

20 September 2011 [17-11]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1066	Date Received: 16 August 2011 Date Due for completion of Administrative Assessment: 6 September 2011 Date Administrative Assessment Completed: 31 August 2011		
Applicant: Monsanto Australia Ltd			Potentially Affected Standards in the Code:
Title: Food derived from Herbicide-tolerant Corn Line MON87427 Brief Description of Application:			Standard 1.5.2 – Food produced using Gene Technology.
To seek permission for food derived from corn line MON87427 which is genetically modified to provide tissue-selective tolerance to glyphosate.			Standard 1.4.2 – Maximum Residue Limits
Procedure: General		Estimated total hours: Maximum 650 hours (Level 2)	Estimated start work: September 2011
		Reasons why: FSANZ will need to undertake a case- specific evaluation of the genetic modification in corn line MON87427.	

DECISION

Application accepted

Date: 31 August 2011

Has the Applicant claimed Confidential Commercial Information status?

Yes ✓ No

What documents are affected?

Information in two of the unpublished studies

Has the Applicant provided justification for Confidential Commercial Information status?

Yes ✓ No

Is the Application for a High Level Health Claim?

Yes No ✓

If so, has the Applicant made an election to have FSANZ give public notice calling for submissions under s.51 of the FSANZ Act?

N/A

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together e.g. a novel food and a related high level health claim.

Yes No ✓
Details: N/A

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes ✓ No

If yes, indicate the reason:

Since the technology behind the Application has been developed solely by the Applicant, the Applicant will gain an exclusive benefit if the Application is approved.

If yes, indicate due date for fees to be paid. Note that if fees are not received by this date, the Application is automatically rejected.

Due date for fees: 28 September 2011. Fees received 15 September 2011.

Does the Applicant want to expedite consideration of this Application? N/A

Application Handbook Requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application: Section 3.1 and Section 3.5.1

Does the Application meet the requirements of the relevant Guidelines?

Yes ✓ No

Is the checklist completed?

Yes ✓ No

What information is not provided?

Does the Application relate to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure?
Yes ✓ No
Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted?
Yes No ✓
Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?
Yes ✓ No
If yes, indicate which Procedure: General

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:	Community
Proposed length of public consultation periods:	Involvement Category:
General Procedure (6 weeks)	2
	(low intensity, broad focus)

Proposed Timeframe for Assessment:

Other Comments or Relevant Matters:

'Early Bird Notification' due: 22 September 2011

General Procedure:

Commence Assessment (clock start)
Completion of Assessment
Public comment
Board to complete Approval

Notification to Ministerial Council
Anticipated gazettal if no review requested

early September late January 2012 late-January – early March 2012 early May 2012 mid-May 2012

late July 2012