Protein hydrolysates in infant and follow-on formula

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

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

Draft Annex

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) proposes to amend the compositional requirements regarding the content, source, processing, and quality of protein for infant and follow-on formula manufactured from protein hydrolysates.

Impacted products

Infant and follow-on formula

What is changing?

The EU proposes to amend 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. Specifically, it proposes to amend the requirements for indispensable and conditionally indispensable amino acids and L-carnitine (Regulation 2016/127, Annex I, 2.3; Annex II, 2.3).

This proposal has been notified to the World Trade Organization Technical Barriers to Trade (WTO TBT) Committee (G/TBT/N/EU/1147).

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

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 a suitable protein source for use in infant and follow-on formula as long as the formula in which it is used contains a minimum of 0.48 g per 100 kJ (2.0 g per 100 kcal).

Timeline

The new Regulation is expected to be adopted in approximately the first quarter of 2026.

Recommended Actions

Where a country is a member of the WTO, comments on the proposal can be submitted via the National TBT notification authority of the country concerned to the EU TBT Enquiry Point until **14 September 2025**.

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). Formula manufactured from protein hydrolysates with a composition that has not been previously approved may only be placed on the market 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): 8063.

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

Draft Commission Delegated Regulation as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates

Draft Annex

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

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