

Summary of the application: Rhamnogalacturonan-I enriched carrot fibre (cRG-I)

Applicant: NutriLeads B.V., Bronland 12 (N), 6708 WH Wageningen, the Netherlands

The application for authorisation of a novel food under Article 10 of Regulation (EU) 2015/2283 concerns rhamnogalacturonan-I enriched carrot fibre (cRG-I), which consists mainly of soluble dietary fibre (> 70 %) and small amounts of simple sugars. cRG-I is derived from fresh carrot pomace by enzymatic hydrolysis of the pectic constituents of carrot, followed by a sequence of purification steps.

The identity of the novel food has been established based on its dietary fibre content, the molecular mass distribution pattern of the polysaccharides, and the typical proportion of the monosaccharides it is composed of. The product shall be used as an ingredient in a range of food applications, with a proposed maximum daily intake of 0.75 g/day for young children (below 3 years of age) and 1.5 g/day for subjects older than 3 years of age. The safety of cRG-I was demonstrated by a thorough analysis of ten representative batches of cRG-I, which confirmed the compliance with all requirements on microbial and contaminants and supported the manufacturing process's robustness and consistency. Based on preliminary stability studies, the applicant proposes a shelf life of 2 years.

The safety of the novel food was further substantiated by a product-specific mutagenicity study (OECD 471), an in-vitro micronucleus assay (OECD 487), and a sub-chronic oral toxicity study according to OECD 408. These studies do not reveal any sign of toxicity of cRG-I, confirming that the intake of the novel food does not pose a risk to consumers. The NOAEL derived from the 90 days study was at least 10.0% (w/w)m, corresponding to a mean daily intake of 6907 and 7753 mg cRG-I /kg body weight/day in males and females, respectively. The information on cRG-I provided by exhaustive studies proves the identity, composition, stability and safety for use and consumption in the European Union.

The application has been prepared following the requirements of Commission Implementing Regulation (EU) 2017/2469 of December 20 2017, laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283, the European Food Safety Authority (EFSA) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283, and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food under Article 10 of Regulation (EU) 2015/2283.

The applicant requests the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283. The data presented in this application demonstrated that the novel food is devoid of any hazards from the product itself, the production process or the raw materials. Based on the analytical and toxicological data, the applicant concluded that cRG-I is safe for consumers and nutritionally not disadvantageous.