

## FSANZ Application

### Nicotinamide riboside chloride as a permitted form of niacin in FSMPs

#### EXECUTIVE SUMMARY

This application requests amendment to the Australia New Zealand Food Standards Code (**the Code**) to permit the use of nicotinamide riboside chloride (hereafter referred to as **NR**) as a permitted form of Vitamin B3 in foods for special medical purposes (hereafter referred to as **FSMPs**).

NR is an innovative chemical substance that is a precursor for nicotinamide adenine dinucleotide (**NAD+**) in the human body, with fewer adverse effects or identified safety issues than is the case for other established and/or permitted NAD+ precursors. Evidence suggests that the use of NR in FSMPs has a particularly strong potential as a method of delivering/increasing the anabolism of NAD+ to support human wellness during metabolic stress and aging.

NR is intended to be used as a source of Vitamin B3 in FSMPs that partially or totally replace the daily diet; products that are recommended to be used under medical supervision. It is therefore possible that NR will be added to FSMPs that are a sole source of nutrition.

Vitamin B3 is permitted to be added to FSMPs by sections S29—20 (in the form of nicotinic acid) and S29—7 (in the form of niacinamide (also known as nicotinamide)). The Code also permits the addition of Vitamin B3 to certain foods other than FSMPs in the form of both nicotinic acid and nicotinamide. Even though Section 2.9.5-6(c) of the Code permits the addition of other permitted substances to FSMPs regardless of form, the applicant wishes to pursue scientific review by FSANZ through the Application process to not only demonstrate the consumer need, efficacy and safety of NR but to also achieve regulatory certainty before entering the Australian market.

NR is currently Generally Recognised as Safe in the United States for use in food products. It is also the subject of novel food approval as a source of Vitamin B3 in the European Union and is listed on the Canadian Natural Health Products Ingredients Database in relation to several products.

The safety of NR has been clearly demonstrated through numerous studies in animals and humans. There is no basis to conclude that NR poses any risk to any particular segment of the general population, including children. NR is a recognized form of Vitamin B3, with a wider safety margin than nicotinic acid and potentially nicotinamide, both established essential nutrients permitted in foods for children, and has been proven to be safe at up to 2 grams per day in healthy older adults with no serious adverse events.

This application does not propose any amendment to the mandatory compositional requirements for FSMPs, but rather requests permission to use a new form of an already-permitted vitamin. As such, the applicant does not consider that it is necessary to make any change to the labelling or other requirements for FSMPs.