SCOTTISH STATUTORY INSTRUMENTS

2019 No. 54

EXITING THE EUROPEAN UNION
FOOD

The Nutrition (EU Exit) (Scotland) (Amendment) Regulations 2019

Made - - - - 18th February 2019
Laid before the Scottish Parliament - - - - 19th February 2019

Coming into force in accordance with regulation 1

The Scottish Ministers make the following Regulations in exercise of the powers conferred on them by paragraph 1(1) and (3) of schedule 2 of the European Union (Withdrawal) Act 2018(**1**) and all other powers enabling them to do so.

There has been consultation 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.

Citation and commencement

1. These Regulations may be cited as the Nutrition (EU Exit) (Scotland) (Amendment) Regulations 2019 and come into force on exit day.

Amendment of the Foods for Special Medical Purposes (Scotland) Regulations 2000

2.—(1) The Foods for Special Medical Purposes (Scotland) Regulations 2000(**2**) are amended as follows.

(2) In regulation 2 (interpretation)—

(a) the existing text is renumbered as paragraph (1),

(b) after that paragraph, insert—

(**1**) 2018 c.16.
(**2**) S.S.I. 2000/130, as amended by S.S.I. 2005/616, 2007/549, 2008/322, 2015/100 and 2018/392.

"(2) For the purposes of these Regulations, the Annex to the Directive is to be read as if, in paragraph 4, for "Directive 91/321/EEC and its subsequent modifications" there were substituted "Directive 2006/141/EC(**3**)".".

(3) For regulation 3 (restrictions on sale), substitute—

"**Restrictions on sale**

3.—(1) No person shall sell a dietary food in Scotland unless—

(a) its formulation, composition and instructions for use comply with the provisions of schedule 1;

(b) it is sold under the name "Food(s) for special medical purposes"; and

(c) it is labelled in accordance with schedule 2.

(2) When a dietary food is placed on the market—

(a) the manufacturer, or

(b) where the dietary food is manufactured outside of the United Kingdom, the importer,

shall notify the competent authority of the territories within the United Kingdom where the dietary food is being marketed by forwarding to it a model of the label used for that dietary food.

(3) The manufacturer or, as the case may be, the importer shall not sell a dietary food in Scotland unless they have provided the notification in accordance with paragraph (2).

(4) The competent authorities for the purposes of this regulation are, in respect of a dietary food manufactured in, or imported from outside the United Kingdom into—

(a) Scotland, Food Standards Scotland(**4**),

(b) England, the Secretary of State,

(c) Wales, the Welsh Ministers,

(d) Northern Ireland, the Food Standards Agency(**5**)."

(4) Into the Regulations, insert—

"SCHEDULE 1 Regulation 3(1)(a)

Formulation, composition and instructions for use of dietary foods

1. The formulation of dietary foods shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.

2. The dietary foods must comply with the compositional criteria specified in the Annex to the Directive.

(**3**) OJNo. L 401, 30.12.2006, p.1, last amended by Commission Delegated Regulation (EU) 2016/127 (OJ No. L 25, 2.2.2016, p.1).
(**4**) Food Standards Scotland was established by section 1 of the Food (Scotland) Act 2015 (asp 1).
(**5**) The Food Standards Agency was established by section 1 of the Food Standards Act 1999 (c.28).

SCHEDULE 2

Regulation 3(1)(c)

Labelling of dietary foods

1. The labelling of dietary foods shall bear, in addition to the particulars provided for in Article 9 of Regulation (EU) No 1169/2011, the following particulars:

(a) the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(b) he average quantity of each mineral substance and each vitamin mentioned in the Annex present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(c) selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components the declaration of which would be necessary for the appropriate intended use of the product, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;

(d) information on the osmolality or the osmolarity of the product where appropriate;

(e) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

2. The labelling shall in addition bear the following particulars, preceded by the words 'important notice':

(a) a statement that the product must be used under medical supervision;

(b) a statement whether the product is suitable for use as the sole source of nourishment;

(c) a statement that the product is intended for a specific age group, as appropriate;

(d) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

3. The labelling shall also include:

(a) the statement 'For the dietary management of…' where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;

(b) where appropriate a statement concerning adequate precautions and contra-indications;

(c) a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;

(d) where appropriate a warning that the product is not for parenteral use.

4. The labelling shall bear instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate.

5. In this schedule—

"the Annex" means the Annex to the Directive, and

"Regulation (EU) No 1169/2011" means 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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.".

Amendment of the Kava-kava in Food (Scotland) Regulations 2002

3.—(1) The Kava-kava in Food (Scotland) Regulations 2002(**6**) are amended as follows.

(2) In regulation 2 (interpretation)—

(a) omit the definitions of "EEA State" and "free circulation",

(b) in the definition of "Kava-kava", for ".", substitute ";", and

(c) after the definition of "Kava-kava", insert–

""third country" means a country other than the United Kingdom.".

(3) In regulation 3 (prohibition on sale etc. of food consisting of or containing Kava-kava) for paragraph (2), substitute–

"(2) The prohibition imposed by paragraph (1) shall not apply where the food consisting of or containing Kava-kava is imported from a third country if the food is being, or is to be, exported to the same or a different third country.".

Amendment of the Food Supplements (Scotland) Regulations 2003

4.—(1) The Food Supplements (Scotland) Regulations 2003(**7**) are amended as follows.

(2) In regulation 2 (interpretation)—

(a) in paragraph (1)—

(i) omit the definition of "Directive 2001/83",

(ii) after the definition of "food supplement", add—

""nutrients" means the following substances:

(i) vitamins, and

(ii) minerals;" and

(iii) after the definition of "sell", add—

""the 2019 Regulations" means the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(**8**);", and

(b) omit paragraphs (3) and (4).

(3) In regulation 3 (scope of regulations), in paragraph (2) for "Directive 2001/83", substitute "regulation 2(1) of the Human Medicines Regulations 2012(**9**)".

(4) In regulation 5 (prohibitions on sale relating to composition of food supplements)–

(a) in paragraph (1)—

(**6**) S.S.I. 2002/523 as amended by S.S.I. 2004/244 and 2013/177 and S.I. 2012/1809.
(**7**) S.S.I. 2003/278 as amended by S.S.I. 2005/616, 2009/438, 2014/312 and S.I. 2011/1043.
(**8**) S.I. 2019/XXX.
(**9**) S.I. 2012/1916.

(i) in sub-paragraph (a) for "Annex I to Directive 2002/46", substitute "schedule 1 of the 2019 Regulations", and

(ii) in sub-paragraph (b)(i) for "Annex II to Directive 2002/46", substitute "schedule 2 of the 2019 Regulations", and

(b) in paragraph (2) for sub-paragraph (a), substitute—

"(a) the purity criteria, if any, specified in retained EU law or in regulations made by the Scottish Ministers or the Secretary of State under regulation 3 of the 2019 Regulations; or".

(5) In regulation 6 (restrictions on sale relating to labelling etc of food supplements), in paragraph (3)(b) for "Annex I to Directive 2002/46", substitute "schedule 1 of the 2019 Regulations".

Amendment of the Nutrition and Health Claims (Scotland) Regulations 2007

5.—(1) The Nutrition and Health Claims (Scotland) Regulations 2007(**10**) are amended as follows.

(2) In regulation 3 (Competent Authorities) in paragraph (a) for "15(2), 16(2) and 18(2)", substitute "15(1B) and (2), 16(2) and 18(1B) and (2)".

Amendment of the Infant Formula and Follow-on Formula (Scotland) Regulations 2007

6.—(1) The Infant Formula and Follow-on Formula (Scotland) Regulations 2007(**11**) are amended as follows.

(2) In regulation 12 (listed substances and their purity criteria (infant formula and follow-on formula)), in paragraph (3)(a) for "EU legislation", substitute "retained EU law".

Amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009

7.—(1) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009(**12**) are amended as follows.

(2) In the schedule (specified provisions), in the "subject-matter" column of the table—

(a) in the entry relating to Article 2(1), for "covered by Directive 2009/39 of the European Parliament and Council on foodstuffs intended for particular nutritional uses", substitute "(foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability)", and

(b) in the entries relating to Article 4(2) and Article 4(3), for "EU legislation", substitute "retained EU law".

St Andrew's House,
Edinburgh
18th February 2019

JOE FITZPATRICK
Authorised to sign by the Scottish Ministers

(**10**) S.S.I. 2007/383 as amended by S.S.I. 2010/307, 2014/312, 2015/100.
(**11**) S.S.I. 2007/549 as amended by S.S.I. 2008/322, 2014/12, 2015/100, 2016/190 and S.I. 2011/1043.
(**12**) S.S.I. 2009/427 as amended by S.I. 2011/1043 and S.S.I. 2015/100.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by paragraph 1(1) and (3) of schedule 2 of the European Union (Withdrawal) Act 2018 (c. 16) to address failures of retained EU law to operate effectively, and other deficiencies, arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to subordinate legislation in the field of food nutrition in relation to Scotland.

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