

## HEALTH (EXTRACTION SOLVENTS IN FOODSTUFFS) REGULATIONS 1995

The Minister for Health, in exercise of the powers conferred on him by sections 5 of the Health Act, 1947 (No. 28 of 1947), section 54 of that Act as amended by the European Communities (Health Act, 1947 Amendment of sections 54 and 61) Regulations, 1991 (S.I. No. 333 of 1991), subsection (3) of section 38 of the Health Act, 1953 (No. 26 of 1953) and section 6 of the Health Act, 1970 (No. 1 of 1970), after consultation with the Minister for Enterprise and Employment, the Minister for Tourism and Trade and the Minister for Agriculture, Food and Forestry hereby makes the following Regulations:

### REG 1

1. These Regulations may be cited as the Health (Extraction Solvents in Foodstuffs) Regulations, 1995.

### REG 2

2. These Regulations shall come into operation on the 7th day of December, 1995.

### REG 3

3. In these Regulations:

(1) Any reference to an article or Schedule shall, except where otherwise indicated be construed as a reference to an article contained in these Regulations or, as the case may be, to a Schedule thereto; any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article.

"the Act" means the Health Act, 1947;

"authorised officer" means an authorised officer for the purposes of Part IX of the Act;

"food" has the meaning assigned to it in Part V of the Act;

"sell" includes supply, offer or expose for sale and have in possession for sale and cognate words shall be construed accordingly;

(2) For the purposes of these Regulations, the supply of food otherwise than by sale, at, in or from any place where food is supplied shall be deemed to be a sale of that food.

(3) Any reference in these Regulations to an owner or to a person responsible for food shall, in the case of food purchased from a vending machine, shall be construed as a reference—

( a ) where the name and address of the proprietor is stated on the machine and such address is in the State, to the proprietor of the machine;

( b ) in other cases, to the occupier of the premises at or on which the machine stands or to which it is affixed.

### REG 4

4. (1) Subject to sub-article (2), these Regulations shall apply to extraction solvents used or intended for use in the production of foodstuffs or food ingredients.

(2) These Regulations shall not apply to extraction solvents used in

the production of food additives, vitamins and other nutritional additives unless such food additives, vitamins or nutritional additives are listed in the Schedule hereto.

(3) Notwithstanding the provisions of sub-article (2), the use of food additives, vitamins and other nutritional additives shall not result in foodstuffs containing extraction solvent residue levels dangerous to human health.

## REG 5

5. (1) The use of an extraction solvent other than one listed in the Schedule (hereinafter referred to as a "permitted extraction solvent") in the manufacture of foodstuffs or food ingredients is prohibited.

(2) Notwithstanding the provisions of sub-article (1):

(i) the use of water to which substances regulating acidity or alkalinity may have been added, other food substances which possess solvent properties and ethanol as extraction solvents for the manufacture of foodstuffs or food ingredients is permissible;

(ii) the use of substances for diluting or dissolving flavourings as solvents for the extraction of flavourings from natural flavouring materials is permissible;

(iii) the use of Acetone in the refining of olive-pomace oil is prohibited;

(iv) the combined use of Hexane and Ethylmethylketone is prohibited;

(v) the presence of n-Hexane in Ethyl-methylketone must not exceed 50mg/kg.

(3) The use of a permitted extraction solvent in the manufacture of foodstuffs or food ingredients shall be subject to the following conditions of use:

(i) in the case of an extraction solvent listed in Part I of the Schedule, in accordance with good manufacturing practice for all uses.

For the purposes of this paragraph, an extraction solvent is considered as being used in accordance 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.

(ii) in the case of an extraction solvent listed in the first column of Part II of the Schedule, in accordance with the conditions specified in the second column and subject to the maximum residue limits in the extracted foodstuff or food ingredients specified in the third column pertaining to such extraction solvent.

For the purposes of this paragraph, Hexane shall mean a commercial product consisting essentially of a cyclic saturated hydrocarbons containing six carbon atoms and distilling between 64°C and 70°C.

(iii) in the case of an extraction solvent listed in the first column of Part III of the Schedule, in accordance with the maximum residue limits in the foodstuff due to its use in the preparation of flavourings from natural flavouring materials specified in the second column opposite such extraction solvent.

## REG 6

6. Substances and materials permitted for use as extraction solvents in accordance with these Regulations shall not contain:

- (i) a toxicologically dangerous amount of any element or substance, or
- (ii) more than 1 mg/kg of arsenic, or
- (iii) more than 1 mg/kg of lead.

## REG 7

7. (1) Substances intended for use as extraction solvents in foodstuffs shall not be marketed unless there is easily visible and legibly and indelibly written in a conspicuous position on the packaging, containers or labels, the following information:

- ( a ) the commercial name as given in the Schedule;
- ( 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 within the Community;
- ( e ) the net quantity given as units of volume;
- ( f ) if necessary, the special storage conditions or conditions of use.

(2) By way of derogation from sub-article (1), the information specified in paragraphs (c), (d), (e) and (f) of that sub-article may appear merely on the trade documents relating to the batch or lot which are to be supplied with or prior to the delivery.

(3) The particulars required in this article shall be given in the Irish or English language unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such particulars from also being indicated in various other languages.

## REG 8

8. (1) A person shall not import, manufacture, prepare, distribute, market, or sell a foodstuff which breaches any of the provisions of these Regulations on extraction solvents used in the production of foodstuffs and food ingredients.

(2) A person shall not import, manufacture, prepare, distribute, market or sell an extraction solvent which breaches any of the provisions of these Regulations on extraction solvents used in the production of foodstuffs and food ingredients.

## REG 9

9. Where the Minister for Health is of the view that the use or intended use in foodstuffs of any extraction solvent listed in the Schedule or the level of one or more of the components referred to in article 6 of these Regulations, although complying with these Regulations, endangers human health he may take appropriate measures

including the temporary suspension or restriction of trade in that extraction solvent or foodstuffs containing that extraction solvent in order to protect public health.

#### REG 10

10. (1) In any proceedings for an offence under these Regulations it shall be a defence for the person charged to show that the food in respect of which the offence is alleged to have been committed was intended for export and complied with the importing country's domestic food legislation relevant to the alleged offence.  
(2) For the purpose of ensuring compliance with these Regulations the control system established under the provisions of the Health (Official Control of Food) Regulations, 1991 (S.I. No. 332 of 1991) shall apply.

#### REG 11

11. (1) Where a sample of any foodstuff or extraction solvent has been certified under the provisions of the Health (Official Control of Food) Regulations, 1991 not to comply with these Regulations, an authorised officer may seize, remove and detain such foodstuffs as being a foodstuff which is unfit for human consumption.  
(2) With the consent in writing of the owner or person responsible for such foodstuff, an authorised officer may destroy or otherwise dispose of it so as to prevent its use for human consumption.  
(3) An authorised officer who has seized any foodstuff in pursuance of the provisions of this article may, on giving notice in writing to the owner or person responsible for such foodstuff of his intention to do so, apply to a Judge of the District Court for an order directing that such food be destroyed or otherwise disposed of as being a foodstuff which is unfit for human consumption.  
(4) A Judge of the District Court to whom the application is made for an order under sub-article (3) shall, if satisfied that such foodstuff does not comply with these Regulations, order that it be destroyed or otherwise disposed of after such period, not exceeding fourteen days, as may be specified in such order, as being a foodstuff which is unfit for human consumption and an authorised officer shall destroy or dispose of it accordingly.

#### REG 12

12. A person shall give to any authorised officer all reasonable assistance that the officer may require in the performance of his duties under these Regulations and such assistance shall include the giving of information relating to the composition and use of any foodstuff and the identity of the person from whom or the place from which any such foodstuff has been obtained and the person to whom and the place to which it has been consigned or the manner in which it has otherwise been disposed of.

REG 13

13. These Regulations shall be enforced and executed by health boards in their functional areas.

REG 14

14. The Health (Extraction Solvents in Foodstuffs) Regulations, 1993 (S.I. No. 387 of 1993) are hereby revoked.

## SCHEDULE

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

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

Propane

Butane

Butyl acetate

Ethyl acetate

Ethanol

Carbon Dioxide

Acetone

Nitrous oxide

## PART II

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	Production or fractionation of fats and oils and production of cocoa butter	5 mg/kg in the fat or oil or cocoa butter
Methyl acetate	Preparation of protein products and defatted flours in the food containing the protein products and defatted flours	10 mg/kg in the protein products and defatted flours
Methyl acetate	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germ
Methyl acetate	Defatted soya products	30 mg/kg in the soya products as sold to the final consumer
Methyl acetate	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
Ethylmethylketone	Production of sugar from molasses	1 mg/kg in the sugar
Ethylmethylketone	Fractionation of fats and oils	5 mg/kg in the fat or oil
Ethylmethylketone	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	All Uses	10 mg/kg
Propan-2-ol	All Uses	10 mg/kg

### PART III

#### 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  
Cyclohexane 1 mg/kg  
Diethyl ether 2 mg/kg  
Hexane 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  
Methyl-propan-1-ol 1 mg/kg  
Propan-1-ol 1 mg/kg

GIVEN under the Official Seal of the Minister for Health,  
this 2nd day of November, 1995.

MICHAEL NOONAN,  
Minister for Health.

#### EXPLANATORY NOTE.

The Regulations specify by name all the substances which may be used as extraction solvents:

- under conditions of good manufacturing practice (Part I of the Schedule);
- and, to take account of protection of public health, the conditions of use of other extraction solvents (Part II of the Schedule);
- the residues permitted (Part III of the Schedule) in food and food ingredients.

The Regulations implement Council Directive No. 88/344/EEC(1) as amended by Council Directive 92/115/EEC(2) relating to approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients and Directive 94/52/EC(3) of the European Parliament and of the Council amending for the second time Directive 88/344/EEC on the approximation of the laws of Member States on extraction solvents used in the production of foodstuffs and food ingredients.

These Regulations come into effect on 7th December, 1995.

(1) Official Journal of the European Communities OJ No. L157, 24-6-88, pages 28-33.

(2) Official Journal of the European Communities OJ No. L409, 31-12-92, pages 31-32.

(3) Official Journal of the European Communities OJ No. L331/10, 21-12-94.