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The application is submitted pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, for the authorisation of melatonin (N-acetyl-5-methoxytryptamine) manufactured by chemical synthesis. The final product contains $\geq 99\%$ of melatonin. The applicant proposes the uses of melatonin in milk at a dose of 5 mg/l, intended to be consumed by healthy adults (excluding pregnant and lactating women) at a maximum dose of 1 glass of milk of 200 ml/day (1 mg melatonin/day).

Melatonin is currently available on the EU market in the form of food supplements. However, its use in foods is considered novel, falling within the category “food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46”.

Melatonin has a low toxicity after single administration. In repeat-dose toxicity studies (rats and dogs), hypertrophy of the liver and genital tract of male rats and female dogs were observed at exposure in large excess compared to the expected maximum daily intake of the novel food. The No-observed-adverse-effect-level (NOAEL) set for maternal toxicity at 100 mg/kg bw/day and the lower dose at which no toxicity was observed in the 90-day rat toxicity study, 15 mg/kg bw/day, would correspond to 7,000 mg/day and 1,050 mg/day respectively in a 70-kg adult. Applying a margin of safety of 100, doses between 10.5 mg/day and 70 mg/day, significantly higher than the intended use level of melatonin, are considered safe.

Melatonin has been evaluated by the European Medicines Agency (EMA) in 2007 and 2018 which concluded that melatonin does not pose safety concerns at 2 mg/day for up to thirteen weeks and 2-10 mg/day (long term use for children) respectively. The European Commission Scientific Committee on Consumer Safety (SCCS), the French Agency for Food, Environmental and Occupational Health and Safety (ANSES), and the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN), have also evaluated the safety of melatonin in 2010, 2018 and 2014 respectively, and concluded that it does not pose safety concerns at 1 mg/day.

Furthermore, the health claims “Melatonin contributes to the alleviation of subject feelings of jet lag” and “Melatonin contributes to the reduction of time taken to fall asleep” are approved for melatonin by Regulation (EU) 432/2012 and are supported by two positive opinions of the European Food Safety Authority (EFSA) published in 2010 and 2011. These health claims are linked to doses of melatonin up to 1 mg/day. No safety concerns were raised by EFSA and the SCCS regarding the use of melatonin at 1 mg/day, thereby supporting the safety of melatonin as a novel food for use in milk at 1 mg/day.