Proposal 1028 Infant formula
Safety and technology Consultation paper

Submission

NSW appreciates the opportunity to comment on Proposal 1028 – safety and technology consultation paper. NSW offers comments on the 4 main issues covered in the paper in the following order:

- Food Additives
- Contaminants
- Lactic acid producing micro-organisms
- Labelling for safe preparation and use.

Food Additives

NSW advocates for a cautious and conservative approach to the use of food additives in infant formula products regulated by Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Code) as persons less than 12 months old represent the most vulnerable consumer demographic in the Australia New Zealand population. NSW seeks further information from FSANZ in some areas and offers in principle support in others.

Pectins – NSW seeks further information from FSANZ on the need to set a limit in the Code for Pectins at 5000 mg/L noting that industry (using these substances for a defined technological purpose) only seeks a permission at 2000 mg/L.

Xanthan Gum – NSW is concerned with the proposal to add Xanthan Gum at 1200 mg/L, which is currently not permitted in infant formula products by the Code in Australia or New Zealand nor is it permitted by Codex. NSW notes JECFA has assessed safety of these thickeners at 1000 mg/L and raised no concerns. NSW suggests FSANZ consider aligning a permission for Xanthan Gum with the level assessed by JECFA and shown to present no health and safety concerns. NSW notes the Royal Australasian College of Physicians (RACP) share this concern.

Sucrose esters of fatty acids – currently not permitted in infant formula products in the Code or Codex. NSW notes that JECFA assessments established an ADI of 0-30 mg/kg/bw, however JECFA recently asked for refined dietary exposure modelling data as laxative effects were noted above 30mg/kg/bw. NSW anticipates FSANZ will consider the outcomes of this refined dietary exposure work.

Diacyltartaric and fatty acid esters of glycerol – NSW supports FSANZ proposal to remove this permission from the Code.

Hydroxypropyl starch – NSW supports FSANZ intention to rectify the error in the listing in the Code to 25,000mg/L to 5000mg/L.

Contaminants

NSW supports the over-arching principle that maximum limits (ML) for contaminants should be set in the Code at a level that is as low as reasonably achievable and are based on the most recent and contemporary risk assessments conducted by competent authorities. NSW offers the following comments with this view in mind:

Cadmium – NSW notes the Code has no ML for cadmium in infant formula products and that 2011 product surveys suggests very low levels are present (0.0006-7mg/kg). However, the European Union introduced a ML for cadmium to protect infants. There appears scope to align the Code with the EU limits to provide a safeguard for infants into the future. NSW notes most of the current supply of soy-based infant formula products is currently from the European Union (EU) where compliance with existing EU limits for cadmium would be required but this may not always the case. Including a limit in the Code would provide a clear threshold of protection for infants into the future rather than relying on 'unsuitable' food provisions in state Food Acts should products be developed with higher levels of Cadmium than what has been seen in previous surveys.

Lead – NSW supports FSANZ proposal to align with Codex lead levels in infant formula products.

Melamine – NSW recognises that melamine is an adulterant when present in infant formula products. NSW supports the principle that a ML should not be included in the Code for a substance that should never be present in infant formula products noting the on-going reliance on 'unsuitable' food provisions in state Food Acts should adulterated products enter the market.

Polycyclic aromatic hydrocarbons (PAH) – NSW notes that the EU set regulatory limits for these substances in infant formula products of 1.0 microgram/kg and suggests FSANZ consider the merits of aligning with EU regulation.

Perchlorate – NSW notes that JECFA has evaluated perchlorates and set an ML of 0.01mg/kg in infant formula products (IFP). Informed by the JECFA advice, the EU has implemented regulatory limits of 0.01mg/kg in IFP. NSW requests FSANZ consider aligning with EU regulation.

Chloropropanol – NSW notes that JECFA established a provisional maximum TDI of 4 micrograms/kg/bw. The EU has set regulatory limits for glycidyl esters of chloroproponal at 6.0 micrograms/kg – 15 micrograms/kg. NSW notes that product sampling of infant formula products suggests very low levels in the Australian and New Zealand markets (0.93 – 3.39 micrograms/kg/bw/day), but with results suggesting there may be exceedances of TDI in 3-month old infants. NSW suggests that FSANZ review data from international jurisdictions on these substances before concluding that an ML in the Code is not necessary.

Lactic acid producing microorganisms

NSW supports FSANZ including clarification in the Code that 'non-pathogenic' L-lactic acid producing microorganisms are permitted to be used in infant formula products.

NSW notes that addition of L-lactic acid producing microorganisms to infant formula products (IFP) has shifted away from its original intent of use as a food additive to use as a 'prebiotic'.

This may require some consideration of the regulatory status of these substances into the future given their purpose of addition may no longer be technological (food additive). It may be prudent to consider such substances as possible novel foods/nutritive substances to ensure appropriate pre-market scrutiny of the bacterial species and the nature of lactic acid generated (is it just L-lactic acid generated, raemic or D isomers as well).

Labelling for safe preparation and use

NSW supports a robust and clear regulatory approach to the labelling of infant formula products. Simplicity, accuracy and clarity are key principles to consider in the labelling and instructions for use of infant formula products (IFP) given the vulnerability of infants.

NSW offers the below observations with the above principles in mind.

Section 5.3.1 Directions for preparation and use

Type of water used to reconstitute powdered infant formula: NSW agrees with FSANZ proposal. Using cooled, boiled water to prepare IFP is best practice and this language is commonly used by midwives and lactation consultants in educating parents and caregivers.

Discarding left over formula: NSW suggests that labelling should advise caregivers to discard unfinished formula 'within one hour' from the commencement of a feed in accordance with the Australian Infant Feeding Guidelines. Experience suggests that most caregivers will adhere to this advice, yet some may extend it slightly. NSW is concerned that extension of this timeline to 'within 2 hours' may result in some caregivers considering that extensions on this timeline are permissible. Given the vulnerability of infants NSW suggests that FSANZ adopt a conservative approach to labelling provisions for caregivers as this will result in lesser risk to infants.

NSW further notes the 2012 Australian Infant Feeding Guidelines states "a feed should take no longer than 1 hour – any formula that has been at room temperature for longer than 1 hour should be discarded".

*Application of preparation and use directions to concentrated and ready-to-drink formula***:** NSW agrees with FSANZ proposal.

Prepare bottles individually: NSW agrees with FSANZ proposal.

Storage of made up formula: NSW agrees with FSANZ proposal.

Additional comment:
NSW based paediatric dietitians expressed concern that some parents take statements regarding the amount of formula an infant should drink quite literally. For example, if the product label says an infant should be drinking Xmls by a certain age and their infant is not this causes worry. Could a statement be included under the

table of amounts such as “this is based on average needs and your baby’s needs may be higher or lower; check with your healthcare professional for further advice if needed”.

Section 5.3.2 Standardised wording of pictures for directions for preparation and use

NSW agrees to maintain current approach. Clear direction (and prescription) to caregivers in the appropriate preparation and dosage of IFP is necessary to mitigate the risk of individual caregivers adopting an efficiency or liberal based approach to the preparation of IFP that may inadvertently place infants at risk. The unique role of IFP as a sole source of nutrition to persons under the age of 12 months necessitates a clear, unambiguous and direct approach to directions for use and storage.

NSW notes the risk identified in SD 4 in support of the above:
- Supporting Document 4 (p11-12) reveals that potentially improved instructions improve compliance by caregivers on the following:
(1) Do not add other food (e.g. cereal) or flavouring to feed
(2) once prepared, formula can spoil quickly. Discard left over formula in the bottle after a feed.
(3) Always put the water into the bottle first, before adding the powder.

There may also be cause to consider standardisation of warning labels on infant formula products (IFP) to inform caregivers against voluntary addition of ingredients to IFP as they are a sole source of nutrition for persons less than 12 months old (i.e no further ingredients are necessary for infant nutrition). Page 11 of SD 4 suggests "do not add any other food e.g. cereal or flavouring to formula” or “do not add any other food or flavouring to formula”.

We note the warning label for ready to drink formula includes “do not add anything” we suggest this could be added to the warning label for powdered formula as well.

RTD: "Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this ‘ready to drink’ formula except on medical advice. Incorrect preparation can make your baby very ill"

POWDER: Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not add anything or change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill.

Section 5.4.1 Date marking: NSW agrees with FSANZ proposal.

Section 5.4.2 Storage instructions for infant formula: NSW agrees with FSANZ proposal.

Section 5.4.3 Measuring scoops: NSW agrees with FSANZ proposal.

Section 5.5.1 Legibility requirements for warning statements: NSW agrees with FSANZ proposal to maintain existing legibility requirements.

Section 5.5.2 Warning statements about following instructions exactly: NSW agrees with FSANZ proposal to revise existing statements.

Section 5.5.3 Warning statements that 'breast is best' : NSW agrees with FSANZ proposal.

Section 5.6.1 Prescribed name: NSW agrees with FSANZ proposal.

Section 5.6.2 Statement that infant formula product may be used from birth: NSW agrees with FSANZ proposal.

Section 5.6.3 Statement about age to offer foods in addition to formula : NSW suggests the wording is changed from ‘the age of 6 months' to 'from around the age of 6 months' as this provides greater alignment with Australian Infant Feeding Guidelines and also consistent with Allergy recommendations to commence introducing solids from around 6 months of age by NHMRC and ASCIA.

https://www.allergy.org.au/patients/allergy-prevention/ascia-how-to-introduce-solid-foods-to-babies

Section 5.6.4 Statement on protein source: NSW would like to information on the specific protein fraction located on the package of infant formula product (IFP) to assist caregivers make informed decisions. This is proposed as protein source fractions (whey/casein/lactoferrin) component of protein profiles are being used by IFP manufacturers as a means of product differentiation in the market.

Section 5.6.5 Co-location of protein source statement with the name of the food : NSW agrees with FSANZ proposal.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.