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171-21

Call for submissions – Application A1226

Food derived from insect-protected corn line MON95379

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Bayer CropScience Proprietary Limited seeking to permit the sale and use of food derived from a food produced using gene technology: corn line MON95379. This corn line has been genetically modified to protect against parasitic lepidopteran insect pest. A draft food regulatory measure has been prepared. 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 variation.

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 1982*. 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 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) 1 November 2021

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:

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Supporting document

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

SD1 Safety Assessment Report

¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1226%20-%20GM-Maize-MON95379.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Bayer CropScience Proprietary Limited to request a variation to Schedule 26 in the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of food derived from a new food produced using gene technology (GM food): corn line MON95379. Corn line MON95379 has been genetically modified for protection from lepidopteran insect pests.

A safety assessment is a critical part of the assessment approval process for all GM food applications. The safety assessment of corn line MON95379 found no potential public health and safety concerns. Based on the data provided and other information, food derived from corn line MON95379 is considered to be as safe for human consumption as food derived from conventional non-GM corn cultivars. The completed safety assessment is in Supporting Document 1 (SD1).

Existing labelling requirements for GM food will apply to food derived from corn line MON95379 in accordance with the Code.

FSANZ has decided to prepare a draft variation to amend Schedule 26 of the Code to include a reference to 'insect-protected corn line MON95379' in the table to subsection S26—3(4). If approved, the effect of the draft variation will be to permit the use or sale of food derived from this corn line in accordance with the Code.

1 Introduction

1.1 The Applicant

Bayer CropScience Proprietary Limited is a technology provider to a number of sectors including the agriculture sector.

1.2 The application

Application A1226 was submitted on 12 April 2021. It seeks approval for the sale and use of food derived from a new food produced using gene technology (GM food): corn line MON95379. Corn line MON95379 has been genetically modified for protection from lepidopteran insect pests.

Protection from lepidopteran insect pests is achieved with the expression of two novel crystal (Cry) proteins, Cry1B.868 and Cry1Da_7, derived from the soil bacterium *Bacillus thuringiensis* (*B. thuringiensis*). These novel substances cause midgut damage specifically in lepidopteran larvae, such as fall armyworm and corn earworm larvae. While FSANZ has assessed and approved numerous applications where *B. thuringiensis* Cry proteins have been introduced into crops for pest protection, this is the first application to assess the Cry1B.868 and Cry1Da_7 proteins.

Food derived from corn line MON95379 may enter the Australian and New Zealand food supply as imported food products. These may include starch, grits, meal, flour, oil and sweetener products. Food from corn line MON95379 containing viable seeds, such as corn cobs, would require prior assessment and approval by the Gene Technology Regulator² in Australia and the Environmental Protection Authority (EPA) in New Zealand.

1.3 The current standard

Pre-market approval is necessary before GM foods can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment. Standard 1.5.2 of the Australia New Zealand Food Standards Code (the Code) sets out the permission and conditions for the sale of food that consists of, or has as an ingredient, a GM food. Foods that have been assessed and approved are listed in Schedule 26 of the Code.

Subject to certain exceptions listed below, section 1.5.2—4 requires food to be labelled as ‘genetically modified’ where novel DNA and/or novel protein remains present in the final food.

Additionally, 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 as ‘genetically modified’ applies to foods for sale that consist of, or have as an ingredient (including food additives and processing aids), food that is a *genetically modified food*³. Standard 1.2.1 provides that the requirements imposed by section

² The Office of the Gene Technology Regulator (OGTR) provides administrative support to the Gene Technology Regulator in the performance of functions under the *Gene Technology Act 2000*.

³ Subsection 1.5.2—4(5) defines **genetically modified food** to mean a *food produced using gene technology that

1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer - see subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

The labelling requirement in section 1.5.2—4 does not apply if the genetically modified food:

- has been highly refined (other than food that is considered to have an altered characteristic as described above), 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%); or
- is unintentionally present in the food in an amount of no more than 10 g/kg (or 1%) of each ingredient.

The above labelling requirement also does not apply if the food for sale is intended for immediate consumption and is prepared and sold from food premises and vending vehicles, including restaurants, take away outlets, caterers, or self-catering institutions.

If the 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)).

Subsection 1.1.1—10(8) of Standard 1.1.1 states that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

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 *Food Standards Australia New Zealand Act 1991* (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 assessment

The safety assessment of corn line MON95379 is provided in Supporting Document 1 (SD1) and included the following key elements:

- a characterisation of the transferred genetic material, its origin, function and stability in the corn genome
- characterisation of novel nucleic acids and protein in the whole food

a) contains novel DNA or novel protein; or

b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section (*that being section 1.5.2—4*).

- detailed compositional analyses
- evaluation of intended and unintended changes
- assessment of the potential for any newly expressed protein to be either allergenic or toxic in humans.

In conducting the safety assessment, FSANZ had regard to information from a variety of sources including, but not limited to, a data package provided by the applicant (application and study reports), the scientific literature and other applications.

The assessment of corn line MON95379 was restricted to human food safety and nutritional issues. This assessment therefore does not address any risks to the environment that may occur as the result of growing corn line MON95379, or any risks to animals that may consume feed derived from corn line MON95379. Cultivation in Australia or New Zealand would require separate regulatory assessment and approval by the Gene Technology Regulator in Australia and by the EPA in New Zealand.

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 corn line MON95379 is considered to be as safe for human consumption as food derived from non-GM corn cultivars.

2.2 Risk management

2.2.1 Regulatory approval

Corn line MON95379 is a GM food for Code purposes as it is developed from ‘an organism that has been modified using gene technology’. FSANZ is proposing to list corn line MON95379 in the table to subsection S26—3(4). If approved, the express permission for corn line MON95379 would provide permission for the sale and use of food derived from corn line MON95379, as a GM food in accordance with the Code.

2.2.2 Labelling

In accordance with the labelling provisions in Standard 1.5.2 (see Section 1.3 of this Report), food for sale derived from a GM food, such as corn line MON95379, would be required to be labelled as ‘genetically modified’ if (among other things) the GM food:

- contains novel DNA or novel protein; or
- is listed in subsection S26—3(2), (2A) or (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 food derived from corn line MON95379 does not have altered characteristics.

As noted in Section 1.2 of this report, the grain from commercial lines derived from corn line MON95379 may be used to produce wet-milled starch for sweetener products and maize oil. In Australia and New Zealand, maize starch and sweeteners are used in a wide range of products such as dessert mixes, canned food products, breakfast cereals, baking products and extruded confectionary. Refined products from corn line MON95379 such as maize starch, maize oil and sweeteners are unlikely to contain any novel protein or novel DNA and would be unlikely to require labelling as ‘genetically modified’.

Products derived from corn line MON95379 such as flour (used in bread), meal (used in polenta) and grits (used in cereals) would likely contain novel protein or novel DNA, and if so, would require labelling as ‘genetically modified’.

The requirements for labelling as 'genetically modified' differ depending on whether the GM food is an ingredient of the food for sale or not. For example, corn flour derived from corn line MON95379 that is sold at retail would require the labelling statement. However, FSANZ notes products derived from corn line MON95379 may be used to manufacture a food that is not itself a food for sale, but is used as an ingredient in foods for retail sale or in a food sold to a caterer (for example, corn meal derived from corn line MON95379 is used to make a crumbed fish then used as an ingredient in a 'ready meal'). As such, these ingredients would not be GM foods and would not be subject to labelling requirements set out in section 1.5.2—4.

2.2.3 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-Committee⁴ to identify and evaluate appropriate methods of analysis associated with all applications to FSANZ, including those applications for food produced using 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 A1226.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, 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 all 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.

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 corn line MON95379 is unlikely to have a significant effect on international trade. 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.

⁴ Now known as the Implementation Subcommittee for Food Regulation.

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) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the food will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting the sale and use of food derived from corn line MON95379.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the sale and use of food derived from corn line MON95379.

Costs and benefits of permitting the sale and use of food derived from corn line MON95379

The sale and use of foods derived from corn line MON95379 would be permitted under the Code, allowing broader market access and increased choice in raw materials. For those food products containing novel DNA or novel protein from corn line MON95379, labelling is required to assist consumers wishing to avoid these products to do so.

Due to the voluntary nature of the permission, manufacturers and retailers would only engage with foods derived from corn line MON95379, where they believe a net benefit exists for them. Part of any cost savings to industry may be passed onto consumers.

There may be small and likely inconsequential costs of monitoring an extra GM food ingredient for regulators to ensure compliance with labelling requirements.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the sale and use of food derived from corn line MON95379, most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than varying Schedule 26 as a result of the Application A1226.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

The applicant has submitted applications for regulatory approval of corn line MON95379 to other countries, as listed in Table 1.

Cultivation in Australia or New Zealand would require independent assessment and approval by the Gene Technology Regulator and New Zealand EPA, respectively.

Table 1: List of countries to whom applications for regulatory approval of MON95379 have been submitted

Country	Authority	Type of approval sought	Status
Brazil	National Biosafety Commission (CTNBio)	Environmental release, food & feed	Approved
Canada	CFIA	Environmental release & feed	Submitted
	Health Canada	Food	Submitted

Further other relevant matters are considered below.

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

FSANZ's assessment did not identify any public health and safety concerns with food derived from corn line MON95379. Based on the best available scientific evidence, including detailed studies provided by the applicant, FSANZ's assessment is that food derived from corn line MON95379 is as safe as food derived from other non-GM corn lines.

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

Existing labelling requirements for GM food will apply to food derived from corn line MON95379 in accordance with the Code to enable informed consumer choice (see Section 2.2.2).

2.4.2.3 The prevention of misleading or deceptive conduct

The provision of DNA sequence information by the applicant (as described in Section 2.2.3) satisfies this objective.

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, 2009). Based on these principles, the risk analysis undertaken for corn line MON95379 used the best scientific evidence available. The applicant submitted 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. Corn line MON95379 is a new food crop designed to provide growers with an additional control option for lepidopteran insect pests.

- **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 specific policy guidelines have been developed.

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.

4 References

Codex (2009) Foods derived from modern biotechnology, Second Edition. Codex Alimentarius Commission, Rome. <http://www.fao.org/3/a1554e/a1554e00.htm>

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 A1226 – Food derived from insect-protected corn line MON95379) 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 the delegate]

Christel Leemhuis
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 clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1226 – Food derived from insect-protected corn line MON95379) 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

Schedule 26—Food produced using gene technology

[1] Subsection S26—3(4) (table item 2)

Insert:

(ze) insect-protected corn line MON95379

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 A1226 which seeks to permit the sale and use of food derived from a new food produced using gene technology (GM food) - corn line MON95379. Corn line MON95379 has been genetically modified for protection from lepidopteran insect pests. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The purpose of the draft variation is to permit the sale and use of food derived from a new GM food - corn line MON95379, in accordance with the Code. Corn line MON95379 has been genetically modified for protection from lepidopteran insect pests.

3. Documents incorporated by reference

This draft variation does 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 A1226 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (including the draft variation) will occur for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as varying Schedule 26 is a consequential change of maintaining a permitted schedule of GM foods. Additionally, permitting a new GM food is deregulatory as using the food will be voluntary if the Application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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 Schedule 26 by inserting new paragraph (ze) into item 2 of the table to subsection S26—3(4) in Schedule 26 in alphabetical order.

The new paragraph refers to insect-protected corn line MON95379.

If approved, the effect of the variation would be to permit the sale and use of food derived from that corn line in accordance with the Code.