

Kathy Wheeler
Regulatory Affairs

Locked Bag 1335
Dandenong South 3164
9 Business Park Drive
Lynbrook Vic 3975
Ph: 03 8773 6300
Fax: 03 8773 6350

Tel: 0409 409 665
kathy.wheeler@syngenta.com

Standards Management Officer
Food Standards Australia New Zealand
55 Blackall Street
Barton ACT 2600
Postal Address
PO Box 7186
CANBERRA BC ACT 2610

Application to amend Standard 1.5.2 – Food Produced Using Gene Technology

Dear Sir or Madam

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), to approve food derived from insect-protected corn line 5307.

Corn line 5307 produces the eCry3.1Ab and PMI proteins. The gene *ecry3.1Ab* encodes the eCry3.1Ab protein, a chimeric protein engineered from portions of modified Cry3A (mCry3A) and Cry1Ab proteins which are derived from *Bacillus thuringiensis*. The eCry3.1Ab protein is insecticidally active against the larvae of Western corn rootworm (*Diabrotica virgifera virgifera* Le Conte), Northern corn rootworm (*D. Longicornis barberi* Smith and Lawrence) and Mexican corn rootworm (*D. Vigifera zea* Krysan and Smith). These important coleopteran pests cause significant damage to U.S. corn crops annually. The *pmi* gene, also known as *manA*, is derived from *Escherichia coli* strain K-12 and encodes the PMI protein, which was utilised as a selectable marker during the development of 5307 corn. GM corn 5307 in breeding stack combinations with other insect-resistant corn products will allow growers to have optimal broad-spectrum insect control.

Syngenta believes that application should be considered under the General Assessment Procedure of up to 500 hours because 5307 corn contains the eCry3.1Ab protein which is an engineered chimera of modified Cry3A (mCry3A) and Cry1Ab proteins; both of these proteins and *pmi* in corn have been evaluated previously by FSANZ. The safety of mCry3A and *pmi* was evaluated in Syngenta's MIR604 corn, Application A564 gazetted in August 2006. The Cry1Ab protein has also been evaluated previously by FSANZ in a number of products including Syngenta's Bt11 (A386) and Bt176 (A385) maize which were gazetted in 2001.

Syngenta does not wish to make any claims for confidential commercial information (CCI) as the patent for line 5307 corn has now been published.

The application is expected to confer an exclusive capturable commercial benefit (ECCB). A signed declaration is attached.

There are no Codex Alimentarius Commission (Codex) Standards relevant to this application.

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

- 2 copies of the application including supporting documentation (each copy comprising 6 Volumes)
- Executive Summary
- A CD containing the application
- ECCB Declaration
- Statutory Declaration
- Checklist.

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

Yours sincerely

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Syngenta is a world leading Agriculture Company committed to sustainable agriculture. Syngenta is one of the leading seed companies in the world, ranking among the top three companies in the high-value commercial seed market. Syngenta is listed on the Swiss stock exchange (SYNN) and in London (SYA), New York (SYT) and Stockholm (SYN). Further information is available at www.syngenta.com.