STATUTORY INSTRUMENTS

2013 No. 2210

FOOD, ENGLAND

The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

Made - - - - 4th September 2013
Laid before Parliament 10th September 2013
Coming into force - - 31st October 2013

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a),(e) and (f),17(1) and (2), 26(1), (2)(e) and (f) and (3), and 48(1) of the Food Safety Act 1990 MI and now vested in him M2, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972 M3.

In accordance with section 48(4A) of the Food Safety Act 1990, he has had regard to relevant advice given by the Food Standards Agency.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for any reference to an Article of or an Annex to any of the EU instruments specified in regulation 2(4) to be construed as a reference to that Article or that Annex as amended from time to time.

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 ^{M4}, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Marginal Citations

- M1 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.
- M2 Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as

- exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scotlish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- M3 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c.51) and amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (2008 c.7).
- M4 OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny Part Four (OJ No. L188, 18.7.2009, p14).

PART 1

Introductory

Modifications etc. (not altering text)

C1 Pt. 1 applied in part (with modifications) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(b), Sch. 2 (with regs. 7, 8)

Title, application and commencement

1. These Regulations may be cited as the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, apply in relation to England only and come into force on 31st October 2013.

Interpretation

- 2.—(1) In these Regulations
 - "the Act" means the Food Safety Act 1990;

F1 ...

- "Regulation 2065/2003" means Regulation (EC) No 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods ^{M5};
- "Regulation 1332/2008" means Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes M6;
- "Regulation 1333/2008" means Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives M7, as read with —
- (a) Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives ^{M8},
- (b) Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

- establishing a Union list of food additives for use in food additives, food enzymes, food flavourings and nutrients ^{M9}, and
- (c) Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council M10:
- "Regulation 1334/2008" means Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods MII, as read with Commission Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) 1334/2008 of the European Parliament and of the Council MII2;
- "authorised officer" means any person who is authorised in writing, either generally or specially, by a food authority to act in matters arising under these Regulations;
- "food authority" has the meaning given by section 5 of the Act except that it does not include the appropriate Treasurer of the Inner Temple and Middle Temple;
- "the [F2retained] EU Regulations" means Regulation 2065/2003, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008.
- (2) Other expressions used in these Regulations and in the ^{F3}... instruments listed in paragraph (4) have the same meaning in these Regulations as they do in those instruments.
- (3) Any reference in these Regulations to an Article of or Annex to any of the ^{F4}... instruments listed in paragraph (4) is a reference to that Article or Annex as amended from time to time.
- (4) The [F5 instruments are] Regulation 2065/2003, Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings M13, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008.
 - (5) Where any functions under the Act are assigned
 - (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984 M14, to a port health authority;
 - (b) by an order under section 6 of the Public Health Act 1936 M15, to a joint board for a united district: or
 - (c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985 M16, to a single authority for a metropolitan county,

any reference in these Regulations to a food authority is to be construed, so far as relating to those functions, as a reference to the authority to which they are so assigned.

Textual Amendments

- F1 Words in reg. 2(1) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(2)(a)(i)
- **F2** Word in reg. 2(1) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **3(2)(a)(ii)**
- Word in reg. 2(2) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(2)(b)
- F4 Word in reg. 2(3) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(2)(c)
- F5 Words in reg. 2(4) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(2)(d)

Marginal Citations

- M5 OJ No. L309, 26.11.2003, p.1. This instrument was amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).
- **M6** OJ No. L354, 31.12.2008, p.7. This instrument was last amended by Commission Regulation (EU) No 1056/2012 (OJ No. L313, 13.11.2012, p.9).
- M7 OJ No. L354, 31.12.2008, p.16. This instrument was last amended by Commission Regulation (EU) No 739/2013 (OJ No. L204, 31.7.2013, p.35).
- **M8** OJ No. L295, 12.11.2011, p.1.
- **M9** OJ No. L295, 12.11.2011, p.178.
- **M10** OJ No. L83, 22.3.2012, p.1. This instrument was last amended by Commission Regulation (EU) No 739/2013 (OJ No. L204, 31.7.2013, p.35).
- **M11** OJ No. L354, 31.12.2008, p.34. This instrument was last amended by Commission Regulation (EU) No 545/2013 (OJ No. L163, 15.6.2013, p.15).
- M12 OJ No. L267, 2.10.2012, p.162.
- M13 OJ No. L354, 31.12.2008, p.1. This instrument is implemented by Commission Regulation (EU) No 234/2011 (OJ No. L64, 11.03.2011, p.15) and that Regulation has been amended by Commission Implementing Regulation (EU) No 562/2012 (OJ No. L168, 28.06.2012, p.21).
- M14 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c.16).
- M15 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.
- M16 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990

PART 2

Food additives, flavourings and enzymes

Offence of contravening EU requirements on food additives

3. Any person who contravenes, or who uses or places on the market a product that fails to comply with, any of the provisions of Regulation 1333/2008 specified in the first column of Table 1 of Schedule 1, as read with transitional measures contained in or to be read with that Regulation, commits an offence.

Offence of contravening EU requirements on flavourings, including smoke flavourings

4. Any person who contravenes, or who uses or places on the market a product which fails to comply with, any of the provisions of Regulation 1334/2008 specified in the first column of Table 1 of Schedule 2, as read with Article 4 (flavouring substances under evaluation) of Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council M17 and with transitional measures contained in or to be read with Regulation 1334/2008, commits an offence.

Marginal Citations

M17 OJ No. L267, 2.10.2012, p.1.

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

5. Any person who contravenes, or who uses or places on the market a product which fails to comply with, any of the provisions of Regulation 2065/2003 specified in the first column of Table 1 of Schedule 3, as read with Article 20 (transitional measures), commits an offence.

Offence of contravening EU requirements on food enzymes

6. Any person who contravenes, or who uses or places on the market a product which fails to comply with, any of the provisions of Regulation 1332/2008 specified in the first column of Table 1 of Schedule 4, as read with Articles 18 and 24 (transitional measures), commits an offence.

Compliance notices

- 7.—(1) If an authorised officer has reasonable grounds for believing that any person has not complied with, is not complying with, or is not likely to comply with
 - (a) any EU provision specified in the first column of Table 2 of Schedule 1, 2, 3 or 4; or
 - (b) regulation 13(2),

the officer may serve a compliance notice on that person.

- (2) A compliance notice must state
 - (a) the steps the person must take;
 - (b) the date and, if appropriate, the time by which each step must be taken;
 - (c) the reason for the service of the notice and for the steps required to be taken;
 - (d) that a failure to comply with the notice is an offence; and
 - (e) the details of the right to appeal against the notice under regulation 8.
- (3) An authorised officer may serve a notice on a person withdrawing, varying or suspending a compliance notice.
 - (4) Any person who fails to comply with a compliance notice served on them commits an offence.

Appeal against a compliance notice

- **8.**—(1) Any person served with a compliance notice may appeal against that notice to a magistrates' court.
- (2) The procedure on appeal to a magistrates' court under paragraph (1) shall be by way of complaint for an order, and the Magistrates' Courts Act 1980 M18 shall apply to the proceedings.
- (3) The period within which an appeal under paragraph (1) may be brought shall be one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint for an order shall be deemed for the purposes of this paragraph to be the bringing of the appeal.
 - (4) A compliance notice is not suspended pending an appeal unless
 - (a) an authorised officer suspends it under regulation 7(3); or
 - (b) the court directs that it be suspended.
 - (5) The court may
 - (a) confirm the notice or any requirement contained in it;
 - (b) vary the notice or any requirement contained in it; or
 - (c) revoke the notice or any requirement contained in it.

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

Marginal Citations

M18 1980 c.43.

PART 3

Extraction solvents

Modifications etc. (not altering text)

C2 Pt. 3 applied in part (with modifications) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(b), Sch. 2 (with regs. 7, 8)

Controls on extraction solvents

^{F6} 9.																

Textual Amendments

- **F6** Reg. 9 omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **3(3)**
- 10. The provisions of this Part do not apply to any extraction solvent
 - (a) used in the production of any food additives, vitamins or any other nutritional additives, unless such food additives, vitamins or other nutritional additives are listed in [F7Schedule 6]; or
 - (b) intended for export outside [F8Great Britain].

Textual Amendments

- F7 Words in reg. 10(a) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(4)
- Words in reg. 10(b) substituted (31.12.2020) by S.I. 2019/860, reg. 3 (as substituted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 (S.I. 2020/1504), regs. 1(2), 18(2))
- 11. In this Part "permitted extraction solvent" means
 - (a) an extraction solvent that
 - (i) is listed in [F9Schedule 6],
 - (ii) is used in accordance with the conditions of use and within any maximum residue limits specified in [F10Schedule 6],
 - (iii) does not contain a toxicologically dangerous amount of any element or substance, [F11 and]

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

(iv)	subject to	any	exceptions	deriving	from	specific	purity	criteria,	does	not	contain
	more than	1 mg	g/kg of arse	nic or mo	re tha	n 1 mg/k	g lead,	F12			

- (b) water to which substances regulating acidity or alkalinity may have been added; or
- (c) food substances which possess solvent properties.

Textual Amendments

- **F9** Words in reg. 11(a)(i) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **3(5)(a)**
- **F10** Words in reg. 11(a)(ii) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **3(5)(b)**
- F11 Word in reg. 11(a)(iii) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(5)(c)
- F12 Word in reg. 11(a)(iv) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(5)(b)
- F13 Reg. 11(a)(v) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(5)(e)
- **12.** No person may use as an extraction solvent in the production of food any extraction solvent that is not a permitted extraction solvent.
 - 13.—(1) No person may place on the market
 - (a) an extraction solvent that is not a permitted extraction solvent; or
 - (b) any food having in it or on it an added extraction solvent that is not a permitted extraction solvent.
- (2) No person may place on the market an extraction solvent that does not meet the requirements of regulation 14.
- **14.**—(1) Subject to paragraph (2), the following information must appear on the packaging, container or label
 - (a) the commercial name as indicated in [F14Schedule 6];
 - (b) a clear indication that the material is of a quality suitable for use for the extraction of food or food ingredients;
 - (c) a reference by which the batch or lot may be identified;
 - (d) the name or business name and address of the manufacturer or packer or of a seller established in the [F15United Kingdom];
 - (e) the net quantity given as units of volume; and
 - (f) if necessary, the special storage conditions or conditions of use.
- (2) The particulars specified in subparagraphs (c), (d), (e) and (f) of paragraph (1) may alternatively appear on the trade documents relating to the batch or lot which are to be supplied with, or prior to, the delivery.
 - (3) The information specified in paragraph (1) must be easily visible, clearly legible and indelible.

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

(4) The information specified in paragraph (1) may be provided in more than one language, but at least one of those languages must be easily understood by the purchaser unless other measures have been taken to ensure that the purchaser is informed of the specified information.

Textual Amendments

- F14 Words in reg. 14(1)(a) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(6)
- F15 Words in reg. 14(1)(d) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 4; 2020 c. 1, Sch. 5 para. 1(1)

PART 4

Administration and enforcement

Textual Amendments F16 Reg. 15 omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 5; 2020 c. 1, Sch. 5 para. 1(1)

Enforcement authorities

Competent authorities

16. It is the duty of each food authority within its area or district to execute and enforce these Regulations and the [F17 retained] EU Regulations.

Textual Amendments

F17 Word in reg. 16 inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **3(7)**

Offences and penalties

- 17.—(1) Any person who contravenes regulation 12 or 13(1) commits an offence.
- (2) Any person guilty of an offence under regulation 3, 4, 5, 6, 7(4) or 17(1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Condemnation of food

18. Where any food is certified by a food analyst as being food which it is an offence to place on the market, that food shall be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed under an order of a justice of the peace) as failing to comply with food safety requirements.

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

Application of various provisions of the Food Safety Act 1990

- **19.**—(1) 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 Part of it is to be construed as a reference to these Regulations
 - (a) section 20 (offences due to fault of another person);
 - (b) section 21 (defence of due diligence) M19 with the modification that
 - (i) subsections (2) to (4) shall apply in relation to an offence under regulation 3, 4, 5, 6, 7(4) or 17(1) as they apply in relation to an offence under section 14 or 15, and
 - (ii) in subsection (4) the references to "sale" are deemed to include references to "placing on the market";
 - (c) section 30(8) (which relates to documentary evidence);
 - (d) section 35(1) (punishment of offences) M20, in so far as it relates to offences under section 33(1) as applied by paragraph (2)(b);
 - (e) section 35(2) and (3) M21, in so far as it relates to offences under section 33(2) as applied by paragraph (2)(c);
 - (f) section 36 (offences by bodies corporate); and
 - (g) section 36A (offences by Scottish partnerships) M22.
- (2) 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 is to be construed as including a reference to the [F18] retained [EU Regulations and these Regulations
 - (a) section 3 (presumption that food is intended for human consumption) with the modification that the references to "sold" and "sale" are deemed to include references to "placed on the market" and "placing on the market" respectively;
 - (b) section 33(1) (obstruction etc. of officers);
 - (c) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (b); and
 - (d) section 44 (protection of officers acting in good faith).
- (3) Section 34 of the Act (time limit for prosecutions) applies to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

Textual Amendments

F18 Word in reg. 19(2) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **3(8)**

Marginal Citations

- **M19** Section 21 was amended by S.I. 2004/3279.
- **M20** Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), **Schedule 26**, paragraph 42, from a date to be appointed.
- M21 Section 35(3) was amended by S.I. 2004/3279.
- M22 Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

PART 5

General

Revocations

21. The instruments listed in the first column of Schedule 5 are revoked to the extent specified in the second column.

Review

- 22.—(1) The Food Standards Agency must from time to time
 - (a) carry out a review of the operation and effect of regulations 2 to 19;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report.

F20(2)																

- (3) The report must in particular
 - (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if they do, the extent to which they could be achieved with a system that imposes less regulation.
- (4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
 - (5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Textual Amendments F20 Reg. 22(2) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 3(9)

[F21 Transitional provisions: withdrawal from the EU

- **23.**—(1) An authorised officer must not serve on a person a compliance notice relating to a failure to comply with regulation 13(2) if—
 - (a) a product does not comply with regulation 14(1)(d);
 - (b) the compliance notice would relate to a product that was placed on the market before [F221 January 2024]; and

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- (c) the matter constituting the alleged failure to comply would not have constituted a failure to comply with these Regulations as they applied immediately before IP completion day.
- (2) In this regulation, "compliance notice" means a compliance notice pursuant to regulation 7.]

Textual Amendments

- **F21** Reg. 23 inserted (29.3.2022) by The Food and Feed Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/377), regs. 1(3), **3(2)**
- **F22** Words in reg. 23(1)(b) substituted (30.9.2022) by The Food Information (Amendment of Transitional Provisions) (England) Regulations 2022 (S.I. 2022/938), regs. 1(1), 5

Signed by authority of the Secretary of State for Health.

Department of Health

Anna Soubry Parliamentary Under-Secretary of State,

SCHEDULE 1

Regulations 3 and 7 $\,$

Specified provisions of Regulation 1333/2008

Provision of Regulation 1333/2008	Subject matter
Article 4.1 (as read with Articles 11.3 and 11.4, 12, 13.2 and 18.1(a), 18.2 and 18.3)	Requirement that only food additives included in the list in Annex II to Regulation 1333/2008 be placed on the market as such and that they be used in accordance with any conditions specified in those Articles and that Annex.
Article 4.2 (as read with Articles 12, 13.2 and 18.3)	Requirement that only food additives included in the list in Annex III to Regulation 1333/2008 may be used in food additives, food enzymes, food flavourings and nutrients and under the conditions of use specified in that Annex.
Article 4.5	Requirement that food additives comply with the specifications referred to in Article 14 of Regulation 1333/2008.
Article 5	Prohibition on placing on the market of food additives or food containing food additives if the use of the food additive does not comply with Regulation 1333/2008.
Article 11.2	Requirement to use food additives in accordance with the <i>quantum satis</i> principle where no maximum numerical level fixed for the additive concerned.
Article 15	Prohibition on use of food additives in unprocessed foods except where provided for in Annex II to Regulation 1333/2008.
Article 16	Prohibition on use of food additives in foods for infants and young children (including dietary foods for infants and young children for special medical purposes) except where provided for in Annex II to Regulation 1333/2008.
Article 17	Requirement to use only food colours listed in Annex II to Regulation 1333/2008 for the purpose of health marking meat or meat products, decorative colouring of eggshells or stamping of eggshells.
Article 18.1(b) (as read with Article 18.2)	Requirement that food additives be present in food to which a food additive, food enzyme or food flavouring has been added, only if the additive is permitted in the additive, enzyme or flavouring under Regulation 1333/2008, has been carried over to the food via the additive,

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	enzyme or flavouring and has no technological function in the final food.
Article 18.1(c) (as read with Article 18.2)	Requirement that food additives be present in foods to be used solely in the preparation of a compound food only if the compound food complies with Regulation 1333/2008.
Article 18.4	Requirement that food additives be used as sweeteners in compound foods with no added sugars, energy reduced compound foods with no added sugars, energy reduced compound foods, compound dietary foods intended for low calorie diets, non cariogenic compound foods and compound foods with an increased shelf life only if the sweetener is permitted in any of the ingredients of the compound food.
Article 26.1	Requirement that producers and users of food additives inform the [F23]Authority] immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive concerned.

Textual Amendments

F23 Word in Sch. 1 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **6(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

Provision of Regulation 1333/2008	Subject matter
Article 21.1 (as read with Article 22)	Requirement that food additives not intended for sale to the final consumer be labelled, in accordance with Article 22 of Regulation 1333/2008, visibly, clearly legibly and indelibly and in [F24 English, or in English and Welsh].
Article 23.1 (as read with Article 23.2 and 23.5)	Prohibition on marketing of food additives sold singly or mixed with each other and/or other food ingredients and intended for sale to the final consumer unless their packaging contains specified information.
Article 23.3 (as read with Article 23.5)	Requirement that the labelling of table-top sweeteners containing polyols and/or aspartame and/or aspartame – acesulfame salt bear specified warnings.
Article 23.4	Requirement that manufacturers of table top sweeteners make available by appropriate means

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

	the information necessary to allow safe use by consumers.
Article 24.1 (as read with Article 24.2)	Requirement that labelling of the food containing the colours listed in Annex V should contain the additional information specified in that Annex.
Article 26.2	Requirement that producers and users of food additives, at the request of the [F25Authority], inform it of the actual use of the food additive concerned.

Textual Amendments

- F24 Words in Sch. 1 Table 2 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 6(b)(i); 2020 c. 1, Sch. 5 para. 1(1)
- F25 Word in Sch. 1 Table 2 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 6(b)(ii); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 2

Regulations 4 and 7

Specified provisions of Regulation 1334/2008

Provision of Regulation 1334/2008	Subject matter
Article 4	Requirement that the use of flavourings or food ingredients with flavouring properties does not pose a safety risk or mislead the consumer.
Article 5	Prohibition on the placing on the market of non-compliant flavourings or non-compliant food.
Article 6.1 (as read with Part A of Annex III)	Prohibition on adding certain specified substances as such in foods.
Article 6.2 (as read with Part B of Annex III)	Requirement that certain substances naturally present in flavourings or food ingredients with flavouring properties should not exceed specified levels in compound foods as a result of the use of flavourings or food ingredients with flavouring properties.
Article 7.1 (as read with Part A of Annex IV)	Prohibition on the use of certain source materials to produce flavourings or food ingredients with flavouring properties.

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

Article 7.2 (as read with Part B of Annex IV)	Restrictions on the use of flavourings or food ingredients with flavouring properties produced from certain source materials.
Article 10	Restriction on the placing on the market or use of flavourings and source materials that are not included on the [F26domestic] list.
Article 19.2	Requirement that a producer or user of an approved flavouring that is prepared by production methods or using starting materials significantly different from those included in the risk assessment must submit the necessary data to the [F27]Authority] to allow an evaluation with regard to the modified production method or characteristics before marketing the flavouring
Article 19.3	Requirement on food business operators to inform the [F28Authority] immediately if they become aware of any new scientific or technical information that might affect the assessment of the safety of a flavouring substance.

Textual Amendments

- **F26** Word in Sch. 2 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **7(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**
- F27 Word in Sch. 2 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 7(b); 2020 c. 1, Sch. 5 para. 1(1)
- F28 Word in Sch. 2 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 7(c); 2020 c. 1, Sch. 5 para. 1(1)

Provision of Regulation 1334/2008	Subject matter
Article 14.1 (as read with Articles 15 and 16)	Requirements for the labelling of flavourings not intended for sale to the final consumer.
Article 17 (as read with Articles 15.1(a) and 16)	Requirements for the labelling of flavourings intended for sale to the final consumer.

SCHEDULE 3

Regulations 5 and 7 $\,$

Specified provisions of Regulation 2065/2003

Provision of Regulation 2065/2003	Subject matter
Article 4.2	Prohibition on marketing a smoke flavouring not on the list of authorised smoke flavourings, or any food in or on which such a smoke flavouring is present
Article 4.2	Prohibition on marketing an authorised smoke flavouring, or any food in or on which such a smoke flavouring is present, otherwise than in accordance with any conditions of use laid down in the authorisation
Article 5.1, first subparagraph	Prohibition on using treated wood, unless it can be demonstrated by appropriate certification or documentation that the substance used in treatment does not give rise to potentially toxic substances during combustion
Article 5.1, second subparagraph	Requirement to be able to demonstrate by documentation or certification that the prohibition in the first paragraph of Article 5.1 has been observed
Article 5.2, first sentence	Requirement to observe conditions in Annex I during production of primary products (primary smoke condensates or primary tar fractions)
Article 5.2, second sentence	Prohibition on the use of water-insoluble oily phase during the production of smoke flavourings
Article 9.4	Requirement that an authorisation holder or any other food business operator using an authorised product, or a derived smoke flavouring produced from an authorised product, must comply with any conditions or restrictions attached to the authorisation
Article 9.5	Requirement that an authorisation holder inform the [F29]Authority] immediately of any new scientific or technical information relating to an authorised product which might influence the assessment of its safety

Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

Textual Amendments

F29 Word in Sch. 3 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **8**; 2020 c. 1, **Sch. 5 para. 1(1)**

Table 2

Provision of Regulation 2065/2003	Subject matter
Article 13.1	Requirement that food business operators ensure the specified information is transmitted to the receiving food business operator when the product is first placed on the market
Article 13.2	Requirement that following the first placing on the market, on each subsequent occasion that the product is placed on the market, food business operators placing products on the market transmit the information specified in Article 13.1 to the receiving food business operators

SCHEDULE 4

Regulations 6 and 7

Specified provisions of Regulation 1332/2008

Provision of Regulation 1332/2008	Subject matter
Article 4	Requirement that food enzymes may not be placed on the market as such or used in foods unless they appear in the [F30]domestic]
	list of authorised enzymes provided for in Article 17 and in accordance with the prescribed specifications and conditions of use.
Article 5	Prohibition on placing on the market of non-compliant food enzymes or foods containing such enzymes which do not comply with Regulation 1332/2008 and its implementing measures.
Article 14.1	Requirement that a producer of user of a food enzyme shall inform the [F31]Authority] immediately of any new scientific or technical information that might affect its safety assessment.
Article 14.2	Requirement that a producer or user of an approved food enzyme that is prepared by

production methods or using starting materials significantly different from those included in the risk assessment must submit the necessary data to the [F32Authority] to allow an evaluation with regard to the modified production method or characteristics before marketing the enzyme.

Textual Amendments

- **F30** Word in Sch. 4 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **9(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**
- F31 Word in Sch. 4 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 9(b); 2020 c. 1, Sch. 5 para. 1(1)
- F32 Word in Sch. 4 Table 1 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 9(c); 2020 c. 1, Sch. 5 para. 1(1)

Table 2

Provision of Regulation 1332/2008	Subject matter
Article 10.1 (as read with Article 11)	Requirements for labelling of food enzymes and preparations not intended for sale to the final consumer.
Article 12.1	Requirements for labelling of food enzymes and preparations intended for sale to the final consumer.

SCHEDULE 5

Regulation 21

Revocations

Name of instrument Extent of revocation

The Extraction Solvents in Food Regulations The whole Regulations 1993 (S.I. 1993/1658)

The Extraction Solvents in Food (Amendment) The whole Regulations Regulations 1995 (S.I. 1995/1440)

The Extraction Solvents in Food (Amendment) The whole Regulations Regulations 1998 (S.I. 1998/2257)

The Extraction Solvents in Food (Amendment) The whole Regulations (England) Regulations 2011 (S.I. 2011/1738)

The Smoke Flavourings (England) Regulations The whole Regulations 2005 (S.I. 2005/464)

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Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. (See end of Document for details)

The Food (Suspension of the Use of E128 Red The whole Regulations 2G Food Colour) (England) Regulations 2007 (S.I. 2007/2266)

The Food Enzymes Regulations 2009 (S.I. Regulations 3, 4, 5, 6, 7(2)(b) and 8 2009/3235)

The Food Additives (England) Regulations 2009 All provisions except regulations 1, 2, 18(4) and (S.I. 2009/3238)

The Food Additives (England) (Amendment) The whole Regulations Regulations 2011 (S.I. 2011/258)

The Food Additives (England) (Amendment) The whole Regulations (No.2) Regulations 2011 (S.I. 2011/1456)

The Food Additives (England) (Amendment) The whole Regulations and the Extraction Solvents in Food (Amendment) (England) Regulations 2012 (S.I. 2012/1155)

The Flavourings in Food (England) Regulations All provisions except regulations 1, 2 and 7. 2010 (S.I. 2010/2817)

[F33SCHEDULE 6

Regulations 10, 11 and 14

EXTRACTION SOLVENTS WHICH MAY BE USED DURING THE PROCESSING OF RAW MATERIALS, OF FOODSTUFFS, OF FOOD COMPONENTS OR OF FOOD INGREDIENTS

Textual Amendments

F33 Sch. 6 inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), reg. 1(1), Sch. 2

Modifications etc. (not altering text)

C3 Sch. 6 applied in part (with modifications) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(b), Sch. 2 (with regs. 7, 8)

Table 1: Extraction solvents to be used in compliance with good manufacturing practice for all uses

Name⁽¹⁾

Propane

Butane

Ethyl acetate

Ethanol

- (1) An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.
- (2) The use of Acetone in the refining of olive-pomace oil is forbidden.

Name⁽¹⁾

Carbon dioxide

Acetone⁽²⁾

Nitrous oxide

- (1) An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.
- (2) The use of Acetone in the refining of olive-pomace oil is forbidden.

Table 2: Extraction solvents for which conditions of use are specified

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
Hexane (1)	Production or fractionation of fats and oils and production of cocoa butter	
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germs
Methyl acetate	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
	Production of sugar from molasses	1 mg/kg in the sugar
Ethylmethylketone (2)	Fractionation of fats and oils	5 mg/kg in the fat or oil
	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea

⁽¹⁾ Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. The combined use of Hexane and Ethylmethylketone is forbidden.

- (2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.
- (3) 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004.
- (4) 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	
Methanol	For all uses	10 mg/kg
Propan-2-ol	For all uses	10 mg/kg
Dimethyl ether	Preparation of defatted animal protein products including gelatine (3)	0.009 mg/kg in the defatted animal protein products including gelatine
	Preparation of collagen (4) and collagen derivatives, except gelatine	5 mg/kg m the conagen and

- (1) Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. The combined use of Hexane and Ethylmethylketone is forbidden.
- (2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.
- (3) 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004.
- (4) 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.

Table 3: Extraction solvents for which conditions of use are specified

Name	Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials
Diethyl ether	2 mg/kg
Hexane (*)	1 mg/kg
Cyclohexane	1 mg/kg
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone (*)	1 mg/kg
Dichloromethane	0.02 mg/kg
Propan-1-ol	1 mg/kg
1,1,1,2-tetrafluoroethane	0.02 mg/kg
Methanol	1.5 mg/kg
Propan-2-ol	1 mg/kg

Name	Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials
* The combined use of Hexane and Ethylmethylketone is forbidden.]	

EXPLANATORY NOTE

(This note is not part of the Regulations)

- **1.** These Regulations, which apply to England only, provide for the execution and enforcement of the following EU Regulations
 - (a) Regulation (EC) No 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods (OJ No. L309, 26.11.2003, p.1);
 - (b) Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes (OJ No. L354, 31.12.2008, p.7);
 - (c) Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ No. L354, 31.12.2008, p.16);
 - (d) Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ No. L354, 31.12.2008, p.34).
- **2.** These Regulations also implement Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ No. L141, 6.6.2009, p.3).
 - 3. These Regulations revoke, in whole or in part, the following Regulations
 - (a) The Extraction Solvents in Food Regulations 1993 (S.I. 1993/1658);
 - (b) The Smoke Flavourings (England) Regulations 2005 (S.I. 2005/464);
 - (c) The Food (Suspension of the Use of E128 Red 2G Food Colour) (England) Regulations 2007 (S.I. 2007/2266);
 - (d) The Food Enzymes Regulations 2009 (S.I. 2009/3235);
 - (e) The Food Additives (England) Regulations 2009 (S.I. 2009/3238);
 - (f) The Flavourings in Food (England) Regulations 2010 (S.I. 2010/2817).
- **4.** These Regulations, in Part 2, provide that it is an offence, subject to any applicable transitional arrangements, to contravene or to use or place on the market a product that contravenes specified requirements of
 - (a) Regulation (EC) No 1333/2008 relating to food additives (regulation 3 and Table 1 of Schedule 1);
 - (b) Regulation (EC) No 1334/2008 relating to food flavourings and foods with flavouring properties (regulation 4 and Table 1 of Schedule 2);
 - (c) Regulation (EC) No 2065/2003 relating to smoke flavourings (regulation 5 and Table 1 of Schedule 3); and

- (d) Regulation (EC) No 1332/2008 relating to food enzymes (regulation 6 and Table 1 of Schedule 4).
- **5.** These Regulations also provide in Part 2 that in the case of certain types of non-compliance, relating to labelling, an authorised officer of an enforcement authority may serve a compliance notice requiring specified steps to be taken, failing which an offence will be committed (*regulation 7 and Table 2 of Schedules 1 to 4*). A person served with a compliance notice may appeal against it to a magistrates court (*regulation 8*).
- **6.** Part 3 of these Regulations implement Directive 2009/32/EC relating to extraction solvents, in particular by
 - (a) specifying the circumstances where the controls on extraction solvents do not apply (regulation 10);
 - (b) defining what constitutes a permitted extraction solvent (regulation 11);
 - (c) prohibiting any person from using an extraction solvent other than a permitted extraction solvent, as defined, in the production of food (*regulation 12*);
 - (d) prohibiting any person from placing on the market an extraction solvent that is not a permitted extraction solvent or which is not accompanied by certain information on the packaging, container or label (*regulations 13 and 14*).
 - 7. These Regulations in Part 4
 - (a) designate the Food Standards Agency as the competent authority for the purposes of applications for authorisation of a smoke flavouring (*regulation 15*);
 - (b) assign the duty of enforcing these Regulations to food authorities (regulation 16);
 - (c) provide for the maximum penalty to which a person may be liable on conviction for an offence under these Regulations (regulation 17);
 - (d) provide that, where food is certified as being food which it is an offence to place on the market, the food will be treated for the purposes of section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements (regulation 18); and
 - (e) apply, with certain modifications, various provisions of the Food Safety Act 1990 for the purposes of these Regulations (regulation 19).
 - **8.** These Regulations in Part 5
 - (a) make a minor amendment to the Food Labelling Regulations 1996 (regulation 20);
 - (b) revoke certain instruments in whole or in part (regulation 21 and Schedule 5); and
 - (c) provide for the Food Standards Agency to carry out a review of the operation and effect of these Regulations within 5 years of them coming into force (regulation 22).
- **9.** A full impact assessment has not been produced for this instrument as no impact on business or on the public or voluntary sectors is foreseen.

Status:

Point in time view as at 01/10/2023.

Changes to legislation:

There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013.