

Protein hydrolysates in infant and follow-on formula

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EU authorises use of protein hydrolysate from whey protein in infant and follow-on formula

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 Commission has approved a specific protein hydrolysate derived from whey protein for use in infant formula and follow-on formula.

Impacted products

Infant and follow-on formula

What is changing?

The European Food Safety Authority (EFSA) evaluates the safety and suitability of each specific infant and follow-on formula containing protein hydrolysates. Following an EFSA evaluation, the EU has 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](#)).

The protein hydrolysate may only be used when it complies with the requirements set out in the Annex to Regulation [2024/2684](#) (Protein-related requirements group D).

Why?

[EFSA \(2023\)](#) concluded that demineralised sweet whey protein derived from cows' milk is a nutritionally safe and suitable protein source for use in infant and follow-on formula.

A new composition of protein hydrolysate has been approved by the EU for use in infant and follow-on formula following an evaluation by the European Food Safety Authority.

Timeline

The Regulation applies from **11 October 2024**.

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.

Regulation [2016/127](#) as regards the specific compositional and information requirements for infant formula and follow-on formula

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