

### 24 February 2010 [6-10]

# **APPLICATION – ADMINISTRATIVE ASSESSMENT**

A1041	Date Received:15 January 2010Date Due for completion of Administrative Assessment:9 February 2010Date Administrative Assessment Completed:9 February 2010				
Applicant: Mor	Potentially Affected Standard in the Code:				
Title: Food deri Brief Descriptio To seek permiss contain stearido	Standard 1.5.2				
Procedure: Major		Estimated total hours:	Estimated start work:		
<b>Reasons why</b> : This is an Application seeking permission for a GM food that carries a nutritional trait. As well as a detailed safety assessment, analysis of the potential dietary impact of this food in the context of the Australian and New Zealand diets will be necessary.		Reasons why: FSANZ has not previously assessed a GM food crop with a consumer- focused nutritional modification. FSANZ will need to undertake a safety assessment of high scientific complexity and include a nutritional assessment, which is not normally required for GM crops expressing agronomic traits. This Application is anticipated to involve an assessment of the risk to public health and safety of above average complexity.	March 2010		

### DECISION

Application accepted	
Date: 9 February 2010	

Has the Applicant claimed Confidential Commercial Information status?					
Yes <b>√</b> No					
What documents are affected?					
Appendix 1: DNA sequence of the insert and adjacent genomic regions in MON 87769;					
) Pages 56-59 and 61: Study#: 06-01-83-23, MSL#: 0021926; and					
(iii) Bioinformatics Evaluation MON 87769, Study #: REG-08-514 (40 pages)					
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?					
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: N/A					

#### Charges

Does FSANZ consider that the application is subject to ECCB?

Yes 🖌 No

If yes, indicate the reason:

The Application will confer an exclusive capturable commercial benefit on 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: 10 March 2010 (Fees received 17 February 2010)

Does the Applicant want to expedite consideration of this Application?  $\ensuremath{\text{N/A}}$ 

## Application Handbook Requirements

Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application:					
Section 3.1 & Section 3.5.1					
Does the Application meet the requirements of the relevant Guidelines?					
Yes <b>√</b> No					
Is the checklist completed?					
Yes <b>√</b> 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:					
Major					
Other Comments or Relevant Matters:					
N/A					

### CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy Proposed length of pub Major Procedure	: lic consultation periods: post-1 <sup>st</sup> Assessment (6 we Post 2 <sup>nd</sup> Assessment (4 we	,	Community Involvement Category: 2 (Low intensity, broader focus)			
Proposed Timeframe for Assessment:						
'Early Bird Notification' due: 24 February 2010						
Major Procedure: Commence Assessment (clock start) Completion of 1 <sup>st</sup> Assessment Public comment Completion of 2 <sup>nd</sup> Assessment Public comment Board to complete Approval Notification to Ministerial Council Anticipated gazettal if no review requested		17 February 2010 Early July 2010 Mid-July – late Augus Late October 2010 Late October- late No Mid-Feb 2011 (17 Fe Late February 2011 Early May 2011	ovember 2010			