



**FOOD STANDARDS**  
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## Office of the Chief Executive Officer

Ms Claire Bleakley  
President  
GE Free New Zealand  
PO Box 13402  
WELLINGTON  
NEW ZEALAND

Dear Ms Bleakley

Thank you for your letter of 10 January 2018 regarding the assessment of Application A1138 – Food derived from Provitamin A Rice Line GR2E.

The Food Standards Australia New Zealand (FSANZ) protocol for conducting safety assessments of genetically modified (GM) foods is based on internationally agreed principles and guidelines developed by the Codex Alimentarius Commission. This protocol is followed by all regulatory agencies around the world. The Codex Alimentarius or "Food Code" was established by Food and Agriculture Organization and the World Health Organization in 1963 to develop harmonised international food standards and guidelines, which protect consumer health and promote fair practices in food trade.

FSANZ, as all other food standards agencies around the world, rely on data supplied by an applicant to support the safety of their particular food (whether that food is genetically modified or not). Experienced FSANZ staff assess the data supplied, making sure the studies have been performed appropriately, and make a conclusion about the safety of a food. FSANZ can, and does, request applicants to undertake additional studies and provide additional data, where necessary. In addition, FSANZ complements the applicant data with information from the scientific literature, other applications and other government agencies.

The safety assessment data requirements used by FSANZ for all applications assessed under Standard 1.5.2 – Food produced using gene technology, and the background rationale for the requirements, are described in detail in the FSANZ *Application Handbook* available on the FSANZ website at

<http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>.

Additionally, a web page entitled *Safety assessment of GM foods* is available at <http://www.foodstandards.gov.au/consumer/gmfood/safety/Pages/default.aspx> and outlines the standard process followed for assessing all GM food applications.

The supporting document (SD1) prepared by FSANZ for considering the safety of any GM food systematically discusses all unpublished studies (provided by the Applicant) that were reviewed by FSANZ, as well as any additional published information, provided by the Applicant and/or sought independently by FSANZ through literature searches, and deemed relevant to include in a safety consideration of a GM food. In the case of Application A1138, as there was a nutritional change (production of beta-carotene in the grain) a nutrition assessment, involving a hazard assessment of beta-carotene as well as a highly conservative dietary exposure assessment, was also undertaken and reported in a separate supporting document (SD2). Both SD1 and SD2 documents associated with Application A1138 are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1138GMriceGR2E.aspx> and provide a full list of all references (including unpublished and published information) used by FSANZ. The A1138 Application (available at [http://www.foodstandards.gov.au/code/applications/Documents/A1138%20Application\\_Redacted.pdf](http://www.foodstandards.gov.au/code/applications/Documents/A1138%20Application_Redacted.pdf)) also lists all unpublished studies and published references cited by the Applicant.

In regard to your question about the dates for face-to-face meetings of the Ministerial Forum, these are available on the Forum website at <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/latest-news>. Please note, however, that out-of-session meetings of the Forum are also held, as required, for discussion of decisions involving statutory timeframes. Please refer to page 27 of the FSANZ *Application Handbook* for an indication of the timeframe involved in a Forum decision on a notification of a FSANZ Board decision.

Yours sincerely



**Mark Booth**  
Chief Executive Officer

12 January 2018