



6 September 2010
[19-10]

APPLICATION – ADMINISTRATIVE ASSESSMENT

PA1053	Date Received: 30 July 2010 Date Due for completion of Administrative Assessment: 20 August 2010 Date Administrative Assessment Completed:	
Applicant: GU Energy		Potentially Affected Standard in the Code: 2.9.4
Title: Ornithine alpha-Ketoglutarate in Sports Foods Brief Description of Application: To approve the use of ornithine alpha-ketoglutarate, an amino acid complex, in formulated supplementary sports foods.		
Procedure: General Reasons why: Ornithine alpha-ketoglutarate is not permitted to be added to formulated supplementary sports foods under Standard 2.9.4. The Application is requesting a variation to a food regulatory measure to permit the use of a substance in a specific category of foods.	Estimated total hours: Maximum of 1000 hours Reasons why: The Application is requesting the addition of a new substance to a limited range of foods, which requires a pre-market approval. The Application involves an assessment of the risk to public health and safety and the potential impact on performance of sports people.	Estimated start work:

DECISION

Application rejected Date: 18 August 2010 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.

Has the Applicant claimed Confidential Commercial Information status?

Yes No

What documents are affected?

Certificate of Analysis, Material Safety Data Sheet

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?

N/A

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 General Requirements, 3.6.2 Special Purpose Foods.

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 Handbook including:

Information on the safety of ornithine alpha-ketoglutarate (OKG), information related to the dietary intake of OKG, information relating to the performance impact of OKG for sports people and information related to the impact on the food industry.

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:

3

Case requires an intensive, narrower focus.

Proposed Timeframe for Assessment: N/A