

**20 December 2017**

**[35-17]**

Approval report – Application A1138

Food derived from Provitamin A Rice Line GR2E

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Food Standards Australia New Zealand (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 carotenoids, especially beta-carotene, in the grain.

On 3 August 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 33 submissions.

FSANZ approved the draft variation on 6 December 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 19 December 2017

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

# Table of contents

<b>EXECUTIVE SUMMARY .....</b>	<b>2</b>
<b>1 INTRODUCTION .....</b>	<b>3</b>
1.1 THE APPLICANT .....	3
1.2 THE APPLICATION .....	3
1.3 THE CURRENT STANDARDS .....	4
1.4 REASONS FOR ACCEPTING APPLICATION .....	4
1.5 PROCEDURE FOR ASSESSMENT.....	5
1.6 DECISION .....	5
<b>2 SUMMARY OF THE FINDINGS.....</b>	<b>5</b>
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS .....	5
2.2 SAFETY AND NUTRITION RISK ASSESSMENT .....	8
2.3 RISK MANAGEMENT .....	9
2.3.1 <i>Labelling</i> .....	10
2.3.2 <i>Detection methodology</i> .....	11
2.3.3 <i>Trade considerations</i> .....	12
2.4 RISK COMMUNICATION .....	12
2.4.1 <i>Consultation</i> .....	12
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS .....	13
2.5.1 <i>Section 29</i> .....	13
2.5.2 <i>Subsection 18(1)</i> .....	15
<b>3 REFERENCES.....</b>	<b>16</b>
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE .....	17
ATTACHMENT B – EXPLANATORY STATEMENT .....	19

## Supporting documents

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

- SD1 Safety Assessment Report (at Approval)
- SD2 Nutrition Risk Assessment Report (at Approval)

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<sup>1</sup> <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 ( $\beta$ )-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.

The FSANZ Board has approved the draft variation to Schedule 26 (including permission for food derived from provitamin A rice line GR2E) and Standard 1.5.2 (a consequential amendment).

# 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 ( $\beta$ )-carotene (the predominant form of provitamin A) and, to a lesser extent, the two other forms of provitamin A ( $\alpha$ -carotene and  $\beta$ -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  $\beta$ -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 i.e. 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 milled<sup>2</sup> rice to Australia or New Zealand.

<sup>2</sup> 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.

## 1.3 The current Standards

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

Approval of such foods is contingent on completion of a comprehensive pre-market safety assessment. Standard 1.5.2 – 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.

Section 1.5.2—4 of 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) 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) 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.

The requirement to label food as 'genetically modified' does not apply to GM food that:

- has been highly refined (other than food that has been altered), where the effect of the refining process is to remove novel DNA or novel protein
- is a substance used as a processing aid or a food additive, where novel DNA or novel protein from the substance does not remain present in the final food
- is a flavouring substance present in the food in a concentration of no more than 1 g/kg (0.1%)
- is intended for immediate consumption and which is prepared and sold from food premises and vending machines, including restaurants, take away outlets, caterers, or self-catering institutions
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

If the GM food for sale is not required to bear a label, the labelling information referred to in section 1.5.2—4 must accompany the food or be displayed in connection with the display of the food (in accordance with subsections 1.2.1—9(2) and (3) of Standard 1.2.1).

## 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 was assessed under the General Procedure.

## 1.6 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A. The related 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.

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

A total of 33 submissions were received of which 11 were very similarly worded. A campaign (entitled *Speak up NOW for Golden Rice*) urging positive comments on GR2E to both FSANZ and the Philippines biotechnology regulator (Bureau of Plant Industry), which was also seeking public comments on GR2E at the same time as FSANZ, was initiated by the [Cornell Alliance for Science](http://allianceforscience.cornell.edu)<sup>3</sup>; and a further nine submissions were most likely generated as a result of the campaign but did not follow exactly the same wording as the 11 similar submissions. As a result of the campaign, submissions to FSANZ were received from individuals and non-government organisations in Japan, India, the Netherlands, Vietnam, China, Kenya, the U.S.A., Brazil, Spain, and Argentina, as well as from Australia and New Zealand.

Of the 33 submissions, 23 directly supported Option 1 – the approval of GR2E in the Code. No submissions from jurisdictions unreservedly supported Option 1 due to questions over whether GM foods were captured as part of fortification policy and labelling issues. Six submissions directly opposed Option 1 and two submissions implied (i.e. did not overtly state) opposition.

All those overtly opposed to approval of GR2E raised issues that are outside the scope of FSANZ's regulatory area and included concern about an approval influencing regulatory processes in the Philippines where GR2E has not yet been approved; the efficacy of GR2E in lessening Vitamin A deficiency (VAD) in affected countries; the social effect (particularly on farmers) of GR2E in VAD-affected countries; and general issues of GM food safety not related to the GR2E application.

The main issues, within scope, raised in the public consultation are addressed in Table 1.

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<sup>3</sup> <http://allianceforscience.cornell.edu/topic/gmo>

**Table 1: Summary of issues**

Issue	Raised by	FSANZ response
<p>Several policy issues regarding nutritionally modified foods by means of genetic modification were raised, including that:</p> <ul style="list-style-type: none"> <li>• policy concerning biofortification should be considered by the Food Regulation Standing Committee (FRSC)</li> <li>• the <i>Fortification of Foods with Vitamins and Minerals</i> Policy Guideline does not expressly exclude fortification by genetic means</li> <li>• as the first nutritionally modified GM food application, it sets an important precedent regarding policy consideration</li> <li>• Codex Alimentarius is currently working on a definition for biofortification.</li> </ul>	<ul style="list-style-type: none"> <li>• NSW Food Authority (NSWFA)</li> <li>• SA Health</li> <li>• Victorian Government Departments of Health &amp; Human Services and Economic Development, Jobs, Transport &amp; Resources (Vic Govt)</li> <li>• New Zealand Ministry for Primary Industries (NZ MPI)</li> </ul>	<p>Policy review and development is the role of FRSC and the Forum on Food Regulation (the Forum), and not FSANZ.</p> <p>As noted in section 2.5.3, fortification through genetic means was explicitly deemed to be beyond the scope in developing the <i>Fortification of Foods with Vitamins and Minerals</i> Policy Guideline. FSANZ is not aware of any further consideration of, or change to, this position by FRSC or the Forum.</p> <p>Noted.</p> <p>The ongoing work by the Codex Committee on Nutrition and Foods for Special Dietary Uses in drafting a biofortification definition is noted. No definition is yet confirmed and cannot be used as clear guidance at this time.</p>
<p>A 'stop clock' on the application could be activated while policy matters are considered.</p>	<ul style="list-style-type: none"> <li>• SA Health</li> <li>• NSWFA</li> </ul>	<p>FSANZ must process applications in accordance with the <i>FSANZ Act 1991</i>. Section 109 of that Act sets out when FSANZ may stop the clock on an application. It permits FSANZ to suspend consideration of an application if the Forum has notified FSANZ that the Forum is formulating a policy guideline and the application, in FSANZ's opinion, would be affected by that policy guideline, once formulated. No such notification has been received from the Forum that would affect FSANZ's consideration of this application.</p>
<p>GR2E rice could be imported and sold in Australia and New Zealand without consideration of the impact on, or need for, the intake of Vitamin A.</p>	<ul style="list-style-type: none"> <li>• Vic Govt</li> </ul>	<p>FSANZ's nutrition risk assessment did consider the impact on potential <math>\beta</math>-carotene (provitamin A) intakes in the population. This found an estimated increase in intake equivalent to the amount of <math>\beta</math>-carotene from approximately 1 teaspoon or less of carrot juice (see sections 2.2, 2.3 and SD2).</p>

Issue	Raised by	FSANZ response
<p>GR2E is the first GM food application FSANZ has assessed that intentionally alters nutritional content; it would set a precedent if nutritional changes are not labelled.</p>	<ul style="list-style-type: none"> <li>SA Health</li> </ul>	<p>FSANZ has previously assessed and approved food from five lines genetically modified for the purpose of changing the nutritional profile:</p> <ul style="list-style-type: none"> <li>– high lysine corn line LY038 (a line specifically targeted to the animal feed industry and not intended to enter the food supply)</li> <li>– high oleic acid soybean line DP-305423-1</li> <li>– herbicide-tolerant high oleic acid soybean line MON87705</li> <li>– soybean line MON87769 producing stearidonic acid</li> <li>– reduced acrylamide potential and reduced browning potato line E12 (containing reduced levels of asparagine, fructose and glucose)</li> </ul> <p>In the last four cases additional labelling to describe the nature of nutritional changes was not mandated. Therefore there is a precedent for not having additional labelling where the GM food has an altered nutritional content.</p> <p>In each of these four cases, FSANZ has considered the potential for consumer confusion – see next response.</p>
<p>Consumers should be informed of the nutritional change through additional labelling, for example in the nutrition information panel (NIP).</p>	<ul style="list-style-type: none"> <li>SA Health</li> <li>NZ MPI</li> </ul>	<p>FSANZ noted in the Call for Submissions that mandating a statement that the food has been genetically modified to contain Vitamin A as <math>\beta</math>-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 to consumers.</p> <p>FSANZ considers that the same issue would apply if a declaration of Vitamin A was mandated in the NIP. Further, consumers may not associate the Vitamin A content in the NIP with the ‘genetically modified’ statement appearing in the ingredient list or in conjunction with the name of the food.</p> <p>A declaration in the NIP for a mixed food may also prevent consumers from linking the Vitamin A content with the GR2E ingredient. Other ingredients may be viewed as the source, and in some cases these other ingredients may also contribute to the Vitamin A content of the food.</p>
<p>Imported processed food containing food derived from GR2E would not be labelled.</p>	<ul style="list-style-type: none"> <li>Slow Food Australia</li> </ul>	<p>All foods imported into Australia or New Zealand are required by law to comply with the Code requirements. FSANZ is proposing to apply the same regulatory approach that applies to all approved GM foods in Australia and New Zealand. If GR2E is approved in the Code, food derived from this GM line containing novel DNA or novel protein and/or beta-carotene would be required to carry the ‘genetically modified’ labelling statement. A few exceptions, as set out in the Code, would apply (for example, food intended for immediate consumption or certain highly refined products).</p> <p>Refer to section 2.3.1 for the labelling requirements.</p>



Issue	Raised by	FSANZ response
GR2E could end up in animal feed and enter the human food chain with no consumer awareness.	<ul style="list-style-type: none"> <li>Slow Food Australia</li> </ul>	<p>The Applicant notes that rice by-products, such as bran and straw, are used in livestock feed. The Code specifically excludes consideration of animals fed with approved GM food (whether intentional or accidental) as the animals are not themselves genetically modified and therefore the food products they produce (e.g. meat, milk and eggs) are not GM foods and do not require labelling. This regulatory approach has been in place since 2000 and applies to all approved GM foods in Australia and New Zealand.</p> <p>FSANZ is not aware of any international or overseas legislation that requires food products derived from animals fed GM food to be labelled.</p>
There has not been an appropriate level of public debate and disclosure within Australia about the potential for genetically modified rice to come into the country.	<ul style="list-style-type: none"> <li>Two private submitters</li> </ul>	<p>There has been ongoing public debate about GM foods in Australia since the GM food standard was first developed nearly 20 years ago. FSANZ welcomes enquiries on GM foods via a variety of communication interfaces and seeks to provide science-based and impartial information to all stakeholders. In addition, there is an open and transparent public consultation process for all GM food applications considered by FSANZ.</p> <p>FSANZ has approved food from over 70 GM lines covering eight species, including rice. The first approval for food from GM rice was made in 2008. The majority of GM foods enter the Australian food supply as imported products as very few GM crops are licensed by the OGTR for commercial growing in Australia. In this respect food from GR2E, in the event it were to become available in Australia, would be no different from these other GM foods.</p>

## 2.2 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  $\beta$ -carotene intake.

FSANZ's safety assessment, as reported in Supporting Document 1 (SD1) and which deals with the genetic modification *per se*, did not identify any potential public health and safety concerns. FSANZ concluded from its safety assessment, 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. SD1 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. Some minor changes in the SD1 released with the call for submissions have been made, related to correction of typographical errors.

Supporting Document 2 (SD2) reports on the nutrition risk assessment undertaken by FSANZ and includes a nutrition hazard assessment that considered potential adverse effects associated with  $\beta$ -carotene intake, and a dietary intake assessment for  $\beta$ -carotene that assumes all rice (including brown and milled rice, rice bran and rice bran oil<sup>4</sup> 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 ( $\alpha$ )-carotene,  $\beta$ -carotene and  $\beta$ -cryptoxanthin, are precursors of vitamin A that are widely available in vegetables, fruits and cereals. However, high intake of  $\beta$ -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  $\beta$ -carotene ( $\geq 30$  mg/day) in supplement form.

Daily intake of up to 50 mg  $\beta$ -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  $\beta$ -carotene supplements per day for 5 to 8 years. This risk was shown to decline within four to six years after discontinuing  $\beta$ -carotene supplementation.

The dietary intake assessment concluded 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  $\mu$ g per day) increase in estimated intakes of  $\beta$ -carotene by Australian and New Zealand population groups. The increase in  $\beta$ -carotene intakes is equivalent to the amount of  $\beta$ -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  $\beta$ -carotene due to consumption of GR2E rice products, FSANZ concluded that GR2E rice consumption will not pose a nutritional risk to the Australian and New Zealand population.

## 2.3 Risk management

FSANZ 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 2.3.3). However, since these current arrangements may change in the future, approval of the GR2E rice line in the Code allows any food derived from it to be sold in Australia and New Zealand. FSANZ's dietary intake assessment (SD2) therefore assumed 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.

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<sup>4</sup> Noting that the inclusion of rice bran and rice bran oil in the modelling is highly conservative as it is unlikely  $\beta$ -carotene would be present in these GR2E products.

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

### **2.3.1 Labelling**

#### **2.3.1.1 Requirement to be labelled as ‘genetically modified’**

In accordance with the existing 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 the existing subsections S26—3(2) 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  $\beta$ -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 will 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 has approved a draft variation to amend the Code, which includes inserting a new subsection S26—3(2A). This new provision extends the requirement to comply with the labelling requirement imposed by section 1.5.2—4 (as mentioned above) to food derived from provitamin A rice line GR2E containing beta-carotene as a result of the genetic modification. Section S26—3 ensures 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  $\beta$ -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 ( $\beta$ -carotene is absent). The composition and characteristics of this highly refined product will therefore be the same as rice bran oil made from conventionally produced (non-GM) rice.

In summary, Table 2 below lists scenarios in which the mandatory statement will or will 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 2: Application of labelling requirements for GR2E food and ingredients**

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

### 2.3.1.2 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 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  $\beta$ -carotene is present. However, FSANZ has not proposed 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  $\beta$ -carotene. Other labelling requirements will 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 ( $\beta$ -carotene as [retinol equivalents](#)<sup>5</sup>) in GR2E will 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  $\beta$ -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.

### 2.3.2 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-Committee<sup>6</sup> 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).

<sup>5</sup> For an explanation of retinol equivalents see <https://www.nrv.gov.au/nutrients/vitamin-a>

<sup>6</sup> Now known as the Implementation Subcommittee for Food Regulation

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](#)<sup>7</sup>

### **2.3.3 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.

In 2013 Australia imported 145,370 tonnes of milled rice (representing around 45% of the rice consumed, according to figures in [Ricepedia](#)<sup>8</sup>) 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.

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

Public submissions were invited on a draft variation which was released for public comment between 3 August and 14 September 2017. The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified.

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<sup>7</sup> 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\\*](http://gmo-crl.jrc.ec.europa.eu/gmomethods/entry?db=gmometh&id=qt-eve-os-001&q=id%3aQT-eve-OS*)

<sup>8</sup> Ricepedia: the online authority on rice <http://ricepedia.org/australia>

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on this Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of the safety assessment.

Documents relating to Application A1138, including submissions received, are available on the [FSANZ website](#)<sup>9</sup>.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

#### **2.5.1.1 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 cost/benefit analysis is based on rice containing event GR2E being commercialised (see section 2.3.3) noting that, if it were, cultivation in Australia or New Zealand would require separate regulatory approval.

Option 1 was selected.

#### *Option 1 – Approve the draft variation*

*Industry:* Rice derived from GR2E and its products would be permitted under the Code and therefore any rice grain imports that contained the GR2E event would not be prevented from entering Australia and New Zealand

The segregation of grain derived 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  $\beta$ -carotene.

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<sup>9</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1138GMriceGR2E.aspx>

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  $\beta$ -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 the draft variation*

As food derived from GR2E has been found to be as safe as food from conventional counterparts, not preparing a draft variation would offer little relative benefit to consumers, government and industry.

The direct and indirect benefits that would arise 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 the food regulatory measure.

#### **2.5.1.2 Other measures**

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

#### **2.5.1.3 Any relevant New Zealand standards**

Standard 1.5.2 and Schedule 26 also apply in New Zealand.

#### **2.5.1.4 Any other relevant matters**

The Applicant has submitted applications for regulatory approval of GR2E to a number of other countries, as listed in Table 3.

**Table 3: 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

#### **2.5.2. Subsection 18(1)**

FSANZ has had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

##### **2.5.2.1 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](#)<sup>10</sup> 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.

As a result of the nutrition assessment undertaken by FSANZ, which specifically considered the intake of  $\beta$ -carotene, FSANZ concluded that GR2E rice consumption will not pose a nutritional risk to the Australian and New Zealand population.

##### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

Food derived from GR2E would have to comply with labelling requirements as discussed in section 2.3.1 of this report. This will enable consumers to make informed choices in relation to such food.

##### **2.5.2.3 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 2.3.2).

#### **2.5.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

<sup>10</sup> <http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx>



- **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 was not a consideration as there are currently no relevant international standards. As noted in Table 1, Codex Alimentarius is undertaking work to develop a definition for biofortification. However, a definition is yet to be confirmed, and therefore the draft definition cannot be considered at this time.

- **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, the approved draft variation will 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 such 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](#)<sup>11</sup>. This is the same approach that equally applies to food containing a modified nutrient content achieved through conventional breeding techniques.

Policy review or development in regard to fortification of foods by genetic means is the role of FRSC and the Forum and not FSANZ (as discussed in Table 1).

## 3 References

### Attachments

- Approved draft variation to the *Australia New Zealand Food Standards Code*
- Explanatory Statement

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<sup>11</sup>[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)

## **Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code***



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

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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 Standards in the *Australia New Zealand Food Standards Code***

The Schedule varies standards 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 – 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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

Section 94 of the FSANZ Act specifies that a variation of a standard in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### **2. Purpose**

The purpose of this instrument is to amend Schedule 26 of the Code to permit the sale, or use in food, of food derived from provitamin A rice line GR2E and make a consequential amendment to Standard 1.5.2.

### **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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 3 August 2017 for a six-week consultation period.

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). Therefore, a Regulation Impact Statement was not required in this case because the proposed amendments to Standard 1.5.2 and Schedule 26 are 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.

Subitem [2.1] inserts new subsection S26—3(2A) into Schedule 26. The new subsection requires food products containing beta-carotene derived from provitamin A rice line GR2E to comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

Subitem [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.