

18 January 2016

[01–16]

Administrative Assessment Report – Application A1124

Alternative DHA-rich Algal Oil for Infant Formula Products

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| <p>Date received: 4 November 2105 Date due for completion of administrative assessment: 25 November 2015 Date completed: 11 December 2015</p> | | |
| <p>Applicant: DSM Nutritional Products</p> | | <p>Potentially affected standards:</p> <p>Sched 3, Std 2.9.1</p> |
| <p>Brief description of Application: To permit the addition of DHA-rich algal oil from <i>Schizochytrium</i> sp. as an alternative or replacement oil for other currently permitted DHA-rich algal oils added to infant formula products.</p> | | |
| <p>Procedure: General</p> | <p>Estimated total hours: Max 1000 hours</p> <p>Reasons why: Nutritive substance to be added to infant formula products.</p> | <p>Provisional estimated start work: Late April 2016</p> |

Decision

Application accepted

Date: 11 December 2015

Has the Applicant requested confidential commercial information status?

Yes No

Has the Applicant provided justification for confidential commercial information request?

Yes No N/A

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?

Yes No

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

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?

3.3.3, 3.6.2

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

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

If no, why not?

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

If no, why not?

The Application seeks permission for DHA use as a nutritive substance in infant formula products. It is noted that there is an approval for similar oils as a novel food.

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:

Nil

Consultation & assessment timeframe

Proposed length of public consultation period:

6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: 14 January 2016

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| Commence assessment (clock start) | Early June 2016 |
| Completion of assessment & preparation of draft food reg measure | Mid-Oct 2016 |
| Public comment | Late Oct – early Dec 2016 |
| Board to complete approval | Early March 2017 |
| Notification to Forum | Mid-March 2017 |
| Anticipated gazettal if no review requested | Late May 2017 |