

SCHEDULE 1

Regulation 6

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Regulation 2(1)

Specified EU Requirements

<i>Column 1 Specified provision of the EU Regulation</i>	<i>Column 2 Provisions to be read with the specified provision of the EU Regulation</i>
Article 4(2) (requirement for relevant food to be pre-packed)	Articles 1(1) and 4(1)
Article 9(1) (requirement for the composition of food to be nutritionally appropriate and suitable)	Articles 1(1), 4(1) and 9(3)
Article 9(2) (prohibition on substances in dangerous quantities)	Articles 1(1) and 4(1)
Article 9(5) (requirements as to labelling, presentation and advertising of relevant food)	Articles 1(1), 4(1) and 9(6)
Article 10 (additional requirements for infant formula and follow-on formula)	Article 4(1)
Article 15(1) (Union list)	Articles 1(1) (a) and (c) and 4(1) and the Annex insofar as it applies to infant formula and follow-on formula and food for special medical purposes
<i>Specified provision of Delegated Regulation (EU) 2016/127</i>	<i>Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127</i>
Article 1(2) (placing on the market)	Article 1(1)
Article 2(1) (compositional requirements for infant formula)	Articles 1(1) and 2(3), Annex 1 and Annex 3
Article 2(2) (compositional requirements for follow-on formula)	Articles 1(1) and 2(3), Annex 2 and Annex 3
Article 2(3) (preparation of infant and follow-on formula)	Articles 1(1), 2(1) and (2)
Article 3(1) (suitability of ingredients for infant formula)	Articles 1(1) and 3(3) and point 2 of Annex 1
Article 3(2) (suitability of ingredients for follow-on formula)	Articles 1(1) and 3(3) and point 2 of Annex 2
Article 4(2) (active substance residue threshold)	Articles 1(1) and 4(1), (3) and (5)
Article 4(3) (derogation from active substance residue threshold)	Articles 1(1) and 4(1), (2) and (5)
Article 4(4) (requirements on pesticides)	Articles 1(1) and 4(1) and (5)
Article 5(1) (name of food not manufactured entirely from cows' or goats' milk protein)	Article 1(1) and Part A of Annex 6

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<i>Specified provision of Delegated Regulation (EU) 2016/127</i>	<i>Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127</i>
Article 5(2) (name of food manufactured entirely from cows' or goats' milk protein)	Article 1(1) and Part B of Annex 6
Article 6 (specific requirements on food information)	Articles 1(1) and 7(1), (2), (3), (5), (6), (7) and (8)
Article 7(1) (specific requirements on the nutrition declaration)	Articles 1(1) and 7(4), Annex 1 and Annex 2
Article 7(3) (repetition of information included in mandatory nutrition declaration)	Article 1(1)
Article 7(4) (nutrition declaration mandatory regardless of size of packaging or container)	Articles 1(1) and 7(1), Annex 1 and Annex 2
Article 7(5) (application of Articles 31 to 35 of Regulation (EU) No. 1169/2011(1))	Articles 1(1) and 7(6), (7) and (8)
Article 7(6) (expression of energy value and amounts of nutrients)	Articles 1(1) and 7(5)
The first sub-paragraph of Article 7(7) (prohibition on expressing energy value and amount of nutrients as a percentage of reference intake)	Articles 1(1) and 7(5)
Article 7(8) (presentation of particulars included in the nutrition declaration)	Article 1(1)
Article 8 (prohibition on making nutrition and health claims on infant formula)	Article 1(1)
Article 9(1) ("lactose only" statement)	Article 1(1)
The first sub-paragraph of Article 9(2) ("lactose free" statement)	Article 1(1)
The second sub-paragraph of Article 9(2), (statement that "lactose free" infant formula and follow-on formula is not suitable for infants with galactosaemia)	Article 1(1)
Article 9(3) (prohibition on references to docosahexaenoic acid where infant formula placed on the market on or after 22 February 2025)	Article 1(1)
Article 10(1) (restriction on advertising for infant formula)	Article 1(1)
Article 10(2) (prohibition of promotional devices to induce sales of infant formula)	Article 1(1)

(1) Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, etc. (O.J. No. L 304, 22.11.2011, p.18)

<i>Specified provision of Delegated Regulation (EU) 2016/127</i>	<i>Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127</i>
Article 10(3) (prohibition of provision of free or low-priced products, samples or other promotional gifts to the general public, pregnant women, mothers or members of their families)	Article 1(1)
Article 10(4) (requirements for donations or low-priced sales of supplies of infant formula to institutions or organisations)	Article 1(1)
Article 11(2) (requirements on information relating to infant and young child feeding)	Article 1(1)
Article 11(3) (requirements on donations of informational or educational equipment or materials)	
Article 12 (notification requirements)	Article 1(1)
Article 10(2) (prohibition of promotional devices to induce sales of infant formula)	Article 1(1)
Article 10(3) (prohibition of provision of free or low-priced products, samples or other promotional gifts to the general public, pregnant women, mothers or members of their families)	Article 1(1)
Article 10(4) (requirements for donations or low-priced sales of supplies of infant formula to institutions or organisations)	Article 1(1)
Article 11(2) (requirements on information relating to infant and young child feeding)	
Article 11(3) (requirements on donations of informational or educational equipment or materials)	
Article 12 (notification requirements)	Article 1(1)
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<i>Specified provision of Delegated Regulation 128</i>	<i>Provision of Delegated Regulation 128 to be read with the specified provision of the Delegated Regulation 128</i>
Article 2(2) (requirement for the formulation of food to be based on sound medical and nutritional principles)	Article 1
The first sub-paragraph of article 2(3) (requirement for food for special medical purposes developed to satisfy the nutritional requirements of infants to comply with the compositional requirements in Part A of Annex I)	Articles 1 and 2(4) and Part A of Annex 1

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<i>Specified provision of Delegated Regulation 128</i>	<i>Provision of Delegated Regulation 128 to be read with the specified provision of the Delegated Regulation 128</i>
The second-sub paragraph of article 2(3) (requirement for food other than that developed to satisfy the nutritional requirements of infants to comply with the compositional requirements in Part B of Annex I)	Articles 1 and 2(4) and Part B of Annex 1
Article 3(2) (requirement relating residue threshold for certain active substances where food for special medical purposes is developed to satisfy the nutritional requirements of infants and young children)	Articles 1 and 3(1), (3) and (5) and Annex 2
Article 3(3) (maximum residue levels for substances listed in Annex II)	Articles 1 and 3(1) and (5) and Annex 2
Article 3(4) (prohibition on the use of plant protection products)	Articles 1 and 3(1) and (5) and Annex 3
Article 4 (name of the food)	Article 1 and Annex 4
Article 5(1) (requirement for food for special medical purposes to comply with Regulation (EU) No. 1169/2011 unless otherwise specified)	Articles 1 and 5(2)
Article 5(2) (additional mandatory particulars relating to food information)	Articles 1 and 5(1) and (3)
Article 5(3) (application of articles 13(2) and (3) of Regulation (EU) No. 1169/2011 to additional mandatory particulars)	Articles 1 and 5(1) and (2)
Article 6 (specific requirements on the nutrition declaration)	Article 1 and Annex 1
Article 7 (nutrition and health claims)	Article 1
Article 8(1) (requirement for mandatory particulars to appear in a language easily understood by consumers)	Article 1
The first sub-paragraph of article 8(2) (prohibition of pictures of infants or certain other pictures or text)	Article 1
Article 8(3) (requirements relating to labelling, presentation and advertising)	Article 1
The first sub-paragraph of article 8(4) (restriction on publication)	Article 1 and the third sub-paragraph of article 8(4)
Article 8(5) (prohibition on use of promotional devices to induce sales)	Article 1
Article 8(6) (prohibition on providing free or low-priced products, samples or other promotional gifts)	Article 1

<i>Specified provision of Delegated Regulation 128</i>	<i>Provision of Delegated Regulation 128 to be read with the specified provision of the Delegated Regulation 128</i>
Article 9 (notification)	Article 1
Article 7(5) (application of articles 31 to 35 of Regulation (EU) No. 1169/2011)	Article 1(1), 7(6), (7) and (8)
Article 7(6) (expression of energy value and amounts of nutrients)	Article 1(1) and 7(5)
The first sub-paragraph of Article 7(7) (prohibition on expressing energy value and amount of nutrients as a percentage of reference intake)	Article 1(1) and 7(5)
Article 7(8) (presentation of particulars included in the nutrition declaration)	Article 1(1)
Article 8 (prohibition on making health claims on infant formula)	Article 1(1)
Article 9(1) (“lactose only” statement)	Article 1(1)
The first sub-paragraph of Article 9(2) (“lactose free” statement)	Article 1(1)
The second sub-paragraph of Article 9(2), (statement that lactose free infant formula and follow-on formula is not suitable for infants with galactosaemia)	Article 1(1)
Article 9(3) (prohibition on references to decosahexaenoic acid where infant formula placed on the market on or after 22 February 2025)	Article 1(1)
The first paragraph of article 10(1) (restriction on advertising for infant formula)	Article 1(1)
Article 10(2) (prohibition of promotional devices to induce sales of infant formula)	Article 1(1)
Article 10(3) (prohibition of provision of free or low-priced products, samples or other promotional gifts to the general public, pregnant women, mothers or members of their families)	Article 1(1)
Article 10(4) (requirements for donations or low-priced sales of supplies of infant formula to institutions or organisations)	Article 1(1)
Article 11(2) (requirements on information relating to infant and young child feeding)	
Article 11(3) (requirements on donations of informational or educational equipment or materials)	
Article 12 (notification requirements)	Article 1(1) ”

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