Public summary

Novel Food application for 3'-Sialyllactose (3'-SL) sodium salt

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The subject of this novel food application is 3'-Sialyllactose (3'-SL) sodium salt (3'-SL*Na) that is manufactured by fermentation with an engineered strain of *E. coli*, followed by a sequence of isolation and purification steps.

3'-SL is an acidic human milk-oligosaccharide (HMO) that is abundant in breast milk. The trisaccharide consists of a molecule lactose that is modified in 3'-position of galactose with N-acetylneuraminic acid (N-Acetyl-**α**-D-neuraminyl-(2→3)-**β**-D-galactopyranosyl-(1→4)-D-glucose).

In 2021, a novel food authorization for 3'-SL*Na was granted according to Article 26 of Regulation (EU) 2015/2283 (European Parliament and Council, 2015). Therefore, Inbiose requests its own authorization for 3'-SL*Na which requires the specifications in the union list to be adapted.

The present application was prepared according to 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 3'-SL*Na purity of not less than 88 % w/w on dry matter. The sum of 3'-SL*Na, sialic acid and lactose is not less than 90 % w/w on dry matter. The identity of 3'-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 proposed specifications. The stability studies with Inbiose's 3'-SL*Na powder under real time and accelerated conditions demonstrated that 3'-SL*Na is stable with no measurable change of 3'-SL content.

As demonstrated in model food applications tested, 3'-SL*Na is also stable under typical food processing conditions over periods 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 sequencing data and the history of safe use of the production host microorganism *E. coli* K-12 MG1655. 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 90-day oral toxicity study in juvenile rats with a dose-range finding study. None of the studies gave rise to substance-related safety concerns.

3'-SL*Na is intended for the general population including infants. Proposed uses and use levels for 3'-SL*Na are the same as already authorized by (EU) 2021/96 (European Commission, 2021). The resulting intake of 3'-SL*Na by bottle-fed infants and the general population is in line with the intake levels that EFSA considered safe (EFSA, 2020).

The data presented in this novel food application support the safety and suitability of 3'-SL*Na for the proposed uses.

References:

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