Southern District Health Board
Piki Te Ora

Public Health South

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ADVICE ON PROPOSAL P1028 – INFANT FORMULA.
CONSULTATION PAPER 1 – SAFETY AND FOOD TECHNOLOGY

To: Food Standards Australia New Zealand

[redacted]
Contact: [redacted]

The Southern District Health Board delivers health services to a population of 335,990 and has responsibility under the *New Zealand Public Health and Disability Act 2000* to improve, promote and protect the health of people and communities. It seeks to promote equity and to reduce adverse social and environmental effects on the wellbeing of people and communities.

Public Health South would like to thank Food Standards Australia New Zealand for the opportunity to comment on Proposal *P1028 – Infant Formula: Consultation paper 1 – safety and food technology*.

As public health professionals we strongly support FSANZ in meeting its three primary objectives, set out in section 18 of the *Food Standards Australia New Zealand Act 1991*:

- **the protection of public health and safety**
- the provision of adequate information relating to food to enable consumers to make informed choices
- the prevention of misleading or deceptive conduct

We are commenting on 5 of the questions for submitters (pp. 117-118).

Questions about food additives and contaminants (Section 2, Section 3) - Health advice

4. In addition to the list above, can you provide any further examples of lack of alignment with EU regulations delaying important formula from reaching vulnerable infants?
5. To what extent would proposed changes to current permissions and limits for Special formula address any perceived delays to vulnerable infants accessing the imported formula that they need?

Under current Food Standards, we are unaware of any delays that vulnerable New Zealand infants are experiencing in accessing the special infant formula that they need.

On 5 June 2021, we spoke to Rhonda Ackroyd, a Metabolic Dietitian who works in the National Metabolic Service, based at Auckland District Health Board's Starship Children's Health. She also sits on the New Zealand Dietitian Board's Prescribing Expert Advisory Group. Through her professional roles, Rhonda and her colleagues communicate with nearly all dietitians from across New Zealand who are supporting infants with diagnosed metabolic conditions*.

[* Metabolic conditions are commonly referred to as an 'inborn error of metabolism'. They are a genetic disease caused by a defect in the function of a cellular protein (e.g. an enzyme or transporter) involved in the metabolism of various chemicals in the body.]

Rhonda said she was unaware of any case where a vulnerable New Zealand infant under dietetic care was experiencing delays in accessing the special formula that they needed. Dietitians can gain special authority (government funded products) for patients/clients needing special foods, including infant formula, in community settings. Pharmac's Community Schedule shows the list of government-funded special infant formula products available to vulnerable infants in New Zealand.

Questions about L(+) lactic acid producing microorganisms (Section 4)

13. Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic. Do these need to be explicitly excluded (or non-pathogenic specifically permitted) or is the base 'safe and suitable' requirement considered sufficient to manage this risk?

We support clarification of the current permission to include 'non-pathological, non-toxigenic' L-lactic acid producing microorganisms in infant formula for healthy, full term infants for the following reasons:

- Your risk assessment (section 4.4) concludes that 'infant formula supplemented with non-pathological, non-toxigenic L-lactic acid producing microorganisms does not present a risk to public health and safety for healthy, full term infants."
- The intent of the original permission was for the addition of non-pathogenic lactic acid producing microorganisms.
- Given limited clinical trials for the safety of pathogenic or toxigenic species, these requests require assessment on a case-by-case basis.

For infants with underlying clinical complications (including preterm, low birth weight and immunocompromised infants), there appears to be insufficient evidence to assure safety of infant formula supplemented with non-pathological, non-toxigenic L-lactic acid producing microorganisms and case reports of associated harm. Therefore, should there be a warning label that states something like: only for use by healthy, full term infants?

Questions about labelling (Section 5)

14. Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach?

Yes, we support the amendments proposed.

20. In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence and quantify impacts where possible.

With regard to legibility requirements for warning statements (**Section 5.5.1**), we agree that the existing warning statements are legible. However, we contend that some of the statements on infant formula currently for sale in New Zealand are not prominent enough and can blend in with other text on the label. Therefore, we propose that all warning statements be presented in separate boxes and that the background colour behind the words "Important Notice" and "Warning – follow instructions exactly" should be different from the surrounding colour so that these labels stand out.

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With input from: [redacted]