Summary of the application: Nicotinamide Riboside Chloride

Applicant: ChromaDex, Inc., 10900 Wilshire Blvd, Suite 600, Los Angeles, CA 90024, USA

Nicotinamide Riboside Chloride (NRC) is a source of niacin (also known as vitamin B3). It was assessed by EFSA in the context of a Novel Food application in 2019) and subsequently authorized as novel food for use in food supplements at a maximum daily amount of 300 mg (Commission Implementing Regulation (EU) 2020/16).

This application requests the extension of the use of Nicotinamide Riboside Chloride (NRC) in four food categories:

1. Foods for special medical purposes (FSMP), defined by Regulation (EU) No 609/2013. FSMP are foods that are specifically formulated to meet the nutritional requirements of patients and are to be used under medical supervision. The use of NRC in FSMP is requested up to a maximum amount corresponding with an intake of 1000 mg/day.

2. Total Diet Replacements Products for Weight Control (TDRWC), as covered by Regulation (EU) No 2017/1798 (EU 2017). These products are intended to be used by healthy, but overweight or obese persons for no longer than 8 weeks, without the advice of a healthcare professional. These products replace the total daily diet and will be the only source of nutrients, including nicotinamide. The use of NRC in TDRWC is requested up to a maximum amount corresponding with an intake of 1000 mg/day.

3. Meal replacements products. These are foods presented as a replacement for one or more meals of the daily diet in accordance with Regulation (EU) 2016/1413), intended for the healthy population. The use of NRC in meal replacement products is requested up to a maximum amount corresponding with an intake of 300 mg/day.

4. Nutritional drink mixes. These products are not defined by legislation. They cover drinks, rich in protein and mostly with added nutrients, intended primarily as nutritional supplement to the daily diet of elderly people. The use of NRC in meal replacement products is requested up to a maximum amount corresponding with an intake of 300 mg/day.

Children, pregnant and lactation women are excluded from the request.

Since the application concerns an already authorized Novel Food, the data relating to the identity, production process, composition, specifications, history of use, nutritional composition, allergenicity data of the food remains unchanged.

All four categories have clear instructions for use on the label and are marketed in dose form. The conditions of use requested are therefore expressed per daily recommended intake.

For meal replacements products and nutritional drink mixes the requested amount of NRC is 300 mg/day. This is identical to the levels that is authorized already for food supplements. It is unlikely that consumers will take two sources of NRC simultaneously. But even if they did, the resulting intake of nicotinamide would be 252 mg from NRC plus the intake of around 80 mg per day from the diet (P95), which is well below the safe upper level of 900 mg/day established by the Scientific Committee for Food. The applicant concludes that this use would not give rise to safety concerns.

FSMP are products that are intended to be used under medical supervision and are formulated to meet the nutritional needs of the patients they are intended for. TDRWC are products that are intended to cover the total daily diet. In both cases, their use is well controlled and additional intake of NRC or nicotinamide is unlikely.

Intake of 1000 mg/day of NRC corresponds with intake of nicotinamide of 420 mg/day. This is well below the safe upper level. Nicotinamide as a nutritional substance is currently permitted for use under the same conditions as those requested.

NRC has been extensively studied in humans at the requested level of intake. The applicant presents data from 6 human trials, investigating both acute (single dose) and chronic intake (up to 12 weeks) of intakes of at least 1000 mg/day). These studies confirm the dose-dependent increase of NAD+, with good tolerance and no serious adverse effects observed.

In addition, the applicant demonstrates that intake of 1000 mg/day of NRC does not lead to intakes of undesirable substances that are of safety concern.

Based on the scientific data provided, the applicant concludes that the use of NRC in these four product categories is safe under the proposed conditions of use.