

15 October 2021
174-21

Administrative Assessment Report – Application A1236

Low-THC hemp leaf, seed sprout and root as food and food ingredients

1. Application details

<p>Date received: 18 August 2021 Date due for completion of administrative assessment: 8 September 2021 Date completed: 10 September 2021</p>		
<p>Applicant: Kavasil Pty Ltd</p>		<p>Potentially affected standards: Standard 1.4.4 and Schedule 23</p>
<p>Brief description of Application: To permit the sale of low-THC hemp leaf, seed sprout and root as food and food ingredients in Australia and New Zealand.</p>		
<p>Procedure: General [Level 5]</p>	<p>Estimated total variable hours: 923 Reasons why: Complex pre-market approval of three novel foods</p>	<p>Estimated start date: September 2022</p>

2. Decision

<p>Application accepted</p> <p>Date: 10 September 2021</p>
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3. Additional matters

Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential? No
Is the Application for a High Level Health Claim? No
Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together? No

4. Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant? No
Does the Applicant want to expedite assessment (i.e. pay) for this Application? No

5. Assessment against FSANZ Act 1991 requirements

Subsection 26(2)
(b) 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
(c) Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it should not be accepted? No
(d) Are there any other matters relevant to the decision whether to accept or reject the application? No

Does the application meet each of the following criteria required by subsection 22(2)?
(a) The application is in writing Yes
(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook Yes
(c) The application includes all information and each thing that the section 23 guidelines of the Act state must be included in such an application. Yes Section 3.1.1 – General requirements Section 3.4.3 – Prohibited and restricted plants and fungi Section 3.5.2 – Novel foods
Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application? Yes Indicate which Procedure: General
Other Comments or Relevant Matters: Nil

6. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment (unpaid)

'Early Bird Notification' due: 15 October 2021

General Procedure:

Commence assessment (clock start)	Early September 2022
Completion of assessment & preparation of draft food reg measure	Early January 2023
Public comment	Mid-Jan to late Feb 2023
Board to complete approval	Early June 2023
Notification to FMM	Late June 2023
Anticipated gazettal if no review requested	Early September 2023

