SCOTTISH STATUTORY INSTRUMENTS

2021 No. 123

FOOD

The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Amendment Regulations 2021

Made - - - -	*at 12.45 p.m. on 8th March 2021*
Laid before the Scottish Parliament - - - -	*at 4.30 p.m. on 8th March 2021*
Coming into force - -	*26th March 2021*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e), 26(1) and (3) and 48(1) of the Food Safety Act 1990(**1**) and all other powers enabling them to do so.

In accordance with section 48(4A) of the Food Safety Act 1990(**2**), the Scottish Ministers have had regard to relevant advice given by Food Standards Scotland.

The urgency of this matter does not allow for open and transparent public consultation through representative bodies as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**3**), during the preparation and evaluation of these Regulations.

Citation and commencement

1. These Regulations may be cited as the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Amendment Regulations 2021 and come into force on 26 March 2021.

(**1**) 1990 c.16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c.40), schedule 9, paragraph 6, the Food Standards Act 1999 (c.28) ("the 1999 Act"), schedule 5, paragraph 10(1) and (3) and S.I. 2002/794. Sections 16(1) and 48(1) were amended by the 1999 Act, schedule 5, paragraph 8 and section 16(1) was also amended by the Food (Scotland) Act 2015 (asp 1), section 34(1). Section 26(3) was partially repealed by the 1999 Act, schedule 6, paragraph 1. Amendments made by schedule 5 of the 1999 Act are to be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) ("the 1998 Act") by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, and in so far as relating to food (including drink) including the primary production of food, those functions were transferred to the Scottish Ministers by S.I. 2005/849.

(**2**) Section 48(4A) was inserted by the 1999 Act, schedule 5, paragraph 21.

(**3**) EUR 2002/178, to which there are amendments, but none are relevant.

Amendment of the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020

2.—(1) The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020(**4**) are amended as follows.

(2) After regulation 6(3) (revocations, savings and transitional provisions) insert—

"(4) Regulations 2 to 5 do not apply in respect of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.

(5) Schedule 4 makes provision in relation to infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.".

(3) After schedule 3 (revocations) insert the schedule in the schedule to these Regulations.

St Andrew's House,
Edinburgh
At 12.45 p.m. on 8th March 2021

BEN MACPHERSON
Authorised to sign by the Scottish Ministers

(**4**) S.S.I. 2020/6.

SCHEDULE Regulation 2(3)

"SCHEDULE 4 Regulation 6(5)

Regulation of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022

Interpretation

1.—(1) In this schedule—

"the Act" means the Food Safety Act 1990,

"the Directive" means Commission Directive 2006/141/EC(**5**) on infant formulae and follow-on formulae and amending Directive 1999/21/EC,

"follow-on formula" means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants,

"health care system" means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child care institutions and health workers in private practice,

"infants" means children under the age of 12 months,

"infant formula" means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding,

"young children" means children aged between one and three years.

(2) Subject to sub-paragraph (3), any expression other than one defined in sub-paragraph (1) that is used both in this schedule and in the Act has the meaning it bears in the Act.

(3) Any expression used both in this schedule and in the Directive has the meaning that it bears in the Directive.

(4) In this schedule any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met

2.—(1) It is an offence for a person to market infant formula which contravenes or fails to comply with paragraphs 4, 5, 7, 9, 10, 11, 13(1), (2) or (3), 14, 16, 18 or 19(1).

(2) It is an offence for a person to market follow-on formula which contravenes or fails to comply with paragraphs 4, 6, 8, 9, 10, 11, 13(1), (2) or (3), 15, 17, 18 or 19(2).

Prohibition on the marketing of products other than infant formula for normal healthy infants

3. It is an offence to market or otherwise represent a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula.

(**5**) OJ L 401, 30.12.2006, p.1. As amended by Article 1(1) of Commission Delegated Regulations (Ref no. C/2021/155) amending Commission Delegated Regulation (EU) No 2016/127 as regards the date of application of certain of its provisions 20.1.2021. These Regulations were adopted on 20.1.2021 but are undergoing scrutiny per European Parliament proceedings and have not yet been published on the Official Journal of the European Union. The text can be found here https://webgate.ec.europa.eu/regdel/#/delegatedActs/1599

Substances in such quantity as to endanger the health of infants and young children

4. Infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children.

Protein hydrolysates and other food ingredients suitable for infants from birth (infant formula)

5.—(1) Infant formula must be manufactured from —

(a) protein hydrolysates, and

(b) other food ingredients the suitability of which for particular nutritional use by infants from birth has been established by generally accepted scientific data and demonstrated in accordance with sub-paragraph (2).

(2) Suitability is to be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Protein hydrolysates and other food ingredients suitable for infants aged over six months (follow-on formula)

6. Follow-on formula must be manufactured from—

(a) protein hydrolysates, and

(b) other food ingredients the suitability of which for particular nutritional use by infants aged over 6 months has been established by generally accepted scientific data and demonstrated in accordance with paragraph 5(2).

Compositional criteria for infant formula

7.—(1) Subject to sub-paragraph (2), infant formula must comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

(2) In the case of infant formula manufactured from protein hydrolysates specified in point 2.2 of Annex I with a protein content between the minimum and 0.56g/100kJ (2.25g/100 kcal)—

(a) the suitability of the infant formula for the particular nutritional use by infants must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies, and

(b) the infant formula must be in accordance with the appropriate specifications set out in Annex VI.

Compositional criteria for follow-on formula

8.—(1) Subject to sub-paragraph (2), follow-on formula must comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.

(2) In the case of follow-on formula manufactured from those protein hydrolysates specified in point 2.2 of Annex II with a protein content between the minimum and 0.56g/100kj (2.25g/100kcal) —

(a) the suitability of the follow-on formula for satisfying the nutritional requirements of normal healthy infants in conjunction with complementary feeding must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies, and

(b) the follow-on formula must be in accordance with the appropriate specifications set out in Annex VI.

Addition of water (infant formula and follow-on formula)

9. In order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water.

Prohibitions and limitations on the use of food ingredients (infant formula and follow-on formula)

10. The prohibitions and limitations on the use of food ingredients in infant formula and follow-on formula, set out respectively in Annexes I and II, must be observed.

Listed substances and their purity criteria (infant formula and follow-on formula)

11.—(1) Only the substances listed in Annex III may be used in the manufacture of infant formula and follow-on formula in order to satisfy the requirements of Annexes I and II respectively on–

(a) mineral substances,

(b) vitamins,

(c) amino acids and other nitrogen compounds, and

(d) other substances having a particular nutritional purpose.

(2) Substances used in the manufacture of infant formula and follow-on formula pursuant to sub-paragraph (1) must meet the relevant purity criteria.

(3) The relevant purity criteria for the purposes of sub-paragraph (2) are—

(a) the purity criteria for substances, as provided for in Retained EU law concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive, and

(b) in the absence of such purity criteria, generally acceptable purity criteria recommended by international bodies.

Notification of infant formula

12. No food business operator may place an infant formula on the market in Scotland that has not yet been placed on the market in the United Kingdom unless the food business operator has notified Food Standards Scotland by forwarding to it a model of the label used for the product.

Pesticide residues (infant formula and follow-on formula)

13.—(1) Subject to sub-paragraphs (2) and (3), infant formula and follow-on formula must not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula must not contain any pesticide residue of a pesticide listed in Table 1 or Table 2 of Annex VIII at a level exceeding 0.003 mg/kg.

(3) Infant formula and follow-on formula must not contain any pesticide residue of a pesticide listed in Annex IX at a level exceeding the maximum residue level specified in that Annex.

(4) The levels referred to in sub-paragraphs (1) to (3) apply to the infant formula or follow-on formula—

(a) manufactured in a form that is ready for consumption, or

(b) if it is not so manufactured, as reconstituted according to the manufacturers' instructions.

(5) Analytical methods for determining levels of pesticide residues for the purposes of this paragraph is to be generally acceptable standardised methods.

Naming of infant formula

14. Infant formula must not be sold unless it is sold under the name "infant formula*"*.

Naming of follow-on formula

15. Follow-on formula must not be sold unless it is sold under the name "follow-on formula".

Labelling of infant formula

16.—(1) Infant formula must not be sold unless the labelling bears—

(a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed,

(b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use,

(c) the average quantity of each mineral substance and of each vitamin mentioned in Annex I and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use,

(d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage, and

(e) the words "Important Notice" or their equivalent immediately followed by—

(i) a statement concerning the superiority of breast feeding, and

(ii) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(2) The labelling of infant formula must—

(a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding, and

(b) not contain the terms "humanised", "maternalised", "adapted" or any similar term.

(3) The labelling of an infant formula must not include—

(a) any picture of an infant, or

(b) any other picture or text which may idealise the use of the product,

but may include graphic representations for easy identification of the product or for illustrating methods of preparation.

(4) The labelling of an infant formula may bear nutrition and health claims only when—

(a) the claim is listed in the first column of Annex IV and is expressed in the terms set out there, and

(b) the condition specified in the second column of Annex IV in relation to the relevant claim made in the first column is satisfied.

(5) The labelling of an infant formula may bear the average quantity of nutrients mentioned in Annex III when such information is not covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use.

Labelling of follow-on formula

17.—(1) Follow-on formula must not be sold unless the labelling bears—

(a) a statement to the effect that—

(i) the product is suitable only for particular nutritional use by infants over the age of 6 months,

(ii) it should form only part of a diversified diet,

(iii) it is not to be used as a substitute for breast milk during the first 6 months of life, and

(iv) the decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before 6 months of age should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal or child care, based on the individual infant's specific growth and development needs,

(b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use,

(c) the average quantity of each mineral substance and of each vitamin mentioned in Annex II and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use,

(d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

(2) The labelling of follow-on formula must—

(a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding, and

(b) not contain the terms "humanised", "maternalised", "adapted" or any similar term.

(3) The labelling of a follow-on formula may bear—

(a) the average quantity of nutrients mentioned in Annex III when such information is not covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use, and

(b) in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given in that Annex, per 100ml of the product ready for use.

Avoidance of the risk of confusion between infant formula and follow-on formula

18. Infant formula and follow-on formula must be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-on formula.

Presentation (infant formula and follow-on formula)

19.—(1) The presentation of infant formula must comply with the provisions of paragraphs 16(1)(e), (2), (3) and (4) and 18.

(2) The presentation of follow-on formula must comply with the provisions of paragraphs 17(2) and 18.

(3) For the purposes of this paragraph presentation includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Restrictions on advertising infant formula

20.—(1) It is an offence to advertise infant formula—

(a) except—

(i) in a scientific publication, or

(ii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public, and

(b) unless the advertisement complies with the provisions of paragraphs 16(1)(e), (2), (3) and (4), paragraph 18 and sub-paragraphs (2) and (3).

(2) Advertisements for infant formula must only contain information of a scientific and factual nature.

(3) Information in advertisements for infant formula must not imply or create a belief that bottle feeding is equivalent or superior to breast feeding.

Restrictions on advertising follow-on formula

21. It is an offence to advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions set out in paragraphs 17(2) and 18, in so far as they are relevant to follow-on formula.

Restrictions on promotion of infant formula

22.—(1) It is an offence at any place where any infant formula is sold by retail to—

(a) advertise any infant formula,

(b) make any special display of an infant formula designed to promote sales,

(c) give away—

(i) any infant formula as a free sample, or

(ii) any coupon which may be used to purchase an infant formula at a discount,

(d) promote the sale of an infant formula by means of premiums, special sales, loss-leaders or tie-in sales, or

(e) undertake any other promotional activity to induce the sale of an infant formula.

(2) It is an offence for a manufacturer or distributor of any infant formula to provide for promotional purposes any infant formula free or at a reduced or discounted price, samples or any gift designed to promote the sale of an infant formula, to—

(a) the general public,

(b) pregnant women,

(c) mothers, or

(d) members of the families of persons mentioned in subparagraphs (b) and (c),

either directly, or indirectly through the health care system or health workers.

Provision of informational and educational material dealing with the feeding of infants

23.—(1) It is an offence to produce or publish any informational or educational material, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, unless that material includes clear information on all the following points–

(a) the benefits and superiority of breast feeding,

(b) maternal nutrition,

(c) the preparation for and the maintenance of breast feeding,

(d) the possible negative effect on breast feeding of introducing partial bottle feeding,

(e) the difficulty of reversing the decision not to breast feed, and

(f) where needed, the proper use of an infant formula.

(2) When the material referred to in sub-paragraph (1) contains information about the use of an infant formula it must include information about–

(a) the social and financial implications of its use,

(b) the health hazards of inappropriate foods or feeding methods, and

(c) the health hazards of improper use of infant formula.

(3) When the material referred to in sub-paragraph (1) contains information about the use of an infant formula it must not use any pictures which may idealise the use of infant formula.

(4) It is an offence for a manufacturer or distributor of an infant formula to make a donation of any informational or educational equipment or materials except in accordance with the following conditions—

(a) the donation must be made following a request by the intended recipient,

(b) the donation must be made with the written authority of the Scottish Ministers or in accordance with guidelines drawn up by the Scottish Ministers,

(c) the equipment and materials must not be marked or labelled with the name of a proprietary brand of infant formula, and

(d) the equipment or materials must be distributed only through the health care system.

Free or reduced rate infant formula

24. An institution or organisation which receives any infant formula free or at a reduced rate must—

(a) if that infant formula is for use in the institution or organisation, only use it for infants who have to be fed on infant formula and only for as long as required by those infants, or

(b) if that infant formula is for distribution outside the institution or organisation, only distribute it for infants who have to be fed on infant formula and only for as long as required by those infants.

Offences and enforcement

25.—(1) Any person who contravenes or fails to comply with any of the provisions contained in paragraphs 2, 3, 12, 20(1), 21, 22, 23 and 24, is guilty of an offence and is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Each food authority must enforce and execute this schedule in its area.

Application of various sections of the Food Safety Act 1990

26. The following provisions of the Act apply for the purposes of this schedule with the modification that any reference in those provisions to the Act or Part thereof are to be construed as a reference to this schedule—

(a) section 3 (presumptions that food intended for human consumption),

(b) section 20 (offences due to fault of another person),

(c) section 21 (defence of due diligence), as it applies for the purpose of section 14 or 15,

(d) section 30(8) (which relates to documentary evidence),

(e) section 33 (obstruction etc. of officers),

(f) section 35(1) to (3) (punishment of offences), in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (e),

(g) section 36 (offences by bodies corporate),

(h) section 36A (offences by Scottish partnerships),

(i) section 44 (protection of officers acting in good faith)."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 (S.S.I. 2020/6) ("the 2020 Regulations") to apply the law that existed before 21 February 2021 in relation to infant formula and follow-on formula manufactured from protein hydrolysates from 26 March 2021 until 22 February 2022.

Regulation 2 amends regulation 6 of the 2020 Regulations to disapply regulations 2 to 5 of the 2020 Regulations from infant formula and follow-on formula manufactured from protein hydrolysates. Regulation 2 also inserts a new schedule 4 into the 2020 Regulations. New schedule 4 contains the regulatory regime that applied to infant formula and follow-on formula manufactured from protein hydrolysates prior to 21 February 2021.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.