

1 October 2009 [17-09]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1034	Date Received: 18 August 2009 Date Due for completion of Administrative Assessment: 8 September 2009 Date Administrative Assessment Completed: 31 August 2009		
Applicant: Ajinomoto Co Inc via Cantox & Biosearch Consulting			Potentially Affected Standard in the
Title: Advantame as a High Intensity Sweetener			Code:
Brief Description of Application:			Standard 1.3.1 – Food Additives
To approve Advantame for use in table top sugar substitutes and a range of powdered beverages including fruit drinks, milks and milk-flavoured drinks, instant tea and coffee and protein drinks.			
Procedure:		Cost Category (Major Procedure):	Estimated start
Major		Estimated total hours 1325 (Major	work:
		Procedure)	Late September 2009
Reasons why: This is an Application for a new intense sweetener that is not currently permitted and involves a comprehensive, pre-market safety assessment. This involves such scientific complexity that it warrants a major procedure.		Reasons why: FSANZ will need to undertake a safety assessment of high scientific complexity and possibly need to establish a reference health level (e.g. an Acceptable Daily Intake) ahead of other regulatory agencies in the world or expert bodies such as JECFA. This Application is anticipated to involve an assessment of the risk to public health and safety of above average complexity.	

DECISION

Application accepted

Date: 25 September 2009

Has the Applicant claimed Confidential Commercial Information status?

Yes ✓ No

What documents are affected?

Manufacturing method for ANS9801 (Appendix B5.1)

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 ✓

Details: N/A

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes ✓ No

If yes, indicate the reason:

Advantame (ANS9801) is a non-nutritive sweetener obtained *via* proprietary manufacturing processes and should be considered a newly developed sweetener. Ajinomoto is seeking permission for the use of ANS9801 under the common name Advantame and anticipates that this would confer ECCB.

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: 2 October 2009 (Fees received 25 September 2009)

Does the Applicant want to expedite consideration of this Application?

N/A as ECCB applies

Application Handbook Requirements

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

Section 3.1 and 3.3.1

Does the Application meet the requirements of the relevant Guideline/s?

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:

Major

Other Comments or Relevant Matters:

The Applicant proposed that the Application would fall under the major procedure (Subdivision F), Cost Category Level 2, requiring up to 1050 hours.

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:

Proposed length of public consultation period/s:

Major Procedure post-1st Assessment (6 weeks)

Post 2nd Assessment (4 weeks)

Community Involvement Category:

3 (intensive, narrower focus)

Proposed Timeframe for Assessment:

'Early Bird Notification' due:

Major Procedure:

Commence Assessment (clock start) 25 September 2009 Completion of 1st Assessment Early March 2010

Public comment Mid-March-Early May 2010

Completion of 2nd Assessment Mid-June 2010

Public comment

Board to complete Approval

Notification to Ministerial Council

Anticipated gazettal if no review requested

Late June-Late July 2010

Mid-September 2010

Late September 2010

Early December 2010