COMMENTS

1. INC as an industry body, covering infant formula products and formulated supplementary foods for young children (otherwise commonly known as toddler milk drinks), has had some experiences relating to recent Applications to the Food Standards Code (FSC). These experiences have raised concerns about jurisdictional consistency in relation to Policy Guidelines both development and application as is noted below.

2. INC members manufacture and import high value dairy products such as infant formula products and toddler milk drinks to the domestic Australian and New Zealand market and are, additionally, also international exporters. INC members are therefore interested not only in jurisdictional consistency with the enforcement of products for domestic sale in Australia and New Zealand, but also in the effect of consistency when that impacts international trade. New Zealand members are well served by the work of the Ministry for Primary Industries (MPI) in terms of enforcement and also benefit from the Trans-Tasman Mutual Recognition Arrangement (TTMRA) which provides that a good legally able to be sold in one jurisdiction can be legally sold in another.

3. The objective of the TTMRA is to remove regulatory barriers to the movement of goods between Australia and New Zealand, and to thereby facilitate trade between the two countries. This is intended to enhance the international competitiveness of Australian and New Zealand enterprises, increase the level of transparency in trading arrangements, encourage innovation and reduce compliance costs for business.

   Question 3 – Has your business been impacted by inconsistent regulatory approaches (or inconsistent interpretation or enforcement of regulation) in any of the following areas: [pick list of labelling, novel foods, processing aids etc] [earlier questions concern submitter name etc]
   Question 4 – What was the nature of the inconsistency?
   Question 5 – What was the impact on your business?

4. Individual companies may provide input through their company submissions of inconsistent regulatory approaches in terms of enforcement of regulation. One area that INC can identify that is of concern is in relation to the notification of food health relationships that then provide permission of use of health claims on labels and advertisements. MPI offers a structured and expert service for New Zealand manufacturers in the area of claims by advising on the preparation of substantiation dossiers that meet the expectations of the level of evidence required by Standard 1.2.7 and Schedule 6 in the Food Standards Code.

5. While INC strongly supports the self-substantiated pathway for general level health claims, INC is aware that some claims examined by MPI and rejected by MPI on the basis of inadequate evidence have subsequently been notified in and used on the market in Australia. The current legislation means that only the owner of the claim can remove a claim from the notification website and this creates tensions between regulators and across regulators and industry. We understand MPI may be able to provide examples.

6. The impact of claims that should not be notified because of incomplete or poor substantiation is the market disadvantage that results from a product making an unsubstantiated claim against a competing product not making a claim. Even if investigated and the notification removed, that is a process that takes some time and the opportunity for a competing brand has, by then, been cemented with the consumer. There is also a disrepute that results for the system.

7. Should legislative amendment be considered to permit FSANZ involvement in some way in the future (the example of post notification substantiation checks on behalf of those Australian jurisdictions who requested FSANZ involved has been previously raised), industry would be very keen to discuss the matter further.

8. INC is also concerned about advice from the Advisory Committee on Novel Foods to an enquirer that might be ignored and a product advised as needing FSANZ assessment goes to market in any case. This disadvantages those who do follow the advice and either make an application to FSANZ or not proceed with inclusion of a product in the food supply.

   Question 6 – Are there any other areas of food regulation (law or practice) that are inconsistent between states and Territories or between Australia and New Zealand, that adversely impact your business?

9. The most significant area of jurisdictional inconsistency that has emerged in recent times is in the application and interpretation of Policy Guidelines by jurisdictions. This is most evident in the recent consideration of *Application A1155: 2'-FL and LNnT in infant formula and other products*. The outcome of A1155 was to deny addition of the human identical milk oligosaccharides to toddler milk drinks (substantially impacting on innovation and trade), and to place only a temporary time period for ingredient permission for infant formula products (5 years, with a request to review the evidence on beneficial effects again in the future and a proposal to potentially remove the permission if the Jurisdictions are not satisfied with the level of evidence).

10. With this application, there were two rounds of consultation and a review process that has been estimated to cost over $1m for FSANZ (and therefore taxpayer funds) alone. This is in addition to cost recovery charges for the Applicant and other substantial costs in generating data (eg clinical trials) and consolidating the application dossier. Safety assessments, independent scientific expert panels, economic impact on innovation, peer review could not sway the policy views of a number of Australian jurisdictions. This is for ingredients that have been approved by key credible international jurisdictions such as the EU, and used and sold in infant formula products and toddler milk drinks in approximately 70 countries to date.

11. The adverse impact for the industry is not only the inability to innovate and provide optimal nutrition to the child when breastfeeding is not possible, but also this would impact on economic trade to other countries where currently Australia and New Zealand are seen as progressive countries delivering nutrition in line with the latest science.

12. Cross border e-commerce (CBEC) exports, a critical sales channel for Asian growth markets, must comply with country of origin regulations. It is therefore essential that local regulations are in step with global standards.

13. Cross-border e-commerce is a critical sales channel for Australian and New Zealand exporters to China, driven by consumer demand for foreign-labelled brands. Of infant formula sold in China 26% is being sold through e-commerce channels and 7% of this through CBEC. In 2019 "Oceania labelled" products comprised almost 50% of CBEC sales, above major EU and US sources. This is an area of advantage for Australian exporters, given 5 of the top 7 exporting countries to China, across all sales channels, are from the EU[1]

14. CBEC also provides an ideal sales channel for new exporters to China and other Asian markets looking for easier and quicker routes to market. Prior to Covid, the CBEC market

[1] Euromonitor Data

(predominantly to China) with Australia/New Zealand origin products was estimated at over $1 billion AUD. The dominance of Australia/New Zealand origin products as a preferred choice is not limited only to the Chinese consumer's perception of such products being of good quality, 'clean-and green', but also an important purchase decision relates to the product's nutritional superiority. If Australia and New Zealand are unable to compete with other CBEC foreign brands on providing optimal nutrition, the INC considers the potential loss of opportunity cost will be significant and create adverse impacts to not only industry, but the reputation of Australia and New Zealand.

15. INC believes the source of the problem is at least in part with the Policy Guideline, possibly in the exclusion of industry from the Policy Guideline development process and resultant policy provisions that are ambiguous at best and unworkable at worst.

16. The Policy Guideline on Infant Formula Products, as applied and interpreted by some jurisdictions, has been shown by independent experts to be impossible to meet. This is because experts' advise that attribution of benefit to a single component in breastmilk cannot be determined to the exclusion of all other components. Even if clinical trials could be designed for this purpose by excluding a single component for one group, it would be unethical to proceed and deprive a population group of infants of an essential component in breastmilk for a theoretical attribution test. No other international jurisdiction has such a criteria that has to be met for an ingredient approval.

17. Policy Guidelines aim to improve outcomes for all by making clear and unambiguous the policy principles that apply to jurisdictions, FSANZ as the standards developer and industry for application. What we are seeing in the Infant Formula Products Guideline is a barrier to innovation, a bar that is impossible to meet and multiple interpretations of meaning.

18. Additionally, the flawed and inconsistent interpretation of the Policy guidelines relating to the Intent of Special purpose foods and therefore toddler milk drinks, have led to permission being denied for toddler milk drinks which presents an adverse outcome for the industry.

19. By excluding industry from the development process, perverse outcomes result. A more recent example of the flawed process for developing policy guidelines is in the recent publication of the *Policy Guideline on Food Labelling to Support Consumers to Make Informed Healthy Food Choices* (Food Labelling Policy Guideline). On 27 Nov 2019 stakeholders were invited to participate in a public consultation on the draft Food Labelling Policy Guideline which was being developed by the Food Regulation Standing Committee (FRSC) for the Forum on Food Regulation. The consultation period closed on 3 Feb 2020.

20. The Food Labelling Policy Guideline emerged on 6 November 2020 some 9 months later during which time there was no specific communication with submitters. In analysing the final Policy Guideline (Attachment A as amended from the consultation draft), INC noted that only 4 paragraphs out of 32 were not amended or deleted and that 14 new paragraphs out of 36 (almost 40% of the policy guideline) were entirely new. Ideally, the Food Labelling Policy Guideline should have been subject to further consultation or, more sensibly, development should have included stakeholders including industry.

21. No legislative amendment appears to be required for the policy guideline development process to be more inclusive. The *FSANZ Act 1996* simply provides that a policy guideline is, according to section 4(1) "a guideline formulated by the Forum on Food Regulation for the purposes of paragraph 18(2)(e)". How the Forum receives a draft Policy Guideline for its formulation is not legislated.

Question 7 – Are there any areas of duplication between the food regulatory system and related regulatory systems?

22. INC has not identified areas of duplication between the food regulatory system and related regulatory systems.

Question 8 – Inconsistency in food regulation is: Not an issue for my business; a minor issue for my business; a somewhat major issue for my business; a significant issue for my business.

23. In relation to Question 8, for INC members manufacturing in Australia, inconsistency in food regulation is a somewhat major issue. For members manufacturing in New Zealand inconsistency in food regulation can be a somewhat major issue particularly in relation to barriers to innovation and trade as is described in the situation stated above on Policy Guidelines. INC considers that it is important these issues are addressed.