

7 March 2013
[03-13]

Administrative Assessment Report – Application A1080

Food derived from Herbicide-tolerant Cotton Line MON88701

<p>Date received: 22 January 2013 Date due for completion of administrative assessment: 14 February 2013 Date completed: 13 February 2013</p>		
<p>Applicant: Monsanto Australia Limited</p>		<p>Potentially affected Standard: Standard 1.5.2</p>
<p>Brief description of Application: To seek permission for food derived from genetically modified cotton tolerant to dicamba and glufosinate ammonium herbicides.</p>		
<p>Procedure: General</p>	<p>Estimated total hours: Maximum 350</p> <p>Reasons why: This application involves assessment of more complex scientific and technical information to determine the potential risk to public health and safety.</p>	<p>Estimated start work: Late February 2013</p>

Decision

Application accepted

Date: 13 February 2013

Has the Applicant requested confidential commercial information status?

Yes No

What documents are affected?

Appendix 1, study MSL0023280, pages 45 – 51 inclusive, and pages 53 – 55 inclusive.

Has the Applicant provided justification for confidential commercial information request?

Yes No N/A

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

Yes No

If yes, indicate the reason:

The technology behind the Application has been developed solely by the Applicant.

Due date for fees: 14 March 2013 (fees received 28 February 2013)

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

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

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 level

Other Comments or Relevant Matters:

As there is no MRL in the Code for use of dicamba on cotton and data provided by the Applicant show herbicide residues in MON 88701 cottonseed, a change to Standard 1.4.2 to insert a relevant MRL for imported foods would be required. The Applicant has advised that an application to the US EPA was made in July 2012, to seek an increase in the tolerance from 0.2 to 3 ppm for dicamba on cotton. This process is unlikely to be finalised before 2014. FSANZ will consider the MRL issues separately through an alternative process.

Consultation & assessment timeframe

Proposed length of public consultation period:

6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: 7 March 2013

Commence assessment (clock start)	28 February 2013
Completion of assessment & preparation of draft food reg measure	Early July 2013
Public comment	Mid-July – Late August 2013
Board to complete approval	Late October 2013
Notification to Forum	Early November 2013
Anticipated gazettal if no review requested	Mid-January 2014