



23 June 2011
[12-11]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1063	Date Received: 27 May 2011 Date Due for completion of Administrative Assessment: 21 June 2011 Date Administrative Assessment Completed: 10 June 2011	
Applicant: Monsanto Australia Limited		Potentially Affected Standards in the Code:
Title: Food derived from Herbicide-tolerant Soybean MON87708 Brief Description of Application: To seek permission for food derived from soybean line MON87708-9 which is genetically modified to provide tolerance to the herbicide Dicamba.		Standard 1.5.2 – Food produced using Gene Technology. Standard 1.4.2 – Maximum Residue Limits
Procedure: General	Estimated total hours: Maximum 1000 hours (Level 3) Reasons why: FSANZ will need to undertake a case-specific evaluation of the genetic modification in soybean line MON87708, including a detailed evaluation of any metabolites that may be produced as a result of spraying the crop with Dicamba.	Estimated start work: July 2011

DECISION

Application accepted: Date: 10 June 2011

<p>Has the Applicant claimed Confidential Commercial Information status?</p> <p>Yes ✓ No</p> <p>What documents are affected?</p> <p>A number of pages containing sequence data in two studies</p> <p>Has the Applicant provided justification for Confidential Commercial Information status?</p> <p>Yes ✓ No</p>
<p>Is the Application for a High Level Health Claim?</p> <p>Yes No ✓</p> <p>If so, has the Applicant made an election to have FSANZ give public notice calling for submissions under s.51 of the FSANZ Act?</p> <p>N/A</p>
<p>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.</p> <p>Yes No ✓</p> <p>Details: N/A</p>

Charges

<p>Does FSANZ consider that the application is subject to ECCB?</p> <p>Yes ✓ No</p> <p>If yes, indicate the reason:</p> <p>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.</p> <p>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.</p> <p><u>Due date for fees: 11 July 2011 (Fees paid 16 June 2011)</u></p>
<p>Does the Applicant want to expedite consideration of this Application?</p> <p>N/A</p>

Application Handbook Requirements

<p>Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application:</p> <p>Section 3.1 and Section 3.5.1</p> <p>Does the Application meet the requirements of the relevant Guideline/s?</p> <p>Yes ✓ No</p> <p>Is the checklist completed?</p> <p>Yes ✓ No</p> <p>What information is not provided?</p> <p>N/A</p>
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<p>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?</p> <p>Yes ✓ No</p>
<p>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?</p> <p>Yes No ✓</p>
<p>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?</p> <p>Yes ✓ No</p> <p>If yes, indicate which Procedure: Major</p>
<p>Other Comments or Relevant Matters:</p>

CONSULTATION & ASSESSMENT TIMEFRAME

<p>Consultation Strategy: Proposed length of public consultation period: General Procedure 6 weeks</p>	<p>Community Involvement Category: 2 (low intensity, broad focus)</p>												
<p>Proposed Timeframe for Assessment: . 'Early Bird Notification' due: 23 June 2011</p> <p><u>General Procedure:</u></p> <table> <tr> <td>Commence Assessment (clock start)</td> <td>16 June 2011</td> </tr> <tr> <td>Completion of Assessment</td> <td>early October 2011</td> </tr> <tr> <td>Public comment</td> <td>mid-October–late November 2011</td> </tr> <tr> <td>Board to complete Approval</td> <td>early March 2012</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>mid-March 2012</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>late May 2012</td> </tr> </table>		Commence Assessment (clock start)	16 June 2011	Completion of Assessment	early October 2011	Public comment	mid-October–late November 2011	Board to complete Approval	early March 2012	Notification to Ministerial Council	mid-March 2012	Anticipated gazettal if no review requested	late May 2012
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