

Summary of the application: Change of proposed uses and use levels for 3'-sialyllactose (3'-SL) sodium salt NF-2023-13753.

Applicant: Chr. Hansen A/S Boege Alle, 10-12 2970 Hoersholm, Denmark.

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 a change of the proposed uses and use levels for 3'-sialyllactose (3'-SL) sodium salt produced from a microbial source.

3'-SL is a HiMO, produced by microbial fermentation. HiMOs are identical to HMOs present in human breast milk, where they have an important function for infant nutrition, the development of the microbiome and a healthy immune system. The manufacture of 3'-SL sodium salt using genetically modified strains of *E. coli* K-12 or genetically modified strains of *E. coli* BL21(DE3) has been authorised previously.

The identity, manufacturing process, compositional data, specifications, ADME and toxicological information have been evaluated previously and 3'-SL sodium salt has been authorised for human consumption (Commission Implementing Regulation (EU) 2023/113 of 16 January 2023)

Building on the established safety of 3'-SL sodium salt, the applicant proposes to increase the use levels for infant formulae and food supplements for infants and young children to provide levels which are closer to natural levels in human breast milk.

The applicant has provided literature data and a rationale to explain this request.

With the information provided, the applicant is confident that the proposed change of the authorised uses and use levels is well supported.