

**27 February 2009**  
**[3-09]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

<b>A1021</b>	<b>Date Received:</b> 20 January 2009 <b>Date Due for completion of Administrative Assessment:</b> 12 February 2009 <b>Date Administrative Assessment Completed:</b> 12 February 2009	
<b>Applicant:</b> <b>SGA Solutions</b> on Behalf of Pioneer Hi-Bred International, Inc.		<b>Potentially Affected Standard in the Code:</b>  1.5.2
<b>Title:</b> Food derived from Herbicide-tolerant Corn Line DP-098140-6  <b>Brief Description of Application:</b> To seek pre-market approval for food derived from corn genetically modified (GM) for tolerance to both glyphosate and acetolactate synthase-inhibiting herbicides.		
<b>Procedure:</b> <b>General</b>  <b>Reasons why:</b> This is an Application for a GM food that is not currently permitted and involves a comprehensive, pre-market safety assessment.  FSANZ has recently assessed a similar application for GM soybean with the same genetic modifications used to confer herbicide tolerance. However, FSANZ will need to undertake a safety assessment of general scientific complexity that is specific for this Application.	<b>Cost Category (General Procedure)</b> Level 2 Up to 850 hours  <b>Reasons why:</b> 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 and toxicological data, including consideration of any compositional changes in this GM corn. The toxicity of two novel glyphosate residues generated in this crop has already been assessed in a separate application (A1006) for dual herbicide-tolerant soybean.	<b>Estimated start work:</b> Mid-March 2009

**DECISION**

**Application accepted**

**Date: 12 February 2009**

**Has the Applicant claimed Confidential Commercial Information status?**

Yes ✓ No

**What documents are affected?**

One study (relating to the DNA sequence of the insert/border regions).

**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?**

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 ✓

### ***Charges***

**Does FSANZ consider that the application is subject to ECCB?**

Yes ✓ No

**If yes, indicate the reason:**

The Applicant has declared that approval of the Application will have an exclusive capturable commercial benefit for the Applicant.

**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: 13 March 2009 (Fees paid 20 February 2009)**

**Does the Applicant want to expedite consideration of this Application?**

Yes No Not known N/A ✓

### ***Application Handbook Requirements***

**Which Guidelines within Part 3 of the *Application Handbook* apply to this Application:**

3.5.1

**Does the Application meet the requirements of the relevant Guideline?**

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 (Level 2)**

**Other Comments or Relevant Matters:**

***CONSULTATION & ASSESSMENT TIMEFRAME***

<p><b>Consultation Strategy:</b> Proposed length of public consultation periods:</p> <p>General Procedure (6 weeks)</p>	<p><b>Community Involvement Category:</b></p> <p>1 (Low intensity, narrow focus)</p>												
<p><b>Proposed Timeframe for Assessment:</b></p> <p><b>'Early Bird Notification' due:</b> 27 February 2009</p> <p><u>General Procedure:</u></p> <table border="0"> <tr> <td>Commence Assessment (clock start)</td> <td>20 February 2009</td> </tr> <tr> <td>Completion of Assessment</td> <td>Early July 2009</td> </tr> <tr> <td>Public comment</td> <td>Mid July – early September 2009</td> </tr> <tr> <td>Board to complete Approval</td> <td>early November 2009</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>Mid-November 2009</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>Late January 2010</td> </tr> </table>		Commence Assessment (clock start)	20 February 2009	Completion of Assessment	Early July 2009	Public comment	Mid July – early September 2009	Board to complete Approval	early November 2009	Notification to Ministerial Council	Mid-November 2009	Anticipated gazettal if no review requested	Late January 2010
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