

18 June 2010
[13-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1046	Date Received: 5 May 2010 Date Due for completion of Administrative Assessment: 26 May 2010 Date Administrative Assessment Completed: 26 May 2010	
Applicant: Dow AgroSciences Australia Limited		Potentially Affected Standards in the Code:
Title: Food derived from herbicide-tolerant soybean line DAS-68416-4 Brief Description of Application: To seek approval of food genetically modified to provide tolerance to the herbicides 2,4-D and glufosinate ammonium.		1.4.2 1.5.2
Procedure: Major Reasons why: <ul style="list-style-type: none"> • This is an Application for a GM food containing a herbicide-tolerance gene that has not previously been assessed and therefore that requires a comprehensive pre-market safety assessment. • In addition to the GM data, it may be necessary to also consider residue data 	Estimated total hours: 850 - 1050 hours Reasons why: This Application is anticipated to involve an assessment of the risk to public health and safety of above average complexity.	Estimated start work: Late June 2010

DECISION

Application accepted

Date: 26 May 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Certain information within two Dow AgroSciences internal studies (091048 and 081008).

NOTE: the information received in a separate CCI volume included in the Application dossier is different from the CCI identified in the cover letter received with the Application. The CCI included in the separate volume is what has been taken as the actual CCI request.

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?

Not applicable

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:

The Applicant has indicated that approval of the Application would contribute to facilitating commercial activities of soybean line DAS-68416-4 in Australia

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: 25 June 2010 (fees received 11 June 2010)

Does the Applicant want to expedite consideration of this Application?

N/A

