23 June 2011
[12-11]

APPLICATION – ADMINISTRATIVE ASSESSMENT

<table>
<thead>
<tr>
<th>A1063</th>
<th>Date Received: 27 May 2011</th>
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<tbody>
<tr>
<td></td>
<td>Date Due for completion of Administrative Assessment: 21 June 2011</td>
</tr>
<tr>
<td></td>
<td>Date Administrative Assessment Completed: 10 June 2011</td>
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<td>Applicant: Monsanto Australia Limited</td>
<td>Potentially Affected Standards in the Code:</td>
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<td>Standard 1.5.2 – Food produced using Gene Technology.</td>
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<tr>
<td>Title: Food derived from Herbicide-tolerant Soybean MON87708</td>
<td>Standard 1.4.2 – Maximum Residue Limits</td>
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<tr>
<td>Brief Description of Application:</td>
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<td>To seek permission for food derived from soybean line MON87708-9 which is genetically modified to provide tolerance to the herbicide Dicamba.</td>
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<td>Procedure: General</td>
<td>Estimated total hours:</td>
</tr>
<tr>
<td></td>
<td>Maximum 1000 hours (Level 3)</td>
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<td>Reasons why:</td>
<td>Estimated start work:</td>
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<tr>
<td>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.</td>
<td>July 2011</td>
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DECISION

Application accepted:

Date: 10 June 2011
Has the Applicant claimed Confidential Commercial Information status?
Yes ✔ No

What documents are affected?
A number of pages containing sequence data in two 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 (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: 11 July 2011 (Fees paid 16 June 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 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:
Major

Other Comments or Relevant Matters:

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:
Proposed length of public consultation period:
General Procedure 6 weeks

Community Involvement Category:
2
(low intensity, broad focus)

Proposed Timeframe for Assessment:
‘Early Bird Notification’ due: 23 June 2011

General Procedure:
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