

1 October 2008
[17-08]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1015	Date Received: 28 August 2008 Date Due for completion of Administrative Assessment: 18 September 2008 Date Administrative Assessment Completed: 11 September 2008	
Applicant: Laboratorios Miret SA via Competitive Advantage		Potentially Affected Standard/s in the Code: Standard 1.3.1 – Food Additives Standard 1.3.4 – Identity and Purity
Title: Lauric Arginate as a Food Additive Brief Description of Application: to approve lauric arginate as a preservative in a number of food groups to control food spoilage micro-organisms.		
Procedure: General Reasons why: This is a new food additive that has not been assessed before by FSANZ. Permission is being requested in a large range of foods.	Cost Category (General Procedure): Up to 850 hours Estimated total hours 800 Reasons why: <ul style="list-style-type: none"> • a safety and dietary exposure assessment is required; • Food technology and efficacy aspects will be considered; • the risk management options are anticipated to be straight forward; and • the amendments being sought are expected to have limited social and economic impact; 	Estimated start work: 4 th Qtr 2008

DECISION

Application accepted

Date: 11 September 2008

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Confidential Appendices 1-31

Has the Applicant provided justification for Confidential Commercial Information status?

Yes No

Is the Application for a High Level Health Claim?

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 is expected to derive a financial gain from the amendment to the Standard.

Due date for fees: 10 October 2008 (Fees received 26 September 2008)

Note that if fees are not received by this date, the Application is automatically rejected.

Does the Applicant want to expedite consideration of this Application?

Not applicable since it is subject to an ECCB

Application Handbook Requirements

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

3.1 – General Requirements

3.3.1 – Food Additives

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:

General

Other Comments or Relevant Matters:

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:

Proposed length of public consultation period:

General Procedure (6 weeks)

Community Involvement Category:

5

Case of minor significance or complexity or with little adverse impact on individual interests

Proposed Timeframe for Assessment:

'Early Bird Notification' due: 8 October 2008

General Procedure:

Commence Assessment (clock start)

26 September 2008

Completion of Assessment

Early February 2009

Public comment

Mid-February to Early April 2009

Board to complete Approval

26 June 2009

Notification to Ministerial Council

Early July 2009

Anticipated gazettal if no review requested

Mid-September 2009