

24 February 2010
[6-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1041	Date Received: 15 January 2010 Date Due for completion of Administrative Assessment: 9 February 2010 Date Administrative Assessment Completed: 9 February 2010	
Applicant: Monsanto Australia Limited		Potentially Affected Standard in the Code:
Title: Food derived from SDA Soybean Line MON 87769 Brief Description of Application: To seek permission for food derived from soybean genetically modified to contain stearidonic acid (SDA), as a plant source of omega-3 fatty acids.		Standard 1.5.2
Procedure: Major Reasons why: 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.	Estimated total hours: 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.	Estimated start work: March 2010

DECISION

Application accepted

Date: 9 February 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

- (i) Appendix 1: DNA sequence of the insert and adjacent genomic regions in MON 87769;
- (ii) 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?

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

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?

N/A

