

**28 October 2008**  
**[18-08]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

<b>A1018</b>	<b>Date Received:</b> 22 September 2008 <b>Date Due for completion of Administrative Assessment:</b> 14 October 2008 <b>Date Administrative Assessment Completed:</b> 9 October 2008	
<b>Applicant:</b> <b>SGA Solutions</b> on behalf of Pioneer Hi-Bred International Inc.		<b>Potentially Affected Standard in the Code:</b>  Standard 1.5.2 – Food produced using Gene Technology.
<b>Title:</b> Food derived from High Oleic Acid Soybean Line DP-305423-1  <b>Brief Description of Application:</b> To seek pre-market approval for food derived from genetically modified (GM) soybean where the purpose of the modification is to alter the fatty acid profile (increased level of oleic acid and reduced levels of linoleic and linolenic acids) in soybean oil to improve stability and cooking properties.		
<b>Procedure: General</b> <b>Reasons why:</b> This is an application for a GM food that is not currently permitted, involving a pre-market safety assessment similar to a previous assessment.  FSANZ has previously assessed and approved different lines of high oleic acid soybean with the same genetic modification used to confer the trait.	<b>Cost Category (General Procedure):</b> Level 1 Up to 500 hours  <b>Reasons why:</b> This Application is anticipated to involve an assessment of the risk to public health and safety of average complexity.	<b>Estimated start work:</b> November 2008

**DECISION**

**Application accepted**

**Date: 9 October 2008**

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

Yes No

**What documents are affected?**

Not applicable.

**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?**

Yes No

**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 approval of the Application will confer an exclusive capturable commercial benefit on 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: 10 November 2008 (Received 20 October 2008)**

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

Yes No Not known N/A

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

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

Section 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?**

Not applicable.

**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:**

FSANZ assessed three lines of High Oleic Soy in Application A387. Amendments relating to high oleic soy lines G94-1, G94-19 and G168 were gazetted on 7 December 2000. The genetic trait in the current Application is the same, however a new transformation event has produced a different line which must be assessed and approved as a distinct line.

***CONSULTATION & ASSESSMENT TIMEFRAME***

<p><b>Consultation Strategy:</b> Proposed length of public consultation period:</p> <p>General Procedure (6 weeks)</p>	<p><b>Community Involvement Category:</b> 3 (intensive, narrower focus)</p>												
<p><b>Proposed Timeframe for Assessment:</b></p> <p><b>'Early Bird Notification' due:</b></p> <p><u>General Procedure:</u></p> <table border="0"> <tr> <td>Commence Assessment (clock start)</td> <td>early November 2008</td> </tr> <tr> <td>Completion of Assessment</td> <td>early March 2009</td> </tr> <tr> <td>Public comment</td> <td>mid March–early May 2009</td> </tr> <tr> <td>Board to complete Approval</td> <td>late July 2009</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>early August 2009</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>late October 2009</td> </tr> </table>		Commence Assessment (clock start)	early November 2008	Completion of Assessment	early March 2009	Public comment	mid March–early May 2009	Board to complete Approval	late July 2009	Notification to Ministerial Council	early August 2009	Anticipated gazettal if no review requested	late October 2009
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