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#### COVER NOTE

|                  |                                                                                                                                                                                                                                                              |
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| From:            | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director                                                                                                                                                                          |
| date of receipt: | 3 October 2024                                                                                                                                                                                                                                               |
| To:              | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union                                                                                                                                                                                  |
| No. Cion doc.:   | C(2024) 6822 final                                                                                                                                                                                                                                           |
| Subject:         | CORRIGENDUM of 3.10.2024 to Commission Delegated Regulation 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 (C(2024) 549) |

Delegations will find attached document C(2024) 6822 final.

Encl.: C(2024) 6822 final



EUROPEAN  
COMMISSION

Brussels, 3.10.2024  
C(2024) 6822 final

## **CORRIGENDUM**

**of 3.10.2024**

**to Commission Delegated Regulation 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**

**(C(2024) 549)**

## CORRIGENDUM

### **to Commission Delegated Regulation 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**

**(C(2024) 549)**

In the Annex, in point 1, which replaces point 2.3 of Annex I to Delegated Regulation (EU) 2016/127, point 2.3.4.3. shall read as follows:

**‘2.3.4.3. Protein processing**

The source material is hydrated and heated. Following the heat-treatment step, the hydrolysis is carried out at a pH of 7.0 to 8.0 and a temperature of 50 to 60°C, using a two-stage hydrolysis process with the use of a serine endopeptidase and a metalloprotease. The food enzymes are inactivated by heat treatment (at 100 to 120°C for at least 30 seconds) during the production process.’

In the Annex, in point 2, which replaces point 2.3 of Annex II to Delegated Regulation (EU) 2016/127, point 2.3.4.3. shall read as follows:

**‘2.3.4.3. Protein processing**

The source material is hydrated and heated. Following the heat-treatment step, the hydrolysis is carried out at a pH of 7.0 to 8.0 and a temperature of 50 to 60°C, using a two-stage hydrolysis process with the use of a serine endopeptidase and a metalloprotease. The food enzymes are inactivated by heat treatment (at 100 to 120°C for at least 30 seconds) during the production process.’

In the Annex, in point 2, which replaces point 2.3 of Annex II to Delegated Regulation (EU) 2016/127:

*for:*

**‘2.3.4.4. Indispensable and conditionally indispensable amino acids**

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.’

*read:*

**‘2.3.4.4. Indispensable and conditionally indispensable amino acids**

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation

purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.’.