

15 March 2010 [7-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1042	Date Received:21 January 2010Date Due for completion of Administrative Assessment:15 February 2010Date Administrative Assessment Completed:11 February 2010					
Applicant: Dow	Potentially Affected Standards in the Code:					
Title: Food deriv	1.5.2 1.4.2					
Brief Description	Brief Description of Application:					
To seek permiss 40278-9 genetics auxin herbicides the 'Fop' herbicid						
Procedure:		Estimated total hours:	Estimated start			
Major		Up to 1050 hours	work:			
			Early March 2010			
Reasons why:		Reasons why:				
 This is an Applic containing a herk trait that has not assessed and th requires a compl market safety as 	previously been erefore that rehensive pre-	It will be necessary to undertake both a GM safety assessment and an assessment of the residue data.				
	e GM data, it will be o consider residue					

DECISION

Application accepted		
Date: 11 February 2010		

Has the Applicant claimed Confidential Commercial Information status?

Yes**√** No

What documents are affected?

- Certain information within Dow AgroSciences internal Study 071008
- Additional information supplied February 2010

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 corn line DAS-40278-9 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: 12 March 2010

Does the Applicant want to expedite consideration of this Application?

Yes No 🗸 Not known

Application Handbook Requirements

Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application:						
3.1 & 3.5.1						
Does the Application meet the requirements of the relevant Guidelines?						
Yes 🗸 No						
Is the checklist completed?						
Yes✔ No						
What information is not provided?						
The Applicant has not supplied toxicology/residue data. This is not a requirement stated in the <i>Application Handbook,</i> but FSANZ will need to consider the data as part of the Safety Assessment (although the data are not required to start the Safety Assessment). The Applicant explained that the residue study data were still being compiled for the US EPA and would be provided to FSANZ as soon as they become available.						
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?						
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 Strateg	Community Involvement Category:						
Major Procedure	post-1 st Assessment (6 weeks)		2				
	Post 2 nd Assessment (4	weeks)	(Low intensity, broader focus)				
Proposed Timeframe for Assessment:							
'Early Bird Notification' due: 17 March 2010							
Major Procedure:							
Commence Assessm	ent (clock start)	10 March 2010	10 March 2010				
Completion of 1 st Assessment		mid-August 2010					
Public comment		late August - early	late August - early October 2010				
Completion of 2 nd Assessment late November 2010		10					
Public comment		late November 207	late November 2010 – late Dec 2010				
Board to complete Approval		10 March 2011	10 March 2011				
Notification to Ministe	rial Council	mid-March 2011	mid-March 2011				
Anticipated gazettal if no review requested		late May 2011	late May 2011				