Appendix A: Regulatory and policy framework

A.1 Infant formula and follow-on formula products are tightly regulated in the UK and across the world in order to not discourage breastfeeding and ensure formula milks provide essential nutrients for babies and are safe.

A.2 In 1981, the World Health Assembly (as the decision making body of the World Health Organization (WHO)) adopted the International Code of Marketing of Breast-milk Substitutes which, along with subsequent resolutions, is an international health policy framework designed to encourage better regulation of the marketing of breastmilk substitutes in order to protect and promote breastfeeding (WHO Code).[1]

A.3 As set out in further detail in the sub-section 'Regulatory and policy framework' later in this appendix, in the UK, the regulation of the composition, marketing, labelling infant formula and follow-on formula products derives from EU regulations which are now assimilated into national law.[2] These regulations give effect in part to the provisions and aims of the WHO Code.

A.4 The Department of Health and Social Care's (DHSC) role and that of other competent authorities in the UK is described below. Enforcement of the regulations is primarily carried out by local authorities and ASA has a role in enforcement of its CAP and BCAP Codes as detailed in the sub-section '*Role of government and public bodies*' later in this appendix.

A.5 DHSC has stated that the legislation for infant formula and follow-on formula in the UK is designed to: ensure that infant formula and follow-on formula products provide essential nutrients for infants and are safe; provide accurate labelling to inform consumer choice; and ensure marketing and advertising does not discourage breastfeeding. The regulatory framework allows for growing scientific understanding and development.

Regulatory and policy framework

Regulatory responsibility

A.6 Nutrition law is an area of devolved competency in the UK, and responsibilities for legislating in relation to infant formula and follow-on formula and enforcing that legislation sit with each of the UK's devolved nations.

[1] World Health Organization (1981), 'International Code of Marketing of Breast-milk Substitutes'.
[2] The situation is different for Northern Ireland where EU legislation relating to nutrition law continues to be directly applicable, please see later in this sub-section for further detail.

Great Britain

A.7 DHSC, the Scottish Government and the Welsh Government are the competent authorities for each nation in Great Britain.

A.8 The regulations relating to the composition, labelling and marketing of infant formula and follow-on formula in Great Britain derive from EU regulations which have now become assimilated in national law.[3] These regulations are explained in greater detail later in this sub-section.

Northern Ireland

A.9 The Food Standards Agency in Northern Ireland is the competent authority for Northern Ireland.

A.10 In Northern Ireland, the Windsor Framework means that EU legislation relating to nutrition (as detailed in Annex 2 to the Windsor Framework[4]) continues to be directly applicable in Northern Ireland to ensure goods in Northern Ireland can move freely to and from Ireland (and the wider EU). As such, a change in EU law relating to nutrition will also apply in Northern Ireland. Further, 'qualifying Northern Ireland goods' that comply with EU requirements may move freely to the rest of the UK as a consequence of the principles of unfettered access and mutual recognition as provided for under the terms of the 2023 Windsor Framework, and the UK Internal Market Act 2020.[5] For example, there have been a number of approvals for use of protein hydrolysates in products in the EU since the UK exited the EU.[6] Products containing these proteins can be sold in Northern Ireland pursuant to the Windsor Framework, and if such products are sold in Northern Ireland they can in turn 'be freely moved to and sold in the rest of the UK'.[7]

A.11 Whilst we have seen no material divergence to date in how infant formula and follow-on formula is regulated (i) between the EU and UK and (ii) within the four UK nations, it is possible that there could be divergence in the future. The four UK nations have entered into a framework which sets out arrangements for co-operation between DHSC, the Scottish Government, the Welsh Government and the Food Standards Agency in Northern Ireland in relation to nutrition related

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[3] As per the Retained EU Law (Revocation and Reform) Act 2003, section 5 legislation formerly known as 'Retained direct EU legislation' is, from 1 January 2024, now known as 'assimilated direct legislation'.
[4] Annex 2 to the Windsor Framework, as amended (see Joint Declaration by the United Kingdom of Great Britain and Northern Ireland and the European Union in the Withdrawal Agreement Joint Committee on the Windsor Framework)
[5] Following the UK's exit from the EU, retained EU regulations and tertiary legislation relating to nutrition were amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020; these changes are necessary to ensure that the UK's obligations under the Windsor Framework are met and that EU nutrition legislation remains directly applicable in Northern Ireland, pursuant to Annex 2 of the Windsor Framework.
[6] See 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 (available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202402684)
[7] See Explanatoru Memorandum on EU law concerning infant and follow-on formula (C(2024)549) - GOV.UK, paragraph 23.

labelling, composition, and standards policy (NLCS Framework).[8][9] DHSC explains in guidance[10] that the NLCS Framework seeks to ensure that any impacts of regulatory divergence on the UK internal market are limited and, in particular, emphasises that Northern Ireland continues to play a vital role in policy development for nutrition legislation in the UK.[11] As we set out in Section 8 Measures to address the concerns we have identified, we expect the impact, and ways to limit such impact, of any potential regulatory divergence would be relevant factors to be considered by the UK governments should they choose to implement our recommendations.

Overview of regulatory framework

A.12 The regulations relating to the composition, labelling and marketing of infant formula and follow-on formula in the UK give effect in part to the provisions of the WHO Code. This legislation is intended to ensure that infant formula and follow-on formula products are safe; provide essential nutrients in sufficient quantities for babies; provide accurate labelling to inform consumer choice; and ensure marketing and advertising does not discourage breastfeeding or otherwise mislead consumers.

A.13 The overarching regulation is the Food for Specific Groups Regulation (EU) No 609/2013 (FSG Regulation) (assimilated direct legislation)[12] which came into force from 2016 and sets out general rules on the composition and labelling of food for infants and young children in Great Britain.[13]

A.14 This overarching regulation is supplemented by two delegated acts which also came into force from 2016:

(a) The first delegated act is Commission Delegated Regulation (EU) 2016/127 (Regulation 2016/127) (assimilated direct legislation)[14] which regulates the nutritional content, labelling and marketing of infant formula and follow-on formula;

[8] DHSC (2020), Nutrition Related Labelling Composition and Standards Provisional Common Framework - October 2020.
[9] In accordance with the NLCS Framework, a group has been formed made up of representatives from each of the four nations which meets to discuss and agree common recommendations regarding policy proposals within the scope of the NLCS Framework.
[10] DHSC (updated April 2024), Guidance on Commission Delegated Regulation (EU) 2016/127.
[11] DHSC (updated April 2024), Guidance on Commission Delegated Regulation (EU) 2016/127.
[12] As per the Retained EU Law (Revocation and Reform) Act 2023, section 5 legislation formerly known as 'Retained direct EU legislation' is, from 1 January 2024, now known as 'assimilated direct legislation'.
[13] The Nutrition (Amendment) And Food For Specific Groups (Food For Special Medical Purposes For Infants, Infant Formula and Follow-On Formula (Information and Compositional Requirements) (Amendment) Regulations 2021 amended the date of application of the provisions relating to infant formula and follow-on formula made from protein hydrolysates under Commission Delegated Regulation (EU) 2016/127 (assimilated direct legislation).
[14] Commission Delegated Regulation (EU) 2016/127 (assimilated direct legislation).

(b) The second delegated act is Commission Delegated Regulation (EU) 2016/128 (Regulation 2016/128) (assimilated direct legislation)[15] which regulates the nutritional content, labelling and marketing of foods for special medical purposes (FSMP).[16]

Key provisions of the FSG Regulation and Regulation 2016/127

A.15 The key regulations relating to the composition, labelling and marketing in the UK are the FSG Regulation and Regulation 2016/127. Infant formula and follow-on formula can only be placed on the UK market if they comply with these regulations (and other applicable legislation).

A.16 The most relevant provisions of the FSG Regulation provide that:

(a) the composition of infant formula and follow-on formula must satisfy the nutritional requirements of babies;[17]

(b) the labelling, presentation and advertising of infant formula and follow-on formula should be designed so as not to discourage breast-feeding[18] and should not include pictures or text which may idealise the use of such formulae;[19] and

(c) certain substances including vitamins, minerals and amino acids may be added to infant formula and follow-on formula provided that these substances are included in the Great Britain list set out in the Annex to the FSG Regulation (which may be updated from time to time).[20]

A.17 Regulation 2016/127 supplements the over-arching provisions set out in the FSG Regulation. It sets out provisions relating to a number of key objectives:

(a) Ensuring that all infant formula and follow-on formula products are safe and contain essential nutrients to meet the nutritional requirements of infants:

(i) Regulation 2016/127 aims to ensure that infant formula and follow-on formula products meet the safest and highest quality standards to support healthy growth and development and ensure that ingredients

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[15] Commission Delegated Regulation (EU) 2016/128 (assimilated direct legislation).
[16] This report focuses on the regulation of infant formula and follow-on formula rather than FSMP but it is worth pointing out that Regulation 2016/127 and Regulation 2016/128 are broadly similar in content. This said, Regulation 2016/128 does not set out detailed compositional rules for FSMP products because of the wide diversity of FSMP, the rapidly evolving scientific knowledge on which it is based, and the need to ensure adequate flexibility to develop innovative products (Regulation 2016/128, recital 5). Further, manufacturers can place FSMP products on the market as long as those products comply with the requirements of Regulation 2016/128 which means that manufacturers are able to classify their own products as FSMP if they consider the products meet the requirements of Regulation 2016/128 without any separate pre-approval or authorisation.
[17] FSG Regulation, Article 9(1).
[18] FSG Regulation, Article 10(1).
[19] FSG Regulation, Article 10(2).
[20] FSG Regulation, Articles 15 and 16.

are safe and do not endanger the health of infants. Specific requirements include:

(1) Compositional requirements: infant formula and follow-on formula must comply with the compositional requirements set out in the Annex I and II to Regulation 2016/127, which include minimum and maximum levels of essential ingredients.[21] The regulations set out compositional standards but are not fully prescriptive with respect to all ingredients and so it is possible for manufacturers to add other ingredients to infant formula and follow-on formula that are not referred to in the Annexes to Regulation 2016/127 so long as those ingredients are not restricted in the regulation (or other regulations).[22]

(2) Suitability of ingredients: Infant formula and follow-on formula must use protein sources specified in Annex I and II to Regulation 2016/127, which are based on widely accepted scientific data to ensure ingredients are safe and reliable.[23]

(3) Specific requirements on the nutrition declaration: In addition to general nutrition information as set out in the applicable articles of Regulation (EU) No 1169/2011 which sets out a list of mandatory particulars that must be included in food labelling including a list of ingredients, the quantity of certain ingredients and a nutrition declaration, there are additional requirements to provide the amounts of minerals, vitamins, and other substances.[24] The information must be accurate, clear and easy for the consumer to understand and must be provided regardless of the size of package; there are also restrictions for measurement units and requirements regarding the order in which nutrients are presented. These requirements provide the consumer with comprehensive, accurate nutritional information and helps ensure consistency across products. Standardised nutritional declarations should make it easier for consumers to compare different products and supports informed consumer choice.

(b) Ensuring accurate labelling:

[21] Regulation 2016/127, Article 2. The Annexes are informed by scientific advice to ensure nutritional adequacy by providing the essential ingredients for health infants: for example, DHSC may review the Annexes and update them to reflect scientific developments from time to time.
[22] For novel food ingredients the Food Standards Agency must first authorise use of these ingredients – see the sub-section 'Role of government and public bodies' later in this appendix for further detail.
[23] Regulation 2016/127, Article 3.
[24] Regulation 2016/127, Article 7.

(i) Infant formula and follow-on formula should be labelled in particular ways to ensure that consumers are provided with accurate, clear and non-misleading information and to ensure the proper use of the products (including information on preparation and storage). Specific requirements include:

(1) The name of infant formula and follow-on formula products must be in line with the guidelines provided in Annex VI to Regulation 2016/127 to ensure consistency and help parents easily identify the type of formula that they are purchasing.[25] The provision also aims to avoid misleading information in relation to product names.

(2) Specific requirements on food information. Infant formula and follow-on formula must comply with the requirements of Regulation (EU) No 1169/2011 unless stated otherwise.[26] In addition, in relation to infant formula products there are requirements to provide: (a) a statement that the product is suitable for infants from birth when they are not breast fed; (b) instructions for appropriate preparation and storage of the product; and (c) a statement concerning the superiority of breast feeding and a statement that the product only be used on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for material and child care. These particulars shall be preceded by the words 'important notice'.[27] For follow-on formula there are requirements to include preparation and storage information and a statement that the product is only suitable for infants over the age of six months, that it should only form part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding should be made on the advice of independent and suitably qualified persons.[28]

(3) All mandatory particulars for infant formula and follow-on formula should appear in language easily understood by consumers.[29]

(4) The labelling, presentation and advertising of infant formula and follow-on formula must provide the necessary information about the appropriate use of the products, so as not to discourage breast feeding.[30] Further, the labelling, presentation and advertising of

[25] Regulation 2016/127, Article 5.
[26] Regulation 2016/127, Article 6.
[27] Regulation 2016/127, Article 6(2).
[28] Regulation 2016/127, Article 6(3).
[29] Regulation 2016/127, Article 6(5).
[30] Regulation 2016/127, Article 6(6).

these products must not use terms such as ‘humanised’ and ‘maternalised’.

(5) Nutrition and health claims[31] are prohibited on infant formula (this includes in the advertising of them).[32] Only nutrition and health claims supported by scientific evidence and included in the GB register are permitted on the labelling of follow-on formula.[33]

(6) Infant formula and follow-on formula can include the statements ‘lactose only’ and ‘lactose free’ as long as they meet the requirements as set out in Regulation 2016/127.[34] This provision is important for transparency and safety and helps consumers make informed decisions should infants have specific medical conditions. Further, docosahexaenoic acid (DHA) is beneficial for infant brain and eye development and has been a mandatory ingredient in infant formula and follow-on formula since 2020. Infant formula and follow-on formula packaging may include a statement indicating the inclusion of DHA in a prescribed form until 22 February 2025.[35]

(c) Ensuring marketing and advertising does not discourage breastfeeding:

(i) Regulation 2016/127 restricts the advertising of infant formula (as well as other promotional and commercial activities) in order to implement the recommendations as set out in the WHO Code. Specific requirements include:

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[31] Regulation (EC) No 1924/2006, Article 2 sets out the definitions of ‘nutrition claims’ and ‘health claims’. Nutrition claims are defined as ‘any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

(a) the energy (calorific value) it
  i. provides;
  ii. provides at a reduced or increased rate; or
  iii. does not provide; and/or
(b) the nutrients or other substances it
  i. contains;
  ii. contains in reduced or increased proportions; or
  iii. does not contain.’

Health claims are defined as ‘any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health’.

[32] Regulation 2016/127, Article 8.

[33] Regulation (EC) No 1924/2006 mandates that the appropriate authority must establish and maintain a ‘Register of nutrition and health claims made on food’ which may be updated from time to time including following authorisations relating to requests made from applicants that a particular claim should be authorised and added to the register. The Great Britain nutrition and health claims (NHC) register is maintained by DHSC and sets out all authorised and rejected nutrition and health claims. Only authorised claims in the Great Britain NHC register may be used in Great Britain. As of 1 January 2021, all nutrition and health claims that were listed in the EU Register on 31 December 2020 were adopted and included in the Great Britain nutrition and health claims register. DHSC (2020) - Great Britain Register and nutrition and health claims.

[34] Regulation 2016/127, Articles 9(1) and 9(2).

[35] Regulation 2016/127, Article 9(3).

(1) Advertising of infant formula is restricted except for some information and educational materials in specific babycare and scientific publications where the advertisements can only include information that is of a scientific and factual nature.[36]

(2) There is a requirement for infant formula and follow-on formula to be clearly distinct from each other to avoid any risk of confusion between infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.[37] The purpose of this provision is to ensure appropriate product use and prevent harm by feeding babies unsuitable formula. The DHSC's guidance on Regulation 2016/127[38] states that this provision also serves to prevent cross promotion and the indirect marketing of infant formula by advertising a follow-on formula product that looks very similar;

(3) Point-of-sale advertising, the giving of samples and other promotional devices to induce sales of infant formula directly to parents at the retail level are prohibited (for example special displays, discount coupons, loss leaders or special sales).[39] DHSC has stated that this provision does not prevent infant formula manufacturers or distributors from reducing the price of infant formula. However, promotional activities around the price reduction may be seen as an inducement to purchase infant formula. Where loyalty card schemes seek to induce the sale of infant formula through rewards, incentives or price reductions they are likely to be prohibited by the regulations;

(4) Manufacturers and distributors of infant formula must not provide free or subsidised products, samples or any other promotional gifts to members of the general public including pregnant women, mothers or members of their families directly or via the health care system or health workers. This includes free or low-priced products, samples or any other promotional gifts;[40] and

(5) Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed

[36] Regulation 2016/127, Article 10(1).
[37] Regulation 2016/127, Article 6(6).
[38] DHSC (2024), Guidance on Regulation 2016/127.
[39] Regulation 2016/127, Article 10(2).
[40] Regulation 2016/127, Article 10(3).

for babies who have to be fed on infant formula and only for as long as required by such babies.[41]

(d) Requirements on information relating to baby and young child feeding:

(i) Information and educational material about the feeding of babies, which is intended to reach pregnant women and mothers of babies and young children, must include certain information. Specific requirements include:

(1) The Secretary of State shall take measures ensuring that objective and consistent information is provided on baby and young child feeding for use by families and those involved in the field of baby and young child nutrition.[42] Informational and educational materials intended to reach pregnant women and mothers of babies and young children shall include clear information on a number of points including the benefits and superiority of breast feeding and on maternal nutrition and the preparation for and maintenance of breast feeding and shall not use any images which may idealise the use of infant formula.[43]

(2) Donations of informational or educational equipment or materials by manufacturers or distributors shall only be made on request and with the written approval of the Secretary of State or within guidelines given by that authority. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formula and shall be distributed only through the health care system.[44] DHSC has stated that in order to gain approval such informational or educational materials should contain information which is consistent with current government policies on breastfeeding and the promotion and advertising of infant formula and follow-on formula; must not be marked or labelled with the name of a proprietary brand of infant formula and must only be distributed through the healthcare system.

(e) Notification requirement:

(i) When infant formula (and follow-on formula made from protein hydrolysates or contained substances other than those listed in Annex II to the regulation) is placed on the market, the food business operator

[41] Regulation 2016/127, Article 10(4).
[42] Regulation 2016/127, Article 11(1).
[43] Regulation 2016/127, Article 11(2).
[44] Regulation 2016/127, Article 11(3).

shall notify the competent authority of each part of Great Britain[45] where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product along with any other information the competent authority may reasonably request to establish compliance with the regulation.[46]

Other relevant legislation

A.18 There are additional regulations which do not focus primarily on infant formula and follow-on formula but which are still relevant to those categories of products and contain provisions that those products must comply with and which complement provisions in the FSG Regulation and Regulation 2016/127. For example:

(a) Regulation (EC) No 178/2002 (assimilated direct legislation)[47] lays down the general principles and requirements of food law including a provision that food law shall aim at the protection of the interests of consumers and provides a basis for consumers to make informed choices in relation to the foods they consume. It aims at the prevention of fraudulent and deceptive practices and any other practices which may mislead the consumer.[48] The regulation also provides that the labelling, advertising and presentation of food shall not mislead consumers;[49]

(b) Regulation (EU) No 1169/2011 (assimilated direct legislation)[50] on the provision of food information to consumers also provides a list of mandatory particulars that must be included in food labelling including a list of ingredients, the quantity of certain ingredients or categories of ingredients and a nutrition declaration.[51] The Regulation also provides that food information shall not be misleading, particularly as to the characteristics of the food and its nature, identity, properties, composition or by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients.[52] The regulation further provides that food information shall be accurate, clear and easy to understand for the consumer;[53]

[45] DHSC is the competent authority for England; the Welsh Government is the competent authority for Wales and Food Standards Scotland is the competent authority for Scotland. DHSC co-ordinates the notification forms for all three nations of Great Britain for the purposes of notifying each of the applicable competent GB authorities – DHSC (2024), Guidance for Reg 2016/127.
[46] Regulation 2016/127, Article 12.
[47] Regulation (EC) No 178/2002.
[48] Regulation (EC) No 178/2002. Article 8.
[49] Regulation (EC) No 178/2002. Article 16.
[50] Regulation (EU) No 1169/2011.
[51] Regulation (EU) No 1169/2011, Article 9.
[52] Regulation (EU) No 1169/2011, Article 7(1).
[53] Regulation (EU) No 1169/2011, Article 7(2).

(c) Regulation (EC) No 1924/2006 (assimilated direct legislation)[54] on nutrition and health claims made on foods which regulates nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. The regulation defines nutrition and health claims and mandates that the appropriate authority must establish and maintain a register of nutrition and health claims made on food;[55] and

(d) The Consumer Protection from Unfair Trading Regulations 2008[56] (CPRs) which prohibit unfair commercial practices including commercial practices which are likely to mislead consumers (for example through action or omission) such that the average consumer takes or is likely to take a transactional decision they otherwise would not have taken. As such, the CPRs are applicable to commercial practices connected with the promotion and marketing of infant formula and follow-on formula.

International conventions and frameworks

A.19 In addition to domestic legislation, certain international conventions and frameworks are relevant to understanding the wider UK legislative and policy framework. As noted above, Regulation 2016/127 gives effect to 'some but not all of the general principles and ambitions' of the WHO Code.[57] The WHO Code itself is better understood as a framework of recommendations, and is not binding law.[58]

A.20 In addition, the UK has signed and ratified the UN Convention on the Rights of the Child (UNCRC).[59]

A.21 States that are parties to the UNCRC commit to, among other things, take appropriate measures to:

(a) combat malnutrition, including through the provision of nutritious foods;[60]

(b) ensure access to education and knowledge of 'child health and nutrition' and 'the advantages of breastfeeding';[61][62]

A.22 Various pieces of domestic legislation protect children's rights in the UK. While the UNCRC is an international treaty, and may affect the interpretation of domestic law, it does not have direct effect within the UK unless Parliament or, to the extent

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[54] Regulation (EC) No 1924/2006.
[55] Regulation (EC) No 1924/2006, Article 20.
[56] Consumer Protection from Unfair Trading Regulations 2008.
[57] Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013): guidance - GOV.UK
[58] The international code of marketing of breast-milk substitutes: frequently asked questions (WHO, 2017)
[59] The United Nations Convention on the Rights of the Child. See also: United Nations Convention on the Rights of the Child (UNCRC): how legislation underpins implementation in England.
[60] UNCRC, Article 24(2)(c)
[61] UNCRC, Article 24(2)(e)
[62] UNCRC, Article 27(3)

falling within the powers of the devolved administrations, the Scottish Parliament, Senedd Cymru or Northern Ireland Assembly (as appropriate) decides to incorporate it into domestic legislation.

A.23 In Scotland, the UNCRC (to the maximum extent possible within the powers of the Scottish Parliament) has been made part of domestic law,[63] by means of the UNCRC (Incorporation) (Scotland) Act 2024.[64]

Role of government and public bodies

DHSC

Compliance role

A.24 As mentioned in the sub-section 'Regulatory and policy framework' earlier in this appendix, when manufacturers place infant formula, specific follow-on formulas and FSMP products on the market in Great Britain they must notify the competent authority and send a copy of the label to be included on the product packaging, along with any further information the competent authority reasonably requests to establish compliance with Regulation 2016/127. DHSC is the competent authority for England and also co-ordinates the notification process on behalf of Scotland and Wales. In Northern Ireland, manufacturers make notifications to the Food Standards Agency Northern Ireland. Through the arrangements of the NLCS, information on notifications is shared between the nations of the UK. Manufacturers may place products on the market as soon as they have notified the competent authority.

A.25 If DHSC considers that, based on the information provided, the label may not comply with Regulation 2016/127 it will notify the manufacturer of its concern and request that the manufacturer amends and resubmits the labelling. Once DHSC receives an amended label it provides a letter of acknowledgement which confirms completion of the notification process. This is not confirmation of compliance with the regulations. Where there may be any difference in views between DHSC and a manufacturer, DHSC may issue an amended acknowledgement letter that highlights its concerns. Acknowledgement letters are shared with enforcement authorities, including where DHSC has raised concerns. DHSC guidance explains that it is the responsibility of individual businesses to ensure their compliance with the law[65] and Regulation 2016/127 states that infant formula and follow-on formula products may only be placed on the market if they comply with this Regulation.[66]

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[63] Annex A. Clarification of conceptual aspects of the UNCRC - UNCRC (Incorporation) (Scotland) Act 2024 - part 2: statutory guidance - gov.scot
[64] United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024
[65] DHSC (2024), Guidance for Reg 2016/127.
[66] Regulation 2016/127, Article 1(1).

Guidance

A.26 DHSC has produced guidance on Regulation 2016/127[67] which is designed to support manufacturers by providing information and advice and to set out DHSC's interpretation of the regulation as well as to support local authorities responsible for enforcing legislation in this area. Further information on the contents of this guidance is set out at Section 6 Impact of the regulatory framework and regime of the main report.

Updating the Regulations

A.27 The regulations may be updated where appropriate. For example, DHSC told us that over many years, the composition of infant formula has evolved due to advances in scientific evidence, with legislation on compositional standards updated to reflect this, which has led to better outcomes for infants. In 2006, for instance, the European Commission adopted a new Directive on infant formula and follow-on formula (Commission Directive 2006/141/EC) which updated the 1991 legislation to reflect updated recommendations from the European Scientific Committee for Food (SCF) based on the latest scientific developments and discussions at an international level in the Codex Alimentarium forum.

A.28 Following the UK's exit from the European Union, updates to Commission Delegated Regulation (EU) 2016/127 (assimilated direct legislation), affecting England, Scotland and Wales, have become a matter of UK law. In many cases, updates can be made through secondary legislation,[68] preceded by a public consultation.[69] In circumstances where there is not a power to amend Regulation 2016/2017 by secondary legislation, this may be done by primary legislation. As described previously, since the UK left the EU, some amendments have been made to authorise certain ingredients for inclusion in infant formula and follow-on formula, within applicable EU laws, which, to date, have not been made in the UK. Inclusion of these ingredients (hydrolysates) is not a mandatory requirement in the EU.

Enforcement of Regulation 2016/127

A.29 Legislation relating to infant formula and follow-on formula is enforced separately in each of the nations of the UK. Regulation 2016/127 is enforced in England under The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional

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[67] DHSC (2024), Guidance for Reg 2016/127.
[68] For example, Articles 11 and 16A of Regulation (EU) No 609/2013, or section 15 of the Retained EU Law (Revocation and Reform) Act 2023.
[69] Regulation (EC) No 178/2002, Article 9 which lays down the general principles and requirements of food law states that 'there shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it'.

Requirements) (Amendment etc.) (England) Regulations 2020[70] which amend and supplement the provisions of the Food Safety Act 1990.[71] Similar legislation applies in Scotland, Wales and Northern Ireland.

A.30 In each case, the enforcement regulations state that a 'food authority' is responsible for enforcing the regulation (usually, the responsibility for enforcement will be given to local trading standards services or environmental health departments at local councils). In enforcing Regulation 2016/127, local authorities in England have a range of interventions at their disposal: enforcement may start with a discussion with a 'food business operator' (which we understand would be typically a manufacturer) about a potential breach and, where necessary, escalate to issuing an improvement notice requiring the food business operator to take action to become compliant with the potential for court action (and a fine on summary conviction[72]) if the food business operator fails to take the necessary action.

A.31 In the case of infant formula and follow-on formula enforcement, manufacturers and retailers may have a 'home authority' or 'primary authority' relationship with the local authority trading standards service. There are differences between these relationships (primarily being that a 'primary authority' relationship arises out of a formal agreement between the local authority and the business) but in both cases the intention is that the business with have a close relationship with the local authority and the local authority will take a lead role in engaging with the business ahead of other local authorities and may also offer informal advice on interpretation of the regulations.

Advertising Standards Authority

A.32 The ASA regulates advertising across all media in the UK including advertisers' own marketing communications on their own websites and advertising on social networking sites.

A.33 The ASA endorses and administers the CAP Code in relation to non-broadcast advertising and the BCAP Code in relation to broadcast advertising. These Codes reflect legislation applicable to advertising and marketing generally such as the CPRs but are not, except in very specific circumstances, law in their own right. The marketing community self-regulates in relation to each of the Codes with the ASA investigating and ruling on complaints. Where the ASA investigates a matter and finds that a marketer has breached the provisions of the CAP Code and/or BCAP Code it publishes a notice on its website and in most cases the marketer

[70] The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020.
[71] Food Safety Act 1990.
[72] The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020, paragraph 4(3).

will remedy the issue by amending, or taking down, the marketing communication and/or advertisement.[73]

A.34 The CAP and BCAP Codes include specific provisions on infant formula and follow-on formula which reflect Regulation 2016/127. The ASA advises marketers to have regard to this regulation and other relevant food law when preparing marketing communications and adverts. The CAP and BCAP Codes state that marketing communications/adverts for infant formula are not permitted[74] and that marketing communications/adverts must not confuse consumers between infant formula and follow-on formula.[75] There are also provisions in each code restricting the use of health and nutrition claims. These provisions of the CAP Code and BCAP Code are currently under review.

A.35 The ASA does not enforce Regulation 2016/127 or any other relevant legislation in this field but does enforce the CAP and BCAP Codes. If the ASA receives a complaint it will usually review and if there is any merit adopt an informal approach in the first instance by issuing an advice notice to the marketer which is usually acted upon; there may also be instances where the marketer admits a breach and agrees to take remedial action. If such remedial action is not forthcoming or the ASA thinks there are issues that require further attention it may also investigate and adjudicate on the possible breach of the CAP Code and BCAP Code formally. The ASA would then publish its ruling and would require the marketer to remove its advert if it found there was a breach of the CAP or BCAP Code.

A.36 The ASA told us it has investigated 47 discrete advertisements relating to infant formula in the past two years. For example, the ASA has ruled that several advertisements had the effect of one or more of the following: marketing infant formula; confusing infant formula and follow-on formula; discouraging breastfeeding; making health claims for infant formula and follow-on formula and making disease treatment claims (all of which breached the CAP Code).[76]

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[73] ASA, 'How we handle complaints' – available at: How we handle complaints, accessed 17/10/24.
[74] ASA – CAP Code, Rule 15.10 CAP Code and ASA – BCAP Code, Rule 13.8 - BCAP Code.
[75] ASA – CAP Code, Rule 15.10.1 CAP Code and ASA – BCAP Code, Rule 13.8.1 - BCAP Code.
[76] Examples include advertisements for infant formula on Kendal Nutricare's Linkedin page and an in-app advertisement on the Candy Crush game (ASA Ruling on Kendal Nutricare - 05/04/2023); an advert on Kendal Nutricare's website which featured customer submitted reviews which were adjudged to advertise infant formula and confuse between infant formula and follow-on formula as well as making a health claim (ASA Ruling on Kendal Nutricare - 04/08/2021); Other rulings relate to a podcast advertisement for Cow & Gate Baby Club which was subsequently discussed on another podcast and made a health claim and confused between infant formula and follow-on formula (ASA Ruling on Nutricia Ltd - 23/02/2022); and four paid-for Google ads for Boots which referenced several different brands of infant formula (ASA Ruling on Boots - 23/08/2023).