



**15 July 2009**  
**[11-09]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

<b>A1028</b>	<b>Date Received:</b> 5 June 2009 <b>Date Due for completion of Administrative Assessment:</b> 29 June 2009 <b>Date Administrative Assessment Completed:</b> 24 June 2009	
<b>Applicant:</b> Bayer CropScience		<b>Potentially Affected Standard in the Code:</b>
<b>Title:</b> Food Derived from Insect-protected & Herbicide-tolerant Cotton Event T304-40 <b>Brief Description of Application:</b> To seek pre-market approval for food derived from cotton genetically modified to provide tolerance to the herbicide glufosinate ammonium, and protection against Lepidopteran insect pests.		Standard 1.5.2
<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 previous assessments. FSANZ has previously assessed and approved different lines of cotton that separately contain the same novel genes contained together in Event T304-40	<b>Cost Category (General Procedure):</b> <b>Level 2:</b> 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 average complexity.	<b>Estimated start work:</b> Late July 2009

***DECISION***

**Application accepted**

**Date: 24 June 2009**

**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?**

Not applicable

**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?**

Not applicable

**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:** Not applicable

### ***Charges***

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

Yes  No

**If yes, indicate the reason:**

The Applicant has indicated that approval of the application would contribute to facilitating commercial activities of cotton event T304-40 in Australia

**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: 22 July 2009**

**Fees Received: 9 July 2009**

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

Yes No Not known Not applicable

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

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

Section 3.1 & 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:**

***CONSULTATION & ASSESSMENT TIMEFRAME***

**Consultation Strategy:**

Proposed length of public consultation period

:

General Procedure      (6 weeks)

**Community Involvement Category:**

**3** (intensive, narrower focus)

**Proposed Timeframe for Assessment:**

**'Early Bird Notification' due: 16 July 2009**

**General Procedure:**

Commence Assessment (clock start)	9 July 2009
Completion of Assessment	early November 2009
Public comment	early November-mid-December 2010
Board to complete Approval	early March 2010
Notification to Ministerial Council	Mid-March 2010
Anticipated gazettal if no review requested	Late May 2010