



23 July 2010
[16-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

PA1052	Date Received: 30 June 2010 Date Due for completion of Administrative Assessment: 21 July 2010 Date Administrative Assessment Completed: 14 July 2010	
Applicant: DSM Food Specialties Pty Ltd		Potentially Affected Standard in the Code: Standard 1.3.1
Title: Extension of Use of Natamycin Brief Description of Application: To extend the use of natamycin as an antimycotic preservative in fermented milk and renneted milk products, breads and bakery products and dairy and fat based desserts, dips and snacks.		
Procedure: General Reasons why: This antifungal preservative is permitted for limited use in the Code. The Applicant is requesting a variation of a food regulatory measure to extend the use of a currently permitted food additive.	Cost Category (General Procedure): Level 2 Estimated total hours: 805 Reasons why: <ul style="list-style-type: none"> • The assessment will require updated safety, dietary exposure and food technology assessments. • The assessment will also need to address antimicrobial resistance concerns. • Requires targeted consultation with key stakeholders and/or special interest groups. • May require more comprehensive consideration of risk management requirements. 	Estimated start work:

DECISION

<p>Application rejected</p> <p>Date: 14 July 2010</p> <p>If rejected, list reasons for rejection: The Application did not meet the mandatory information and format requirements under subsection 22(2) of the FSANZ Act which are set out in Part 3 of the FSANZ <i>Application Handbook</i>. The Administrative Assessment does not consider the merits of the Application.</p>

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Appendix 2 of the Application

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?

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:

Does the Applicant want to expedite consideration of this Application?

Yes No

Application Handbook Requirements

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

3.1 General Requirements and 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?

FSANZ requires further information to meet the requirements of the relevant guidelines of the Application Handbook including:

Executive summary, copies of all references, data on the safety of the additive and data to support its preservative effect in all foods in which it is proposed to be added.

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 Level 2

Other Comments or Relevant Matters:

The Applicant was advised that in submitting an application to extend the use of natamycin, the issues raised during Application A542 in relation to antimicrobial resistance would need to be addressed.

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:

Proposed length of public consultation period:

General Procedure (6 weeks)

Community Involvement Category:

3

Case requires an intensive, narrower focus.

Proposed Timeframe for Assessment: N/A