Priority – Medium **Security Level –** In Confidence

Distribution
Minister
Minister's Advisor
Minister's Office

Ministry for Primary Industries
Manatū Ahu Matua

26 January 2018 **Document Number: B17-0832**

Forum on Food Regulation Out-of-Session Response: Food Standards Australia New Zealand Notifications A1138 and A1143

Purpose:

This briefing recommends you agree to and accept changes to the Australia New Zealand Food Standards Code (the Food Standards Code), as recommended by Food Standards Australia New Zealand (FSANZ). Your decision is being sought via an out-of-session response for the Australia and New Zealand Forum on Food Regulation (the Forum).

The notifications seek approval for the use (i.e. the sale) of two genetically modified (GM) foods.

The notifications are:

- Application A1138 – Food derived from Provitamin A Rice Line GR2E**;** and
- Application A1143 – Food derived from DHA Canola Line NS-B50027-4

Minister	Action Required:	Minister's Deadline
Minister for Food Safety	**Agree** to the changes to the Food Standards Code arising from the notifications listed above and as contained in this brief, and **Sign** the attached Response Sheet and return to the Secretariat.	Response required to Food Regulation Secretariat by 2 February 2018

Contact for telephone discussion (if required**)**

	Name	Position	Work	Mobile
Responsible Manager	Jenny Reid	Manager, Food Science and Risk Assessment	s 9(2)(a)	s 9(2)(a)
Principal Author	s 9(2)(a)	Specialist Adviser, Food Science	s 9(2)(a)	

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Key Messages

1. FSANZ has recommended the approval of two GM-food applications
   - Application A1138 – Food derived from Provitamin A Rice Line GR2E which is a rice developed for countries with vitamin A deficiency, and
   - Application A1143 – Food derived from DHA Canola Line NS-B50027-4, which is a canola oil that is modified to have higher levels of an omega-3 fatty acid.

2. As New Zealand's representative on the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum), you have been asked to consider the FSANZ notifications and decide if they should be accepted or sent back to FSANZ for review. The notifications contain the Approval Reports, which is FSANZ's published reports on the applications. If you accept the recommendations, this means that you are agreeing that these foods can be sold in Australia and New Zealand.

3. MPI is satisfied that the consultation process undertaken by FSANZ, including the analysis of, and response to, submissions meets the requirements in the Food Act 2014. The Food Act 2014 and FSANZ Act matters are listed in Appendix 1. GE Free New Zealand did not make a submission to FSANZ during the public consultation period, but has recently contacted MPI with concerns around the approval of A1138 – Food derived from Provitamin A Rice Line GR2E, regarding the safety assessment. As they did not make a submission, FSANZ was not able to address their concerns. MPI met with GE Free New Zealand on 23 January 2018 to discuss their concerns, and we are satisfied that no new issues have been raised that affect the outcome of the safety assessment by FSANZ. GE Free NZ indicated that they would be writing to you, requesting that you seek a review of the recommendation, i.e. that you do not agree to the change to the Food Standards Code to permit GM rice as a food.

4. GE Free NZ are concerned about the safety of food derived from Provitamin A rice. FSANZ and MPI have not identified any public health and safety concerns with this GM rice. While not negating the need for a full safety assessment, it is important to note that this GM rice is not intended for sale in New Zealand and Australia. FSANZ is not able to reject an application on the grounds that the GM food is not intended to be sold in Australia and New Zealand i.e. it is not a requirement that the GM food has some benefit for our populations. In the case of this GM rice, the Application was made by the International Rice Research Institute (a non-government humanitarian organisation) to seek approval for rice that is genetically modified to produce more vitamin A (to be grown in countries at risk of vitamin A deficiency). It is not the role of FSANZ to determine if the rice is suitable for developing countries. The application has been submitted in order to avoid trade issues, meaning that trace amounts could be present in shipments of imported conventional rice, without disrupting trade. The likelihood of this is considered very low, for reasons outlined in this briefing.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

5. This application has highlighted that FSANZ must assess GM foods that are not intended for sale in Australia and New Zealand. This may be something for future consideration by officials in regards to our joint food regulation system with Australia. However, if you agree with our advice that the GM rice is safe, then in our view that are no grounds for requesting a review by FSANZ. In our view, the other grounds on which you can request a review, do not apply, for reasons provided in this briefing.

6. This briefing recommends that you accept the recommendations relating to the two genetically modified food notifications on the Response Sheet, by selecting the words “do not” (i.e. you do not wish to request that FSANZ review its decision). You have been provided with a separate briefing (B17-0512) outlining the role of the Forum and how decision making is undertaken

7. Once all responses are received from Ministers, FSANZ will be notified whether the notifications are accepted or are to be reviewed. A decision is taken by a majority. If accepted, FSANZ will make the necessary amendments to the Food Standards Code. To incorporate the changes into New Zealand law, you will need to issue an amendment to a food standard under the Food Act 2014.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Recommendations

8. MPI recommends that you:

a) **Agree** that you accept the changes to the Food Standards Code arising from Application A1138 – Food derived from Provitamin A Rice Line GR2E.

Agreed / Not Agreed

b) **Agree** that you accept the changes to the Food Standards Code arising from Application A1143 – Food derived from DHA Canola Line NS-B50027-4.

Agreed / Not Agreed

c) **Agree** to accept these recommendations by no ing on the attached Ministerial Response Sheet that you 'do not' wish to seek a review, and then sign and return the attached Response Sheet.

Agreed / Not Agreed

Chris Kebbell
Acting Deputy Director-General
Regulation & Assurance
for Director-General

Hon Damien O'Connor
Minister for Food Safety

/ / 2018

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Background

9. Applications A1138 and A1143 both relate to approvals for new genetically modified (GM) foods. This briefing contains MPI's recommendations for your response. You have recently been provided with a separate briefing (B17-0687), which outlines how GM foods are regulated, including the labelling rules that apply. An earlier briefing (B17-0512) outlined the role of the Forum and how decision making is undertaken.

10. At the Forum meeting on 24 November 2017, you will recall that some Ministers raised concerns with these applications and requested that they be discussed at a face-to-face meeting, rather than out-of-session. Ministers requested the provision of process advice in relation to managing the way forward with these two applications. The Food Regulation Secretariat has provided this information, and in summary, FSANZ has advised that the applications need to be progressed before the next Forum meeting, in order to meet statutory timeframes. For this reason, an out-of-session response is required by 2 February 2018, and it is not possible to 'stop the clock' and delay consideration of these applications.

11. A1138 and A1143 both relate to nutritional modifications using genetic modification. During the submission period, and at the 24 November 2017 Forum meeting, several jurisdictions raised questions around the applicability of two Policy Guidelines: the *Fortification of Foods with Vitamins and Minerals*, and the *Addition of Substances other than Vitamins and Minerals*. FSANZ is required to have regard to relevant Policy Guidelines when assessing applications. The FSANZ Board considered the above Policy Guidelines are not applicable, but noted that FSANZ supports any further work on the development of the Policy Guidelines (see Appendix 2).

12. MPI agrees that the above Policy Guidelines are not applicable to these applications, and supports further work by officials to address how changes in food composition through genetic means are contained in Policy Guidelines. FSANZ views (to which MPI agrees) regarding the applicability of Policy Guidelines for each application are as follows:
    - A1138 – fortification by genetic means is specifically deemed beyond the scope of the *Fortification of Foods with Vitamins and Minerals* Policy Guideline; and
    - A1143 – changing the fatty acid profile of a food by genetic modification is not within the scope of either the *Fortification of Foods with Vitamins and Minerals* or the *Addition of Substances other than Vitamins and Minerals* Policy Guideline. The policy guideline *The Regulation of Infant Formula Products* is applicable, and was applied by FSANZ when preparing the recommendations concerning A1143.

13. MPI has reviewed the FSANZ reports for A1138 and A1143 and considers that FSANZ has competently assessed the applications, and that there are no grounds for New Zealand to oppose the acceptance of these applications (meaning that the Food Standards Code is amended to allow the sale of these new GM foods).

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

14. As noted in B17-0687, the FSANZ assessment for new GM foods has two main elements – mandatory pre-market approval, and mandatory labelling elements. These elements are addressed below, for each application.

Application A1138– Food derived from Provitamin A Rice Line GR2E

15. Application A1138 was made by the International Rice Research Institute (a non-government humanitarian organisation) to seek approval for food derived from rice line GR2E. This rice is also known as 'Golden Rice' and is genetically modified to produce beta-carotene (the predominant form of provitamin A) and other minor provitamin A carotenoids. The main purpose is to provide a source of vitamin A in a staple food that is commonly eaten for populations at risk of vitamin A deficiency. Vitamin A deficiency has significant detrimental effects and is common in a number of developing countries. There are other versions of Golden Rice, based on different genetic modifications. Golden Rice is therefore a collective term, covering a number of versions of rice with this particular nutritional modification.

16. The Institute intends for Golden Rice to be grown in developing countries where there is a risk of vitamin A deficiency, including Bangladesh, Indonesia and the Philippines), for humanitarian purposes. A Humanitarian Use Licence must be obtained, which will not be applicable or needed in Australia or New Zealand, as vitamin A deficiency is not prevalent in our populations. The Licence states the following: "*No export allowed (except for research to other licensees): this is a humanitarian project, i.e. the seeds are meant to cover the daily requirements of the poor that are deficient in vitamin A".* The rice is therefore not permitted to be exported from countries that hold a licence, and is therefore not intended for sale in New Zealand or Australia.

17. The application has been submitted in order to avoid trade issues, meaning that trace amounts could be present in shipments of imported conventional rice, without disrupting trade. It is important to note that the countries that New Zealand primarily imports rice from (Australia, Thailand and the USA), are not in general regions where the rice may be grown for the humanitarian purpose. Nevertheless, the application is on the basis that a consignment of rice could potentially contain a very small amount of the GR2E rice, and approval of the application will mean the shipment is not rejected at the Australia or New Zealand border.

18. While the rice is not intended for sale in Australia or New Zealand, FSANZ is required to assess the safety and labelling requirements, as if it were to be sold and part of our food supply. FSANZ's dietary intake assessment therefore assumed the replacement of all rice in the Australian and New Zealand markets with GR2E rice.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

FSANZ Assessment – Premarket approval

19. FSANZ conducted a safety assessment, and concluded that food derived from rice line GR2E is considered to be as safe for human consumption as food derived from conventional rice cultivars. MPI, in consultation with experts from the Environmental Science and Research (ESR) reviewed the safety assessment, agrees with FSANZ that no risks were identified.

20. FSANZ conducted a nutrition risk assessment, and based on a comparison of the β–carotene doses resulting in no adverse effects in human studies and the relatively small increase in total dietary intake of β–carotene due to consumption of GR2E rice, concluded that GR2E rice consumption will not pose a nutritional risk to the Australian and New Zealand population. As noted above, this assumes the replacement of all rice in our diets with GR2E rice. MPI reviewed this nutrition risk assessment, and agrees with FSANZ that no nutritional risks are identified.

FSANZ assessment - Labelling

21. As noted in B17-0687, GM foods are subject to labelling provisions. In the case of food derived from GR2E rice, the following applies, based on the principles set out in the Food Standards Code and FSANZ's assessment of the requirements:
    - Whole rice and unrefined rice (whether sold whole or used as an ingredient) – *must be labelled as 'genetically modified'*
    - Any rice product derived from GR2E that contains beta-carotene (eg rice malt syrup) – *must be labelled as 'genetically modified'*
    - Rice products derived from GR2E that do not contain novel protein or novel DNA, and do not contain beta-carotene (therefore the same as the conventional counterpart food, e.g. rice bran oil) – *not required to be labelled as 'genetically modified'.*

22. The above requirements apply to GR2E rice (noting that this unlikely to be a reality, as the rice is not intended for sale in New Zealand or Australia). However, if there was inadvertent contamination of an imported shipment of another rice with GR2E rice, at a level greater than 10 g GR2E per kg of the imported rice (i.e. more than 1%), then the above GM labelling scenarios will apply. It is the responsibility of the supplier of rice to determine if there is any inadvertent contamination. Any supplier of imported rice would need to provide a data sheet with the shipment, which provides information on any contamination (and the level). This is in order to be able to comply with labelling requirements. In the case of this GM rice, the rice grains are a golden colour so contamination is more easily identified, than with other cases of inadvertent contamination of non-GM rice with GM rice.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

FSANZ consultation

23. FSANZ received 33 submissions, including one from MPI. Of the 33 submissions, 23 directly supported Option 1- the approval of GR2E in the Food Standards Code. Six submissions directly opposed Option 1 and two submissions implied (i.e. did not overtly state) opposition. All those overtly opposed to approval GR2E raised issues that are outside the scope of FSANZ's regulatory area.

24. No submissions from jurisdictions, including MPI, unreservedly supported Option 1, primarily due to questions over whether GM foods are captured as part of the *Fortification of Foods with Vitamins and Minerals* Policy Guideline. MPI commented that the Policy Guideline does not capture food fortified through genetic means. We therefore support the approach identified in paragraph 10 above, where further work on the Policy Guideline is undertaken as soon as possible.

25. South Australia Health and the New South Wales Food Authority stated in their submissions that a 'stop clock' on the application should be activated while policy matters are considered. These issues are addressed by FSANZ in the Approval report.

26. None of the submissions opposing the applications raised technical points related to the FSANZ safety assessment. However, MPI has been approached by GE Free New Zealand, who have raised a number of technical points. GE Free NZ did not make these points in a submission to FSANZ, during the consultation period. MPI has responded to the points made by GE Free NZ, firstly by email and then with a follow-up meeting on 23 January.

27. At the meeting on 23 January, GE Free NZ reiterated the points raised in their correspondence. They apologised for missing the opportunity to provide comments during the public consultation period, and were appreciative of the opportunity to meet with officials

28. In our view, GE Free NZ has not raised substantive points that would change the outcome of the FSANZ safety assessment, or our view of the assessment. GE Free NZ raised questions about the safety of two of the three introduced proteins, and the evidence FSANZ used to demonstrate any potential toxicity or allergenicity. GE Free NZ believe this GM food should be subject to animal feeding studies. An expert workshop conducted by FSANZ in 2007 identified there is no need for a routine requirement for submitting animal feeding studies to support the safety of GM foods. The need for feeding studies is considered on a case-by-case basis. There was no indication from the FSANZ assessment that feeding studies were required in this case (as the safety assessment did not contain any areas of uncertainty where animal feeding studies would reliably provide further information). GE Free NZ are concerned with the impact the rice will have on infants consuming rice-based weaning foods. While noting that the rice is not intended for our market, the FSANZ assessment demonstrates that no potential public health and safety concerns have been identified.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

29. GE Free NZ indicated that they would be writing to you, requesting that you seek a review of the recommendation, i.e. that you do not agree to the change to the Food Standards Code to permit GM rice as a food.

MPI view on the FSANZ recommendation

30. A noted earlier, if you agree with our advice that the GM rice is safe then in our view that are no grounds for requesting a review by FSANZ. The other grounds for requesting a review, are set out below. In our view, there are no grounds for requesting a review.
    - it is not consistent with existing policy guidelines set by the Council;
    - it is not consistent with the objectives of the legislation which establishes the Authority;
    - it does not protect public health and safety;
    - it does not promote consistency between domestic and international food standards where these are at variance;
    - it does not provide adequate information to enable informed choice;
    - it is difficult to enforce and/or comply with in both practical or resource terms;
    - it places an unreasonable cost burden on industry or consumers;
    - it is not consistent with the principles for the establishment of food standards set down in this Agreement, including consistency with both countries' World Trade Organization obligations and consistency with the domestic laws and regulations of both countries; and/or
    - it is inappropriate on the grounds of exceptional environmental or cultural factors.

31. MPI has reviewed the safety assessment prepared by FSANZ and agrees that food from GR2E rice does not present any public health or safety concerns, and therefore should be permitted for sale in Australia or New Zealand (while noting that the rice in not intended for sale in Australia or New Zealand, and that the application is based on preventing trade disruption should there be inadvertent presence in imported shipments of milled rice). MPI recommends that you accept this recommendation by FSANZ. MPI officials will consider if this application has raised an issue regarding the requirement by FSANZ to assess all GM foods, regardless of their intended use for the New Zealand and Australian population.

Application A1143 – Food derived from DHA Canola Line NS-B50027-4

32. This application from Nuseed Pty Ltd (a specialised global seed company) seeks approval for a new GM canola (*Brassica napus*) line, NS-B50027-4 (henceforth referred to as DHA canola). This canola line has been genetically modified to produce omega-3 long chain fatty acids, particularly docosahexaenoic acid (DHA), in the seed. Nuseed developed the seed, in collaboration with the Commonwealth Scientific and Industrial Research Organization (CSIRO). This land based source of omega-3 long chain fatty acids are a potential alternative to marine or algal sources.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

33. Canola seeds are processed into two major products, oil and meal. Canola oil is the major product intended for human consumption whereas the meal is used primarily as animal feed. In addition whole canola seeds can be used in products such as breads.

FSANZ Assessment - premarket approval

34. FSANZ conducted a safety assessment and concluded that food derived from DHA canola is considered to be as safe for human consumption as food derived from conventional canola cultivars. MPI reviewed the safety assessment prepared by FSANZ, and agrees that no public health and safety risks are identified.

35. FSANZ conducted a nutrition risk assessment, and concluded that DHA canola poses no nutritional public health risk as a result of increase in omega-3 long chain fatty acid intakes. MPI agrees with this view.

FSANZ assessment - Labelling

36. Food derived from DHA canola will be required to be labelled with the mandatory statement *'genetically modified'* if it contains novel DNA or novel protein, or if its nutritional profile differs from conventional variants. DHA canola oil is unlikely to contain novel DNA or novel protein due to the refining process used to extract the oil from the seed but it will have a nutritional profile that differs from canola oil derived from conventional (non-GM) canola seeds and thus will require the mandatory statement *'genetically modified'*. Whole DHA canola seeds will also require the mandatory statement *'genetically modified'* on the label of a package of food as the seeds contain novel DNA and novel protein as well as an altered nutritional profile.

37. Where food products include DHA canola oil or whole canola seeds as ingredients, but are not required to bear a label (for example, 'fresh' bread containing whole canola seeds made and packaged on the premises from which it is sold), the mandatory statement will need to accompany the food or be displayed in connection with the display of the food.

FSANZ consultation

38. FSANZ received three submissions, all from jurisdictions, including MPI. No submitters were opposed to the application. There were, however, several issues raised, that were addressed by FSANZ. All of MPI's suggestions for amendments have been made in the Approval report. The Victorian Government and South Australia Health raised specific policy issues regarding nutritionally-modified foods by means of genetic modification, including that Policy Guidelines should be reviewed to consider new fortification technologies. Paragraph 11 above notes that this will be considered by officials.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

MPI view on the FSANZ recommendation

39. MPI has reviewed the assessment prepared by FSANZ and agrees that food derived from DHA canola can be considered to be safe for human consumption. MPI recommends that you accept this recommendation and do not seek a review.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Appendix 1 – MPI's view in relation to Food Act 2014 matters

In amending or making food standards under the Food Act 2014, the Minister is required to take into account several matters set out in section 397 of the Food Act 2014.

Application A1138– Food derived from Provitamin A Rice Line GR2E

MPI's view is that FSANZ has met these requirements, as follows:

a) **the need to protect public health**: *Rice derived from GR2E has been assessed based on the data requirements for GM foods provided in the FSANZ Application Handbook which, in turn reflect internationally-accepted GM food safety assessment guidelines. No public health and safety concerns were identified in this assessment. Based on the available evidence, including detailed studies provided by the Applicant, food derived from GR2E is considered to be as safe and wholesome as food derived from other commercial rice lines.*

A nutrition assessment specifically considering intake of β-carotene concluded that GR2E rice consumption will not pose a nutritional risk to the Australian and New Zealand population.

b) **the desirability of avoiding unnecessary restrictions on trade**: *A food approval would prevent trade disruption should there be inadvertent presence in imported shipments of milled rice.*

c) **the desirability of maintaining consistency between the adopted joint food standards and those standards that apply internationally**: *the provision is enabling so is not inconsistent with any provisions applying internationally.*

d) **the need to give effect to New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol**: *the proposed changes meet the FSANZ Act objectives.*

e) **any other matters that the Minister considers relevant:** *we will consider the need for policy work to address GM approaches that are not intended for New Zealand or Australian populations.*

Adequate consultation - FSANZ undertook one round of public consultation, and FSANZ considered all submissions made. Documents relating to the application are available on the FSANZ website.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Application A1143 – Food derived from DHA Canola Line NS-B50027-4

MPI's view is that FSANZ has met these requirements, as follows:

a. **the need to protect public health**: Food derived from DHA canola has been assessed based on the data requirements in the FSANZ Application Handbook. No public health and safety concerns were identified in the safety assessment. The nutrition assessment concluded that food derived from DHA canola will not pose a nutritional risk to the Australian or New Zealand population.

b. **the desirability of avoiding unnecessary restrictions on trade**: *the provision is enabling and therefore facilitates trade.*

c. **the desirability of maintaining consistency between the adopted joint food standards and those standards that apply internationally**: *the provision is enabling so is not inconsistent with any provisions applying internationally.*

d. **the need to give effect to New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol**: *the proposed changes meet the FSANZ Act objectives.*

e. **any other matters that the Minister considers relevant:** *no matters identified by MPI.*

Adequate consultation - FSANZ undertook one round of public consultation, and FSANZ considered all submissions made. Documents relating to the application are available on the FSANZ website.

FSANZ Act 1991 section 18 Objectives of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
   a. the protection of public health and safety; and
   b. the provision of adequate information relating to food to enable consumers to make informed choices; and
   c. the prevention of misleading or deceptive conduct.

2. 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;
   e. any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Appendix 2– Letter from the FSANZ Board to Ministers, contained in Information provided by the Food Regulation Secretariat, attachment 2 of email dated 19 January 2018

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

55 Blackall Street
BARTON ACT 2600

AustraliaPO Box 5423

KINGSTON ACT 2604
Australia
Tel + 61 2 6271 2222 **Fax** +61 2 6271 2278
www.foodstandards.gov.au

Office of the Chair

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

The Hon Dr David Gillespie MP
Assistant Minister for Health
Parliament House
CANBERRA ACT 2600

Dear Minister

I am writing to you in your capacity as the Chair of the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) to notify you of an approval by the Board of Food Standards Australia New Zealand (FSANZ).

At its meeting on 6 December 2017, the FSANZ Board approved draft variations relating to the following genetically modified (GM) food applications:

- A1138 – Food derived from Provitamin A Rice Line GR2E
- A1143 – Food derived from DHA Canola Line NS-B50027-4

The Approval Reports are attached for the Forum's consideration.

During the public consultation period for Application A1138, several jurisdictions[1] raised concerns that FSANZ had not given regard to the Policy Guideline for *Fortification of Foods*

[1] SA Health, NSWFA, NZ MPI and VicDHHS

with Vitamins and Minerals. To a lesser extent a similar concern was raised for Application A1143 in relation to the Policy Guideline for *Addition of Substances other than Vitamins and Minerals*.

In approving the two applications, the FSANZ Board did not consider that these two Policy Guidelines should be applied to Applications A1138 and A1143 for different reasons. With respect to A1138, the *Fortification of Foods with Vitamins and Minerals* was considered out of scope because consultation documents accompanying the development of the Guideline clearly stated that 'fortification through genetic means is deemed to be beyond the scope of the paper'. Also, Standard 1.3.2 – Vitamins and Minerals which regulates addition of permitted chemical forms of vitamins and minerals to food was referenced in that Guideline. The Policy Guideline for *Addition of Substances other than Vitamins and Minerals* was not applied to A1143 because the Australia New Zealand Food Standards Code currently regulates oils rich in DHA as novel food rather than (nutritive) substances.

On this basis, the Board considered that fortification through the use of breeding tools that involve any changes to the genome of an organism are not covered by the Guidelines.

The Board nevertheless recognised the concerns of some stakeholders around the applicability of certain Policy Guidelines to the recently approved GM food applications.
Without wishing to have the Forum's process interrupted, the Board would welcome further development of the suite of Policy Guidelines as a result of issues raised by these two Applications. Such a development would set out the Forum's expectations on future GM food applications involving a nutritional change and guide the insertion into the FSANZ Application Handbook of legislative data requirements that may need to be considered by an Applicant.

Given the highly technical nature of changes in food composition through genetic means, FSANZ wishes to offer our expertise to contribute to any deliberations the Forum may have on further development of the Policy Guidelines.

Yours sincerely

s 9(2)(a)

19 December 2017

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982

Appendix 3 – Minister Out-of-Session Response Sheet

RELEASED UNDER THE OFFICIAL INFORMATION ACT 1982