

18 August 2010
[18-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1051	Date Received: 30 June 2010 Date Due for completion of Administrative Assessment: 21 July 2010 Date Administrative Assessment Completed: 21 July 2010	
Applicant: Bayer CropScience Pty Ltd		Potentially Affected Standards in the Code:
Title: Food derived from Herbicide-tolerant Soybean Line FG72 Brief Description of Application: To seek approval of food derived from a genetically modified soybean with tolerance to glyphosate and isoxazole herbicides.		1.4.2 1.5.2
Procedure: General Level 2 Reasons why: This is an Application for a GM food that is not currently permitted and involves a comprehensive, pre-market safety assessment. One of the novel proteins in soybean line FG72 (2mEPSPS) has been assessed previously by FSANZ. The other novel protein (HPPDW336) has not been previously assessed. FSANZ will need to undertake an assessment of general scientific complexity that is specific for this Application.	Estimated total hours: Up to 850 hours Reasons why: This application is anticipated to involve an assessment of the risk to public health and safety of a relatively high level of complexity. FSANZ will need to undertake a case-specific safety assessment including an evaluation of detailed molecular characterisation data uniquely relevant to this product. In addition to the GM data, it may be necessary to also consider residue data	Estimated start work: Mid- August 2010

DECISION

Application accepted

Date: 21 July 2010

Has the Applicant claimed Confidential Commercial Information status?

Yes ✓ No

What documents are affected?

Certain information contained in tables, figures and appendices within five of Bayer CropScience's unpublished studies.

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 with soybean varieties containing the FG72 event 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: 18 August 2010 (fees received 12 August 2010)

Does the Applicant want to expedite consideration of this Application?

N/A

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?

Residue/toxicological data for isoxaflutole have not been provided and neither has the Applicant indicated whether a variation to Standard 1.4.2 will be required. The Applicant has indicated that this information will be provided when it becomes 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?

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:

2

(Low intensity, broader focus)

Proposed Timeframe for Assessment:

'Early Bird Notification' due: 17 August 2010

General Procedure:

Commence Assessment (clock start)

12 August 2010

Completion of Assessment

mid-January 2011

Public comment

mid-January 2011 – late February 2011

Board to complete Approval

early May 2011

Notification to Ministerial Council

mid-May 2011

Anticipated gazettal if no review requested

late July 2011