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STATUTORY INSTRUMENTS

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**1993 No. 1658**

**FOOD**

**The Extraction Solvents in Food Regulations 1993**

<i>Made</i>	- - - -	<i>28th June 1993</i>
<i>Laid before Parliament</i>		<i>8th July 1993</i>
<i>Coming into force</i>	- -	<i>29th July 1993</i>

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly, in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in exercise of the powers conferred on them by sections 6(4), 16(1) (a), (c) and (e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(1) and of all other powers enabling them in that behalf, hereby make the following Regulations, after consultation in accordance with section 48(4) of the said Act with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations:—

**Title and commencement**

1. These Regulations may be cited as the Extraction Solvents in Food Regulations 1993 and shall come into force on 29th July 1993.

**Interpretation**

2.—(1) In these Regulations, except where the context requires otherwise—

“the Act” means the Food Safety Act 1990;

“extraction procedure” means either—

- (i) the extraction from a food of any ingredient or other component part of that food, including any contaminant which is in or on that food, or
- (ii) the extraction of food from any other article or substance;

“extraction solvent” means any solvent which is used or intended to be used in an extraction procedure and includes in any particular case, further to its use in such a procedure, any substance other than such a solvent but deriving exclusively from such a solvent;

“permitted extraction solvent” means—

- (i) any extraction solvent described in Column 1 (as read, where applicable, with the corresponding entry in Column 2) of Part I of Schedule 1 which satisfies the general purity criteria in relation to extraction solvents specified in the first Note to that Part of

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(1) 1990 c. 16; “the Ministers” is defined in section 4(1) of the Act.

that Schedule and, so far as is not otherwise provided in relation to particular extraction solvents, any mixture of two or more such extraction solvents, and

- (ii) any substance or material described in Column 1 of Part II of Schedule 1 when used (where applicable) in accordance with the conditions specified in Column 2 of that Part;

“residue” includes any residual substance other than an extraction solvent but deriving exclusively from an extraction solvent;

“solvent” means any substance which is capable of dissolving food, or any ingredient or other component part of food, including any contaminant which is in or on a food.

(2) Any reference in these Regulations to a numbered regulation or Schedule shall, unless the reference is to a regulation of, or a Schedule to, specified Regulations, be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

### **Exemption**

3. The provisions of these Regulations shall not apply to any extraction solvent used in the production of any of—

- (a) food additives, or
- (b) vitamins, or
- (c) any other nutritional additive,

save where any such food additive, vitamin or other nutritional additive is specified anywhere in either Schedule 1 or 2.

### **Sale of food containing extraction solvents and of extraction solvents**

4.—(1) Subject as hereinafter provided, no person shall sell, or import into Great Britain from outside the European Economic Community—

- (a) any food having in it or on it any added extraction solvent other than a permitted extraction solvent, or
- (b) any extraction solvent other than a permitted extraction solvent.

(2) No person shall sell, or import into Great Britain from outside the European Economic Community, any food having in it or on it any added permitted extraction solvent specified in Column 1 of Part I or II of Schedule 1 unless—

- (a) it is a food having in it or on it any added permitted extraction solvent listed in items 1 to 8 (or, in the case of olive-pomace oil, any added permitted extraction solvent listed in items 1 to 6 and 8) in Column 1 of Part I of Schedule 1, and the use of such extraction solvent has resulted in the presence in or on that food only of residues of that extraction solvent in technically unavoidable quantities that present no danger to human health; or
- (b) it is a food having in it or on it either or both of the permitted extraction solvents listed in items 9 and 10 in Column 1 of Part I of Schedule 1, and the use of such extraction solvent or extraction solvents has resulted in the presence in or on that food of a residue of such extraction solvent (or a combined residue of such extraction solvents) of not more than 10 milligrams per kilogram of the food; or
- (c) it is a food having in it or on it any added permitted extraction solvent listed in Column 1 of Part II of Schedule 1; or
- (d) in respect of any food specified in Column 1 of Schedule 2 having in it or on it any added permitted extraction solvent listed in items 11 to 14 in Column 1 of Part I of Schedule 1, such extraction solvent—

- (i) is that (or, if applicable, those) specified in Column 2 of Schedule 2 in relation to that food, and
  - (ii) has been used only for the purpose described in Column 3 of Schedule 2 in relation to that food, and
  - (iii) has resulted in residues in or on that food (or, where so specified, in any food in which that food is an ingredient) of the added permitted extraction solvent specified in relation to it (or, as the case may be, to a food in which it is an ingredient) in an amount not exceeding that specified in Column 4 of Schedule 2, or
- (e) in respect of any food containing or consisting of flavourings prepared from natural flavouring materials prepared by using any added permitted extraction solvent listed in items 11 to 19 in Column 1 of Part I of Schedule 1, such use has resulted in the presence in such food of residues of such extraction solvent (or extraction solvents) in an amount not exceeding that specified in Column 2 of Schedule 3 in relation to each such specified extraction solvent,

subject (where appropriate) to the Notes to Part I of Schedule 1.

(3) No person shall sell, or import into Great Britain from outside the European Economic Community, any permitted extraction solvent described in Column 1 of Part I of Schedule 1 unless the information concerning it that is specified in Part I of Schedule 4 is given in accordance with the provisions of Part II of Schedule 4.

#### **Penalties and enforcement**

5.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these Regulations he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Subject to paragraph (3) below, each food authority shall enforce within its area the provisions of these Regulations.

(3) In this regulation “food authority” does not include—

- (a) the council of a district in a non-metropolitan county in England and Wales, and
- (b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple).

#### **Defence in relation to exports**

6. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove that the food or, as the case may be, the extraction solvent in respect of which the offence is alleged to have been committed was intended for export outside the European Economic Community and complied with the importing country’s domestic legislation relevant to the alleged offence.

#### **Application of various provisions of the Food Safety Act 1990**

7. The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of section 14 or 15 of the Act and, unless the context otherwise requires, any reference in them to the Act shall be construed for the purposes of these Regulations as a reference to these Regulations—

- (a) section 2 (extended meaning of “sale” etc.);
- (b) section 3 (presumption that food is intended for human consumption);
- (c) section 20 (offence due to fault of another person);

- (d) section 21 (defence of due diligence);
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 33 (obstruction etc. of officers);
- (g) section 36 (offences by bodies corporate);
- (h) section 44 (protection of officers acting in good faith).

**Transitional provision**

8. It shall not be an offence under these Regulations—

- (a) to sell, or import into Great Britain from outside the European Economic Community—
  - (i) any food having in it or on it any added extraction solvent, or
  - (ii) any extraction solvent, or
- (b) in respect of any permitted extraction solvent, to fail to give the required information specified in Schedule 4,

where the food or extraction solvent in question was put into the packaging in which it is to be sold or imported before 29th July 1993.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

28th June 1993.

*Gillian Shephard*  
Minister of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health:

23rd June 1993

*Cumberlege*  
Parliamentary Under Secretary of State,  
Department of Health

23rd June 1993

*John Redwood*  
Secretary of State for Wales

25th June 1993

*Hector Monro*  
Parliamentary Under Secretary of State, Scottish  
Office

## SCHEDULE 1

Regulation 2(1)

**PART I**  
**PERMITTED EXTRACTION SOLVENTS**

Column 1 Extraction solvent (see note 1)	Column 2 Detailed description of extraction solvent
1. Propane	
2. Butane	
3. Butyl acetate	
4. Ethyl acetate	
5. Ethanol	
6. Carbon Dioxide	
7. Acetone	
8. Nitrous Oxide	
9. Methanol	
10. Propan-2-ol	
11. Hexane (see note 2)	the commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64°C and 70°C
12. Methyl acetate	
13. Ethylmethylketone (see note 2)	containing not more than 50 mg/kg of n-Hexane
14. Dichloromethane	
15. Diethyl ether	
16. Butan-1-ol	
17. Butan-2-ol	
18. Methyl-propan-1-ol	
19. Propan-1-ol	

**Notes**

1. The extraction solvents listed in Column 1 above shall satisfy the following general purity criteria—
  - (a) subject to sub-paragraph (b) below they shall not contain a toxicologically dangerous amount of any element or substance;
  - (b) they shall not contain more than 1 mg/kg of, respectively, arsenic or lead.
2. The combined use of Hexane and Ethylmethylketone is not permitted.

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## PART II

### OTHER SUBSTANCES OR MATERIALS QUALIFYING AS PERMITTED EXTRACTION SOLVENTS WHEN USED AS EXTRACTION SOLVENTS

Column 1 Substance or material	Column 2 Conditions of use as extraction solvents
1. Water	Whether or not other substances regulating acidity or alkalinity have been added to it
2. Any food possessing solvent properties	Where use is as an extraction solvent

### SCHEDULE 2

Regulation 4(2)(d)

#### FOODS IN WHICH ONLY CERTAIN PERMITTED EXTRACTION SOLVENTS MAY BE USED AND THEN ONLY FOR CERTAIN PURPOSES

Column 1 Specified foods	Column 2 Permitted extraction solvent	Column 3 Purpose for which permitted extraction solvent may be added	Column 4 Maximum permitted residue of permitted extraction solvent in the specified food (or, where indicated, in any food in which the specified food is an ingredient)
1. Fats	(a) Hexane, or (b) Ethylmethylketone	(a) in respect of Hexane, the production or fractionation of the fats	5 mg/kg
		(b) in respect of Ethylmethylketone, the fractionation of the fats	
2. Oils	(a) Hexane, or (b) Ethylmethylketone	(a) in respect of Hexane, the production or fractionation of the oils	5 mg/kg
		(b) in respect of Ethylmethylketone, the fractionation of the oils	

Column 1 Specified foods	Column 2 Permitted extraction solvent	Column 3 Purpose for which permitted extraction solvent may be added	Column 4 Maximum permitted residue of permitted extraction solvent in the specified food (or, where indicated, in any food in which the specified food is an ingredient)
3. Cocoa butter	Hexane	production of the cocoa butter	5 mg/kg
4. Protein products	Hexane	preparation of the protein products	10 mg/kg in any food in which the protein products are an ingredient
5. Defatted flours	Hexane	preparation of the defatted flours	10 mg/kg in any food in which the defatted flours are an ingredient
6. Defatted cereal germs	Hexane	preparation of the defatted cereal germs	5 mg/kg
7. Defatted products	soya Hexane	preparation of the defatted soya products	30 mg/kg in the defatted soya product as sold to the final consumer
8. Coffee	(a) Methyl acetate, or (b) Ethylmethylketone, or (c) Dichloromethane, alone or in combination	(a) decaffeination, (b) removal of irritants and bitterings, or both	(a) in respect of methyl acetate or ethylmethylketone, 20 mg/kg, and if these are used in combination their combined total shall not exceed 20 mg/kg  (b) in respect of dichloromethane, 2 mg/kg
9. Tea	(a) Methyl acetate, or (b) Ethylmethylketone, or (c) Dichloromethane, alone or in combination	(a) decaffeination, (b) removal of irritants and bitterings, or both	(a) in respect of methyl acetate or ethylmethylketone, 20 mg/kg, and if these are used in combination their

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Column 1 Specified foods	Column 2 Permitted extraction solvent	Column 3 Purpose for which permitted extraction solvent may be added	Column 4 Maximum permitted residue of permitted extraction solvent in the specified food (or, where indicated, in any food in which the specified food is an ingredient)
			combined total shall not exceed 20 mg/kg
			(b) in respect of dichloromethane, 5 mg/kg
10. Sugar molasses	from Methyl acetate	production of the sugar from molasses	1 mg/kg

SCHEDULE 3

Regulation 4(2)(e)

Maximum residues of extraction solvent permitted in foods due to the use in those foods of food consisting of flavourings prepared from natural flavouring materials by using those extraction solvents.

Column 1 Extraction solvent	Column 2 Maximum residue
Diethyl ether	mg/kg
Hexane	mg/kg
Methyl acetate	mg/kg
Butan-1-ol	mg/kg
Butan-2-ol	mg/kg
Ethyl methyl ketone	mg/kg
Dichloromethane	mg/kg
Methyl propyl ketone	mg/kg
Propan-1-ol	mg/kg

SCHEDULE 4

Regulation 4(3)

LABELLING OF PERMITTED EXTRACTION SOLVENTS

Part I

The following information shall be given in relation to any permitted extraction solvent described in Column 1 of Part I of Schedule 1—

- (a) the name of the permitted extraction solvent as given in Column 1 of Part I of Schedule 1,
- (b) a clear statement that the permitted extraction solvent is of suitable quality for use in an extraction procedure,

- (c) a reference by which the batch or lot of which the permitted extraction solvent in question forms part may be identified,
- (d) the name or business name and address of the manufacturer or packer, or of a seller established within the European Economic Community,
- (e) the net quantity by volume, in metric units of measurement, of the permitted extraction solvent in any container or other packaging in which it is to be sold or imported,
- (f) if such are necessary, any special storage conditions or conditions of use.

## Part II

The information that is specified in Part I of this Schedule—

- (a) shall be given in such a way that it is easily visible, clearly legible and indelible;
- (b) shall be given on the packaging, container or label of the permitted extraction solvent to which it relates or, in the case of the information specified in sub-paragraphs (c) to (f) in that Part, in the trade documents which relate to the batch or lot of permitted extraction solvents and which accompany or precede its delivery, and
- (c) may, in the case of the information specified in sub-paragraph (e) in that Part, be accompanied by an indication using other units of measurement provided that the indication of the metric quantity predominates over any such accompanying indication and is expressed in characters which are no smaller than those in the accompanying indication.

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### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, which apply to Great Britain, come into force on 29th July 1993. They implement the provisions of Council Directive [88/344/EEC](#) (OJNo. L157, 24.6.88, p. 28), as amended by Council Directive [92/115/EEC](#) (OJ No. L409, 31.12.92, p. 31), on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

The principal provisions of these Regulations—

- (a) define extraction solvents (regulation 2) and list permitted extraction solvents (regulation 2 and Schedule 1);
- (b) prohibit the sale, or importation into Great Britain from outside the European Economic Community, of—
  - (i) any extraction solvent other than a permitted extraction solvent (regulation 4(1)(b)), and
  - (ii) any food having in it or on it any extraction solvent other than, provided certain conditions are met, a permitted extraction solvent (regulation 4(1)(a) and (2) and Schedules 1, 2 and 3); and
- (c) require, on the sale or importation into Great Britain from outside the European Economic Community of a permitted extraction solvent, that certain information be given (regulation 4(3) and Schedule 4).

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