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Request for Submissions P1024 Revision of the regulation of nutritive substances and novel foods

Thank you for the opportunity to provide feedback to FSANZ on its Proposal for the Revision of the Regulation of Nutritive Substances and Novel Foods (P1024).

1. Introduction

- 1.1. Goodman Fielder (GF) supports changes to the food regulations that serve to protect public health and safety while being objective, enforceable and proportionate with risk so that industry is not subject to an unreasonable regulatory burden. Any opportunity to further assure the safety of the food supply for Australian consumers is welcomed by our business.
- 1.2. GF has contributed to, and broadly supports, submissions made by the Australian Food and Grocery Council (AFGC) on P1024 and wishes to provide further comments and examples in relation to particular experiences that have impacted our business in the past that relate to this standard. Such further examples are provided as **Commercial in Confidence** via a separate document.
- 1.3. We have not dealt with all of the questions for submitters nor each additional item provided in the consultation package. GF is, however, committed to participating in the future consultation on the final proposal.

2. About Goodman Fielder

- 2.1. GF is a food company with a proud tradition of making and selling quality food products to Australians since 1909. While our head office is in Sydney, we also operate in New Zealand and the Asia-Pacific region.
- 2.2. In Australia, GF manufactures bakery and grocery products at its 16 factory sites, located in every State and Territory. We also operate 80 depots, again located in every state and territory across Australia. Many of GF's manufacturing facilities and depots are located in regional areas of Australia, providing valuable employment opportunities for people in these regions and adding to the local economies. We have an extensive network of delivery and transport service providers, co-manufacturers and service providers to deliver our food products to approximately 9,000 outlets in Australia every day, including supermarkets, petrol stations, corner stores and food service customers.

3. Key Issues and Considerations

- 3.1. **Principle of approach:** GF strongly supports the regulatory principle of minimum effective regulation, and accordingly supports the concept, introduced in Option 3, of matching regulatory intervention to the nature and severity of the risk posed by a novel food or nutritive substance. The current situation leads us to adopt a cautious approach, often not proceeding due to such uncertainty. Meanwhile, other players in the market, who may be more risk adverse, or perhaps naive, have launched products outside the regulatory pathway. The playing field is not level.
- 3.2. **Publication of Dossiers:** GF recognises and agrees with the principle that regulatory outcomes should be transparent and we acknowledge that applications lodged with FSANZ, if accepted, are typically published as part of the call for submissions process, subject to the redaction of any commercial-in-confidence material. Further, GF has borne witness to a degree of regulatory disquiet in relation to a lack of any supervisory function of the notification system for self-assessment of general level health claims. On the other hand, any requirement to disclose confidential information serves as a disincentive for companies like ours to seek approval for innovative technology, or to invest in developing such technology in the first place. We stress that there needs to be a balance between these competing principles and so we do not support full publication of substantiation dossiers. In our view, publication of scientific and technical dossiers serves no communication benefit to the general public who are not trained to do risk and safety assessment and may be confused or misled by the highly technical nature of such papers.
- 3.3. **International approval:** GF advocates a less qualified adoption of safety and risk assessments conducted by other jurisdictions with similar regulatory approaches than is the current situation with overseas risk assessments. The Australian Government has implemented the principle of adopting international standards and risk assessments.¹ That is, where an international standard or risk assessment already exists, the Government has decided that this should be adopted unless it can be demonstrated that there is a good reason to maintain a unique Australian standard or risk assessment. On the defence of the position that Australian and New Zealand diets are dramatically different from those in the assessing economy, we challenge FSANZ to demonstrate a radical difference in dietary exposure for any such economies not formally recognised as 'comparable'. A 'novel' product that has gained approval as a food or food ingredient in comparable economy such as the EU, USA or Canada should enjoy the 'free' path to market without further requirement for self- or regulatory assessment. Our experience is that overseas suppliers are often unaware of the requirements in Australia around this, often assuming bringing a new ingredient to market with GRAS approval will mean full compliance with domestic food regulations.
- 3.4. **Combining nutritive substances with novel foods:** GF considers that the regulation of nutritive substances was misconceived from the start, covering substances that were already regulated (vitamins and minerals) as well as having a confusing and complex overlap with novel food regulation. A more objective regulatory definition for 'novel food' would largely negate the need for continued, separate regulation of nutritive substances, the possible exception being the regulation of amino acids. We support the AFGC position that appropriate consequential amendments to those few standards that reference nutritive substances (largely special purpose foods and formulated caffeinated beverages) could address all outstanding concerns such that the definition and concept of 'nutritive substance' could be removed from the Code entirely. Further, we support the AFGC recommendation that FSANZ regulates specific substances of concern and otherwise

¹ https://www.cuttingredtape.gov.au/sites/default/files/files/International_Standards_FAQ.pdf, accessed 22.03.2016

remove the concept of 'nutritive substance' from the Code, leaving novel foods regulation as the basis for regulating such ingredients in the future.

4. Goodman Fielder Response – Questions for Submitters

4.1 Risk Assessment

How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

The AFGC response to this question is echoed in our experience too, in that the existing definitions create -

- Uncertainty as to whether a substance is novel or nutritive and therefore whether approval is required, requiring costly specialist advice and delays in time to market;
- An uneven playing field as difference in interpretation may result in one company bringing a product to market that another company may consider to be captured by the current definitions and therefore requiring pre-market approval;
- Lost opportunity for sales of products available in overseas markets due to uncertainty and hurdles to market;
- Lost opportunity for consumers to experience new products, some of which may be available in overseas markets; and
- Loss of investment in domestic markets and operations.

Examples of past experiences are provided in a separate document in confidence to illustrate the effect of the current definitions on our business.

5. Conclusion

In summary, GF is supportive of a graduated risk approach to the consideration of novel foods taken in Option 3. GF does, however, stress that it is critical to get the detail underpinning this right and therefore encourages the second round of consultation to focus on two critical questions:

- What are the criteria for determining exempted, assessed and reported; and
- What exactly is the nature and content of the self-assessment

GF appreciates the opportunity to comment on Proposal P1024 and is looking forward to further participation in any additional consultation on the revised Standard.



Regulatory and Product Guidance Senior Manager
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