Regulation (EC) No 852/2004 of the european parliament and of the council of 29 April 2004 on the hygiene of foodstuffs

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

- 1 This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:
 - a primary responsibility for food safety rests with the food business operator;
 - b it is necessary to ensure food safety throughout the food chain, starting with primary production;
 - c it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;
 - d general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;
 - e guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;
 - f it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;
 - g it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in [FIGreat Britain], or are of an equivalent standard.

This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.

- 2 This Regulation shall not apply to:
 - a primary production for private domestic use;
 - b the domestic preparation, handling or storage of food for private domestic consumption;
 - the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
 - d collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

F23																

Textual Amendments

F1 Words in Art. 1(1)(g) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 3(a) (as substituted by S.I. 2020/1504, regs. 1(2), 11(2)); 2020 c. 1, Sch. 5 para. 1(1)

F2 Art. 1(3) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **3(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Definitions

- 1 For the purposes of this Regulation:
 - a 'food hygiene', hereinafter called 'hygiene', means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;
 - b 'primary products' means products of primary production including products of the soil, of stock farming, of hunting and fishing;
 - c 'establishment' means any unit of a food business;
 - d 'competent authority' means the central authority ^{F3}... competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;
 - e 'equivalent' means, in respect of different systems, capable of meeting the same objectives;
 - f 'contamination' means the presence or introduction of a hazard;
 - [F4g "potable water" means
 - i as regards England, water meeting the requirements laid down in the Private Water Supplies (England) Regulations 2016;
 - ii as regards Wales, water meeting the requirements laid down in the Private Water Supplies (Wales) Regulations 2017;
 - iii as regards Scotland, water meeting the requirements laid down in the Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017;]
 - h 'clean seawater' means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;
 - i 'clean water' means clean seawater and fresh water of a similar quality;
 - j 'wrapping' means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;
 - k 'packaging' means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
 - 1 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of hazards;
 - m 'processing' means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;
 - n 'unprocessed products' means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
 - o 'processed products' means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council. (See end of Document for details)

- [F5p "Food Safety Authority" means
 - i as regards England and Wales, the Food Standards Agency;
 - ii as regards Scotland, Food Standards Scotland;
 - q "prescribed" means prescribed by regulations;
 - r "appropriate authority" means
 - i in relation to England, the Secretary of State;
 - ii in relation to Wales, the Welsh Ministers;
 - iii in relation to Scotland, the Scottish Ministers.]
- The definitions laid down in Regulation (EC) No 178/2002 shall also apply.
- In the Annexes to this Regulation the terms 'where necessary', 'where appropriate', 'adequate' and 'sufficient' shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.

Textual Amendments

- **F3** Words in Art. 2(1)(d) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **4(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4 Art. 2(1)(g) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 4(b) (as amended by S.I. 2020/1504, regs. 1(2), 11(3)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F5 Art. 2(1)(p)-(r) inserted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 4(c) (as amended by S.I. 2020/1504, regs. 1(2), 11(3)(b)); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligation

Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

Article 4

General and specific hygiene requirements

- Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.
- 2 Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.

- Food business operators shall, as appropriate, adopt the following specific hygiene measures:
 - a compliance with microbiological criteria for foodstuffs;
 - b procedures necessary to meet targets set to achieve the objectives of this Regulation;
 - c compliance with temperature control requirements for foodstuffs;
 - d maintenance of the cold chain;
 - e sampling and analysis.
- [^{F6}4 The criteria, requirements and targets referred to in paragraph 3, and associated sampling and analysis methods shall be prescribed by the appropriate authority.]
- When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other [F7applicable legislation in force in the relevant constituent territory of Great Britain] or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.
- Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.

Textual Amendments

- **F6** Art. 4(4) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **5(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7 Words in Art. 4(5) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 5(b) (as substituted by S.I. 2020/1504, regs. 1(2), 11(4)); 2020 c. 1, Sch. 5 para. 1(1)

Article 5

Hazard analysis and critical control points

- 1 Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
- The HACCP principles referred to in paragraph 1 consist of the following:
 - a identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - b identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
 - establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
 - d establishing and implementing effective monitoring procedures at critical control points;
 - e establishing corrective actions when monitoring indicates that a critical control point is not under control;
 - f establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;

and

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council. (See end of Document for details)

g establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

- Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.
- 4 Food business operators shall:
 - a provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
 - b ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
 - c retain any other documents and records for an appropriate period.

F8 <i>z</i>																
3																

Textual Amendments

F8 Art. 5(5) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 6; 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Official controls, registration and approval

- Food business operators shall cooperate with the competent authorities in accordance with the legislation in force in the relevant constituent territory of Great Britain.
- In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has upto-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

[F103] However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required under Regulation (EC) No. 853/2004.]

Textual Amendments

F9 Art. 6(1) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 7(a) (as amended by S.I. 2020/1504, regs. 1(2), 11(5)); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC)

No 852/2004 of the european parliament and of the council. (See end of Document for details)

F10 Art. 6(3) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **7(b)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

GUIDES TO GOOD PRACTICE

I^{F11}Article 7

Development, dissemination and use of guides

The Food Safety Authority shall encourage the development of guides to good practice for hygiene and for the application of the HACCP principles in accordance with Article 8. The dissemination and use of guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

Textual Amendments

F11 Art. 7 substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 8; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

F12... Guides

- When F13... guides to good practice are developed, they shall be developed and disseminated by food business sectors:
 - in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;
 - having regard to relevant codes of practice of the *Codex Alimentarius*;

and

- when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.
- [F142 Guides may be developed under the aegis of a standards institute].
- [F15The Food Safety Authority shall assess guides in order to ensure that—] 3
 - they have been developed in accordance with paragraph 1;
 - their contents are practicable for the sectors to which they refer;

they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

^{F16} 4																
^{F17} 5																

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council. (See end of Document for details)

Textual Amendments

- F12 Word in Art. 8 heading omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 9(a); 2020 c. 1, Sch. 5 para. 1(1)
- F13 Word in Art. 8(1) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 9(b); 2020 c. 1, Sch. 5 para. 1(1)
- **F14** Art. 8(2) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 9(c); 2020 c. 1, Sch. 5 para. 1(1)
- F15 Words in Art. 8(3) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 9(d); 2020 c. 1, Sch. 5 para. 1(1)
- F16 Art. 8(4) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 9(e); 2020 c. 1, Sch. 5 para. 1(1)
- F17 Art. 8(5) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 9(f); 2020 c. 1, Sch. 5 para. 1(1)

F18 Article 9

Community guides

Textual Amendments

F18 Art. 9 omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **10**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IV

IMPORTS AND EXPORTS

Article 10

Imports

As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

Article 11

Exports

As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

CHAPTER V

FINAL PROVISIONS

F19Article 12

Textual Amendments

F19 Art. 12 omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 11; 2020 c. 1, Sch. 5 para. 1(1)

Article 13

Amendment and adaptation of Annexes I and II

- $[F^{20}]$ Annexes 1 and 2 may be adapted or updated by the appropriate authority taking into account
 - the need to revise the recommendations set out in Annex 1. Part B, paragraph 2;
 - the experience gained from the implementation of HACCP-based systems pursuant to Article 5:
 - technological developments and their practical consequences and consumer expectations with regard to food composition;
 - scientific advice, particularly new risk assessments;
 - microbiological and temperature criteria for foodstuffs.]
- Derogations from Annexes 1 and 2 may be prescribed by the appropriate authority, in particular in order to facilitate the implementation of Article 5 for small businesses, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation.]
- Nothing in this Regulation prevents the appropriate authority from using any power which the appropriate authority has to make subordinate legislation adapting the requirements set down in Annex 2 where that legislation does not compromise the achievement of the objectives of this Regulation and
 - the adaptations have the aim of
 - i enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food; or
 - ii accommodating the needs of food businesses situated in regions that are subject to special geographical constraints;
 - in cases not involving the matters at (a), the adaptations apply only to the construction, layout and equipment of establishments.]

^{F23} 4																	
F235																	
F236																	
F237																	

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council. (See end of Document for details)

Textual Amendments

- **F20** Art. 13(1) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **12(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- **F21** Art. 13(2) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **12(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F22 Art. 13(3) substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 12(c); 2020 c. 1, Sch. 5 para. 1(1)
- **F23** Art. 13(4)-(7) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **12(d)**; 2020 c. 1, Sch. 5 para. 1(1)

I^{F25}Article 14

[F24Regulations and devolved powers]

- 1 Any power to make regulations under this Regulation
 - a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
 - b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument.
- 2 For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
- 3 Any power to make regulations under this Regulation includes power
 - a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
 - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
- 4. Any statutory instrument, Scottish statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution
 - a in the case of England, of either House of Parliament;
 - b in the case of Wales, of Senedd Cymru;
 - c in the case of Scotland, of the Scottish Parliament.

In this Regulation, any power—

- a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
- b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
- c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only.]

Textual Amendments

F24 Art. 14 heading substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **13(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F25 Art. 14 substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **13(b)** (as amended by S.I. 2020/1504, regs. 1(2), **11(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 15

Consultation of the F26... Food Safety Authority

The [F27 appropriate authority] shall consult the F28... Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).

Textual Amendments

- **F26** Word in Art. 15 heading omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **14(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- **F27** Words in Art. 15 substituted (31.12.2020) by The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **14(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- **F28** Word in Art. 15 omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **14(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F29 Article 16

Report to the European Parliament and the Council

Textual Amendments

F29 Art. 16 omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **15**; 2020 c. 1, Sch. 5 para. 1(1)

Article 17

Repeal

- 1 Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.
- 2 References to the repealed Directive shall be construed as being made to this Regulation.
- However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3)(a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council. (See end of Document for details)

F304

Textual Amendments

F30 Art. 17(4) omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, **16**; 2020 c. 1, Sch. 5 para. 1(1)

Article 18

Entry into force

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

- (a) Regulation (EC) No 853/2004;
- (b) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption⁽¹⁾;

and

(c) Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption⁽²⁾.

However, it shall apply no earlier than 1 January 2006.

F31 ...

Textual Amendments

F31 Words in Signature omitted (31.12.2020) by virtue of The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/642), regs. 1, 17; 2020 c. 1, Sch. 5 para. 1(1)

- (1) See page 83 of this Official Journal.
- (2) OJ L 157, 30.4.2004, p. 33.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 852/2004 of the european parliament and of the council.