Protein hydrolysates in infant and follow-on formula

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EU amends specifications for protein hydrolysates in infant and follow-on formula

Commission Delegated Regulation (EU) 2025/2017 of 8 October 2025 amending Delegated Regulation (EU) 2016/127 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates

Commission Delegated Regulation (EU) 2024/2684 of 2 February 2024 amending Delegated Regulation (EU) 2016/127 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates

Update

The European Union (EU) has changed the compositional requirements regarding the content, source, processing, and quality of protein for infant and follow-on formula manufactured from protein hydrolysates. Protein from cow's milk consisting of 100% whey protein concentrate with a minimum protein content of 80% can now be used as protein hydrolysates in follow-on formula under certain conditions.

Impacted products

Infant and follow-on formula

What is changing?

The EU has updated the compositional requirements set out in Regulation 2016/127 for the content, source, processing, and quality of protein for infant and follow-on formula manufactured from protein hydrolysates. It has introduced compositional requirements for protein from cow's milk consisting of 100% whey protein concentrate with a minimum protein content of 80%. This protein hydrolysate can be used in follow-on formula if it complies with the compositional criteria set out in Regulation 2016/127, including the amino acid pattern (Section A, Annex III), and has a minimum protein content of 0.48 g/100 kJ (2.0 g/100 kcal).

In February 2024, Regulation 2024/2684 approved a specific protein hydrolysate (whey protein derived from cow's milk, consisting of 100% sweet whey protein concentrate with a minimum protein content of 70%) with a different composition from those previously approved (under

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Regulation 2016/127).

Why?

Following a request by Fonterra Co-operative Group Ltd for an evaluation of two infant and follow-on formula products that did not comply with current rules, the European Food Safety Authority (EFSA 2025) concluded that this specific protein hydrolysate is nutritionally safe and is a suitable protein source for use in infant and follow-on formula if certain conditions are met.

Timeline

The Regulation applies from **1 January 2026**.

Background

Infant formula and follow-on formula manufactured from protein hydrolysates must comply with certain requirements for the content, source, and processing of protein, as well as with requirements for indispensable and conditionally indispensable amino acids and L-carnitine (Regulation 2016/127). These requirements may be updated at the request of a formula manufacturer, following a safety and suitability evaluation by EFSA.

Resources

EFSA (2023) Nutritional safety and suitability of a specific protein hydrolysate derived from a whey protein concentrate and used in an infant formula and follow-on formula manufactured from hydrolysed protein by FrieslandCampina Nederland B.V. EFSA Journal, 21(7): e08063

EFSA (2025) Nutritional safety and suitability of a specific protein hydrolysate manufactured by Fonterra Co-operative Group Ltd derived from a whey protein concentrate and used in infant formula and follow-on formula. EFSA Journal, 23(1): e9160

Regulation 2016/127 as regards the specific compositional and information requirements for infant formula and follow-on formula

Sources

Commission Delegated Regulation (EU) 2025/2017 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates

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