

July 8, 2015

Food Standards Australia and New Zealand
Ground Floor
Boeing House
55 Blackall Street
BARTON ACT 2600

**APPLICATION TO AMEND STANDARD 1.5.2-
Food Produced Using Gene Technology Event MZIR098**

Dear Food Standards Australia and New Zealand

Please find enclosed an application to amend Standard 1.5.2-Food produced using Gene Technology, in the Australia New Zealand Food Standards Code (the Code). An amendment to the code will allow the use of genetically modified corn (maize; *Zea mays* L.) derived from **MZIR098** corn in Australia and New Zealand food industries.

Syngenta Crop Protection LLC, on behalf of Syngenta AG and its affiliates, has developed MZIR098 corn (maize; *Zea mays* L.), a new cultivar that has been genetically modified to provide dual modes of action for corn rootworm control in a single event. In addition, **MZIR098** also offers commercial levels of tolerance to glufosinate-ammonium herbicide products.

Syngenta believes that the application should be considered under the General Assessment Procedure of up to 350 hours because **MZIR098** corn contains no novel proteins. Numerous regulatory agencies around the world, including FSANZ have assessed the safety of these *ecry3.1Ab*, *mcry3A* and *PAT* proteins, in the context of 5307, MIR604 and Bt 11.

Syngenta would like to claim the following reports as containing Confidential Commercial Information:

1. Event **MZIR098** Maize :Insert and Flanking Sequence Analysis Final Report 2. Report Number **TK0144270**
2. Event **MZIR098** Maize :Genomic Insert Site Analysis Final Report, Volume 2. Report Number **TK0117489**

Meaning the information within these reports are not to be disclosed, released for public consultation, or be accessible by way of a request for access to information under the *Freedom of Information Act 1982*. All reports declared as containing Confidential Business Information, or Confidential Commercial Information have been selected because they contain "Trade Secrets" which will be used to file the patent application for the **MZIR098** corn. Any information released may affect "patent protection" and destroy the commercial value.

The application is expected to confer an exclusive capturable commercial benefit (ECCB). A signed declaration has been provided with this application.

In support of this application the following items have been provided:

- One Paper Copy of the Application
- One Paper Copy of Relevant Study Reports
- One Paper Copy of the Executive Summary separate to the main application
- One Paper Copy of the ECCB declaration
- One Paper Copy of the Statutory Declaration
- One Formal Request for CCI/CBI
- Completed Checklist
- An Electronic Version of all of the above
- Any Supplemental Materials (as required on a case-by-case basis)

Please do not hesitate to contact me, if you have any questions.

Yours sincerely

A large black rectangular redaction box covering the signature area.A black rectangular redaction box covering the name area.

July ^{8th}, 2015

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STATUTORY DECLARATION-AUSTRALIA

*Statutory Declarations Act 1959*¹

I, [REDACTED]

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

[Signature of person making the declaration] *Rhonda*

Robina 08 July 2015

Declared at [place] on [day] of [month] [year]

Before me, [REDACTED]

[Signature of person before whom the declaration is made]²

[Full name, qualification and address of person before whom the declaration is made in printed letters]

J P QUALIFIED (Robina)

¹ <http://www.comlaw.gov.au/Series/C1959A00052>.

² A statutory declaration must be made before a prescribed person under the *Statutory Declarations Act 1959*. The list of prescribed persons is available in the *Statutory Declarations Regulations 1993* at <http://www.comlaw.gov.au/Series/F1996B00198>.



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DECLARATION- EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT

I, [REDACTED] declare that the application to amend Standard 1.5.2 – Food Produced Using Gene Technology to include foods derived from **MZIR098** corn, will have exclusive capturable commercial benefit for Syngenta.

For this purpose, Section 8 of the FSANZ Act provides

*An **exclusive, capturable commercial benefit** is conferred upon a person who applies for the development of a food regulatory measure or the variation of a food regulatory measure under section 22 if:*

(a) the applicant can be identified as a person or body that may derive a financial gain from the coming into effect of the draft standard or draft variation of the standard that would be prepared in relation to the application; and

(b) any other unrelated persons or bodies, including unrelated commercial entities, would require the agreement of the applicant in order to benefit financially from the approval of the application.

Signature ... [REDACTED]

the 8th day of July 2015

[REDACTED]
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July 8, 2015

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CONFIDENTIAL COMMERCIAL INFORMATION

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Please do not hesitate to contact me, if you have any questions.

Yours sincerely

[REDACTED]

[REDACTED]

Check Lists-MZIR098

General requirements (3.1)

X	3.1.1 Form of application X Application, abstracts and other key documents in English X Executive Summary (separated from main application electronically and in hard copy) X Relevant sections of Part 3 clearly identified X Pages sequentially numbered X Electronic copy (searchable) X 1 hard copy X Electronic and hard copy identical X Hard copy capable of being laid flat X All references provided (in electronic)	X	3.1.6 Assessment procedure X General <input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> High level health claim variation
X	3.1.2 Applicant details	X	3.1.7 Confidential Commercial Information X Confidential material separated in both electronic and hard copy X Formal request including reasons <input type="checkbox"/> Non-confidential summary provided
X	3.1.3 Purpose of the application	X	3.1.8 Exclusive Capturable Commercial Benefit <input type="checkbox"/> Justification provided
X	3.1.4 Justification for the application <input type="checkbox"/> Regulatory impact information <input type="checkbox"/> Impact on international trade	X	3.1.9 International and other national standards <input type="checkbox"/> International standards <input type="checkbox"/> Other national standards
X	3.1.5 Information to support the application <input type="checkbox"/> Data requirements	X	3.1.10 Statutory Declaration
		X	3.1.11 Checklist/s provided with application X 3.1 Checklist <input type="checkbox"/> Any other relevant checklists for Parts 3.2-3.7

Foods Produced using Gene Technology (3.5.1)

X	A.1 Nature and identity of GM food	X	B.4 Toxicity of novel protein(s)/substances
X	A.2 History of use of host and donor organisms	X	B.5 Potential allergenicity of novel protein(s)
X	A.3 Nature of genetic modification	X	B.6 Toxicity of novel herbicide metabolites
NA	A.4 Labelling information on GM food	X	B.7 Compositional Analyses
X	B.1 Equivalence studies	X	C.1 Nutritional impact of GM food
NA	B.2 Antibiotic resistance marker genes (if used)	NA	C.2 Animal feeding studies (if available)
X	B.3 Characterisation of novel protein(s)/substances		