



FOOD ADDITIVES, FLAVOURINGS, ENZYMES AND EXTRACTION SOLVENTS REGULATIONS 2019

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Statutory Document No. 2019/0365



European Communities (Isle of Man) Act 1973

FOOD ADDITIVES, FLAVOURINGS, ENZYMES AND EXTRACTION SOLVENTS REGULATIONS 2019¹

Laid before Tynwald: 8 October 2019
Coming into Operation: in accordance with regulation 2

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

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

PART 1 – INTRODUCTORY

1 Title

These Regulations are the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations 2019.

2 Commencement

These Regulations come into operation on the day after they are made¹.

3 Interpretation

(1) In these Regulations –

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

“**authorised officer**” means any person who is authorised in writing, either generally or specially, by the Department to act in matters arising under these Regulations;

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

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

“**Directive 2009/32**” [Revoked]²

“**the retained EU Regulations**” means Regulation 2065/2003, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008;³

“**Regulation 2065/2003**” means Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods²;

“**Regulation 1332/2008**” means Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes³;

“**Regulation 1333/2008**” means Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁴, as read with –

- (a) Commission Regulation (EU) No 1129/2011 of 11 November 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 additives⁵;
- (b) Commission Regulation (EU) No 1130/2011 of 11 November 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 approved for use in food additives, food enzymes, food flavourings and nutrients⁶; and
- (c) Commission Regulation (EU) No 231/2012 of 9 March 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 Council⁷; and

“**Regulation 1334/2008**” means Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods⁸, as read with Commission Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source

² OJ L 309, 26.11.2003, p.1. This instrument was amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ L 188, 18.7.2009, p. 14).

³ OJ L 354, 31.12.2008, p. 7. This instrument was amended by Regulation (EU) No 1056/2012 (OJ L313, 13.11.2012, p. 9).

⁴ OJ L 354, 31.12.2008, p. 16. This instrument was last amended by Commission Regulation (EU) 2019/891 (OJ L 142, 29.5.2019, p. 54).

⁵ OJ L 295, 12.11.2011, p. 1. This instrument was last amended by Commission Regulation (EU) No 1152/2013 (OJ L 311, 20.11.2013, p. 1).

⁶ OJ L 295, 12.11.2011, p. 178.

⁷ OJ L 083, 22.3.2012, p. 1. This instrument was last amended by Commission Regulation (EU) 2018/1481 (OJ L 251, 5.10.2018, p. 13).

⁸ OJ L354, 31.12.2008, p. 34. This instrument was last amended by Commission Regulation (EU) 2019/799 (OJ L 132, 20.5.2019, p. 12).

materials set out in Annex I to Regulation (EC) 1334/2008 of the European Parliament and of the Council⁹;

- (2) Other expressions used in these Regulations and in the instruments listed in paragraph (4) have the same meaning in these Regulations as they do in those instruments.⁴
- (3) Any reference in these Regulations to an Article of or Annex to any of the instruments listed in paragraph (4) is a reference to that Article or Annex as amended from time to time.⁵
- (4) The instruments are Regulation 2065/2003, Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings¹⁰, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008.⁶

PART 2 — FOOD ADDITIVES, FLAVOURINGS AND ENZYMES

4 Offence of contravening EU requirements on food additives

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.

5 Offence of contravening EU requirements on flavourings, including smoke flavourings

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 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council¹¹ and with transitional measures contained in or to be read with Regulation 1334/2008, commits an offence.

⁹ OJ L 267, 2.10.2012, p.162. This instrument was last amended by Commission Regulation (EU) 2018/1259 (OJ L 238, 21.9.2018, p. 28).

¹⁰ OJ L 354, 31.12.2008, p. 1. This instrument is implemented by Commission Regulation (EU) No 234/2011 (OJ L 064, 11.03.2011, p. 15) and that Regulation has been amended by Commission Implementing Regulation (EU) No 562/2012 (OJ L 168, 28.06.2012, p. 21).

¹¹ OJ L 267, 2.10.2012, p. 1.

6 Offence of contravening certain requirements of Regulation 2065/2003

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) of Regulation 2065/2003, commits an offence.

7 Offence of contravening EU requirements on food enzymes

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 and entry into force) of Regulation 1332/2008, commits an offence.

8 Compliance notices

- (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 14(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 9.
- (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.

9 Appeal against a compliance notice

- (1) Any person served with a compliance notice may appeal against that notice to a court of summary jurisdiction.

- (2) The procedure on appeal to a court of summary jurisdiction under paragraph (1) is by way of a complaint, and the Summary Jurisdiction Act 1989 applies to the proceedings.
- (3) The period within which an appeal under paragraph (1) may be brought is one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint is 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 8(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.

PART 3 — EXTRACTION SOLVENTS

10 [Revoked]⁷

11 Application of Part 3

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 Schedule 5; or⁸
- (b) intended for export outside the British Islands.⁹

12 Definition of permitted extraction solvent

In this Part, “permitted extraction solvent” means —

- (a) an extraction solvent that —
 - (i) is listed in Schedule 5;¹⁰
 - (ii) is used in accordance with the conditions of use and within any maximum residue limits specified in Schedule 5;¹¹
 - (iii) does not contain a toxicologically dangerous amount of any element or substance; 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; or

- (v) [Revoked]¹²
- (b) water to which substances regulating acidity or alkalinity may have been added; or
- (c) food substances which possess solvent properties.

13 Offence of using a non-permitted extraction solvent

No person may use as an extraction solvent in the production of food any extraction solvent that is not a permitted extraction solvent.

14 Offence of placing on the market a non-permitted extraction solvent

- (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 15.

15 Labelling requirements

- (1) Subject to paragraph (2), the following information must appear on the packaging, container or label —
 - (a) the commercial name as indicated in Schedule 5;¹³
 - (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 British Islands;¹⁴
 - (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 sub-paragraphs (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.

PART 4 – ADMINISTRATION AND ENFORCEMENT

16 [Revoked]¹⁵

17 Enforcement authority

It is the duty of the Department to execute and enforce these Regulations and the retained EU Regulations.¹⁶

18 Offences and penalties

- (1) Any person who contravenes regulation 13 or 14(1) commits an offence.
- (2) Any person guilty of an offence under regulation 4, 5, 6, 7, 8(4) or 18(1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

19 Condemnation of food

Where any food is certified by a food analyst as being food which it is an offence to place on the market, that food must be treated for the purposes of section 7 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.

20 Application of various provisions of the Food Act 1996

- (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 31 (offences due to fault of another person);
 - (b) section 32 (defence of due diligence) with the modification that –
 - (i) subsections (2) to (4) apply in relation to an offence under regulation 4, 5, 6, 7, 8(4) or 18(1) as they apply in relation to an offence under section 15 or 16 of the Act; and
 - (ii) in subsection (4) the references to “sale” are deemed to include references to “placing on the market”;
 - (c) section 24(7) (which relates to documentary evidence);
 - (d) section 29(1) (punishment of offences), in so far as it relates to offences under section 27(1) as applied by paragraph (2)(b); and
 - (e) section 30 (offences by bodies corporate).
- (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 EU Regulations and these Regulations –

- (a) section 3 (presumptions that food 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 27(1) (obstruction etc. of officers); and
 - (c) section 27(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b)” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (b).
- (3) Section 28 of the Act (time limit for prosecutions) applies to offences under these Regulations as it applies to offences punishable under section 29(2) of the Act.
- (4) A person who contravenes section 27(2) of the Act (which relates to furnishing false information) as applied by paragraph (2)(c) is liable to the following maximum penalties –
- (a) on summary conviction, to 3 months’ custody, a fine of level 5 on the standard scale or both; or
 - (b) on conviction on information, to 2 years’ custody, a fine or both.

21 Transitional provisions: withdrawal from the EU

- (1) An authorised officer must not serve on a person a compliance notice relating to a failure to comply with regulation 14(2) if –
- (a) a product does not comply with regulation 15(1)(d);
 - (b) the compliance notice would relate to a product that was placed on the market before 1 January 2024; and
 - (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 8.¹⁷

MADE

24 SEPTEMBER 2019

SCHEDULE 1

[Regulations 4 and 8]

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

<i>Provision of Regulation 1333/2008</i>	<i>Subject matter</i>
Article 18.4	Regulation 1333/2008. 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 Authority immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive concerned. ¹⁸

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 English. ¹⁹
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.
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 Authority, inform it of the actual use of the food additive concerned. ²⁰

SCHEDULE 2

[Regulations 5 and 8]

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 domestic list. ²¹
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 Authority to allow an evaluation with regard to the modified production method or characteristics before marketing the flavouring ²²
Article 19.3	Requirement on food business operators to inform the Authority immediately if they become aware of any new scientific or technical information that might affect the assessment of the safety of a flavouring substance. ²³

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 6 and 8]

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
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 Authority immediately of any new scientific or technical information relating to an authorised product which might influence the assessment of its safety ²⁴

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

<i>Provision of Regulation 2065/2003</i>	<i>Subject matter</i>
	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 7 and 8]

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 domestic list of authorised enzymes provided for in Article 17 and in accordance with the prescribed specifications and conditions of use. ²⁵
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 Authority immediately of any new scientific or technical information that might affect its safety assessment. ²⁶
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 Authority to allow an evaluation with regard to the modified production method or characteristics before marketing the enzyme. ²⁷

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.

SCHEDULE 5²⁸

[Regulation 11]

**EXTRACTION SOLVENTS WHICH MAY BE USED DURING THE PROCESSING
OF RAW MATERIALS, OF FOODSTUFFS, OF FOOD COMPONENTS OR OF
FOOD INGREDIENTS****Table 1: Extraction solvents to be used in compliance with good manufacturing
practice for all uses**

Name (1)
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) 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	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
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	2 mg/kg in the roasted coffee and 5 mg/kg in the tea

	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	3 mg/kg in the collagen and collagen derivatives, except gelatine
<p>(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.</p> <p>(2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.</p> <p>(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.</p> <p>(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.</p>		

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
* The combined use of Hexane and Ethylmethylketone is forbidden.	

ENDNOTES

Table of Endnote References

- ¹ The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.
- ² Definition of “Directive 2009/32” revoked by SD2023/0284.
- ³ Definition of “the retained EU Regulations” amended by SD2023/0284.
- ⁴ Para (2) amended by SD2023/0284.
- ⁵ Para (3) amended by SD2023/0284.
- ⁶ Para (4) amended by SD2023/0284.
- ⁷ Reg 10 revoked by SD2023/0284.
- ⁸ Subpara (a) amended by SD2023/0284.
- ⁹ Subpara (b) amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ¹⁰ Para (i) amended by SD2023/0284.
- ¹¹ Para (ii) amended by SD2023/0284.
- ¹² Para (v) revoked by SD2023/0284.
- ¹³ Subpara (a) amended by SD2023/0284.
- ¹⁴ Subpara (d) amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ¹⁵ Reg 16 revoked by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ¹⁶ Reg 17 amended by SD2023/0284.
- ¹⁷ Reg 21 inserted by SD2023/0284.
- ¹⁸ Entry amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ¹⁹ Entry amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ²⁰ Entry amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
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- ²⁶ Entry amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ²⁷ Entry amended by SD2019/0374 with effect from 31/12/2020 at 23:00.
- ²⁸ Sch 5 inserted by SD2023/0284.