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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control

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1. Introduction

This report meets the obligation set out for the Commission by Article 18(2) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control (hereinafter 'Food for Specific Groups Regulation')[1]. The Food for Specific Groups Regulation establishes compositional and information requirements for (a) infant formula and follow-on formula, (b) processed cereal-based food and baby food, (c) food for special medical purposes and (d) total diet replacement for weight control. The Regulation also establishes a Union list of substances that may be added to one or more of these categories of food and lays down rules applicable to the updating of that list.

Article 18(2) of the Food for Specific Groups Regulation requires the Commission to present to the European Parliament and to the Council a report on the exercise of the delegation conferred on the Commission by that Regulation. Pursuant to Article 18(2), the power to adopt delegated acts was conferred on the Commission for an initial period of 5 years running from 19 July 2013. The Commission had to present a report on the exercise of the delegation of power conferred by the Food for Specific Groups Regulation not later than 9 months before the end of the 5-year period. The delegation of power is to be extended tacitly for periods of 5 years, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

The Commission adopted a first report on the exercise of the delegation of powers under the Food for Specific Groups Regulation on 22 August 2017[2].

2. Legal Basis

Article 18(2) of the Food for Specific Groups Regulation lays down the conditions concerning the power to adopt delegated acts conferred on the Commission by Article 11, Article 15(6) and Article 16(1) of that Regulation.

Article 11(2) of the Food for Specific Groups Regulation empowers the Commission to adopt delegated acts in order to lay down specific compositional and informational requirements for the different categories of Food for Specific Groups. Those requirements are currently set out in the following Regulations:

[1] OJ L 181, 29.6.2013, p. 35.

[2] Report from the Commission to the European Parliament and the Council on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control. COM(2017) 0438 final.

- Commission Delegated Regulation (EU) 2016/127 supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding[3],
- Commission Delegated Regulation (EU) 2016/128 supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for food for special medical purposes[4] and
- Commission Delegated Regulation (EU) 2017/1798 supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for total diet replacement for weight control[5].

Article 15(6) of the Food for Specific Groups Regulation empowers the Commission to add or remove a category of substances to the Annex to the Regulation, which lays down the Union list of substances that may be added to the specific categories of foods, in order to take into account technical progress, scientific developments or the protection of consumer's health.

Article 16(1) of the Food for Specific Groups Regulation empowers the Commission to adopt delegated acts in accordance with Article 18 of that Regulation, in order to amend the Annex of the Regulation which lays down the Union list of substances that may be added to the specific categories of foods.

3. Exercise of the delegation

3.1. During the period starting on 22 August 2017 to date, the Commission has adopted the following nine delegated acts under Article 11(2) of the Food for Specific Groups Regulation:

a) Commission Delegated Regulation (EU) 2019/828 amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula[6]

This legal act was adopted on 14 March 2019 with the objective to ensure the highest level of protection of infants by lowering the maximum Vitamin D content permitted in

[3] Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ L 25, 2.2.2016, p. 1.
[4] Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes, OJ L 25, 2.2.2016, p. 30.
[5] Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control, OJ L 259, 7.10.2017, p. 2.
[6] Commission Delegated Regulation (EU) 2019/828 of 14 March 2019 amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula, OJ L 137, 23.5.2019, p. 12.

infant formula and the maximum level of erucic acid for infant formula and follow-on formula, based on the scientific opinions[7],[8] of the European Food Safety Authority (EFSA).

b) Commission Delegated Regulation (EU) 2018/561 amending Delegated Regulation (EU) 2016/127 with regard to protein requirements for follow-on formula[9]

This Delegated Regulation was adopted on 12 April 2018, with the objective to allow food business operators to adjust the composition of follow-on formula by introducing more flexibility, while ensuring a high level of protection of infants` health. It introduced technical adjustments to already existing protein requirements for follow-on formula based on the scientific opinion[10] of EFSA.

c) Commission Delegated Regulation (EU) 2021/572 amending Delegated Regulation (EU) 2016/127 as regards the date of application of certain of its provisions[11]

Regulation (EU) 2016/127 establishes that formulae manufactured from protein hydrolysates can only be placed on the market following a case-by-case evaluation of their safety and suitability by EFSA. Such assessment was not required under the previous Commission Directive 2006/141/EC on infant and follow-on formula[12]. Commission Delegated Regulation (EU) 2021/572 was adopted on 20 January 2021 with the objective to avoid potential market disruptions, by deferring the entry into application of the new requirement of a case-by-case assessment of hydrolysed infant formula and follow-on formula laid down in Delegated Regulation (EU) 2016/127. In fact, the COVID-19 pandemic and the associated public health crisis caused unexpected delays in the scientific assessments of the formulae by EFSA. The one-year postponement of the entry into application of the new requirements prevented the products, which were legitimately on the market in accordance with Commission Directive 2006/141/EC, and for which no adverse health effects had been reported, from becoming unnecessarily non-conform to the new requirements.

[7] Scientific opinion on erucic acid in feed and food, Erucic acid in feed and food | EFSA (europa.eu)
[8] Scientific opinion on the Update of the tolerable upper intake level for vitamin D for infants, Update of the tolerable upper intake level for vitamin D for infants - - 2018 - EFSA Journal - Wiley Online Library
[9] Commission Delegated Regulation (EU) 2018/561 amending Delegated Regulation (EU) 2016/127 with regard to protein requirements for follow-on formula OJ L 94, 12.4.2018, p. 1.
[10] Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal, Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal | EFSA (europa.eu)
[11] Commission Delegated Regulation (EU) 2021/572 of 20 January 2021 amending Delegated Regulation (EU) 2016/127 as regards the date of application of certain of its provisions OJ L 120, 8.4.2021, p. 4.
[12] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1.

d) Commission Delegated Regulations (EU) 2022/519, (EU) 2023/589 and (EU) …/… amending Delegated Regulation (EU) 2016/127 as regards the protein requirements for infant and follow-on formula manufactured from protein hydrolysates[13,14,15]

Delegated Regulation (EU) 2016/127 recalls that EFSA considers that the safety and suitability of each specific formulae manufactured from protein hydrolysates has to be established by clinical evaluation and allows the placing on the market of those formulae positively evaluated by EFSA. Three delegated acts were adopted by the Commission on 14 January 2022, 10 January 2023, and on 2 February 2024 with the objective to allow the placing on the market of infant and follow-on formulae manufactured from the protein hydrolysates that were evaluated nutritionally safe and suitable by EFSA[16,17,18] for use by infants between 2020 and 2023.

e) Commission Delegated Regulation (EU) 2022/2182 amending Delegated Regulation (EU) 2017/1798 as regards the lipid and magnesium requirements for total diet replacement for weight control[19]

This legal act was adopted on 30 August 2022 with the objective to update certain compositional requirements for total diet replacement for weight control products, on the basis of the scientific opinion of EFSA[20] and taking into account relevant technical and scientific progress, including data provided by interested parties.

f) Commission Delegated Regulation amending Delegated Regulation (EU) 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to

[13] Commission Delegated Regulation (EU) 2022/519 of 14 January 2022 amending Delegated Regulation (EU) 2016/127 as regards the protein requirements for infant and follow-on formula manufactured from protein hydrolysates, OJ L 104, 1.4.2022, p. 58.
[14] Commission Delegated Regulation (EU) 2023/589 of 10 January 2023 amending Delegated Regulation (EU) 2016/127 as regards the protein requirements for infant and follow-on formula manufactured from protein hydrolysates, OJ L 79, 17.3.2023, p. 40.
[15] Commission Delegated Regulation (EU) …/... amending Delegated Regulation (EU) 2016/127 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates,
[16] Nutritional safety and suitability of a specific protein hydrolysate derived from whey protein concentrate and used in an infant and follow-on formula manufactured from hydrolysed protein by Danone Trading ELN B.V., https://www.efsa.europa.eu/en/efsajournal/pub/6304
[17] Nutritional safety and suitability of a specific protein hydrolysate derived from whey protein concentrate and used in an infant and follow-on formula manufactured from hydrolysed protein by HIPP-Werk Georg Hipp OHG, https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7141
[18] 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., https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8063
[19] Commission Delegated Regulation (EU) 2022/2182 of 30 August 2022 amending Delegated Regulation (EU) 2017/1798 as regards the lipid and magnesium requirements for total diet replacement for weight control, OJ L 288, 9.11.2022, p. 18.
[20] Statement on additional scientific evidence in relation to the essential composition of total diet replacement for weight control, https://www.efsa.europa.eu/en/efsajournal/pub/6494

satisfy the nutritional requirements of infants and young children[21] and Commission Delegated Regulation (EU) 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula[22]

These two delegated acts were adopted by the Commission on 16 April 2021 with the objective to align the definition of "pesticide residues" laid down in Delegated Regulation (EU) 2016/128 and Delegated Regulation (EU) 2016/127 with the more precise definition provided for in Regulation (EC) No 396/2005[23] on maximum residue levels of pesticides.

3.2. So far, the Commission has not yet invoked the legal basis of Article 15(6) of the Food for Specific Groups Regulation, as the conditions to add or remove a category of substances to the Annex to the Regulation have not been fulfilled yet.

3.3 During the period starting on 22 August 2017 to date, the Commission has adopted the three delegated acts below under Article 16(1) of the Food for Specific Groups Regulation:

a) Commission Delegated Regulation (EU) 2021/571 amending the Annex to the Food for Specific Groups Regulation as regards the list of substances that may be added to infant and follow-on formula, baby food and processed cereal-based food[24]

This delegated act was adopted by the Commission on 20 January 2021 with the objective to update the Union list of substances that may be added to the specific categories of food to authorise the addition of calcium L-methylfolate as a source of folate to infant formula, follow-on formula, processed cereal-based food and baby food on the basis of the scientific opinion of EFSA[25].

b) Commission Delegated Regulation (EU) 2023/439 amending the Annex to the Food for Specific Groups Regulation to allow the use of nicotinamide riboside chloride as a source

[21] Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021 amending Delegated Regulation (EU) 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, OJ L 225, 25.6.2021, p. 1.
[22] Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021 amending Delegated Regulation (EU) 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula, OJ L 225, 25.6.2021, p. 4.
[23] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70, 16.3.2005, p. 1.
[24] Commission Delegated Regulation (EU) 2021/571 of 20 January 2021 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the list of substances that may be added to infant and follow-on formula, baby food and processed cereal-based food, OJ L 120, 8.4.2021, p. 1.
[25] Calcium l-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food, https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.5947

of niacin in food for special medical purposes and total diet replacement for weight control[26]

This legal act was adopted by the Commission on 16 December 2022 with the objective to update the Union list of substances that may be added to the specific categories of food to authorise the addition of nicotinamide riboside chloride as a source of niacin to food for special medical purposes and total diet replacement for weight control based on the scientific opinion of EFSA[27].

c) Commission Delegated Regulation amending the Annex to the Food for Specific Groups Regulation to allow the use of iron milk caseinate as a source of iron in total diet replacement for weight control and in food for special medical purposes, excluding food for infants and young children[28]

This delegated act was adopted on 29 January 2024 with the objective to update the Union list of substances that may be added to the specific categories of food to authorise the addition of iron milk caseinate as a source of iron to total diet replacement for weight control and food for special medical purposes, excluding food for infants and young children, based on the scientific opinion of EFSA[29].

4. Conclusion

Since 22 August 2017, the Commission has regularly exercised the delegated powers conferred to it under the Food for Specific Groups Regulation. The Commission has adopted delegated acts to update specific compositional requirements on infant and follow-on formula as well as on total diet replacement for weight control, based on EFSA`s opinions and taking into account relevant technical and scientific progress. Furthermore, the Commission updated the Union list of substances that may be added to the specific categories of food, on the basis of EFSA`s advice taking into account technical progress, scientific developments and protection of consumers' health. The Commission invites the European Parliament and the Council to take note of this report.

[26] Commission Delegated Regulation (EU) 2023/439 of 16 December 2022 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of nicotinamide riboside chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control, OJ L 64, 1.3.2023, p. 1.

[27] Extension of use of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283, https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6843

[28] Commission Delegated Regulation (EU) …/... amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of use of iron milk caseinate as a source of iron in total diet replacement for weight control and food for special medical purposes

[29] Safety of iron milk proteinate as a novel food pursuant to Regulation (EU) 2015/2283 and bioavailability of iron from this source in the context of Directive 2002/46/EC, https://www.efsa.europa.eu/en/efsajournal/pub/7549