

3 August 2017
[20–17]

Call for submissions – Application A1138

Food derived from Provitamin A Rice Line GR2E

FSANZ has assessed an Application made by the International Rice Research Institute to seek approval for food derived from rice line GR2E genetically modified to produce provitamin A in the grain. A draft food regulatory measure has been prepared and, pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 14 September 2017

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

| | |
|--|-----------|
| EXECUTIVE SUMMARY | 2 |
| 1 INTRODUCTION | 3 |
| 1.1 THE APPLICANT | 3 |
| 1.2 THE APPLICATION..... | 3 |
| 1.3 THE CURRENT STANDARDS | 3 |
| 1.4 REASONS FOR ACCEPTING APPLICATION | 4 |
| 1.5 PROCEDURE FOR ASSESSMENT | 4 |
| 2 SUMMARY OF THE ASSESSMENT | 4 |
| 2.1 SAFETY AND NUTRITION ASSESSMENT | 4 |
| 2.2 RISK MANAGEMENT | 5 |
| 2.2.1 <i>Labelling</i> | 6 |
| 2.2.2 <i>Detection methodology</i> | 7 |
| 2.2.3 <i>Trade considerations</i> | 7 |
| 2.3 RISK COMMUNICATION..... | 8 |
| 2.3.1 <i>Consultation</i> | 8 |
| 2.3.2 <i>World Trade Organization (WTO)</i> | 8 |
| 2.4 FSANZ ACT ASSESSMENT REQUIREMENTS | 9 |
| 2.4.1 <i>Section 29</i> | 9 |
| 2.4.2 <i>Subsection 18(1)</i> | 11 |
| 2.4.3 <i>Subsection 18(2) considerations</i> | 12 |
| 3 DRAFT VARIATION | 12 |
| 4 REFERENCES | 13 |
| ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> | 14 |
| ATTACHMENT B – DRAFT EXPLANATORY STATEMENT..... | 16 |

Supporting documents

The [following documents](#)¹ which informed the assessment of this Application are available on the FSANZ website:

- SD1 Safety Assessment Report
- SD2 Nutrition Risk Assessment Report

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1138GMriceGR2E.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from the International Rice Research Institute on 16 November 2016. The Applicant requested a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) rice (*Oryza sativa*) line, GR2E. This rice line has been genetically modified to produce beta (β)-carotene (the predominant form of provitamin A) and other minor provitamin A carotenoids in the endosperm of the rice grain.

GR2E is a new food crop designed to mitigate vitamin A deficiency in developing countries. GR2E is not intended to be used in the Australian or New Zealand food supplies. Approving this crop will prevent trade disruption should GR2E be inadvertently present in imported shipments of milled rice.

The primary objective of FSANZ in developing or varying a food regulatory measure, as stated in section 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), is the protection of public health and safety. Accordingly, the safety assessment is a central part of considering an application.

The Safety Assessment of GM rice line GR2E is provided in Supporting Document 1 and the Nutrition Risk Assessment is provided in Supporting Document 2. No potential public health and safety concerns have been identified. Based on the data provided in the present Application, and other available information, food derived from line GR2E is considered to be as safe for human consumption as food derived from conventional rice cultivars.

FSANZ has prepared a draft variation to Schedule 26 that includes a reference to food derived from provitamin A rice line GR2E.

1 Introduction

1.1 The Applicant

The International Rice Research Institute (IRRI) is an independent, non-profit, research and educational institute dedicated to: reducing poverty and hunger through rice science; improving the health and welfare of rice farmers and consumers; and protecting the rice-growing environment for future generations.

1.2 The Application

Application A1138 was submitted by IRRI on 16 November 2016. It seeks a variation to Schedule 26 in the *Australia New Zealand Food Standards Code* (the Code) to include food from a new genetically modified (GM) rice (*Oryza sativa*) line, GR2E. This rice line has been genetically modified to produce beta (β)-carotene (the predominant form of provitamin A) and, to a lesser extent, the two other forms of provitamin A (α -carotene and β -cryptoxanthin) in the endosperm of the rice grain. This trait has been achieved through expression of a phytoene synthase protein (PSY1) encoded by a gene (*Zmpsy1*) from *Zea mays* (corn) and a carotene desaturase protein (CRTI) encoded by a gene (*crtI*) from the bacterium *Pantoea ananatis*. These two proteins, normally absent in rice endosperm, supply the necessary intermediates to support a functional β -carotene biosynthetic pathway. The collective name 'Golden Rice' has been used to describe a number of versions of rice containing these two proteins (not necessarily from the same genes as used in GR2E).

GR2E also contains the bacterial *phosphomannose isomerase* (*pmi*) gene which is derived from *Escherichia coli* strain K-12. Expression of the PMI protein in cells allows growth on mannose as a carbon source. This was used as a selectable marker to assist with identification of transformed rice cells in the early stages of selection. The PMI protein has been previously assessed by FSANZ in four corn applications – A564 (FSANZ 2006), A580 (FSANZ 2008a), A1001 (FSANZ 2008b) and A1060 (FSANZ 2012).

It is the Applicant's intention that lines containing the GR2E event be cultivated for humanitarian purposes in developing countries including Bangladesh, Indonesia and the Philippines which are at high risk of vitamin A deficiency (VAD) and where 30–70% of energy intake is derived from rice. The Applicant notes that GR2E rice will not solve the issue of population-based VAD for these populations but can be part of an overarching strategy to reduce VAD. Countries wishing to adopt the Golden Rice technology are free to introduce the GR2E event into preferred varieties that suit the local environment and meet certain criteria outlined in a Humanitarian Use Licence Agreement, subject to local regulatory arrangements.

Rice containing the GR2E event is not intended for commercialisation in Australia or New Zealand (either for growing or intentional sale in the food supply). The Applicant has however applied for food approval because it is possible the rice could inadvertently enter the food supply via exports from countries that may supply significant quantities of milled² rice to Australia or New Zealand.

1.3 The current standards

Pre-market approval is necessary before a GM food may enter the Australian and New Zealand food supply.

² Milled or white rice is rice that has had the embryo and outer seed layers removed, and therefore consists only of the starchy storage tissue known as the endosperm.

Approval of such foods is contingent on completion of a comprehensive pre-market safety assessment. Standard 1.5.2 – Food produced using gene technology, sets out the permission and conditions for the sale and use of food produced using gene technology (a GM food). Foods that have been assessed and approved are listed in Schedule 26 – Food produced using gene technology.

Standard 1.5.2 also contains specific labelling provisions for approved GM foods. GM foods and ingredients (including food additives and processing aids from GM sources) must be identified on labels with the words 'genetically modified' if novel DNA or novel protein (as defined in Standard 1.5.2) is present in the food.

Foods listed in subsections S26—3(2), (2A) and (3) of Schedule 26 must also be labelled with the words 'genetically modified', as well as any other additional labelling required by the Schedule regardless of the presence of novel DNA or novel protein in the foods. Foods listed in subsections S26—3(2), (2A) and (3) are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not produced using gene technology.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Safety and nutrition risk assessment

In conducting an assessment of food derived from GR2E, several criteria have been addressed including: a characterisation of the transferred gene sequences, their origin, function and stability in the rice genome; the changes at the level of DNA and protein in the whole food; compositional analyses; an evaluation of intended and unintended changes; and a nutrition risk assessment in relation to β -carotene intake.

Supporting Document 1 (SD1) which deals with the genetic modification *per se* did not identify any potential public health and safety concerns. It concludes that, based on the data provided in the Application and other available information, food derived from GR2E is considered to be as safe for human consumption as food derived from conventional rice cultivars. It is noted this document focusses on human food safety and therefore does not address any risks to the environment that may occur as the result of growing GM plants used in food production or any risks to animals that may consume feed derived from GM plants.

Supporting Document 2 (SD2) reports on the nutrition risk assessment and includes a nutrition hazard assessment that considered potential adverse effects associated with β -carotene intake, and a dietary intake assessment for β -carotene that assumes all rice (including brown and milled rice, rice bran and rice bran oil³ that are consumed as is or in processed foods and mixed dishes) consumed in Australia and New Zealand are replaced with GR2E products.

Provitamin A carotenoids present in GR2E, namely alpha (α)-carotene, β -carotene and β -cryptoxanthin, are precursors of vitamin A that are widely available in vegetables, fruits and cereals. However, high intake of β -carotene in foods or from supplements has not been associated with vitamin A toxicity. Carotenemia, a clinically benign condition involving yellow to orange skin pigmentation, can occur after intakes of large amounts of carotene-rich foods or high doses of β -carotene (≥ 30 mg/day) in supplement form. Daily intake of up to 50 mg β -carotene in supplemental form for several years did not result in adverse health effects in healthy people or people with different forms of cancer, except those with or at risk of developing lung cancer. A slight, but statistically significant, increased incidence of lung cancer and mortality rate was shown in heavy smokers taking 20 mg β -carotene supplements per day for 5 to 8 years. This risk was shown to decline within four to six years after discontinuing β -carotene supplementation.

The dietary intake assessment concludes that if all rice in the Australian and New Zealand markets was replaced with GR2E products this may result in a 2–13% (40-336 μg per day) increase in estimated intakes of β -carotene by Australian and New Zealand population groups. The increase in β -carotene intakes is equivalent to the amount of β -carotene from approximately 1 teaspoon or less of carrot juice.

Based on a comparison of the 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 products, it is concluded that GR2E rice consumption will not pose a nutritional risk to the Australian and New Zealand population.

2.2 Risk management

FSANZ has considered the safety of the GR2E genetic modification, and public health nutrition issues that may arise should food derived from GR2E be sold in Australia and New Zealand (section 2.1, SD1 and SD2).

FSANZ notes that rice containing the GR2E event is not intended for commercialisation in Australia or New Zealand (as noted under section 1.2). It is also noted that GR2E paddy or brown rice could not be imported into Australia or New Zealand without an environmental approval from the Office of the Gene Technology Regulator in Australia (OGTR) or the Environmental Protection Authority in New Zealand (EPA) (see section 2.2.3). However, since these current arrangements may change in the future, approval of the GR2E rice line in the Code would allow any food derived from it to be sold in Australia and New Zealand. FSANZ's dietary intake assessment (SD2) therefore assumes the replacement of all rice in the Australian and New Zealand markets with GR2E rice and its products, should these be commercialised in Australia and New Zealand in the future.

Based on the conclusions of the safety assessment on the GR2E genetic modification (SD1), and the conclusions of the nutrition risk assessment (SD2), FSANZ considers that permitting food derived from GR2E to be sold in Australia and New Zealand poses no risk to public health and safety.

³ Noting that the inclusion of rice bran and rice bran oil in the modelling is highly conservative as it is unlikely β -carotene would be present in these GR2E products.

2.2.1 Labelling

2.2.1.1 Requirement to be labelled as 'genetically modified'

In accordance with the labelling provisions in Standard 1.5.2, food derived from GR2E would be required to be labelled as 'genetically modified' if it: contains novel DNA or novel protein; or is listed in subsections S26—3(2), (2A) and (3) of Schedule 26 as being subject to the condition that the labelling must comply with section 1.5.2—4 of Standard 1.5.2 (such food has altered characteristics).

FSANZ has determined that whole rice and unrefined rice products derived from line GR2E will contain novel DNA and novel protein, as well as an altered nutritional profile (contains β -carotene), and as such would be required to carry the mandatory statement 'genetically modified' on the label of the package of food. This labelling requirement would apply to rice sold as a single ingredient food (e.g. a package of rice) and when the rice is used as an ingredient in another food (e.g. rice flour, rice milk).

FSANZ is also proposing to list foods derived from GR2E, that contain β -carotene as a result of the genetic modification, in subsection S26—3(2A) of Schedule 26. The purpose of this listing is to ensure foods with an altered characteristic are labelled with the mandatory 'genetically modified' statement irrespective of the presence of novel DNA or novel protein. For example in the case of GR2E, there may be products such as rice malt syrup where novel DNA and novel protein is absent but the product may have an altered nutritional profile (contains β -carotene) that would trigger the requirement for the mandatory statement.

Another product from rice is rice bran oil. In accordance with the existing labelling provisions in Standard 1.5.2, rice bran oil derived from GR2E is unlikely to require labelling because it is unlikely to contain novel DNA or novel protein, or have an altered nutritional profile (β -carotene is absent). The composition and characteristics of this highly refined product would therefore be the same as rice bran oil made from conventionally produced (non-GM) rice.

In summary, Table 1 below lists scenarios in which the mandatory statement would or would not apply, if food derived from GR2E was ever made commercially available in Australia or New Zealand or was unintentionally present in a food (e.g. an imported food) in an amount of more than 10 g per kilogram of each ingredient.

Table 1: Application of labelling requirements for GR2E food and ingredients

| GR2E Food/Ingredient | Mandatory statement |
|--|---------------------|
| Contains novel DNA or novel protein | ✓ |
| Contains β -carotene | ✓ |
| Novel DNA or protein absent but contains β -carotene | ✓ |
| Novel DNA or protein and β -carotene not present i.e. the same as its conventional (non-GM) counterpart | x |

2.2.1.2 Need for additional labelling requirements

Labelling of GM food is intended to address the objective set out in paragraph 18(1)(b) of the FSANZ Act—the provision of adequate information relating to food to enable consumers to make informed choices. For this reason, FSANZ has considered whether additional labelling (i.e. in addition to the mandatory 'genetically modified' statement described above) is required to alert consumers to the nature of the altered characteristic when compared to non-GM rice. Rice from line GR2E will appear yellow because β -carotene is present. However, FSANZ is not proposing additional mandatory labelling for the following reasons:

- Rice containing the GR2E event is not intended at this time to be sold commercially in Australia or New Zealand (as noted under section 1.2).
- If sold in Australia or New Zealand, rice containing the GR2E event will be required to be labelled as 'genetically modified' (see above). Ingredients derived from GR2E, would also be required to have the 'genetically modified' labelling statement if they contain novel DNA, novel protein or β -carotene. Other labelling requirements would also apply to such foods, including the requirements contained in Standards 1.2.2 (Information requirements – food identification) and 1.2.4 (Information requirements – statement of ingredients).
- If rice containing the GR2E event is unintentionally present in a food sold in Australia or New Zealand (e.g. imported rice) in an amount of more than 10 g per kilogram of each ingredient (that is, more than 1%), that food will be required to be labelled as 'genetically modified' (see above).
- Suppliers are unlikely to be able to make voluntary nutrition content claims or health claims because the amount of Vitamin A (β -carotene as [retinol equivalents](#)⁴) in GR2E would be insufficient to meet claim conditions. To require a statement to the effect that the food has been genetically modified to contain Vitamin A as β -carotene could imply the food contributes a nutritionally significant amount of this vitamin, when the actual amount may be negligible, and therefore be potentially misleading.

2.2.2 Detection methodology

An Expert Advisory Group (EAG), involving laboratory personnel and representatives of the Australian and New Zealand jurisdictions was formed by the Food Regulation Standing Committee's Implementation Sub-Committee⁵ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food derived from gene technology (GM applications).

The EAG indicated that for GM applications, the full DNA sequence of the insert and adjacent genomic DNA are sufficient data to be provided for analytical purposes. Using this information, any DNA analytical laboratory would have the capability to develop a PCR-based detection method. This sequence information was supplied by the Applicant for A1138. Further to this, however, an event-specific quantitative method for detection of GR2E has been developed and has been referenced on the website of the [European Commission Joint Research Centre](#)⁶

2.2.3 Trade considerations

The Applicant has indicated there is no intention to apply for commercial cultivation of GR2E in Australia or New Zealand. If cultivation were sought, it would require independent assessment and approval by the OGTR or EPA. Providing permission for growing, and/ or distributing GR2E rice overseas is the responsibility of local regulatory agencies.

Although GR2E rice is not likely to be grown or sold in Australia or New Zealand, it may be inadvertently present in imported consignments of milled rice.

⁴ For an explanation of retinol equivalents see <https://www.nrv.gov.au/nutrients/vitamin-a>

⁵ Now known as the Implementation Subcommittee for Food Regulation

⁶ JRC method for detection of GR2E - http://gmo-crl.jrc.ec.europa.eu/gmomethods/entry?db=gmometh&id=qt-eve-os-001&q=id%3aQT-eve-OS*

In 2013 Australia imported 145,370 tonnes of milled rice (representing around 45% of the rice consumed, according to figures in [Ricepedia](#)⁷) with the main suppliers being Thailand (49%), India (19%) and Pakistan (13%) (FAOSTAT 2017). In the same year, New Zealand imported 42,381 tonnes of milled rice with the main suppliers being Australia (39%), Thailand (26%), and the U.S. (13%). While none of these countries is currently targeted for growing GR2E, some of them are in general regions where GR2E rice may be grown and may inadvertently enter export consignments. Without a permission in the Code, a consignment of milled rice with a very small amount of GR2E rice present could be rejected at the Australian or New Zealand border and thereby create trade disruption. This Application therefore facilitates trade and ensures the ongoing supply of milled rice into Australia and New Zealand.

It should be noted that uncooked GR2E paddy or brown rice could not be imported into Australia or New Zealand without an environmental approval from the OGTR or EPA because the presence of the embryo means the rice could be germinated i.e. would be regarded as a viable genetically modified organism.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received on this call for submissions.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum on Food Regulation. If the Board's decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the website.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit food derived from GR2E is unlikely to have a significant effect on international trade, given the humanitarian intention of the growing of GR2E. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

⁷ Ricepedia: the online authority on rice <http://ricepedia.org/australia>

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 24 November 2010, granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of genetically modified foods (ref 12065).

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a cost benefit analysis. That analysis found the direct and indirect benefits arising from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, government or industry that would arise from the development or variation of that measure. A consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

The options below are based on rice containing event GR2E being commercialised (see section 2.2.3) noting that, if it were, cultivation in Australia or New Zealand would require separate regulatory approval.

Option 1 – Prepare a draft variation to Schedule 26

Industry: Rice derived from GR2E and its products would be permitted under the Code and therefore any rice grain imports that inadvertently contained the GR2E event would not be prevented from entering either country.

The segregation of grain from GR2E from conventional rice grain, as for any GM crop, will be driven by industry based on market preferences. Implicit in this will be a due regard to the cost of segregation.

There may be additional costs to the food industry as food ingredients derived from GR2E would require the 'genetically modified' labelling statement if they contain novel DNA, novel protein or β -carotene.

Since the permission relates to rice derived from GR2E and noting current OGTR or EPA requirements, this could potentially include future imports of such milled rice grain, or food products made overseas containing this brown or milled rice, or domestic products containing imported milled rice.

Consumers: Rice derived from GR2E has been assessed as being as safe as food from conventional lines of rice.

For GR2E rice grain or products containing novel DNA, novel protein or β -carotene, labelling would allow consumers wishing to avoid these products to do so.

If GR2E rice is approved for growing in overseas countries, it could be used in the manufacture of products using this co-mingled rice grain. This means that there would be no cost involved in having to exclude GR2E grain from co-mingling and hence that there would be no consequential need to increase the prices of foods that are manufactured using co-mingled rice grain.

Since the permission relates to rice derived from GR2E and noting current OGTR or EPA requirements, consumers could potentially have access to future imports of such milled rice grain, food products containing this brown or milled rice made overseas, or domestically made products containing imported milled rice.

Government: Approval would avoid any conflict with WTO obligations. As mentioned above, food from GR2E has been assessed as being as safe as food from conventional lines of rice.

This option would be cost neutral in terms of compliance costs, as monitoring is required irrespective of whether or not a GM food is approved.

In the case of approved GM foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of GM foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply.

Option 2 – Reject application

Industry: Possible restriction on imports of rice grain and products, if GR2E were to be commercialised overseas.

Consumers: Possible restriction in the availability of imported rice products which may be produced after inadvertent co-mingling of grain from GR2E. There would be no effect for consumers wishing to avoid GM foods, as food from GR2E is not currently permitted in the food supply.

A potential increase in price of imported rice food products could occur due to requirement for segregation of GR2E grain.

Government: Potential effect if considered inconsistent with WTO obligations but this would be in terms of trade policy rather than for government revenue.

As rice from GR2E has been found to be as safe as food from conventional lines of rice, not preparing a draft variation offers little benefit to consumers, as approval of GR2E by other countries (in the event this should occur) could limit the availability of imported rice products in the Australian and New Zealand markets. FSANZ has decided to prepare a draft variation to Schedule 26 because the potential benefits of approving the variation outweigh the potential costs, and because no public health or safety concerns resulting from consumption of food derived from GR2E were identified in the safety assessment.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of Application A1138.

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.2 and Schedule 26 also apply in New Zealand.

2.4.1.4 Any other relevant matters

The Applicant has submitted applications for regulatory approval of GR2E to a number of other countries, as listed in Table 2.

Table 2: List of countries to which applications for regulatory approval of GR2E have been submitted

| Country | Agency | Type of approval sought | Status |
|-------------|---|-------------------------|------------------|
| USA | Food & Drug Administration (FDA) | food & feed | Under assessment |
| Canada | Health Canada | food | Under assessment |
| Philippines | Department of Agriculture, Bureau of Plant Industry | food, feed, processing | Under assessment |

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

Rice derived from GR2E has been assessed based on the data requirements for GM foods provided in the FSANZ [Application Handbook](#)⁸ 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.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

In accordance with existing labelling provisions to enable informed consumer choice, food derived from GR2E would have to be labelled as 'genetically modified' if it contains novel DNA, novel protein or β -carotene (see section 2.2.1).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of an event-specific detection method by the Applicant will permit the detection of food derived from GR2E (see section 2.2.2).

⁸ <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's approach to the safety assessment of all GM foods applies concepts and principles outlined in the Codex Principles for the Risk Analysis of Foods derived from Biotechnology (Codex 2004). Based on these principles, the risk analysis undertaken for GR2E used the best scientific evidence available. The Applicant submitted to FSANZ a comprehensive dossier of quality-assured raw experimental data. In addition to the information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in the safety assessment.

- **the promotion of consistency between domestic and international food standards**

This is not a consideration as there are no relevant international standards.

- **the desirability of an efficient and internationally competitive food industry**

The inclusion of GM foods in the food supply, providing there are no safety concerns, allows for innovation by developers and a widening of the technological base for producing foods. GR2E is a new food crop designed to mitigate vitamin A deficiency in developing countries. While GR2E is not intended for the Australian or New Zealand food supplies, a food approval would prevent trade disruption should there be inadvertent presence in imported shipments of milled rice.

- **the promotion of fair trading in food**

Issues related to consumer information and safety are considered in sections 2.2 and 2.3 above.

- **any written policy guidelines formulated by the Forum on Food Regulation**

No policy guidelines apply to this Application. FSANZ notes that, in developing the Policy Guideline *Fortification of Food with Vitamins and Minerals*, 'fortification through genetic means' was explicitly deemed to be [beyond the scope of the Guideline](#)⁹. This is the same approach that equally applies to food containing a modified nutrient content achieved through conventional breeding techniques.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on the date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

⁹[http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/24E85FF75806731ACA257FE300077FA7/\\$File/12-2003-FRSC-Consultation%20Paper-Fortification%20Food%20supply%20with%20Vitamins%20Minerals.docx](http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/24E85FF75806731ACA257FE300077FA7/$File/12-2003-FRSC-Consultation%20Paper-Fortification%20Food%20supply%20with%20Vitamins%20Minerals.docx)

4 References

Codex (2004) Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. Codex Alimentarius Commission, Rome.

<http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/>

FSANZ (2006) Application A564 - Food derived from insect-protected corn line MIR604. Report prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/code/applications/pages/applicationa564foodd2972.aspx>

FSANZ (2008a) Application A580 - Food derived from amylase-modified corn line 3272. Report prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/code/applications/pages/applicationa580foodd3243.aspx>

FSANZ (2008b) Application A1001 - Food derived from insect-protected corn line MIR162. Report prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/code/applications/pages/applicationa1001food3769.aspx>

FSANZ (2012) Application A1060 - Food derived from insect-protected corn line 5307. Report prepared by Food Standards Australia New Zealand.

<http://www.foodstandards.gov.au/code/applications/pages/applicationa1060food5180.aspx>

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1138 – Food derived from Provitamin A Rice Line GR2E) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1138 – Food derived from Provitamin A Rice Line GR2E) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 1.5.2 is varied by omitting the words ‘subsections S26—3(2) and (3)’ from subparagraph 1.5.2—4(1)(a)(ii), substituting ‘section S26—3’.

[2] Schedule 26 is varied by

[2.1] inserting after the Note to subsection S26—3(2)

(2A) Products containing beta-carotene from item 6(b) are subject to the condition that their labelling must comply with section 1.5.2—4

[2.2] inserting in the table to subsection S26—3(4), in alphabetical order under item 6

(b) provitamin A rice line GR2E

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1138 which seeks permission for the sale and use of food derived from a genetically modified rice line, GR2E, which produces provitamin A in the grain. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The variation inserts a reference to provitamin A rice line GR2E into Schedule 26 in order to permit the sale, or use in food, of food derived from that rice line.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1138 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement was not required because the sale of food derived from rice line GR2E, if approved, would be voluntary and would be likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Standard 1.5.2 by replacing the reference to 'subsections S26—3(2) and (3)' in subparagraph 1.5.2—4(1)(a)(ii) with a reference to 'section S26—3.' This is a consequential amendment required as a result of the variation proposed by Item [2.1] below.

Item [2] amends Schedule 26.

Item [2.1] inserts new subsection S26—3(2A) into Schedule 26. The new subsection will provide food derived from provitamin A rice line GR2E that contains beta-carotene as a result of the genetic modification must comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

Item [2.2] inserts new paragraph (b) into Item 6 in the table to subsection S26—3(4). Paragraph (b) refers to 'provitamin A rice line GR2E'. This amendment will permit the sale, or use in food, of food derived from provitamin A rice line GR2E.