



28 January 2010

[3-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1039	Date Received: 4 December 2009 Date Due for completion of Administrative Assessment: 29 December 2009 Date Administrative Assessment Completed: 22 December 2009	
Applicant: Dr Andrew Katelaris (MD)		Potentially affected Standards in the Code: 1.4.4 1.4.1 1.2.3
Title: Low THC Hemp as a Food Brief Description of Application: To approve the use of <i>Cannabis sativa</i> with low levels of tetrahydrocannabinol, in both seed and seed oil, as a food.		
Procedure: General Reasons why: Application to allow a food that is currently prohibited in Standard 1.4.4. Premarket safety assessment already conducted for hemp foods as part of Application A360.	Cost Category (General Procedure): Up to 850 hours Reasons why: Premarket safety assessment already conducted for hemp foods as part of Application A360.	Estimated start work: October 2010

DECISION

Application accepted

Date: 22 December 2009

Has the Applicant claimed 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

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes No

Does the Applicant want to expedite consideration of this Application?

Yes No Not known

Application Handbook Requirements

Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application:
3.1.1, 3.4.3

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

The Application is similar to Application A360, which was previously assessed and approved by FSANZ in 2002, but was subsequently rejected by the Australia New Zealand Food Standards Council. FSANZ considers that this Application should be accepted for assessment again.

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:

- Application A360 was recommended by FSANZ for approval, but was rejected by the Australia New Zealand Food Standards Council based on the concern that the use of hemp in food may send a confused message to consumers about the acceptability and safety of *Cannabis*. There were also concerns about law enforcement issues, particularly from a policing perspective that there were difficulties in distinguishing between high THC *Cannabis* and low THC hemp products.

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy: Proposed length of public consultation period: General Procedure (6 weeks)	Community Involvement Category: 3 (intensive, narrower focus)
Proposed Timeframe for Assessment: 'Early Bird Notification' due: 22 January 2010 <u>General Procedure:</u> Commence Assessment (clock start) Mid-October 2010 Completion of Assessment Early-March 2011 Public comment Late March-Mid May 2011 Board to complete Approval Mid-July 2011 Notification to Ministerial Council Late July 2011 Anticipated gazettal if no review requested Early October 2011	