Public summary

Novel Food application for 6'-Sialyllactose (6´-SL) sodium salt

Applicant: Inbiose N.V., Technologiepark 82 – bus 41, B-9052 Zwijnaarde, Belgium

The subject of this novel food application is 6'-Sialyllactose (6'-SL) sodium salt (6'-SL*Na) that is manufactured by fermentation with an engineered strain of *E. coli*, followed by a sequence of isolation and purification steps.

6'-SL is an acid human milk-oligosaccharide that is abundant in breast milk. The trisaccharide consists of a molecule of lactose that is modified in 6'-position of galactose with N-acetylneuraminic acid (N-acetyl α-neuraminic-(2→6)-β-D-galactose-(1→4)-D-glucose).

In 2021, a novel food authorization for 6'-SL sodium salt was granted according to Article 26 of Regulation (EU) 2015/2283 (European Commission, 2021). Therefore, INBIOSE requests an own authorization for 6'-SL*Na which requires the specifications in the union list to be adapted.

The present application was prepared pursuant with the most recent EFSA guidance for applicants (EFSA, 2021) and the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA, 2018).

The novel food is manufactured using a genetically modified strain of *E. coli* K12 MG1655, which is quantitatively removed from the product. A sequence of filtration and chromatography steps results in 6'-SL*Na of high purity (≥85 % w/w on dry matter). The total concentration of HMOs is not less than 94 % w/w on dry matter, with sialic acid and lactose being the most relevant carbohydrates. The identity of 6'-SL has been unequivocally demonstrated by ^{13}C and ^{1}H-NMR. The applicant demonstrated in five independently manufactured product batches that the novel food meets the specifications with respect to purity, and the provisions laid down in Regulations (EC) 1881/2006 (European Commission, 2006) and (EC) 2073/2005 (European Commission, 2005) concerning chemical or microbial contaminations.

The stability studies with Inbiose´s 6'-SL*Na powder under normal and accelerated conditions demonstrated that the NF is stable with no measurable change in the content of 6'-SL up to 24 months. The applicant aims at an extended shelf life of this novel food. Therefore, the stability study is set up for a period of 5 years at real time conditions. As demonstrated in model food applications, 6'-SL*Na is also stable under typical food processing conditions over periods of time that are relevant for these applications.

The production process including the generation of the production strain, the fermentation process and the downstream processing have been described in detail. The safety of the production strain is supported by Whole Genome Sequence data and the history of safe use of

the production host microorganism. The final product does not contain viable cells or recombinant DNA resulting from the production strain.

The safety of the novel food presented here has been verified in a series of toxicity studies, including a bacterial reverse mutation assay, an *in vitro* micronucleus assay and a chromosomal aberration assay with human peripheral lymphocytes, and a 90 days oral toxicity study in juvenile rats with dose-range finding study. None of the studies gave rise to substance-related safety concerns.

6'-SL*Na is intended for the general population including infants. Proposed uses and use levels for 6'-SL*Na are the same as already authorized by (EU) 2021/82 (European Commission, 2021). The resulting intake of 6'-SL*Na by bottle-fed infants and the general population is in-line with the intake levels that EFSA considered safe (EFSA, 2020).

The designation of the novel food on the labelling of the foodstuffs containing it shall be "6'-Sialyllactose sodium salt". The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt shall bear a statement that they should not be consumed: a) if foods containing added 6'-Sialyllactose sodium salt are consumed on the same day. b) by infants and young children.

The data presented in this novel food application support the safety and suitability of 6'-SL*Na for the proposed uses and use levels.

References

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