



## FOOD SUPPLEMENTS REGULATIONS 2019

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Statutory Document No. 2019/0409

*European Communities (Isle of Man) Act 1973*

## FOOD SUPPLEMENTS REGULATIONS 2019<sup>1</sup>

*Approved by Tynwald: 10 December 2019*  
*Coming into operation in accordance with regulation 2*

The Council of Ministers makes the following Regulations under section 2B and 2C of the European Communities (Isle of Man) Act 1973.

**Editorial Note:** This instrument, made under the European Communities (Isle of Man) Act 1973, is continued by virtue of section 6 of the European Union and Trade Act 2019.

### 1 Title

These Regulations are the Food Supplements Regulations 2019.

### 2 Commencement

These Regulations come into operation on the day after they are made<sup>1</sup>.

### 3 Interpretation

[SI2003/1387/2 and drafting]

(1) In these Regulations —

“**the Act**” means the Food Act 1996;

“**catering establishment**” means a restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer and is ready for consumption without further preparation;

“**Department**” means the Department of Environment, Food and Agriculture;

“**Directive 2001/83**” [Revoked]<sup>2</sup>

“**Directive 2002/46**” [Revoked]<sup>3</sup>

<sup>1</sup> Section 2B(9) of the European Communities (Isle of Man) Act 1973 specifies that regulations shall be laid before Tynwald as soon as possible after they are made and if Tynwald at the sitting before which the regulations are laid or at the next following sitting resolves that the regulations shall be annulled, the regulations shall upon such resolution cease to have effect.

“**dose form**” means a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities;

“**food supplement**” means any food the purpose of which is to supplement the normal diet and which —

- (a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and
- (b) is sold in dose form;

“**preparation**” includes manufacture and any form of processing or treatment, and “prepared” must be construed accordingly;

“**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<sup>2</sup>;

“**sell**” includes possess for sale and offer, expose or advertise for sale; and

“**ultimate consumer**” means any person who purchases otherwise than —

- (a) for the purpose of resale;
  - (b) for the purposes of a catering establishment; or
  - (c) for the purposes of a manufacturing business.
- (2) A food supplement is regarded as prepacked for the purposes of these Regulations if —
- (a) it is ready for sale to the ultimate consumer or to a catering establishment; and
  - (b) it is put into packaging before being offered for sale in such a way that the food supplement cannot be altered without opening or changing the packaging.
- (3) [Revoked]<sup>4</sup>
- (4) [Revoked]<sup>5</sup>

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<sup>2</sup> OJ L 304, 22.11.2011, p. 18.

#### **4 Scope of Regulations**

[SI2003/1387/3]

- (1) These Regulations apply to food supplements sold as food and presented as such.
- (2) These Regulations do not apply to medicinal products as defined by section 1(2) of the Medicines Act 2003.<sup>6</sup>

#### **5 Restriction on form in which food supplements are sold to the ultimate consumer**

[SI2003/1387/4 and drafting]

A person must not sell any food supplement to the ultimate consumer unless it is prepacked.

#### **6 Prohibitions on sale relating to composition of food supplements**

[SI2003/1387/5 and drafting]

- (1) A person must not sell a food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral –
  - (a) is listed in Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019<sup>116</sup> (of Parliament) as amended from time to time; and<sup>7</sup>
  - (b) is in a form which –
    - (i) is listed in Schedule 2 to the Nutrition (Amendment) (EU Exit) Regulations 2019 (of Parliament) as amended from time to time; and<sup>8</sup>
    - (ii) meets the relevant purity criteria.
- (2) The relevant purity criteria for the purposes of paragraph (1)(b)(ii) are –
  - (a) the purity criteria, if any, specified in retained EU law or in regulations made by the Secretary of State under regulation 3 of the Nutrition (Amendment) (EU Exit) Regulations 2019 (of Parliament); or<sup>9</sup>
  - (b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

#### **7 Restrictions on sale relating to labelling etc of food supplements**

[SI2003/1387/6 and drafting]

- (1) A person must not sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is “food supplement”.
- (2) Without prejudice to Regulation (EU) No 1169/2011, a person must not sell a food supplement which is ready for delivery to the ultimate consumer

or to a catering establishment unless it is marked or labelled with the following particulars —

- (a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;
  - (b) the portion of the product recommended for daily consumption;
  - (c) a warning not to exceed the stated recommended daily dose;
  - (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
  - (e) a statement to the effect that the product should be stored out of the reach of young children; and
  - (f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.
- (3) The information required by paragraph (2)(f) must —
- (a) be given in numerical form;
  - (b) in the case of a vitamin or mineral listed in Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019 (of Parliament) be given using the relevant unit specified in brackets after the name of that vitamin or mineral;<sup>10</sup>
  - (c) be the amount per portion of the product as recommended for daily consumption on the labelling of the product;
  - (d) be an average amount based on the manufacturer's analysis of the product; and
  - (e) in the case of a vitamin or mineral listed in point 1 of Part A of Annex XIII to Regulation (EU) No 1169/2011, be expressed also as a percentage (which may also be given in graphical form) of the relevant reference value specified in that point.
- (4) A person must not sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the labelling, presentation or advertising of that food supplement includes any mention, express or implied, that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

## 8 Manner of marking or labelling

[SI2003/1387/7 and drafting]

- (1) A person must not sell any food supplement which —
- (a) is ready for delivery to the ultimate consumer; or
  - (b) is ready for delivery to a catering establishment and is prepacked,
- unless the particulars with which it is required to be marked or labelled by virtue of regulation 7(2) appear —

- (i) on the packaging;
- (ii) on a label attached to the packaging; or
- (iii) on a label which is clearly visible through the packaging,

save that where the sale is otherwise than to the ultimate consumer such particulars may, alternatively, appear only on the commercial documents relating to the food supplement where it can be guaranteed that such documents, containing all such particulars, either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement, and provided always that the particulars required by points (a), (f), (g) and (h) of Article 9(1) Regulation (EU) No 1169/2011 are also marked or labelled on the outermost packaging in which that food supplement is sold.

- (2) A person must not sell any food supplement which is ready for delivery to a catering establishment and is not prepacked, unless the particulars with which it is required to be marked or labelled by virtue of regulation 7(2) appear –
  - (a) on a label attached to the food supplement;
  - (b) on a ticket or notice which is readily discernible by the intending purchaser at the place where he chooses the food supplement; or
  - (c) in commercial documents relating to the food supplement where it can be guaranteed that such documents either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement.
- (3) A person must not sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the particulars with which it is required to be marked or labelled by virtue of regulation 7(2) are easy to understand, clearly legible and indelible and, when a food is sold to the ultimate consumer, those particulars are marked in a conspicuous place in such a way as to be easily visible.
- (4) A person must not sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the particulars with which it is required to be marked or labelled by virtue of regulation 7(2) are in any way hidden, obscured or interrupted by any other written or pictorial matter.

## 9 Enforcement

The Department must enforce and execute these Regulations.

## 10 Offences and penalties

If any person contravenes regulation 5, 6, 7 or 8 that person is guilty of an offence. Maximum penalty – (summary) – a fine of level 5 on the standard scale, 3 months' custody, or both.

## 11 Application of various provisions of the Act

[SI2003/1387/11 and drafting]

The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or a Part of the Act is to be construed as a reference to these Regulations —

- (a) section 2 (extended meaning of “sale” etc);
- (b) section 3 (presumptions that food intended for human consumption);
- (c) section 31 (offences due to fault of another person);
- (d) section 32 (defence of due diligence) as it applies for the purposes of section 6, 15 or 16;
- (e) section 33 (defence of publication in the course of business);
- (f) section 24(7) (which relates to documentary evidence);
- (g) section 27(1) (obstruction etc of officers);
- (h) section 27(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b)” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by subparagraph (g);
- (i) section 29(1) (punishment of offences) in so far as it relates to offences under section 27(1) as applied by subparagraph (g);
- (j) section 29(2) in so far as it relates to offences under section 27(2) as applied by paragraph (h) above, with the modifications that for “the relevant amount” substitute “level 5 on the standard scale” and for “6 months” substitute “3 months”; and
- (k) section 30 (offences by bodies corporate).

## 12 Transitional provision

- (1) In any proceedings for an offence under regulation 10 relating to a breach of regulation 7 or 8 consisting of a contravention of, or a failure to comply with, regulation 7(3)(b), it shall be a defence to prove that —
  - (a) zinc was used in the manufacture of the food supplement and the food supplement was marked or labelled before the day after the European Union and Trade Act 2019 (Amendments) (DEFA) (Food and Feed) Regulations 2023 come into operation; and
  - (b) the matters constituting the alleged offence would not have constituted an offence under these Regulations as they had effect immediately before the day after the European Union and Trade Act 2019 (Amendments) (DEFA) (Food and Feed) Regulations 2023 come into operation.



- (2) In any proceedings for an offence under regulation 10 relating to a breach of regulation 7 or 8 consisting of a contravention of, or a failure to comply with, regulation 7(3)(b), it shall be a defence to prove that —
- (a) copper was used in the manufacture of the food supplement and the food supplement was marked or labelled before 10 August 2024; and
  - (b) the matters constituting the alleged offence would not have constituted an offence under these Regulations as they had effect immediately before 10 August 2024.<sup>11</sup>

**MADE 22 NOVEMBER 2019**

## ENDNOTES

### Table of Endnote References

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<sup>1</sup> The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.

<sup>2</sup> Definition of “Directive 2001/83” revoked by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>3</sup> Definition of “Directive 2002/46” revoked by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>4</sup> Para (3) revoked by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>5</sup> Para (4) revoked by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>6</sup> Para (2) amended by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>7</sup> Subpara (a) amended by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>8</sup> Para (i) amended by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>9</sup> Subpara (a) substituted by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>10</sup> Subpara (b) amended by SD2019/0446 with effect from 31/12/2020 at 23:00.

<sup>11</sup> Reg 12 inserted by SD2023/0284.