

Summary of the dossier :

Applicant: Hayashibara Co., Ltd. Nihon-Seimei Okayama Bldg., II Shinkan, 1-1-3 Shimoishii, Kita-ku, Okayama Represented by Pen & Tec Consulting SLU Address: Pl. Ausias March 1, 4th floor D01, 08195 Sant Cugat del Vallès, Barcelona, Spain.

Name and description of the novel food : Glucosyl hesperidin

The applicant, Hayashibara Co., Ltd, submits an application in order to include Glucosyl hesperidin (GH) in the Union list of novel foods to be used in teas, carbonated drinks, confectionary & food supplements at a maximum dose of 500mg per serving and per day, intended to be consumed by the general population (excluding < 1year-old). GH is listed in List of Existing Food Additives, monographed in Japan's Specifications and Standards for Food Additives under the name of "Enzymatically modified hesperidin", and available in Japan since before 1998 for a wide variety of uses and use levels. GH is also authorised in Korea and Taiwan and marketed in the US under notified GRAS status (No. GRN 000901).

The novel food GH is produced from hesperidin and dextrin by enzymatic reactions. The final product contains 75.0 – 85.0% (on dry basis) of monoglucosyl hesperidin.

The applicant has followed the tiered toxicity testing approach. As a first step a standard battery of genotoxicity tests was conducted according to OECD principles of good laboratory practice (in force at the time the studies were conducted with GH) and the Japanese "Guidelines for the designating of food additives and for revision of standards for use of food additives." A repeated dose 90-day oral toxicity study in rats was carried out after initial information on toxicity had been obtained from a 28-day dose range finding study. The test showed absence of any toxicologically significant changes at the highest tested dose, therefore it was shown that GH does not cause adverse effects at the highest dose of 3,084 mg/kg-bw/day. No studies from the literature have reported adverse effects from consumption of GH on human health. Human studies involving acute and long-term consumption of GH reported no adverse reactions.

The applicant considers that the available evidence is sufficient to support the safety of GH. The novel food does not pose a risk to the consumer.