Associate Professor Julie Smith
ARC Future Fellow
School of Regulation and Global Governance (REGNET)
College of Asia and The Pacific
Australian National University

Response to consultation paper on P1028 Regulation of Infant formula – Infant formula products for special dietary use

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The Author

Dr Julie Smith is an Australian Research Council (ARC) Future Fellow, and Professor (Associate) in the School of Regulation and Global Governance (REGNET) at the Australian National University. Before joining REGNET, she was an ARC Postdoctoral Fellow and Research Fellow at the Australian Centre for Economic Research on Health (ANU College of Medicine, Biology and Environment) from 2004.

Her current ARC funded research focusses on the economics of breastfeeding and regulation of markets in mothers' milk.

She was awarded her PhD in 2003, having held an Australian Postgraduate Award and appointments at ANU's Research School of Social Sciences, and Centre for International and Public Law (College of Law) from 1992. Previously, she was a senior economist in the Australian and New Zealand treasuries and Department of Finance, and the Parliamentary Library Research Service. She has published over thirty articles in health and economics journals, as well as two books *(Taxing Popularity* and *Gambling Taxation in Australia*) and several book chapters. She was an expert advisor to the World Health Organisation (WHO) and the US Department of Health and Human Services and led a consultancy for WHO on marketing of commercial complementary foods for infants and young children.

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Response to consultation paper on P1028 Regulation of Infant formula – Infant formula products for special dietary use

1. FSANZ is calling for submissions to help assess a Proposal to consider the regulation of specific infant formula products – 'infant formula for special dietary use' (IFPSDU). FSANZ consultation paper presents its preliminary assessment of key issues and invites further information to assist understanding. FSANZ notes that in previous consultations (2012 and 2016), stakeholders generally supported co-locating provisions for IFPSDU in Standard 2.9.1 to ensure that the general provisions for infant formula applied to these products. Given the requirement for IFPSDU to comply with the provisions of Standard 2.9.1, FSANZ proposes retaining the provisions for IFPSDU in Standard 2.9.1. FSANZ notes that a broad range of infant formula products fall under the IFPSDU category. Currently Division 4 of Standard 2.9.1 includes three subcategories of IFPSDU. While IFPSDU products are suitable for the age range from birth to <12 months, it notes that some specialised products are intended for use up to 3 years of age or older. FSANZ highlights that there are some areas of regulatory uncertainty related to the broad nature of the current subcategories, the range of products in each category and related definitions.
2. FSANZ noted stakeholder concerns about the numbers of products falling into a grey area between general infant formula and IFPSDU, and the names these products are given. It was unclear if some current products (such as those for colic, reflux, constipation, and hungry babies) fall into the special product category and if health professionals support the need for their use. It was also noted that some stakeholders raised concerns around the need and evidence for their use. Confusion may arise where products marketed for specific conditions are sold alongside general infant formula products in supermarkets. Questions arose as to whether the regulatory subcategories relating to these products were optimal to manage any potential risks with products in each subcategory. FSANZ proposes to creates a new subcategory of infant formula products for special medical purposes (IFPSMP) within the IFPSDU Division to cover 'products for metabolic, immunological, renal, hepatic and malabsorptive conditions'.

3. With regard to the question 2 posed by FSANZ, on the advantages or disadvantages of the three options, I offer the following comments.

- Products such as those referred to as 'slightly specialised products for transient conditions' and 'protein substitute' product subcategories should be categorised as general infant formula unless there is strong evidence of their effectiveness in treating diagnosed conditions. In the absence of such evidence, claims should not be permitted on any infant formula product, consistent with

regulation of general infant formula products. Products included in the IFPSDU category should only be available under medical supervision, i.e. with a prescription or in hospital settings.

- While most attention has focussed on concerns about inappropriate promotion of milk formula products for older children (1, 2), similar concerns are raised by the categorisation of milk formula products purportedly for 'special dietary use'. It should be noted that a number of studies have challenged whether specialised formula products such as for colic or containing specific ingredients have benefits, and there is evidence to suggest that such formula product categories are created to assist in marketing to the vulnerabilities of new parents and 'create' purportedly unregulated market segments rather to treat diagnosed conditions or meet essential nutritional requirements of infants and young children (3-8).
- Any proposal for categorisation of such products should reflect recent WHO guidance (9) which clarifies that all products for children 0-3 years are breastmilk substitutes, and their marketing should be subject to regulation to prevent inappropriate promotion. That is, any Proposal for the IFPSDU category should not open up new opportunities for industry to promote breastmilk substitutes by using cross promotion of products for other markets such as older children or adults.

Conclusion

Inappropriate promotion of milk formula products can take many forms including the creation of new product categories to define new market segments. Promotion of breastmilk substitutes risks undermining breastfeeding, or breastmilk feeding including in hospital settings or in treating medical conditions. Regulators should beware of inadvertently facilitating inappropriate promotion of breastmilk substitutes, whether in health settings or to the public.

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