



[7-08]
22 April 2008

APPLICATION – ADMINISTRATIVE ASSESSMENT

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| A1006 | Date Received: 18 March 2008 Date Due for completion of Administrative Assessment: 10 April 2008 Date Administrative Assessment Completed: 18 March 2008 | |
| Applicant: SGA Solutions on Behalf of Pioneer Hi-Bred International, Inc. | | Potentially Affected Standard in the Code: |
| Title: Food derived from Herbicide-tolerant Soybean Line DP-356043-5 Brief Description of Application: To approve food derived from soybean genetically modified to provide tolerance to both glyphosate and acetolactate synthase-inhibiting herbicides. | | 1.5.2 1.4.2 |
| Procedure: Major Reasons why: This is an application for a variation to a food regulatory measure involving the granting of a permission involving a pre-market safety assessment, with no similar previous assessments. This application involves such scientific complexity that it is necessary to adopt this procedure in considering it. Assessment is likely to require consultation with government agencies and involve external peer review of the safety/risk assessment. | Estimated total hours (Major Procedure) 1225 hours Reasons why: This application will require a safety assessment of a GM food expressing novel proteins not considered in previous assessments (glyphosate acetyltransferase and modified acetolactate synthase), and a complete toxicological assessment, including dietary modelling, of herbicide residues not previously assessed (N-acetyl glyphosate). The assessment will also need to consider whether the existing MRL for glyphosate in soybean is appropriate for this crop. | Estimated start work: 2 nd Qtr 2008 |

DECISION

Application accepted

Date: 10 April 2008

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Two studies (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 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: 9 May 2008

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

