

# AUSTRALIA AND NEW ZEALAND MINISTERIAL FORUM ON FOOD REGULATION

5 March 2020

## REVIEW REQUEST

### Application A1155 - 2'-FL and LNnT in infant formula and other products

The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) has requested that Food Standards Australia New Zealand (FSANZ) review the draft variation to the Australia and New Zealand Food Standards Code (the Code) for Application A1155, 2'-FL and LNnT in infant formula and other products.

The application sought to amend the Code to permit the voluntary addition of 2'-O-fucosyllactose (2'-FL), either alone or in combination with Lacto-N-neotetraose (LNnT) to infant formula products and formulated supplementary foods for young children (FSFYC). The FSANZ Board approved draft variations to permit 2'-FL and LNnT for use in infant formula and FSFYC with specified maximum levels and to provide an exclusive use period of 15 months for the Applicant's brand of 2'-FL and LNnT.

Forum Ministers have requested a review of the draft variation as they consider that:

- The draft variation is not consistent with, and does not have sufficient regard to, relevant Ministerial Policy Guidelines: Policy Guideline on Regulation of Infant Formula; and Policy Guideline on Intent of Part 2.9 – Special Purpose Foods.
- The draft variation is not consistent with the objectives of the legislation that establishes FSANZ. Ministers noted claims that 2'-FL and LNnT 'reduce severity of invasive *Campylobacter jejuni* infection' and provide 'inhibitory effect against invasive *C. jejuni* infection' are about alleviating or preventing disease and therefore therapeutic rather than nutritive in nature.
- It has not been demonstrated that addition of 2'-FL and LNnT to infant formula at the proposed levels is consistent with the protection of public health and safety, nor has the safety of long term consumption of 2'-FL at levels of up to 2.4 g/L been demonstrated in the target population. Ministers also noted the health outcomes cited by the applicant (i.e. anti-infective and bifidogenic effects) are not sufficiently established in the FSANZ assessment or in the scientific literature.
- The addition of 2'-FL to a maximum level of 2.4 g/L is twice the 1.2 g/L level permitted in most comparable international jurisdictions' standards.
- The draft variation does not provide adequate information to enable informed choice. The minimum 2'-FL and LNnT levels in a serve to support the bifidogenic effect are not specified. Failure to require minimum effective concentrations in products may result in consumers being misled as to the efficacy of the products for the stated benefits, and prevent consumers making informed decisions about the claimed bifidogenic effects.
- Failure to specify minimum 2'-FL and LNnT levels would also result in there being no legislative basis for regulators to respond adequately to complaints that may be received during the 15-month exclusivity period for A1155 or subsequently.

FSANZ has until 17 May 2020 to finalise the review of the draft standard and re-affirm, re-affirm with amendments, or withdraw its approval of the draft standard.

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### **The process for requesting a review**

After FSANZ notifies the Forum of a draft standard or variation the Forum may request a review if the Forum believes that one or more of the Criteria/Ground/s set out in the Food Regulation Agreement 2000 (as amended in 2010) (the Agreement) or the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (the Treaty) applies. The Criteria / Grounds set out in the Agreement and in the Treaty are:

- (i) it is not consistent with existing policy guidelines set by the Forum;
- (ii) it is not consistent with the objectives of the legislation which establishes FSANZ;
- (iii) it does not protect public health and safety;
- (iv) it does not promote consistency between domestic and international food standards where these are at variance;
- (v) it does not provide adequate information to enable informed choice;
- (vi) it is difficult to enforce or comply with in both practical or resource terms; and / or
- (vii) it places an unreasonable cost burden on industry or consumers.

In exercising this power the Forum must comply with the Agreement and the Treaty. Under the Agreement the Forum will request a review if the Forum considers that one or more of the Criteria applies. The Forum would also, at this point in the process, request a review if New Zealand notifies the Forum of concerns that the standard would be inappropriate for New Zealand (Annex C(2) of the Treaty).