



Food Standards Australia New Zealand
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Submission on Food Standards Australia New Zealand Proposal P1044 Plain English Allergen Labelling

To Whom It May Concern

Danone Nutricia (Danone) welcomes the opportunity to comment on Proposal P1044 Plain English Allergen Labelling and as a major supplier of Food for Special Medical Purposes (FSMP) and Infant Formula Products for Special Dietary Uses (IFPSDU) would welcome further discussions with FSANZ on the impact of this proposal on these special purpose foods.

Please find a summary of our comments immediately below. A more expansive explanation of these points therein follows.

- Danone supports option 3, with modifications, under the proposal for all foods except Food for Special Medical Purposes (FSMP) and Infant Formula Products for Special Dietary Uses (IFPSDU). FSMP and IFPSDU are highly specialised products that are predominantly imported into Australia and New Zealand, often in relatively small volumes.
- FSMP and IFPSDU are designed to be used under professional medical advice and recommended by a health practitioner who has assessed the individual's specific health condition (including any allergies they may suffer from) and then tailors the product based on suitability. Many of these products are critical for an individual's quality of life and survival.
- Allergen labelling is already required and Danone considers that alignment with international labelling requirements for FSMP and IFPSDU to ensure the availability, continuity of supply and



affordability of these highly specialised products, outweighs any potential assistance of further mandating allergen format for consistency.

- Danone supports a 2-year transition period to update labels and a stock-in-trade provision for product manufactured before this date. We do not support a 2-year stock-in-trade transition.
- As the Infant Formula Standard is under significant review in P1028 for labelling and composition, Danone would support alignment in timing for implementation of allergen labelling to P1028 to ensure multiple label updates are not required within a short period for this product category. Any changes to product labelling greatly impact the end consumer so the ability to minimise the number of changes over a given period is preferred.

Yours Sincerely



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Danone Nutricia



About Danone (www.danone.com)

Dedicated to bringing health through food to as many people as possible, Danone is a leading global food & beverage company building on health-focused and fast-growing categories in three businesses: Essential Dairy & Plant-Based Products, Waters and Specialised Nutrition. Danone aims to inspire healthier and more sustainable eating and drinking practices, in line with its 'One Planet. One Health' vision which reflects a strong belief that the health of people and that of the planet are interconnected. To bring this vision to life and create superior, sustainable, profitable value for all its stakeholders, Danone has defined its 2030 Goals: a set of nine integrated goals aligned with the Sustainable Development Goals (SDGs) of the United Nations. Danone commits to operating in an efficient, responsible and inclusive manner; it holds itself to the highest standards in doing business, as reflected by its ambition to become one of the first multinationals certified as B CorpTM. With more than 100,000 employees, and products sold in over 120 markets, Danone generated €24.7 billion in sales in 2018. Danone's portfolio includes leading international brands (*Actimel, Activia, Alpro, Aptamil, Danette, Danio, Danonino, evian, Nutricia, Nutrilon, Volvic*, among others) as well as strong local and regional brands (including *Karicare, AQUA, Blédina, Bonafont, Cow & Gate, Horizon, Oikos, Prostokvashino, Silk, Vega*).

Listed on Euronext Paris and on the OTCQX market via an ADR (American Depositary Receipt) program, Danone is a component stock of leading social responsibility indexes including the Dow Jones Sustainability Indexes, Vigeo Eiris, the Ethibel Sustainability Index, MSCI Global Sustainability, MSCI Global SRI Indexes and the FTSE4Good Index.

General Food

Danone understands the importance of clear and consistent allergen labelling on food packaging to enable informed choice by allergic consumers. As such, Danone applies and adheres to all current labelling for allergens across its portfolio of products.

Danone supports option 3 of P1044, with the modifications as proposed by the Australian Food and Grocery Council (AFGC) for general food. Option 3 requires the declaration of allergens using mandatory specified terms in bold font, with additional requirements to declare in the statement of ingredients, as well as a separate allergen summary statement.

Notably, the AFGC raises a principle-based approach on the positional requirements of the summary statement as being in close proximity to and in the same view as the statement of the ingredients, which Danone is in agreement with. There is severe space restriction on some packaging formats, including single serve round yoghurt cups, which are large enough to require full labelling. Allowing for this principle-based approach ensures that, in these extreme circumstances, there can be some more practical flexibility on the format whilst allowing for the full allergen declaration to be included on the label.

Food for Special Medical Purposes (FSMP) and Infant Formula Products for Special Dietary Uses (IFPSDU)

Standard 2.9.5 Food for Special Medical Purposes (FSMP) as per the definition, as a food that is

- a) specially formulated for the dietary management of individuals:
 - i. by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
 - ii. whose dietary management cannot be completely achieved without the use of the food; and
- b) intended to be used under medical supervision; and
- c) represented as being:
 - i. a food for special medical purposes; or
 - ii. for the dietary management of a disease, disorder or medical condition

Additionally, FSMP are distributed via highly restricted and controlled channels. Hence, these products are not readily accessible to purchase by the average allergic consumer.

Infant Formula Products for Special Dietary Uses (IFPSDU) are not specifically defined in the Food Standards Code and the definition and structure is currently being reviewed as part of P1028. The current Standard covers infant formula products for premature or low birthweight infants, products for special dietary use based on a protein substitute and products for metabolic, immunological, renal, hepatic and malabsorptive conditions. Again, these products are for specific health conditions many of which are highly specialised conditions.

Notably the recommended Policy Guidelines on the intent of Part 2.9 – Special Purpose Foods states the following: *In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:*

- a) the need for standards to be based on risk analysis using the best available scientific evidence;*
- b) the promotion of consistency between domestic and international food standards;*
- c) the desirability of an efficient and internationally competitive food industry;*
- d) the promotion of fair trading in food;*

As per the Proposal P242 Final Assessment Report on Food for Special Medical Purposes harmonizing with overseas regulations is a key issue. As raised in P242 nearly all FSMP in Australia and New Zealand are imported from Europe Union (EU) or the United States of America (USA), with the majority from the EU. P242 goes on to state that, due to the specialised, and essential, nature of some of these foods and the volumes being imported into Australia and New Zealand being relatively small, non-alignment could mean imported FSMP is withdrawn from the domestic market, due to increased cost burden associated with re-labelling and small unviable order quantities. Therefore, when setting Standard 2.9.5, FSANZ sought to harmonise the labelling requirements internationally, in particular with EU, but also with consideration of USA and Codex Alimentarius. However, at the time when Standard 1.2.3 clause 4 was considered in relation to FSMP the requirements were similar to the EU and USA. As such, products manufactured outside of Australia and New Zealand did not require re-labelling.

P1024 raises that the EU currently does not permit an allergen summary statement underneath the ingredient list. Therefore, there is a direct contradiction between the proposed option 3 and the EU labelling requirements. This means, that if option 3 is fully adopted as proposed, labels will need to be developed specifically for Australian and New Zealand only for FSMP and IFPSDU products.

FSMP and IFPSDU are highly specialised products which are intended to be used with professional medical advice given by practitioners who can assess the suitability of a product given an individual's specific health condition, including any allergies. Patients using these products require specific nutrient and dietary requirements (including any intolerances to allergens) impacted by their medical condition that are not met by regular foods or formulas. Medical Practitioners would tailor and monitor patients' nutrition provided through these products under medical supervision. Additionally, due to the highly specialised nature of these products, Danone supports medical practitioners with fact sheets and scientific education. The fact sheets detail nutritional compositions including outlining ingredients and allergens, to enable tailored management plans. The scientific education events are provided to ensure healthcare professionals remain up to date on the latest clinical evidence and science.

As prescribing and recommending of products is tailored to the individual patient needs, Danone believes that standardising the labelling of allergens on pack would not benefit the healthcare professionals or patients. Danone considers that alignment with international labelling requirements for FSMP and IFPSDU is most important to ensure availability, continuity of supply and affordability of these highly specialised products required by a vulnerable group of the population.

Danone is one of only of a few suppliers of many highly specialised FSMP and IFPSDU products in Australia and NZ; and is the only supplier of products for the management of inborn errors of metabolism in NZ.

Under the proposed change approximately 186 FSMP and IFPSDU products for Danone would be impacted; 80 of which we are the sole source supplier in New Zealand. If the current labels used on products manufactured in EU or USA are no longer able to be brought into Australia and New Zealand a label would need to be developed

specifically for Australia and New Zealand. Due to the rarity of the conditions we are serving, it would be impossible for the products to be manufactured in the quantities required for Australia and New Zealand, making these highly specialised products financially non-feasible. There are approximately 1600 people in Australia and 150 people in New Zealand with metabolic conditions that would have their health severely impacted if specialised products that are essential for life are no longer available. Also, having as much variability in specialised products is also important for quality of life, as people with a metabolic condition often must adhere to life-long strict dietary requirements.

Transition

It is important to assess the impact of the transition period on the safe and continuous supply of all products which P1044 would apply to. Danone does not support a 2-year stock in trade provision particularly for shelf-stable products with a long shelf-life. This includes most formula products which can have up to a 2-year shelf life, where pack labels would require urgent update after gazettal.

Allergen labelling is already mandatory; the proposal is to make existing allergen labelling clearer. Hence, there is no health and safety risk of extending the time of the proposed stock in trade. Therefore, Danone proposes that the transition is a 2-year at time of manufacture and that stock in trade is able to be sold through, provided the labels comply with current requirements and the product was made before the end of the transition period.

Having a shorter transition period increases the cost to industry, as a label change specifically for allergen requirements alone will be required for many products. Regulating on stock in trade could also lead to costly withdrawal and dumping of product that is otherwise safe and adheres to current regulations, including those on allergens. This would not only increase the costs for the food industry but also the dumping of safe product, which has an environmental impact.

Furthermore, as the Infant Formula Standard is under significant review in P1028 for labelling and composition, Danone would support the alignment of timing for the implementation of allergen labelling to P1028, to ensure multiple label updates are not required within a short period for this product category.

Questions for Submitters

1. What proportion of foods are likely to be affected by the changes?

All food products supplied in Australia and New Zealand will require updated labels. This is due to the very prescriptive nature of the specified terms and format requirements.

2. Is there likely to be a material difference in costs between Options 2 and 3? If yes, why?

Yes, option 2 is more aligned with the EU requirements and therefore some special purpose foods would not require a label update and a consistent label with Europe could be used. However, to ensure that labels are able to always be aligned with the EU and the USA with any future regulatory updates internationally, an exemption from the highly prescribed format requirements in P1044 is required and the status quo maintained to simply require the declaration of allergens with flexibility in terms and format.

3. Is there likely to be a material difference in the benefit to consumers between Options 2 and 3?

Unable to comment.

4. Is option 2 or 3 sufficient for consumers to make quick and reliable assessments of foods?

Unable to comment.

5. What would be an appropriate duration of time for stock in trade provisions?

As previously raised, Danone is not supportive of a 2-year stock in trade provision and proposes that the transitional period is 2-year at time of manufacture. Danone also proposes that infant formula products covered in P1028 are able to update labels in accordance with the transition period under this proposal so that multiple updates are not required within a short period of time.

6. Do you expect to have any notifications, education, permission, purchasing, record keeping, enforcement, publication and documentation, procedural, delay, labelling or any other costs associated with the proposed changes to the Food Standards Code?

Costs include:

- Approximately AUD \$5.6million (\$30,000 for 186 stock-keeping-unit's SKUs) to update labels for FSMP and IFPSDU
- Product write-off due to not meeting the minimum order quantities for products.
- Resource to update hospital tender material with new labels including updating education materials for consumers and healthcare professionals for all products.
- Loss of business for products that become financially non-viable (approximate sales revenue provided in commercial in confidence).

7. Any view in relation to unintended consequences associated with Option 2 or 3?

As previously raised, non-alignment with EU and USA labelling for special purpose foods will result in many products becoming financially non-viable and could ultimately mean these products are no longer made available to individuals who require these products. Some of these products are critical for life and therefore non-availability will impact the health of people which depend upon these products.

