

18 June 2010 [13-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

C	D46Date Received: 5 May 2010Date Due for completion of Administrative Assessment: 26 May 2010Date Administrative Assessment Completed: 26 May 2010				
Applicant: Dow A	Potentially Affected Standards in the Code:				
Title: Food derive Brief Description	1.4.2 1.5.2				
To seek approval of herbicides 2,4-D a					
Procedure: Major		Estimated total hours: 850 - 1050 hours	Estimated start work: Late June 2010		
Reasons why:		Reasons why:			
 This is an Applicati containing a herbic gene that has not p assessed and then requires a compreh market safety asse 	cide-tolerance previously been efore that nensive pre-	This Application is anticipated to involve an assessment of the risk to public health and safety of above average complexity.			
 In addition to the G be necessary to als residue data 					

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? $\ensuremath{\mathsf{N/A}}$

Application Handbook Requirements

Which Guidelines within the Part 3 of the Application Handbook apply to this Application: 3.1 & 3.5.1 Does the Application meet the requirements of the relevant Guidelines? Yes ✓ No NOTE: There are some errors in the presentation of the Application dossier (2 volumes) These errors are not sufficient to reject the Application. Is the checklist completed? Yes ✓ No What information is not provided? 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:	Application Handbook Requirements					
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Major	Yes 🗸 No					
	If yes, indicate which Procedure:					
Other Comments or Relevant Matters:	Major					
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CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy: Proposed length of public consultation periods:	Community Involvement Category:				
	Iajor Procedurepost-1 st Assessment (6 weeks)post 2 nd Assessment (4 weeks)				
post 2 Assessment (4					
Proposed Timeframe for Assessment:					
'Early Bird Notification' due:					
Major Procedure:Commence Assessment (clock start)11 June 2010Completion of 1st AssessmentLate October 2010Public commentLate October 2010 – mid-December 2010Completion of 2nd AssessmentLate January 2011Public commentLate January 2011Public commentLate January 2011 – late February 2011Board to complete ApprovalLate May 2011Notification to Ministerial CouncilEarly June 2011Anticipated gazettal if no review requestedmid-August 2011					