



**1 October 2009**  
**[17-09]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

<b>A1034</b>	<b>Date Received:</b> 18 August 2009 <b>Date Due for completion of Administrative Assessment:</b> 8 September 2009 <b>Date Administrative Assessment Completed:</b> 31 August 2009	
<b>Applicant:</b> Ajinomoto Co Inc via Cantox & Biosearch Consulting  <b>Title:</b> Advantame as a High Intensity Sweetener  <b>Brief Description of Application:</b> 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.		<b>Potentially Affected Standard in the Code:</b> Standard 1.3.1 – Food Additives
<b>Procedure:</b> <b>Major</b>  <b>Reasons why:</b> 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.	<b>Cost Category (Major Procedure):</b> <b>Estimated total hours 1325 (Major Procedure)</b>  <b>Reasons why:</b> 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.	<b>Estimated start work:</b> Late September 2009

**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

