposed changes and the

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Questions for submitters
cost of steps needed in order to comply with amended requirements. 9. Are any food additive preparations (food category 0 in Schedule 15) used in infant formula products? If so, how? We are aware that some additives in S15-5 (0) are used in specialised raw materials used in infant formula production, including ascorbyl palmitate (304) and tocopherols (307, 307b, 308 and 309). It is difficult to ascertain if these are used in food additive preparations or added directly during production. Only the producers of these raw materials would be privy to this information. The following questions are targeted mainly to industry and relate to carry over provisions (Section 2.3) 10. What would be the practical steps involved in ensuring compliance of your products with the carry over provisions proposed in this paper? The first step will be to determine if any food additives currently carried over into infant formula products manufactured are no longer permitted by the Food Standards Code. Being an exporting company we currently aim to meet FSANZ carry-over provisions, Codex infant formula carry-over provisions and where applicable EU infant formula carry over provisions. If the proposed carry over provisions are implemented for infant formula are implemented within the Food Standards Code we hope these are sufficiently aligned with Codex and EU carry over provisions for infant formula that there will be no raw materials currently used that will no longer be permitted. The proposed changes to carry over provisions need to reconsidered and scraped or significantly modified to achieve this. In the event that currently used raw materials are no longer permissible then we will need to: a. Research if alternative ingredients are available which will comply with new food additive carry-over provisions b. Source and evaluate samples of potential alternative materials for suitability c. Reformulate product using alternative raw material(s) d. Make trial batch(es) e. Undertake storage trials to assess impact on storage stability. It may be necessary to evaluate multiple alternatives to achieve acceptable product characteristics and shelf-life. 11. Do you have any more information on how much ensuring compliance would cost per effected product? Refer to response to Question 10. The cost could be very significant. 12. Would different sized businesses be generally equally impacted from our proposed changes to the carry-over principle? No. The impact for each business depend on the number of their product formulations impacted by the proposed changes and the cost of steps needed in order to comply with amended requirements.
Questions about L(+) lactic acid producing microorganisms (Section 4)

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Questions for submitters
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? We do not consider it necessary to amend the current voluntary permission for addition of L(+) lactic acid producing microorganisms due to the Food Standards Code overarching requirement for food to be safe and suitable. The Codex Infant Formula Standard refers to L(+) lactic acid producing cultures without further qualification. However, we can accept the proposed insertion of the term 'non-pathogenic' as proposed if this is preferred by most stakeholders.
Questions about labelling (Section 5)
14. Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach? We are supportive most of the changes proposed. The exceptions are that we do not support: • Retaining the existing labelling statement indicating that infant from the age of 6 months should be offered food in addition to infant formula (2.9.1—19(4)(c). We recommend "around," is added so it reads: "…from around the age of 6 months should be offered food in addition to infant formula." The insertion of 'around' provides alignment to both the New Zealand[2] and Australian dietary guidelines for infants and toddlers[3]. • We do not support the proposed clarification regarding source of protein to limit the information included to animal milk or plant source of protein only. In this context we support inclusion of information on the protein source which assists health professionals and consumers to have a better understanding of the protein content. • We also do not support adding the additional text, "or add anything to this formula,' to the warning statement. As per the INC submission we recommend that if this extra text concerned is to be added to the label this would be better incorporated into the mixing instructions. 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? No. 16. How often do you change labels on your products voluntarily for marketing or other purposes? Typically every 3-4 years.

[2] New Zealand Ministry of Health (2021). *Draft Dietary Guidelines for Babies and Toddlers*. 2021

[3] NHMRC (National Health and Medical Research Council) (2013). *Infant Feeding Guidelines: Summary*. 2013. Canberra: National Health and Medical Research Council

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Questions for submitters
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)? There would be negligible additional cost incurred. 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 cost of amending each packaging artwork would probably be relatively minor but artwork changes incur multiple other costs including set-up of new packaging specification and new packaging component within manufacturing systems plus write-offs of stocks of existing packaging. The costs involved can be very significant especially if changes are need to artworks for multiple products. 19. Apart from any costs, would there be any other practical challenges of changing your products' labels as proposed? If change to the warning statement proposed is implemented this could lead to issues relating to fitting it on some labels due to the minimum font size required for this statement.
General question related to the Consultation paper
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. As already covered in our comments above the proposed changes to the carry over provisions for infant formula will result in overly complicated regulation. If these are implemented without complex 'fixes' it is very likely that some raw materials used currently in infant formula manufacture here and overseas will no longer be permitted for use in ANZ. Overly complicated regulations that introduce such barriers are a disincentive for infant formula production in ANZ. Consideration needs to be given to how changes such as those proposed for food additives and labelling requirements will be implemented given the relevant sections of 2.9.1 apply to follow-on as well as infant formula. Misalignment between infant formula and follow-on formula requirements would be best avoided if at all possible. We also recommend that consideration is given to transition arrangements. These will need to take into account the range of changes that will be implemented as a result of the revised standard and the number of products impacted. They are likely to include composition and/or additive changes in addition to the labelling changes proposed.