

2 September 2011
[16-11]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1064	Date Received: 25 July 2011 Date Due for completion of Administrative Assessment: 15 August 2011 Date Administrative Assessment Completed: 15 August 2011	
Applicant: BASF Plant Science Company GmbH		Potentially Affected Standards in the Code: Standard 1.5.2 – Food produced using Gene Technology. Standard 1.4.2 – Maximum Residue Limits
Title: Food derived from Herbicide-tolerant Soybean Line CV127 Brief Description of Application: To seek permission for food derived from soybean line CV127 which is genetically modified to provide tolerance to imidazolinone herbicides.		
Procedure: General	Estimated total hours: Maximum 650 hours (Level 2) Reasons why: FSANZ will need to undertake a case-specific evaluation of the genetic modification in soybean line CV127.	Estimated start work: September 2011

DECISION

Application accepted Date: 15 August 2011
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Has the Applicant claimed Confidential Commercial Information status?

Yes No ✓

What documents are affected? N/A

Has the Applicant provided justification for Confidential Commercial Information status? N/A

NOTE: The Applicant has, however, requested that the personal details of personnel mentioned in the unpublished studies supplied as part of the Application, be suppressed for legal, ethical and security reasons. FSANZ has agreed to this.

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:

Since the technology behind the Application has been developed solely by the Applicant, the Applicant will gain an exclusive benefit if the Application is approved.

If yes, indicate due date for fees to be paid. Note that if fees are not received by this date, the Application is automatically rejected.

Due date for fees: 12 September 2011. Fees received: 26 August 2011.

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:

Section 3.1 and Section 3.5.1

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

Yes ✓ No

Is the checklist completed?

Yes ✓ 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:

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: 2 (low intensity, broad focus)</p>
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<p>Proposed Timeframe for Assessment: . 'Early Bird Notification' due: <u>General Procedure:</u> 2 September 2011</p> <table data-bbox="240 1249 1364 1428"> <tr> <td>Commence Assessment (clock start)</td> <td>26 August 2011</td> </tr> <tr> <td>Completion of Assessment</td> <td>mid-January 2012</td> </tr> <tr> <td>Public comment</td> <td>mid-January – late February 2012</td> </tr> <tr> <td>Board to complete Approval</td> <td>early May 2012</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>mid-May 2012</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>late July 2012</td> </tr> </table>		Commence Assessment (clock start)	26 August 2011	Completion of Assessment	mid-January 2012	Public comment	mid-January – late February 2012	Board to complete Approval	early May 2012	Notification to Ministerial Council	mid-May 2012	Anticipated gazettal if no review requested	late July 2012
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