Increased maximum level of 3′-Sialyllactose sodium salt in infant formula

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Commission approves increased maximum level of 3′-SL sodium salt in infant formula

Commission Implementing Regulation (EU) 2023/1582 of 1 August 2023 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food 3′-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3)

Update

The European Commission has approved an increased maximum level of 3′-Sialyllactose sodium salt (3′-SL sodium salt) in infant formula, closer to the levels naturally found in human milk. The increase also applies to foods for special medical purposes for infants and young children.

Impacted products

baby foods, baby foods for special medical purposes, food supplements, infant formula, follow-on formula, milk-based drinks

What is changing?

In January 2023 the EU authorised 3′-SL sodium salt as a novel food. The level of 3′-SL sodium salt that can be used in infant formula is increased from 0.23 to 0.28 g/kg or g/l. This increase also applies to foods for special medical purposes for infants and young children (as defined under Regulation 609/2013).

Why?

This change in the conditions of use is not liable to affect human health. The slightly increased intake of 3′-SL sodium salt in infant formula is still lower than the intake of 3′-SL from breast milk.

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Timeline

The use of increased levels of 3′-SL sodium salt is permitted from 22 August 2023.

What are the major implications for exporting countries?

Only Chr. Hansen A/S, which applied for authorisation, can place 3′-SL sodium salt on the EU market. The applicant has also obtained data protection on the supporting data submitted until 6 February 2028. Before that date, other companies must obtain authorisation to place the novel food on the EU market, and cannot use proprietary scientific evidence or protected scientific data when applying for authorisation. After 6 February 2028, other companies may apply for authorisation with reference to that data.

Background

3′-SL sodium salt obtained by microbial fermentation using genetically modified derivative strains of *E. coli* BL21(DE3) is authorised on the EU market as a novel food by Implementing Regulation (EU) 2023/113. An application to increase the maximum level of 3′-SL sodium salt in infant formula from 0.23 to a maximum level of 0.28 g/kg or g/l was submitted in February 2023 in order to bring its intake closer to the levels of 3′-SL naturally found in human milk.

Resources

EFSA (2022) Safety of 3'-sialyllactose (3'-SL) sodium salt produced by derivative strains of *Escherichia coli* BL21 (DE3) as a Novel Food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 20(5): 7331.

Implementing Regulation (EU) 2023/113 authorising the placing on the market of 3′-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3) as a novel food

Regulation (EU) 2015/2283 (consolidated version: 27/03/2021)

Regulation (EU) No 609/2013 (consolidated version: 21/03/2023)

Sources

Implementing Regulation 2023/1582 regarding the conditions of use of the novel food 3′-Sialyllactose sodium salt produced by derivative strains of *Escherichia coli* BL21(DE3)

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