



23 July 2010
[16-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1049	<p>Date Received: 4 June 2010 Date Due for completion of Administrative Assessment: 29 June 2010 Date Administrative Assessment Completed: 24 June 2010</p>	
<p>Applicant: Monsanto Australia Limited</p>		<p>Potentially Affected Standard in the Code: 1.5.2</p>
<p>Title: Food from herbicide-tolerant, high oleic acid soybean Line MON 87705</p> <p>Brief Description of Application: To seek permission for food derived from soybean genetically modified to contain an improved fatty acid profile.</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. Two of the novel/silenced genes in soybean line 87705 (<i>cd4 epsps</i>, <i>fad2</i>) used to confer herbicide tolerance and silence the <i>fad2</i> gene have 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>Estimated total hours: Up to 850</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: Late July 2010</p>

DECISION

Application accepted

Date: 24 June 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected? DNA sequence (6 pages), Skipworth *et al* pp51-55, 57-58; Tu *et al* pp23-26, 30-83; Silvanovich *et al* pp5-24

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: Not applicable

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes No

If yes, indicate the reason:

Approval of the application would contribute to facilitating commercial activities of soybean line MON 87705.

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 2010

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:

3.1.1, 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?

There are some minor omissions from the Handbook Requirements, but these are not sufficient to reject the application.

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

Other Comments or Relevant Matters:

CONSULTATION & ASSESSMENT TIMEFRAME

<p>Consultation Strategy: Proposed length of public consultation periods: General Procedure (6 weeks)</p>	<p>Community Involvement Category: 1 (Low intensity, narrow focus)</p>												
<p>Proposed Timeframe for Assessment:</p> <p>'Early Bird Notification' due: 27 July 2010</p> <p><u>General Procedure:</u></p> <table> <tr> <td>Commence Assessment (clock start)</td> <td>20 July 2010</td> </tr> <tr> <td>Completion of Assessment</td> <td>Mid- December 2010</td> </tr> <tr> <td>Public comment</td> <td>Mid-December 2010 – early Feb 2011</td> </tr> <tr> <td>Board to complete Approval</td> <td>Mid-April 2011</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>Late April 2011</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>Early July 2011</td> </tr> </table>		Commence Assessment (clock start)	20 July 2010	Completion of Assessment	Mid- December 2010	Public comment	Mid-December 2010 – early Feb 2011	Board to complete Approval	Mid-April 2011	Notification to Ministerial Council	Late April 2011	Anticipated gazettal if no review requested	Early July 2011
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