



7-07

9 November 2007

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1001	Date Received: 10 October 2007 Date Due for completion of Administrative Assessment: <u>1 November 2007</u> Date Administrative Assessment Completed: 30 October 2007	
Applicant: Syngenta	Potentially Affected Standard in the Code: 1.5.2	
Title: Food derived from Insect-protected Corn Line MIR162 Brief Description of Application: To approve food derived from corn genetically modified to provide resistance to Lepidopteran species.		
Procedure: General Reasons why: This is an application for a variation allowing a food that is not currently permitted, granting a permission involving a pre-market safety assessment similar to a previous assessment. FSANZ has previously favourably assessed both of the novel proteins present in GM corn MIR162 (Vip3A and PMI), and has assessed numerous GM corns.	Cost Category (General Procedure): Up to 500 hours Reasons why: This assessment is anticipated to involve an assessment of the risk to public health and safety of average complexity.	Estimated start work: 4 th Qtr 2007

DECISION

Application accepted

Date: 30 October 2007

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Has the Applicant provided justification for Confidential Commercial Information status?

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:

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes No

If yes, indicate the reason:

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

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: 28 November 2007 (fees received 5 November 2007)

Does the Applicant want to expedite consideration of this Application?

Yes No Not known

Application Handbook Requirements

Which Guideline/s within the Part 3 of the *Application Handbook* apply to this Application:

3.5.1

Does the Application meet the requirements of the relevant Guideline/s?

Yes No

Is the checklist completed?

Yes (old checklist) No

What information is not provided?

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

<p>Consultation Strategy: Proposed length of public consultation period: General Procedure (6 weeks)</p>	<p>Community Involvement Category: 3 (intensive, narrower focus)</p>												
<p>Proposed Timeframe for Assessment:</p> <p>‘Early Bird Notification’ due: mid November 2008</p> <p><u>General Procedure:</u></p> <table> <tr> <td>Commence Assessment (clock start)</td> <td>end November 2007</td> </tr> <tr> <td>Completion of Assessment</td> <td>early April 2008</td> </tr> <tr> <td>Public comment</td> <td>mid April – late May 2008</td> </tr> <tr> <td>Board to complete Approval</td> <td>end August 2008 (possibly to FSANZ32 in late July 2008)</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>mid September 2008</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>end November 2008</td> </tr> </table>		Commence Assessment (clock start)	end November 2007	Completion of Assessment	early April 2008	Public comment	mid April – late May 2008	Board to complete Approval	end August 2008 (possibly to FSANZ32 in late July 2008)	Notification to Ministerial Council	mid September 2008	Anticipated gazettal if no review requested	end November 2008
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