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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for submissions – Application A1253 Bovine lactoferrin in infant formula products.*

Yours sincerely

Raewyn Bleakley
Chief Executive

Call for Submissions – Application A1253 Bovine lactoferrin in infant formula products

Submission by the New Zealand Food & Grocery Council

10 November 2022

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("**NZFGC**") welcomes the opportunity to comment on the *Call for submissions – Application A1253 Bovine lactoferrin in infant formula products* ("**CFS**").

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.

OVERARCHING COMMENTS

3. NZFGC strongly supports the voluntary addition of bovine lactoferrin ("**bLF**") to infant formula products up to a maximum of 40mg/100kJ (equivalent to around 1109mg/L). This is entirely consistent with the maximum levels for the addition of bLF infant formula products in the legislation of EU, China and Singapore. NZFGC therefore strongly supports the maximum level proposed of 40mg/100kJ of bLF added to infant formula products.

4. Whilst bLF contributes important and beneficial properties (anti-viral and anti-bacterial) to the consuming infant, the rationale for its classification as a nutritive substance is unclear and open to interpretation. We are also very concerned about its categorisation as a nutritive substance for infant formula and its use as an ingredient in products in the general food supply.

5. To address this lack of clarity, and in the absence of progress with *Proposal P1024 Novel foods and nutritive substances,* NZFGC supports the recommendation made by the Infant Nutrition Council ("**INC**") that, following conclusion of this Application, FSANZ convenes a workshop of stakeholders to discuss the future application/use of the term 'nutritive substance' across the general food supply and considers the prospect of guidance around its use going forward. This would ensure that the issues presented to the infant formula industry and jurisdictions in recent months are also discussed transparently with stakeholders from the wider industry and other stakeholders in public health.

6. In relation to the proposed specification in the Standard (the "**proposed specification"**), NZFGC considers it is overly detailed and not risk-based or proportionate. It imposes a regulatory burden where the risk is not clear (especially for the extent of parameters) and is therefore not fit-for-purpose nor supportive of a balanced regulatory setting insofar as it is specific to a single manufacturer's specification.

7. The principle for regulatory best practice is that a regulatory standard should present minimum effective regulation. In NZFGC's view, FSANZ has not applied this principle insofar as the proposed specification, especially for the burden of contaminants, will be the tightest regulatory standard for bLF in the world.

8. To address this, NZFGC recommends that where there is no EU or China specification for a parameter, the proposed specification for the Food Standards Code should not present a parameter and where parameters are in place in the EU and/or China then the stricter of these should be preferred. In this way, the regulatory standard for the specification will truly accommodate other brands of bLF. This would avoid the need for multiple applications requiring many hundreds of hours work by subsequent applicants, FSANZ and

jurisdictions. In this way also, all stakeholders would be leveraging the learnings from the costly EU experience which ultimately delivered a broad regulatory standard for all manufacturers.

9. Finally, NZFGC is supportive of the concept of exclusive capturable commercial benefit and fully recognises the value that this must deliver on investment for the food industry and for innovation. We are concerned, however, at the way in which the concept appears to be implemented and suggest a more consistent approach be applied to ensure visibility for the broader food industry.

DETAILED COMMENTS

Support for voluntary addition of bLF to infant formula products

10. NZFGC strongly supports the voluntary addition of bLF to infant formula products up to a maximum of 40mg/100kJ (equivalent to around 1109mg/L). bLF is widely used globally and has a long history of safe use in infant formula internationally. It is significant that infants in many other countries and regions already benefit from the voluntary addition, and we note that first infant formula product containing bLF was released in Japan in 1986[1].

Maximum level of addition of bLF in infant formula products

11. Lactoferrin is a protein found in human breast milk at a concentration of 1230-3390 mg/L as reported in the CFS[2]. In mammalian milks (cow, goat and sheep), the concentrations as reported in the CFS are much lower at 80-177 mg/L (cows' milk) and 17-166 mg/L (goat and sheep milk). NZFGC notes that, as with human milk, the bLf concentrations in mammalian milk can vary depending on the animal and stage of lactation but a typical concentration value of 100 mg/L covers all. We note the content of bLf in made-up infant formula under the current Standard (unfortified with lactoferrin) would be only 10-27 mg/L.

12. The level proposed is at the lower end of the concentration in mature human breast milk but is a level consistent with the maximum levels for infant formula products in the legislation of the EU, China and Singapore. Taking these factors into account, NZFGC strongly supports the maximum level proposed of 40mg/100kJ of bLF added to infant formula products.

bLF as a 'nutritive substance'

13. NZFGC notes that bLF for voluntary addition to infant formula products has been proposed as a nutritive substance. bLF provides benefit to infants because of its anti-viral and anti-bacterial properties, as demonstrated in numerous research studies cited in the CFS. This is therefore significant for its voluntary addition to infant formula products so that those infants who are not breastfed and using fortified infant formula, can benefit from these properties that are otherwise only available to breast fed infants.

14. In the general food supply, bLF is treated as an ingredient so we now have the confusion of use as a nutritive substance in infant formula and use in the general food supply as an ingredient. The confusion this raises in terms of when is a substance an ingredient versus a nutritive substance is concerning. To address this, NZFGC supports reactivation of Proposal P1024 to provide industry and stakeholders regulatory clarity of the use of the nutritive substance categorisation. In the absence of the completion of that proposal, NZFGC supports the recommendation by INC that FSANZ convenes a workshop of

[1] Section 3.1.4 Post market surveillance, SD1

[2] Rai D, Adelman AS, Zhuang W, Rai GP, Boettcher J, Lönnerdal B. (2014). Longitudinal changes in lactoferrin concentrations in human milk: a global systematic review. Critical Reviews in Food Science and Nutrition, 54(12), 1539-1547. doi:10.1080/10408398.2011.642422

stakeholders to discuss the future application/use of the term 'nutritive substance'. The outcomes of such a workshop could contribute to production of guidance around its use going forward, as an interim measure until Proposal P1024 is reactivated and concluded. This would ensure the issues evident primarily to the infant formula industry are presented to the wider food industries in a more transparent way.

Specification

15. We note the EU first issued an opinion on bLF for one company ten years ago (2012) and subsequently (until in 2018) several other companies were granted 'substantial equivalence' for the bLF products they manufactured on application. In 2018, this mechanism was replaced by an updated regulation[3] allowing any bLf that met the EU specification for bLf as listed in the EU list of authorised novel foods[4] to be used within the EU. This last development was a sensible approach but came after many other costly applications for equivalence. Even so the more encompassing standard eventually put in place saved many more hundreds of hours work by subsequent applicants, stakeholders and EU governments.

16. The CFS and the applicant both state that the industry will be able to use the permission in due course. The CFS states that "the permission would apply to all brands of bLf in accordance with the Code"[5] (NZFGC emphasis). This is not quite true. Some elements of the applicant's manufacturing specification have been taken for inclusion in a regulatory standard and, while explaining why some are not taken up (eg microbiological elements), it is not clear why others have been taken up when neither of the two international standards contain the parameters and no risk assessment of the need for, or level of, the parameters for bLF has been undertaken. The result is a significant limitation on the broader use of the regulatory standard for other brands of bLF that do not meet the proposed specification in the future, irrespective of any other conditions on access. Many in the industry will NOT be able to use the permission in due course.

17. In short, the proposed specification is very detailed and not risk-based or proportionate. It imposes a regulatory burden where the risk is not clear (especially for the extent of parameters). NZFGC therefore recommends that:

    a) where there is no EU or China specification for a parameter, the proposed standard for the Australia New Zealand Food Standards Code should not present a parameter. This would omit parameters for fat, solubility, cadmium, mercury, aflatoxin, melamine, aluminium, nitrate and nitrite.
    b) Where parameters are in place in the EU or China then these limits should be preferred.
    c) Where parameters are in place in the EU and China, then the more stringent should be preferred.
    d) Specifically, we recommend that the Iron content is amended to < 35 mg/100g to align with EU and China regulatory limits.

18. The principle for regulatory best practice is that a regulatory standard should present minimum effective regulation. In NZFGC's view, FSANZ has not applied this principle, insofar as the proposed specification , especially for the burden of contaminants, will be the tightest regulatory standard for bLF in the world. The recommendation in paragraph 17 above would present the minimum effective regulation.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2470&from=EN
[5] CFS, section 2.2.10, 5th paragraph

19. The proposed specification will actually prevent, in perpetuity, the use of the standard by many other companies. We do not believe this serves the industry, consumers or governments well since any other manufacturer will, as was the case in the EU between 2012 and 2018, need to go through the resource-intensive process of submitting an application in order to seek a variation to the regulatory standard. This would appear to be an inefficient and laborious approach creating unnecessary technical barriers to market entry.

20. The NZFGC was not able to discern what principles FSANZ had applied to make its decisions about inclusion or exclusion of parameters eg there are many parameters in the proposed specification that do not appear in the EU or China regulations. We noted that some references to "greater than" or "greater than or equal to" appear random insofar as they are not based on other specifications or the Application. The differences between "greater than" and "greater than or equal to" are important. We note there may be an error in relation to iron whereby the CFS refers to 15g/100g and SD1 refers to 15mg/100g.

21. Applying the principle of regulatory best practice described above, NZFGC recommends the proposed specification is amended in line with the foregoing. Without doing so will raise high trade impacts of such a detailed specification.

22. The proposed specification does not meet expectations of regulatory best practice set by FSANZ itself. It is not fit-for-purpose nor supportive of a balanced regulatory setting nor reductive of compliance costs insofar as it favours a single manufacturer's specification which may not be met by other manufacturers. NZFGC recommends a broader specification for the standard that will truly accommodate other manufacturers of bLF in the future, in alignment with the EU and China approach. In this way we would be leveraging the learnings from the costly EU experience and saving similar costs across the board in this region.

Exclusivity

23. NZFGC is not commenting on the specifics of the exclusivity proposed either by the applicant or in the CFS.

24. NZFGC is supportive of the concept of exclusivity and recognises the clear benefits it delivers to innovation and research and development and advocates the continuation of the facility. However, when exclusivity emerged as a concept in 2007 in the final assessment report on *Proposal P305 Permission for exclusivity of use of novel foods*[6], it was for data protection and to remove the potential for competitors to take advantage of FSANZ's transparent processes upon gazettal of an amended standard:

    "*That is, a competitor is able to access the information relevant to the application and undertake product development to coincide with the gazettal of an approved novel food, thus removing the benefit for the applicant*."

25. NZFGC is supportive of the concept of exclusive capturable commercial benefit and fully recognises the value that this must deliver on investment for the food industry and for innovation. We are concerned, however, at the ad hoc way in which the concept appears to be implemented and suggest a more consistent approach be applied (such as through an industry workshop on exclusivity) to ensure visibility for the broader food industry.

[6] Microsoft Word - P305 Novel Food exclusivity FAR FINAL.doc (foodstandards.gov.au)