13 November 2018
[63-18]

Approval report – Application A1156

Food derived from Super High Oleic Safflower Lines 26 and 40

Food Standards Australia New Zealand (FSANZ) has assessed an application made by GO Resources Pty Ltd to seek approval for food derived from safflower line 26 and food derived from safflower line 40.

On 26 June 2018, FSANZ sought submissions on a draft variation to Schedule 26 and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 31 October 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 12 November 2018.

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

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website:

SD1 Safety Assessment Report (at Approval)
Supplementary Information – Dietary Intake Assessment Report

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from GO Resources Pty Ltd on 9 January 2018. The applicant requested a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to include food from two new genetically modified safflower (*Carthamus tinctorius*) lines, GOR-73226-6 or GOR-73240-2 (also referred to as SHO26 and SHO40 respectively). These two lines have been genetically modified to produce very high levels of oleic acid in the seed.

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 SHO26 and SHO40 is provided in Supporting Document 1. 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 SHO26 or SHO40 is considered to be as safe for human consumption as food derived from conventional safflower cultivars.

The FSANZ Board has approved the draft variation to Schedule 26 that inserts a reference into that Schedule to food derived from super high oleic safflower lines 26 and 40. The effect of the variation is to permit the use or sale of food derived from those lines in accordance with Standard 1.5.2.

1 Introduction

1.1 The applicant

GO Resources Pty Ltd (GO Resources) is an Australian technology business, whose focus is the sustainable production and supply of renewable and biodegradable raw materials for use in industrial and oleochemical markets.

1.2 The application

Application A1156 was submitted by GO Resources on 9 January 2018. It sought a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to include a permission for food from two new genetically modified (GM) safflower (*Carthamus tinctorius*) lines, GOR-73226-6 or GOR-7240-2 (also referred to as SHO26 and SHO40 respectively). These two lines have been genetically modified to produce very high levels of oleic acid and concomitantly lower levels of linoleic acid in the seed.

The genetic modification uses RNA interference (RNAi) to suppress the expression of two native safflower genes involved in fatty acid synthesis – the palmitoyl-ACP thioesterase (*CtFATB*) gene and the Δ12 desaturase (*CtFAD2-2*) gene. Fragments of these safflower genes have been introduced and transcribed to produce double-stranded RNA (dsRNA) which is processed by the endogenous cellular machinery of the host into short interfering RNAs (siRNAs). These siRNAs direct the degradation of the messenger RNA (mRNA) transcribed from the host endogenous genes, thereby suppressing the expression of the encoded proteins. Suppression of these genes results in an increase in the amount of oleic acid in the safflower seed, as well as a concomitant decrease in linoleic acid levels.

SHO26 and SHO40 also contain the hygromycin resistance gene, *hph*, expressing the enzyme hygromycin B phosphotransferase (APH4), which confers resistance to the antibiotic hygromycin. The gene is used as a selectable marker to assist with identifying transformed safflower cells in the early stages of selection. APH4 has been previously assessed by FSANZ.

The applicant states the main use of SHO safflower will be to produce oil for applications in the lubricant, fine chemical, bioplastics, pharmaceutical and cosmeceutical as well as food and personal care industries. The technology will be commercialised within a specialised, ‘closed-loop’ identity preserved (CLIP) quality assured management program. The oil will be sold to domestic and export market processors, with the meal being directed to use as a stock feed. There is no intention that SHO safflower grain would enter the export or domestic grain markets.

1.3 The current Standard

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. Subject to certain exceptions listed below, 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. These foods 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 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 (Requirements to have labels or otherwise provide information)).

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 rejected1.

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

Submissions on FSANZs assessment report were received from the New Zealand Ministry for Primary Industries (MPI), the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (VicHealth) , and the NZ Food and Grocery Council. All three submissions supported the proposed changes.

VicHealth noted a discrepancy in the SD1 in the conclusions drawn from the sequencing results (which indicated incorporation of 191 bp of a replication of origin sequence from the binary vector in SHO26) and the plasmid backbone results (which concluded that no vector backbone sequences are present in SHO26). FSANZ has corrected the information in the SD1 (at Approval) noting that no safety concerns are raised by the presence of the 191 bp vector sequence (see Section 3.4.2 of the SD1 at Approval)

Both MPI and VicHealth asked FSANZ to consider expanding the dietary intake assessment to consider the potential impact of SHO safflower on linoleic acid consumption. FSANZ has carefully considered this request and, having reviewed both the oleic acid dietary modelling results and the context of linoleic acid in the current food supply, maintains that such a dietary assessment is not warranted. This has now been addressed in Section 6.2 of the SD1 at Approval.

2.2 Safety assessment

In assessing food derived from the two safflower lines, a number of criteria have been addressed including: characterisation of the transferred gene sequences, their origin, function and stability in the safflower genome; the changes at the level of DNA, RNA and protein in the whole food; compositional analyses; an evaluation of intended and unintended changes; and a dietary intake assessment.

The safety assessment, as reported in supporting document 1 (SD1), 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 either SHO26 or SHO40 is considered to be as safe for human consumption as food derived from conventional safflower cultivars. Changes to the SD1 released with the call for submissions have been made to report the licence issued by the Gene Technology Regulator (Section 2.5.1.4), to include updated information, received from the Applicant, on APH4 protein levels in the seed and leaves (Section 4.1.1), to correct the inconsistency highlighted by the VicHealth submission, and to clarify why a dietary intake assessment of linoleic acid was not considered necessary.

The safety assessment 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.

A dietary intake assessment was conducted by FSANZ that considered the intake of oleic acid from the current food supply (baseline intake) and two scenarios to account for potential additional intake of oleic acid due to the introduction of SHO safflower to the Australian and New Zealand food supplies. The modelling indicated the addition of SHO safflower oil would make little to no difference to oleic acid intakes. Given this, and the fact that oils are not the major source of linoleic acid in the diet, the introduction of SHO safflower oil to the food supply is unlikely to decrease linoleic acid intake outside of normal daily variation in intakes. It is concluded that consumption of SHO safflower will not pose a nutritional concern to the Australian and New Zealand populations.

2.3 Risk management

2.3.1 Labelling

2.3.1.1 Requirement to be labelled as 'genetically modified'

In accordance with the labelling provisions in Standard 1.5.2 and subject to certain exceptions listed in Part 1.3 above, food derived from SHO26 or SHO40 would generally be required to be labelled as 'genetically modified' if it contains novel DNA or novel protein. In addition, if the product is listed in section S26—3 of Schedule 26, labelling must comply with section 1.5.2–4 of Standard 1.5.2 (such food has altered characteristics).

FSANZ has determined that whole seeds and meal from SHO26 and SHO40 contain novel DNA and novel protein and have an altered nutritional profile that is outside the compositional variation found in existing counterpart food. As such, whole seeds and meal would be required to be labelled as 'genetically modified', although for reasons outlined in the SD1 (Section 5.2.7) neither meal nor seed would be likely to be consumed in western diets.

Oil is the major product of SHO26 and SHO40 intended for human consumption. This oil is unlikely to contain novel DNA or novel protein due to the refining process used to extract the oil from the seed. The product will, however, have intentionally elevated levels of oleic acid and reduced levels of linoleic acid compared to safflower oil derived from conventional (non-GM) safflower seeds and would therefore be required to be to be labelled as 'genetically modified'.

In summary, Table 1 lists scenarios in which labelling as 'genetically modified' would or would not apply, if food derived from SHO26 and SHO40 was approved.

Table 1: Application of labelling requirements for food derived from SHO safflower

SHO26 and SHO40 food/ingredient	Mandatory labelling as 'genetically modified'
Contains novel DNA or novel protein	✓
Contains altered fatty acid profile	✓
Novel DNA or protein absent but contains altered fatty acid profile	✓
Novel DNA or protein not present and no altered fatty acid profile i.e. the same as its conventional (non-GM) counterpart	×

Mandatory labelling would apply to the oil if it was sold as a food, or if it was used as an ingredient in a packaged or unpackaged food. Existing labelling provisions specify that food intended for immediate consumption that is prepared and sold from food premises and vending vehicles is exempt from labelling requirements for food as 'genetically modified' (see section 1.3).

However, paragraph 1.2.1—15(f) of Standard 1.2.1 requires information relating to foods produced using gene technology to be on labelling for food sold to a caterer. Subsection 1.1.2—2(3) of Standard 1.1.2 defines 'caterer' to mean a person, establishment or institution (for example, a catering establishment, a restaurant, a canteen, a school, or a hospital) which handles or offers food for immediate consumption. Consequently, in relation to such food, a consumer may seek information about the food from the food business. Any representations made by the food business about a food derived from SHO26 or SHO40 would be subject to other Australian and New Zealand laws designed to prevent misleading or deceptive conduct, including in relation to food.

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 has considered whether additional labelling (i.e. in addition to the mandatory 'genetically modified' labelling described above) is required to alert consumers to the nature of the altered characteristic in SHO26 and SHO40 when compared to non-GM safflower products.

FSANZ is not proposing to list food derived from SHO26 and SHO40 in subsection S26—3(2) of Schedule 26. As with food from two GM high oleic acid soybean lines assessed by FSANZ (A1018[1] and A1049[2]) specific labelling to indicate the changes in concentrations of oleic acid and linoleic acid are not considered to be informative for consumers as there is no significant change to the overall level of unsaturated fatty acids in the oil. Following public education campaigns consumers are more likely to have a better understanding of the terms 'monounsaturated', 'polyunsaturated' and 'saturated' with regard to fats, than to have an understanding of the differences between individual fatty acids.

Additional labelling could also imply that the food contributes a nutritionally significant amount of monounsaturated fatty acids, when the actual amount may be negligible (for example, when oil from SHO26 or SHO40 is used as a minor ingredient in food).

In this context, additional labelling for individual fatty acid changes is likely to be confusing and potentially misleading to consumers.

2.3.1.3 Voluntary representations made about food

As a result of the nutrition assessment (refer Section 6 of SD1), FSANZ has concluded that oil produced from SHO26 and SHO40 has the potential to be used as a source of monounsaturated fatty acids. Safflower oil derived from these lines may meet the requirements for making a nutrition content claim in relation to its monounsaturated fatty acid content. The conditions for making such claims are set out in section S4—3 of Schedule 4 and other nutrition content claim requirements are set out in Standard 1.2.7 (Nutrition, health and related claims). The onus is on the supplier to determine whether their food product containing oil from SHO26 or SHO40 as an ingredient meets these conditions and requirements before making a nutrition content claim.

Additionally, as mentioned in section 2.2.2.1 above, representations made about a food derived from SHO26 and/or SHO40 would also be subject to other Australian and New Zealand laws designed to prevent misleading or deceptive conduct, including in relation to food.

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[3] 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).

[1] http://www.foodstandards.gov.au/code/applications/pages/applicationa1018food4091.aspx
[2] http://www.foodstandards.gov.au/code/applications/pages/applicationa1049food4840.aspx
[3] 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 A1156.

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 requested 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 26 June and 7 August 2018. 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.

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 A1156, including submissions received, are available on the FSANZ website.

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 GM 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 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 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.

Option 1 was selected. It is noted that a licence for the commercial growing of the two safflower lines in Australia was issued by the Gene Technology Regulator in June 2018. Cultivation in New Zealand would require separate regulatory approval (see Section 2.5.1.4). The Applicant may seek approval for commercial growing in other countries.

Option 1 – Approve the draft variation to Schedule 26

Consumers: Food from SHO26 and SHO40 has been assessed as being as safe as food from conventional lines of safflower.

There would be broader availability of imported safflower products since, if SHO26 and SHO40 are approved for commercial growing in other countries, there would be no restriction on imported foods containing these lines.

Labelling of food products derived from SHO26 and SHO40 containing novel DNA, novel protein or an altered fatty acid profile, and is sold packaged (e.g. a bottle of mayonnaise containing SHO safflower oil) would allow consumers wishing to avoid these products to do so. Consumers are able to seek information from food premises (e.g. restaurants, takeaway outlets or caterers) that prepare food intended for immediate consumption using SHO safflower products.

SHO26 and SHO40 approvals for commercial growing in either overseas countries or Australia/New Zealand would mean that both lines could be used to manufacture products using co-mingled safflower seed. There would therefore be no cost involved in having to exclude the SHO safflower seed from co-mingling and hence that there would be no consequential need to increase the prices of foods that are manufactured using co-mingled seed.

Government: Approval would avoid any conflict with WTO obligations. As mentioned above, food from SHO26 and SHO40 has been assessed as being as safe as food from conventional lines of safflower.

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.

Industry: Foods derived from SHO26 and SHO40 would be permitted under the Code, therefore allowing broader market access and increased choice in raw materials. Retailers may be able to offer a broader range of safflower products or imported foods manufactured using safflower derivatives.

Segregation of SHO26 and SHO40 seed from conventional safflower seed, 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 SHO26 and SHO40 would require the ‘genetically modified’ labelling statement if they contain novel DNA, novel protein or an altered fatty acid profile.

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 varied as a result of Application A1156.

2.5.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

2.5.1.4 Any other relevant matters

A licence for commercial growing of the two lines in Australia has been issued by the Gene Technology Regulator. Should cultivation in New Zealand be sought, this would require assessment by the Environmental Protection Authority in New Zealand.

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

Food derived from SHO26 or SHO40 has been assessed based on the data requirements provided in the FSANZ *Application Handbook*[4] 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 SHO26 or SHO40 is considered as safe and wholesome as food derived from other commercial safflower lines.

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

Existing labelling requirements for food derived from SHO26 or SHO40 would enable informed consumer choice (see section 2.3.1). In addition, consumers can seek information about food intended for immediate consumption, that is prepared and sold from a restaurant or take away outlet, from the caterer. Information relating to foods produced using gene technology is required on labelling for food sold to a caterer.

2.5.2.3 The prevention of misleading or deceptive conduct

The provision of detection methodology by the Applicant (see section 2.3.2) addresses this objective.

[4] http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

2.5.3 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 SHO26 and SHO40 used the best scientific evidence available. The applicant submitted to FSANZ a 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. SHO safflower is a new crop designed to provide a high oleic acid oil source primarily for industrial use but also for human consumption and livestock feed.

- **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**

Not applicable

3 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/codex-texts/guidelines/en/

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

Food Standards (Application A1156 – Food derived from Super High Oleic Safflower Lines 26 and 40) 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 the Delegate]

[Insert Name of General Manager]
[Insert Title of General Manager]
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 A1156 – Food derived from Super High Oleic Safflower Lines 26 and 40) 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] **Schedule 26** is varied by

[1.1] inserting in subsection S26—3(2) immediately after '7(h)'

, and 9(a)

[1.2] inserting after Item 8 in the table to subsection S26—3(4)

9	**Safflower**	(a)	super high oleic safflower lines 26 and 40 (see subsection (2))

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 A1156 which seeks permission for the sale and use of food derived from either of two genetically modified safflower lines, 26 and 40, which produce very high levels of oleic acid in the seed. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Schedule 26.

2. Purpose

The Authority has approved the draft variation to amend Schedule 26 of the Code to permit the sale, or use in food, of food derived from either of super high oleic safflower lines 26 and 40.

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 A1156 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 26 June 2018 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 26 is 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] of the draft variation varies Schedule 26.

Item [1.1] inserts into subsection S26—3(2) a reference to Item 9(a) of the table to subsection S26—3(4). The effect of this variation will be to require a food for sale that consists of super high oleic safflower lines 26 and 40, or that has either of the latter as an ingredient, to comply with the labelling requirement imposed by section 1.5.2—4 of the Code.

Item [1.2] inserts Item 9 paragraph (a) into the table to subsection S26—3(4). The new paragraph refers to super high oleic safflower lines 26 and 40. The effect of the variation is to permit the sale and use of food derived from either of those safflower lines in accordance with Standard 1.5.2.