Summary of the application: β-Nicotinamide Mononucleotide (NMN)
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This application is submitted in pursuant to Regulation (EU) 2015/2283 of the European Parliament and the Council of 25 November 2015 on novel foods, requesting the authorisation of β-Nicotinamide Mononucleotide (NMN) as a food ingredient for use in food supplements, with a recommended daily intake of up to 500 mg/day. The NMN is produced by enzymatic synthesis in a multi-step process under controlled conditions, with a Hazard Analysis and Critical Control Points (HACCP) plan in place to ensure product safety and consistency.

NMN is a derivative of nicotinamide, an essential precursor of NAD+, which is involved in several critical metabolic pathways in the body. NAD+ is essential for cellular energy production and plays a key role in regulating various cellular functions related to energy, aging, and stress responses. NMN has been demonstrated to rapidly convert to NAD+ upon ingestion and is therefore proposed as a food supplement for supporting overall metabolic health. NMN supplementation is designed to boost the biosynthesis of NAD+.

The identity, manufacturing process, compositional data, specifications of NMN have been established and provided according to the requirements of the EFSA Guidance on Novel Foods and related ones. Analytical data for five independent representative batches of NMN confirms that the production process consistently yields a final ingredient that complies with the proposed specifications and is free from potential contaminants. Stability data, accelerated and long-term ones, were also provided to support NMN is stable for its intended shelf-life of 24 months.

The absorption, distribution, metabolism, and excretion (ADME) profile of NMN has been thoroughly examined. Literature data shows that NMN is absorbed intact through the gastrointestinal tract and increases blood levels of nicotinamide and NAD+.

Toxicology studies conducted with NMN include multiple genotoxicity studies, such as bacterial reverse mutation test (OECD 471), *in vitro* chromosome aberration test, *in vivo* bone marrow micronucleus test, and a 90-day toxicity study in rats (OECD 408). NMN was confirmed as non-genotoxic, and the highest dose tested was the no-observed-adverse-effect level (NOAEL) in the 90-day study. This NOAEL provides a sufficient margin of safety compared with the highest exposure from its intended use in food supplements for adults. Additionally, NMN has been well-tolerated in several controlled clinical trials, as reported in the literature.

According to Article 26, data protection is asked for the newly generated toxicological data. However, confidentiality is requested for production process and sensitive data of people involved in the project, including the Applicant. A non-confidential version of all the abovementioned documents is given within the application according to the Transparency Regulation requirements.

Overall, it can be concluded that the production process of NMN under controlled conditions, along with the provided nutritional, safety, and toxicological data, ensures the product's safety and consistency and

that the proposed use of NMN as a novel food ingredient in the specified food category and use level is safe for human health.