
WELSH STATUTORY INSTRUMENTS

2013 No. 2591 (W. 255)

FOOD, WALES

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

<i>Made</i>	- - - -	<i>7 October 2013</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>9 October 2013</i>
<i>Coming into force</i>	- -	<i>31 October 2013</i>

The Welsh Ministers make 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 ^{F1} and now vested in them ^{F2}, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972 ^{F3}.

In accordance with section 48(4A) of the Food Safety Act 1990, they have 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 Welsh Ministers 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 ^{F4}, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

F1 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 \(c.28\)](#), “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 \(c.40\)](#), [Schedule 6](#) to the 1999 Act, [S.I. 2004/2990](#) and [S.I. 2004/3279](#).

F2 Functions of “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the [National Assembly for Wales \(Transfer of Functions\) Order 1999 \(S.I. 1999/672\)](#) as read with section 40(3) of the [Food Standards Act 1999 \(c.28\)](#), and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the [Government of Wales Act 2006 \(c.32\)](#).

Status: Point in time view as at 14/04/2023.

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

- F3** 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the [Legislative and Regulatory Reform Act 2006 \(c.51\)](#) and amended by Part 1 of the Schedule to the [European Union \(Amendment\) Act 2008 \(c.7\)](#).
- F4** 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

Title, application and commencement

1. The title of these Regulations is the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013, they apply in relation to Wales and come into force on 31 October 2013.

Interpretation

2.—(1) In these Regulations —

“the Act” (“*y Ddeddf*”) means the Food Safety Act 1990;

^{F5} ...

“Regulation 2065/2003” (“*Rheoliad 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 ^{F6};

“Regulation 1332/2008” (“*Rheoliad 1332/2008*”) means Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes ^{F7};

“Regulation 1333/2008” (“*Rheoliad 1333/2008*”) means Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives ^{F8}, 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 ^{F9},
- (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 establishing a Union list of food additives for use in food additives, food enzymes, food flavourings and nutrients ^{F10}, 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 ^{F11},

“Regulation 1334/2008” (“*Rheoliad 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 ^{F12}, 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 ^{F13};

“authorised officer” (“swyddog awdurdodedig”) 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” (“awdurdod bwyd”) means —

- (d) a county council; and
- (e) a county borough council;

“the ^{F14}retained EU Regulations” [^{F15}(“*Rheoliadau’r UE a ddargedwir*”)] means Regulation 2065/2003, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008.

(2) Other expressions used in these Regulations and in the ^{F16}... 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 ^{F17}... instruments listed in paragraph (4) is a reference to that Article or Annex as amended from time to time.

(4) The ^{F18}... instruments are ^{F18}... 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 ^{F19}, 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 of the Public Health (Control of Disease) Act 1984 ^{F20}, to a port health authority; or
- (b) by an order under section 6 of the Public Health Act 1936 ^{F21}, to a joint board for a united district;

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.

- F5** Words in [reg. 2\(1\)](#) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, [3\(2\)\(a\)\(i\)](#)
- F6** 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).
- F7** 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).
- F8** OJ No. L354, 31.12.2008, p.16. This instrument was last amended by Commission Regulation (EU) No. 510/2013 (OJ No. L150, 4.6.2013, p.17).
- F9** OJ No. L295, 12.11.2011, p.1.
- F10** OJ No. L295, 12.11.2011, p.178.
- F11** OJ No. L83, 22.3.2012, p.1. This instrument was last amended by Commission Regulation (EU) No. 497/2013 (OJ No. L143, 30.5.2013, p.20).
- F12** OJ No. L354, 31.12.2008, p.34. This instrument was last amended by Commission Implementing Regulation (EU) No 545/2013 (OJ No. L163, 15.6.2013, p.15).
- F13** OJ No. L267, 2.10.2012, p.162.
- F14** Word in [reg. 2\(1\)](#) inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, [3\(2\)\(a\)\(ii\)](#)
- F15** Words in [reg. 2\(1\)](#) substituted (14.4.2023) by [The Food Additives, Food Flavourings, and Novel Foods \(Authorisations\) and Food and Feed \(Miscellaneous Amendments\) \(Wales\) Regulations 2023 \(S.I. 2023/343\)](#), regs. 1(3), [8\(b\)](#) (with [reg. 4](#))
- F16** Word in [reg. 2\(2\)](#) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, [3\(2\)\(b\)](#)
- F17** Word in [reg. 2\(3\)](#) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, [3\(2\)\(c\)](#)

*Status: Point in time view as at 14/04/2023.**Changes to legislation: There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013. (See end of Document for details)*

- F18** Words in [reg. 2\(4\)](#) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, [3\(2\)\(d\)](#)
- F19** 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.2).
- F20** [1984 c.22](#); [section 7\(3\)\(d\)](#) was substituted by paragraph 27 of Schedule 3 to the [Food Safety Act 1990](#) (1990 c.16).
- F21** [1936 c.49](#); [section 6](#) is to be read with paragraph 1 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 ^{F22} and with transitional measures contained in or to be read with Regulation 1334/2008, commits an offence.

F22 OJ No. L267, 2.10.2012, p.1.

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 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.

Improvement notices – application of subsections (1) and (2) of section 10 of the Food Safety Act 1990

7.—(1) Subsections (1) and (2) of section 10 of the Act (improvement notices) apply for the purposes of these Regulations with the following modifications.

(2) For subsection (1), substitute—

“(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with a provision of the Food Additives,

Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013 specified in paragraph (1A), the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—

- (a) state the officer's grounds for believing that the person is failing to comply with the relevant provision;
 - (b) specify the matters which constitute the person's failure so to comply;
 - (c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and
 - (d) require the person to take those measures, or measures that are at least equivalent to them, within such period as may be specified in the notice.
- (1A) Any EU provision specified in the first column of Table 2 of—
- (a) Schedule 1;
 - (b) Schedule 2;
 - (c) Schedule 3; or
 - (d) Schedule 4; or
 - (e) regulation 13(2)”.

Appeal against improvement notice – application of subsections (1) and (6) of sections 37 and section 39 of the Food Safety Act 1990

8.—(1) Subsections (1) and (6) of section 37 of the Act (appeals) apply for the purposes of these Regulations with the following modifications—

- (a) for subsection (1), substitute—

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1), as applied and modified by regulation 7 of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013, may appeal to a magistrates court.”; and
- (b) in subsection (6), for “(3) or (4)”, substitute “ [F23(1)] ”.

F23 Word in reg. 8(1)(b) substituted (26.7.2018) by [The Food and Feed \(Miscellaneous Amendments and Revocations\) \(Wales\) Regulations 2018 \(S.I. 2018/806\)](#), regs. 1(3), **24**

PART 3

Extraction solvents

Controls on extraction solvents

F24 9.

F24 Reg. 9 omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(3)**

10. The provisions of this Part do not apply to any extraction solvent —

Status: Point in time view as at 14/04/2023.

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- (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 [^{F25}Schedule 4A]; or
- (b) intended for export outside [^{F26} Great Britain].

- F25** Words in [reg. 10\(a\)](#) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(4)**
- F26** Words in [reg. 10\(b\)](#) substituted (31.12.2020) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments and Saving Provision\) \(Wales\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1581\)](#), regs. 1(3), **13(2)**

11. In this Part “permitted extraction solvent” means —

- (a) an extraction solvent that —
 - (i) is listed in [^{F27}Schedule 4A],
 - (ii) is used in accordance with the conditions of use and within any maximum residue limits specified in [^{F28}Schedule 4A],
 - (iii) does not contain a toxicologically dangerous amount of any element or substance, [^{F29}and]
 - (iv) subject to any exceptions deriving from specific purity criteria, does not contain more than 1 mg/kg of arsenic or more than 1 mg/kg lead, and [^{F30}; or]
 - ^{F31}(v)
- (b) water to which substances regulating acidity or alkalinity may have been added; or
- (c) food substances which possess solvent properties.

- F27** Words in [reg. 11\(a\)\(i\)](#) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(5)(a)**
- F28** Words in [reg. 11\(a\)\(ii\)](#) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(5)(b)**
- F29** Word in [reg. 11\(a\)](#) inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(5)(c)**
- F30** Word in [reg. 11\(a\)](#) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(5)(d)**
- F31** [Reg. 11\(a\)\(v\)](#) omitted (31.12.2022) by virtue of [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 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 [^{F32}Schedule 4A];
- (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 [^{F33}United 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.

(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.

- F32** Words in reg. 14(1)(a) substituted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 1, **3(6)**
- F33** Words in reg. 14(1)(d) substituted (31.12.2020) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments and Saving Provision\) \(Wales\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1581\)](#), regs. 1(3), **13(3)**

PART 4

Administration and enforcement

Competent authorities

^{F34}**15.**

- F34** [Reg. 15](#) omitted (31.12.2020) by virtue of [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments and Saving Provision\) \(Wales\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1581\)](#), regs. 1(3), **13(4)**

Enforcement authorities

16. It is the duty of each food authority within its area or district to execute and enforce these Regulations and the [^{F35}retained] EU Regulations.

- F35** Word in reg. 16 inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), regs. 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 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.

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) ^{F36} 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) ^{F37}, in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);
- (e) section 35(2) and (3) ^{F38}, in so far as it relates to offences under section 33(2) as applied by paragraph (1)(c);
- (f) section 36 (offences by bodies corporate); and
- (g) section 36A (offences by Scottish partnerships) ^{F39}.

(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 [^{F40}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.

F36 Section 21 was amended by S.I. 2004/3279.

- F37** Section 35(1) is amended by the Criminal Justice Act 2003 (c.44), **Schedule 26**, paragraph 42, from a date to be appointed.
- F38** Section 35(3) was amended by S.I. 2004/3279.
- F39** Section 36A was inserted by the Food Standards Act 1999 (c.28), **Schedule 5**, paragraph 16.
- F40** Word in reg. 19(2) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022 (S.I. 2022/1362), regs. 1, **3(8)**

PART 5

General

Consequential and other amendments

F41 **20.**

- F41** Reg. 20 revoked (13.12.2014) by The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 6 Pt. 1**

Revocations

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

[^{F42}Transitional provision: withdrawal from the EU

22.—(1) An authorised officer must not serve on a person an improvement notice relating to a failure to comply with regulation 13(2), in respect of the requirement set out in regulation 14(1)(d), if—

- (a) the improvement notice would relate to a product that was placed on the market [^{F43}before 1 January 2024]; and
- (b) the matter would not have constituted a failure to comply with those provisions of these Regulations as they had effect immediately before IP completion day.

(2) In this regulation, “improvement notice” means an improvement notice pursuant to regulation 7.]

- F42** Reg. 22 inserted (14.4.2021) by The Food, Animal Feed and Seeds (Miscellaneous Amendments and Transitional Provisions) (Wales) (EU Exit) Regulations 2021 (S.I. 2021/371), regs. 1(2), **5**
- F43** Words in reg. 22(1)(a) substituted (30.9.2022) by The Food Information (Amendment of Transitional Provisions) (Wales) Regulations 2022 (S.I. 2022/939), regs. 1(2), **6**

Mark Drakeford
Minister for Health and Social Services, one of
the Welsh Ministers

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SCHEDULE 1

Regulations 3 and 7

Specified provisions of Regulation 1333/2008

Table 1

<i>Provision of Regulation 1333/2008</i>	<i>Subject matter</i>
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,

	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 [^{F44} Authority] immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive concerned.

F44 Word in [Sch. 1](#) substituted (31.12.2020) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments and Saving Provision\) \(Wales\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1581\)](#), regs. 1(3), 13(5)(a)

Table 2

<i>Provision of Regulation 1333/2008</i>	<i>Subject matter</i>
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 [^{F45} 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 the information necessary to allow safe use by consumers.

Status: Point in time view as at 14/04/2023.

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

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 [^{F46} Authority], inform it of the actual use of the food additive concerned.

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| F45 | Words in Sch. 1 substituted (31.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581) , regs. 1(3), 13(5)(b)(i) |
| F46 | Word in Sch. 1 substituted (31.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581) , regs. 1(3), 13(5)(b)(ii) |

SCHEDULE 2

Regulations 4 and 7

Specified provisions of Regulation 1334/2008

Table 1

<i>Provision of Regulation 1334/2008</i>	<i>Subject matter</i>
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.
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 Union 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 Commission 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 Commission immediately if they become aware of any new scientific or technical information that might affect the assessment of the safety of a flavouring substance.

Table 2

<i>Provision of Regulation 1334/2008</i>	<i>Subject matter</i>
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

Table 1

<i>Provision of Regulation 2065/2003</i>	<i>Subject matter</i>
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

Status: Point in time view as at 14/04/2023.**Changes to legislation:** There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013. (See end of Document for details)

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 Commission immediately of any new scientific or technical information relating to an authorised product which might influence the assessment of its safety

Table 2

<i>Provision of Regulation 2065/2003</i>	<i>Subject matter</i>
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

Table 1

<i>Provision of Regulation 1332/2008</i>	<i>Subject matter</i>
Article 4	Requirement that food enzymes may not be placed on the market as such or used in foods unless they appear in the Union 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 or user of a food enzyme shall inform the Commission 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 Commission to allow an evaluation with regard to the modified production method or characteristics before marketing the enzyme.

Table 2

<i>Provision of Regulation 1332/2008</i>	<i>Subject matter</i>
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.

[^{F47}SCHEDULE 4A

Regulations 10, 11 and 14

Extraction solvents which may be used during the processing of
raw materials, of food, of food components or of food ingredients

F47 Sch. 4A inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1362\)](#), reg. 1, **Sch. 2**

Status: Point in time view as at 14/04/2023.

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

Table 1

Extraction solvents to be used in compliance with good manufacturing practice for all uses()

Name:
Propane
Butane
Ethyl Acetate
Ethanol
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) Acetone is not permitted for use in the refining of olive-pomace oil.

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	1 mg/kg in the fat or oil or 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

- (1) Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. Combined use of Hexane and Ethymethylketone is not permitted.
- (2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. Combined use of Hexane and Ethymethylketone is not permitted.
- (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 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin.
- (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.

Status: Point in time view as at 14/04/2023.**Changes to legislation:** There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013. (See end of Document for details)

<i>Name</i>	<i>Conditions of use (summary description of extraction)</i>	<i>Maximum residue limits in the extracted foodstuff or food ingredient</i>
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
Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	2 mg/kg in the roasted coffee and 5 mg/kg in the 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	3 mg/kg in the collagen and collagen derivatives, except gelatine

(1) Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. Combined use of Hexane and Ethylmethylketone is not permitted.

(2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. Combined use of Hexane and Ethylmethylketone is not permitted.

(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 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin.

(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**

<i>Name</i>	<i>Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials</i>
Diethyl ether	2 mg/kg
Hexane ⁽¹⁾	1 mg/kg
Cyclohexane	1 mg/kg

(1) Combined use of Hexane and Ethylmethylketone is not permitted.]

Status: Point in time view as at 14/04/2023.**Changes to legislation:** There are currently no known outstanding effects for the The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013. (See end of Document for details)

<i>Name</i>	<i>Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials</i>
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone ⁽¹⁾	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

(1) Combined use of Hexane and Ethylmethylketone is not permitted.]

SCHEDULE 5

Regulation 21

Revocations

<i>Name of instrument</i>	<i>Extent of revocation</i>
The Extraction Solvents in Food Regulations 1993 (S.I. 1993/1658)	The whole Regulations
The Extraction Solvents in Food (Amendment) Regulations 1995 (S.I. 1995/1440)	The whole Regulations
The Extraction Solvents in Food (Amendment) Regulations 1998 (S.I. 1998/2257)	The whole Regulations
The Extraction Solvents in Food (Amendment) (Wales) Regulations 2011 (S.I. 2011/1849 (W.199))	The whole Regulations
The Smoke Flavourings (Wales) Regulations 2005 (S.I. 2005/1350 (W.98))	The whole Regulations
The Food (Suspension of the Use of E128 Red 2G Food Colour) (Wales) Regulations 2007 (S.I. 2007/2315 (W.186))	The whole Regulations
The Food Enzymes Regulations 2009 (S.I. 2009/3377 (W.299))	Regulations 3, 4, 5, 6, 7(2)(b) and 8
The Food Additives (Wales) Regulations 2009 (S.I. 2009/3378 (W.300))	All provisions except regulations 1, 2, 18(4) and 19
The Food Additives (Wales) (Amendment) Regulations 2011 (S.I. 2011/655 (W.93))	The whole Regulations

The Food Additives (Wales) (Amendment) The whole Regulations
(No.2) Regulations 2011 (S.I. 2011/1450
(W.172))

The Food Additives (Wales) (Amendment) and The whole Regulations
the Extraction Solvents in Food (Amendment)
(Wales) Regulations 2012 (S.I. 2012/1198
(W.148))

The Flavourings in Food (Wales) Regulations All provisions except regulations 1, 2 and 7.
2010 (S.I. 2010/2922 (W.243))

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply to Wales, 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 (Wales) Regulations 2005 (S.I. 2005/1350 (W.98));
- (c) The Food (Suspension of the Use of E128 Red 2G Food Colour) (Wales) Regulations 2007 (S.I. 2007/23315 (W.186));
- (d) The Food Enzymes (Wales) Regulations 2009 (S.I. 2009/3377 (W.299));
- (e) The Food Additives (Wales) Regulations 2009 (S.I. 2009/3378 (W.300));
- (f) The Flavourings in Food (Wales) Regulations 2010 (S.I. 2010/1198 (W.2922)).

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*);

Status: Point in time view as at 14/04/2023.

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

- (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 an improvement 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 an improvement 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*); and
- (b) revoke certain instruments in whole or in part (*regulation 21 and Schedule 5*).

9. The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

Status:

Point in time view as at 14/04/2023.

Changes to legislation:

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