FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

1 October 2008
[17-08]

APPLICATION – ADMINISTRATIVE ASSESSMENT

<table>
<tr><td>A1014</td><td colspan="2">Date Received: 27 August 2008
Date Due for completion of Administrative Assessment: 17 September 2008
Date Administrative Assessment Completed: 16 September 2008</td></tr>
<tr><td colspan="2">Applicant: Unilever</td><td rowspan="2">Potentially Affected Standards in the Code:
1.5.1 - Novel Foods (including exclusivity provisions)

1.3.4 – Identity and Purity

1.2.3 – Mandatory Warning and Advisory Statements and Declarations

2.6.2 – Non-Alcoholic beverages and brewed soft drinks

1.3.1 – Food Additives (Tocopherol permissions)</td></tr>
<tr><td colspan="2">Title: Exclusive Use of Vegetable Oil Phytosterol Esters in Flora pro.activ® Shots

Brief Description of Application:
To permit the exclusive use of vegetable oil phytosterol esters as a permitted novel food in a different food matrix from those already permitted, namely, a flavoured shot to be consumed once a day. This Application also requests permission to use Schedule 2, 3 and 4 additives and the food additive tocopherol as an antioxidant in flavoured shots where vegetable oil sterol esters are permitted to be added.</td></tr>
<tr><td>Procedure:
General

Reasons why:
The Applicant is seeking a new exclusive novel food permission under Standard 1.5.1</td><td>Cost Category (General Procedure):
Up to 850 hours
Reasons why:
The assessment will require detailed toxicological, nutritional, and dietary exposure assessments. There will be risk management considerations which may be complex, including labelling and legal drafting.</td><td>Estimated start work:</td></tr>
</table>

DECISION

Application rejected

Date: 16 September 2008

If rejected, list reasons for rejection:
The Application does not meet the mandatory information requirements under Part 3 of the *Application Handbook*, as required under subsection 22(2) of the FSANZ Act.

Has the Applicant claimed Confidential Commercial Information status?

(tick ✓) Yes ✓ No

What documents are affected? Appendix I and II (+ 2 related documents)

Has the Applicant provided justification for Confidential Commercial Information status?

(tick ✓) Yes ✓ No

Is the Application for a High Level Health Claim?

(tick ✓) 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?

(tick ✓) 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.

(tick ✓) Yes ✓ No

- This Application is seeking permission for the exclusive use of vegetable oil phytosterol esters in a flavoured shot under clause 3 of Standard 1.5.1 of the Code.

For inclusion in Table to Clause 3:

Novel Food: Vegetable oil sterol esters
Brand: Flora pro.activ® Shots
Class of Food: low fat shot
Conditions of Use: to meet the required defining elements of the low fat shot

The Applicant requests exclusive permission for this food format and the Flora pro.activ brand for the period of 15 months after gazettal as stated under subclause 3 (4) of Standard 1.5.1.

Charges

Does FSANZ consider that the application is subject to ECCB?

(tick ✓) Yes ✓ No

If yes, indicate the reason:

The Applicant has requested exclusive permission for this food format and the Flora pro.activ brand for the period of 15 months after gazettal as stated under subclause 3 (4) 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: N/A as Application 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:

3.3.1 and 3.5.2

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

(tick ✓) Yes No ✓

Is the checklist completed?

(tick ✓) Yes ✓No

What information is not provided?

FSANZ requires further information to meet the requirements of the relevant guidelines (3.3.1 and 3.5.2) of the Application Handbook:

1. Description of the novel food ingredient;
2. Justification on the use of the proposed food additives in single shots;
3. Further information on the safety and dietary exposure impacts of the novel food ingredient;
4. Further information on consumer awareness, actual and/or potential behaviour of consumers and information on any potential adverse effects on any population groups; and
5. Data on projected impacts of the novel food ingredient on the food industry and international trade.

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?

(tick ✓) 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?

(tick ✓) Yes No ✓

Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?

(tick ✓) Yes✓ No

If yes, indicate which Procedure:

General

Other Comments or Relevant Matters:

Clarification of the nature of the low-fat flavoured shots will allow FSANZ to assign specific food categories in order that an appropriate dietary exposure assessment can be undertaken.

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy:	**Community Involvement Category:**
Proposed length of public consultation period: • General Procedure (6 weeks)	**3** Intensive, narrower focus

Proposed Timeframe for Assessment: N/A