

**17 October 2020**  
**[142-20]**

## **Administrative Assessment Report – Application A1214**

Nicotinamide riboside chloride as Vitamin B3 in FSMP

### **1. Application details**

<p><b>Date received:</b> 9 October 2020  <b>Date due for completion of administrative assessment:</b> 2 November 2020  <b>Date completed:</b> 2 November 2020</p>		
<p><b>Applicant:</b> ChromaDex Inc.</p>		<p><b>Potentially affected standard/s:</b>  <i>Standard 2.9.5 – Food for special medical purposes</i>  <i>Schedule 29-20 – Special Purpose Foods</i></p>
<p><b>Brief description of Application:</b>          Application to amend the Food Standards Code to permit the use of nicotinamide riboside chloride as a permitted form of Vitamin B3 in food for special medical purposes (FSMPs).</p>		
<p><b>Procedure:</b>          General</p>	<p><b>Estimated total variable hours:</b>          540 hours</p> <p><b>Reasons why:</b>          The Application is requesting the addition of a new permitted form of Vitamin B3 for use in FSMPs, requiring detailed safety and efficacy assessments.</p>	<p><b>Estimated start date:</b>          Late November 2020</p>

### **2. Decision**

<p><b>Application accepted</b></p> <p><b>Date:</b> 2 November 2020</p> <p><b>If fees for ECCB are not received, date of rejection:</b> 1 December 2020</p>
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### 3. Additional matters

**Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?**

Yes – CCI only

**What documents are affected?**

All information provided by the Applicant in:

- Annex 1 (11 documents)
- Annex 2 (14 documents)
- Annex 4 (40 documents)

**Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?**

No, all CCI requests relate to whole documents

**Has the Applicant provided justification for why information is CCI or confidential?**

Yes

**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?**

Yes

**Reason:**

The Applicant is the owner of a patent/s in relation to nicotinamide riboside chloride. The Applicant states that they expect to have exclusive control over the distribution of nicotinamide riboside chloride, the subject of this application.

**Due date for fees:** 30 November 2020

### 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 – Guidelines 3.1.1, 3.3.3, 3.6.3

**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 period:**

6 weeks

**Proposed timeframe for assessment**

'Early Bird Notification' due: 7 December 2020

General Procedure:

Commence assessment (clock start)	Early December 2020
Completion of assessment & preparation of draft food reg measure	March 2021
Public comment	Late April – Early June 2021
Board to complete approval	Late August 2021
Notification to Forum	Early September 2021
Anticipated gazettal if no review requested	Mid-November 2021

