



12 February 2010
[4-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1040	Date Received: 16 December 2009 Date Due for completion of Administrative Assessment: 11 January 2010 Date Administrative Assessment Completed: 11 January 2010	
Applicant: Bayer CropScience Pty Ltd		Potentially Affected Standard in the Code:
Title: Food Derived from Insect-protected & Herbicide-tolerant Cotton Line GHB119 Brief Description of Application: To seek permission for food derived from cotton genetically modified to provide protection against Lepidopteran insect pests and tolerance to the herbicide glufosinate ammonium.		Standard 1.5.2
Procedure: General Reasons why: <ul style="list-style-type: none"> • This is an application for a GM food that is not currently permitted and involves a comprehensive pre-market safety assessment. • FSANZ has previously assessed and approved different lines of cotton that contain one of the novel genes (<i>bar</i>) contained in Line GHB119. • The other gene (<i>cry2Ae</i>) in Line GHB119 has not been previously assessed but is similar to <i>cry2A</i> genes assessed and approved in two other cotton applications. • Nutrition and Dietary Modelling input will not be required. 	Cost Category (General Procedure): Level 2: Up to 850 hours Reasons why: This Application is anticipated to involve an assessment of the risk to public health and safety of average complexity. FSANZ will need to undertake a case-specific safety assessment including an evaluation of detailed molecular characterisation data uniquely relevant to this product.	Estimated start work: Early February 2010

DECISION

Application accepted

Date: 11 January 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Certain Information in the Bayer CropScience studies provided in Appendices 3, 4, 5, 6, 7, and 8 contains confidential commercial information.

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 cotton Line GHB119 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: 10 February 2010 (Fees received 8 February 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 *Application Handbook* 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?

Not applicable

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

Other Comments or Relevant Matters:

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:

Proposed length of public consultation period:

General Procedure (6 weeks)

Community Involvement Category:

3 (intensive, narrower focus)

Proposed Timeframe for Assessment:

'Early Bird Notification' due:

General Procedure:

Commence Assessment (clock start)	early February 2010
Completion of Assessment	early July 2010
Public comment	mid-July 2010 – late August 2010
Board to complete Approval	early November 2010
Notification to Ministerial Council	mid-November 2010
Anticipated gazettal if no review requested	mid-January 2011