



[3-08]
6 March 2008

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1005	Date Received: 22 February 2008 Date Due for completion of Administrative Assessment: 17 March 2008 Date Administrative Assessment Completed: 29 February 2008
Applicant: Cognis GmbH via Axiome Pty Ltd	Potentially Affected Standards in the Code: 1.5.1 – Novel Foods 1.2.8 – Nutrition Information Requirements 1.3.4 – Identity and Purity
Title: Conjugated Linoleic Acid Triglycerides as a Novel Food Brief Description of Application: To approve exclusive use of a chemically defined mixture of conjugated linoleic acid triglycerides derived from food-grade safflower oil with a high linoleic acid content as a novel food.	
Procedure: General Reasons why: The Application is requesting a variation of a food regulatory measure to approve a novel food that is not currently permitted.	Cost Category (General Procedure): Up to 850 hours Reasons why: The assessment of the Application will require a complete toxicological assessment, including dietary modelling, as well as assessment of the nutritional impact of the novel food and labelling considerations.
	Estimated start work: March 2008

DECISION

Application accepted
Date: 29 February 2008

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Appendix 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?

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: The Applicant is seeking permission for exclusive use of the novel food, Conjugated Linoleic Acid Triglycerides in the brand Tonalin® CLA.

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes No

If yes, indicate the reason: The Applicant has sought permission for exclusive use of the novel food ingredient under clause 3 of Standard 1.5.1.

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 April 2008

Does the Applicant want to expedite consideration of this Application?

Not applicable as the Application is subject to ECCB.

Application Handbook Requirements

<p>Which Guideline within the Part 3 of the <i>Application Handbook</i> apply to this Application:</p> <p>3.5.2</p> <p>Does the Application meet the requirements of the relevant Guideline/s?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>Is the checklist completed?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>What information is not provided?</p>
<p>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?</p> <p>Yes <input checked="" type="checkbox"/> No</p>
<p>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?</p> <p>Yes No <input checked="" type="checkbox"/></p>
<p>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?</p> <p>Yes <input checked="" type="checkbox"/> No</p> <p>If yes, indicate which Procedure:</p> <p>General</p>
<p>Other Comments or Relevant Matters:</p>

CONSULTATION & ASSESSMENT TIMEFRAME

<p>Consultation Strategy:</p> <p>Proposed length of public consultation period:</p> <p>General Procedure (6 weeks)</p>	<p>Community Involvement Category:</p> <p>3</p> <p>Intensive narrower focus</p>												
<p>Proposed Timeframe for Assessment:</p> <p>'Early Bird Notification' due:</p> <p><u>General Procedure:</u></p> <table> <tr> <td>Commence Assessment (clock start)</td> <td>early March 2008</td> </tr> <tr> <td>Completion of Assessment</td> <td>early August 2008</td> </tr> <tr> <td>Public comment</td> <td>mid-August-end September 2008</td> </tr> <tr> <td>Board to complete Approval</td> <td>early December 2008</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>end December 2008</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>early March 2009</td> </tr> </table>		Commence Assessment (clock start)	early March 2008	Completion of Assessment	early August 2008	Public comment	mid-August-end September 2008	Board to complete Approval	early December 2008	Notification to Ministerial Council	end December 2008	Anticipated gazettal if no review requested	early March 2009
Commence Assessment (clock start)	early March 2008												
Completion of Assessment	early August 2008												
Public comment	mid-August-end September 2008												
Board to complete Approval	early December 2008												
Notification to Ministerial Council	end December 2008												
Anticipated gazettal if no review requested	early March 2009												