

# [7-08] 22 April 2008

# **APPLICATION – ADMINISTRATIVE ASSESSMENT**

A1006	Date Received: 18 March 2008						
	Date Due for completion of Administrative Assessment: 10 April 2008						
	Date Administrative Assessment Completed: 18 March 2008						
Applicant: SGA	Potentially Affected Standard in the Code:						
Title: Food deriv	1.5.2						
	1.4.2						
Brief Description	Brief Description of Application:						
To approve food derived from soybean genetically modified to provide tolerance to both glyphosate and acetolactate synthase-inhibiting herbicides.							
Procedure: Major		Estimated total hours (Major	Estimated start				
		Procedure) 1225 hours	work:				
			2 <sup>nd</sup> Qtr 2008				
Reasons why:		Reasons why:					
This is an application for a variation to a food regulatory measure involving the granting of a permission involving a pre- market safety assessment, with no similar previous assessments. This application involves such scientific complexity that it is necessary to adopt this procedure in considering it. Assessment is likely to require consultation with government agencies and involve external peer review of the safety/risk assessment.		This application will require a safety assessment of a GM food expressing novel proteins not considered in previous assessments (glyphosate acetyltransferase and modified acetolactate synthase), and a complete toxicological assessment, including dietary modelling, of herbicide residues not previously assessed (N-acetyl glyphosate). The assessment will also need to consider whether the existing MRL for glyphosate in soybean is appropriate for this crop.					

## DECISION

Application accepted	
Date: 10 April 2008	

#### Has the Applicant claimed Confidential Commercial Information status?

Yes 🖌 No

#### What documents are affected?

Two studies (relating to the DNA sequence of the insert/border regions).

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 🗸

### Charges

Does FSANZ consider that the application is subject to ECCB?

Yes 🖌 No

If yes, indicate the reason:

The applicant has declared that approval of the application will have exclusive capturable commercial benefit for the applicant.

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: 9 May 2008

Does the Applicant want to expedite consideration of this Application?

Yes No Not known N/A 🗸

### Application Handbook Requirements

 Which Guidelines within Part 3 of the Application Handbook apply to this Application:

 3.5.1

 Does the Application meet the requirements of the relevant Guideline?

 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:

General (Level 2)

**Other Comments or Relevant Matters:** 

## **CONSULTATION & ASSESSMENT TIMEFRAME**

Consultation Strateg	Community Involvement					
Proposed length of pu	Category:					
Major Procedure	post-1 <sup>st</sup> Assessment (6 v	veeks)	(Low intensity, narrow focus)			
	Post 2 <sup>nd</sup> Assessment (4	weeks)	This may need to be upgraded depending on public interest.			
Proposed Timeframe for Assessment:						
'Early Bird Notification' due: 24 April 2008						
Major Procedure:						
Commence Assessme		early May 200	early May 2008			
Completion of 1 <sup>st</sup> Assessment		early Septem	early September 2008			
Public comment		early Septem	early September – mid-October 2008			
Completion of 2 <sup>nd</sup> Assessment		mid-January 2	mid-January 2009			
Public comment		late January -	late January – late February 2009			
Board to complete Approval			early May 2009			
Notification to Minister	ial Council	mid-May 200	mid-May 2009			
Anticipated gazettal if	no review requested	late July 2009	late July 2009			