

7 October 2009
[17-09]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1035	<p>Date Received: 27 August 2009 Date Due for completion of Administrative Assessment: 17 September 2009 Date Administrative Assessment Completed: 17 September 2009</p>	
<p>Applicant: Monsanto Australia Limited</p>		<p>Potentially Affected Standard in the Code:</p> <p>Standard 1.5.2</p>
<p>Title: Food derived from insect protected soybean MON 87701</p> <p>Brief Description of Application: To seek pre-market approval for food derived from insect-protected soybean genetically modified to provide protection from feeding damage caused from Lepidopteran pests in tropical and subtropical growing regions</p>		
<p>Procedure: General Level 2</p> <p>Reasons why: This is an Application for a GM food that is not currently permitted and involves a comprehensive, pre-market safety assessment. The novel gene in soybean line 87701 (<i>cry1Ac</i>) used to confer insect protection has been assessed previously by FSANZ in other GM food applications. However, FSANZ will need to undertake an assessment of general scientific complexity that is specific for this Application.</p>	<p>Cost Category (General Procedure): Up to 850 hours</p> <p>Reasons why: This application is anticipated to involve an assessment of the risk to public health and safety of a relatively high level of complexity. FSANZ will need to undertake a case-specific safety assessment including an evaluation of detailed molecular characterisation data uniquely relevant to this product.</p>	<p>Estimated start work: Early October 2009</p>

DECISION

<p>Application accepted</p> <p>Date: 30 September 2009</p>
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Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Appendix 1

Has the Applicant provided justification for Confidential Commercial Information status?

Yes No

Is the Application for a High Level Health Claim?

Yes No

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 Applicant has declared that approval of the Application will have an exclusive capturable commercial benefit for 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: 16 October 2009 (Fees received 30 September)

Does the Applicant want to expedite consideration of this Application?

Yes No Not known N/A

Application Handbook Requirements

Which Guideline/s within the Part 3 of the *Application Handbook* apply to this Application:

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?

N/A

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:

N/A

Other Comments or Relevant Matters:

CONSULTATION & ASSESSMENT TIMEFRAME

<p>Consultation Strategy: Proposed length of public consultation period:</p> <p>General Procedure (6 weeks)</p>	<p>Community Involvement Category:</p> <p>1 (Low intensity, narrow focus)</p>
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Proposed Timeframe for Assessment:

'Early Bird Notification' due: 23 October 2009

<u>General Procedure:</u>	
Commence Assessment (clock start)	30 September 2009
Completion of Assessment	Late February 2010
Public comment	Early March-mid-April 2010
Board to complete Approval	Mid-June 2010
Notification to Ministerial Council	Late June 2010
Anticipated gazettal if no review requested	Early September 2010