

19 March 2013

[04-13]

Administrative Assessment Report – Application A1081

Food derived from Herbicide-tolerant Soybean Line SYHT0H2

<p>Date received: 29 January 2013 Date due for completion of administrative assessment: 20 February 2013 Date completed: 20 February 2013</p>		
<p>Applicant: Bayer CropScience Pty Ltd & Syngenta Seeds Pty Ltd</p>		<p>Potentially affected Standard:</p>
<p>Brief description of Application: To seek permission for food derived from herbicide-tolerant soybean, genetically modified to provide tolerance to the herbicide glufosinate-ammonium and tolerance to herbicides that inhibit p-hydroxyphenylpyruvate dioxygenase (HPPD).</p>		<p>Standard 1.5.2</p>
<p>Procedure: General</p>	<p>Estimated total hours: Maximum 350</p> <p>Reasons why: This kind of application involves an assessment of the potential risk to public health and safety.</p>	<p>Estimated start work: March 2013</p>

Decision

Application accepted

Date: 20 February 2013

Has the Applicant requested confidential commercial information status?

Yes No

The following documents within the Application Dossier are effected.

Appendix 1

- Table 3
- Figure 5 (A, B & C)
- Appendix A
- Appendix B

Appendix 3

- Table 2
- Figure 2
- Figure 3
- Figure 5
- Appendix A
- Appendix B

Appendix 5

- Table A1

In information separately received from Syngenta, a request for CCI, of all residue data generated on mesotrione, has been made. The request includes that the information not be shared with the co-Applicant, Bayer CropScience.

Has the Applicant provided justification for confidential commercial information request?

Yes No N/A

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

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.

NOTE: The Applicants do not consider an ECCB is justified

Due date for fees: 21 March 2013 (fees received 14 March 2013)

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?

3.1.1, 3.5.1

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

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:

Nil

Consultation & assessment timeframe

Proposed length of public consultation period

6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: 21 March 2013

Commence assessment (clock start)	14 March 2013
Completion of assessment & preparation of draft food reg measure	Early July 2013
Public comment	Mid-July – Early September 2013
Board to complete approval	Early December 2013
Notification to Forum	Mid-December 2013
Anticipated gazettal if no review requested	Late February 2014