

3 July 2009
[10-09]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1029	Date Received: 10 June 2009 Date Due for completion of Administrative Assessment: 1 July 2009 Date Administrative Assessment Completed: 24 June 2009	
Applicant: Monsanto Australia Ltd		Potentially Affected Standard in the Code: 1.5.2
Title: Food derived from Drought-tolerant Corn MON87460 Brief Description of Application: To seek pre-market approval for food derived from corn genetically modified (GM) to reduce yield loss under water-limited conditions.		
Procedure: Major Reasons why: This is an Application for a GM food that is not currently permitted and involves a comprehensive, pre-market safety assessment of a trait that has not previously been assessed.	Cost Category: Major Procedure Reasons why: FSANZ has not previously assessed a GM food crop with 'drought tolerance'. FSANZ will need to undertake a safety assessment of higher scientific complexity than would be required for previously assessed traits. This Application is anticipated to involve an assessment of the risk to public health and safety of above average complexity.	Estimated start work: Late July 2009

DECISION

Application accepted

Date: 24 June 2009

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

4 volumes of confidential information provided as Attachment

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:

The Application will confer an exclusive capturable commercial benefit on the Applicant.

If yes, indicate due date for fees to be paid (20 business days after notification of Admin Assess made). **Note that if fees are not received by this date, the Application is automatically rejected.**

Due date for fees: 22 July 2009

Fees Received: 30 June 2009

Does the Applicant want to expedite consideration of this Application?

Yes No Not known N/A

Application Handbook Requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application:

Section 3.1 & Section 3.5.1

Does the Application meet the requirements of the relevant Guideline/s?

Yes No ✓

Is the checklist completed?

Yes ✓ No

What information is not provided?

The Applicant has not identified the Procedure that, in their view, applies to the consideration of this Application (Section 3.1.6)

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:

Other Comments or Relevant Matters:

While it is mandatory for the Applicant to identify the Procedure they consider appropriate, the failure to do so, in this case, does not warrant rejection of the Application.

CONSULTATION & ASSESSMENT TIMEFRAME

<p>Consultation Strategy: Proposed length of public consultation periods: Major Procedure First Assessment Consultation: 6 weeks Second Assessment Consultation: 4 weeks</p>	<p>Community Involvement Category: 3 (intensive, narrower focus)</p>
--	---

Proposed Timeframe for Assessment:

'Early Bird Notification' due: 22 July 2009

Major Procedure:

Commence Assessment (clock start)	30 June 2009
Completion of 1 st Assessment	mid-Dec 2009
Public comment	mid-Dec 2009 to early-Feb 2010
Completion of 2 nd Assessment	late-March 2010
Public comment	late-Mar to late-Apr 2010
Board to complete Approval	mid-June 2010
Notification to Ministerial Council	late June 2010
Anticipated gazettal if no review requested	early Sept 2010