

# S.I. No. 387/1993 - Health (Extraction Solvents in Foodstuffs) Regulations, 1993.

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S.I. No. 387 of 1993.

HEALTH (EXTRACTION SOLVENTS IN FOODSTUFFS) REGULATIONS, 1993.

In exercise of the powers conferred on the Minister for Health, by sections 5 and 59 of the Health Act, 1947 (No. 28 of 1947), and section 54 of that Act as amended by the European Communities ( Health Act 1947 , Amendment of Sections 54 and 61) Regulations, 1991 (S.I. 333 of 1991), and section 38(3) of the Health Act, 1953 (No. 26 of 1953), which said powers are delegated to me by the Health (Delegation of Ministerial Functions) Order, 1993 ( S.I. No. 62 of 1993 ), I, WILLIAM O'DEA, Minister of State at the Department of Health and, after consultation with the Minister for Enterprise and Employment, the Minister for Tourism and Trade and the Minister for Agriculture, Food and Forestry hereby make the following Regulations:

1. These Regulations may be cited as the Health (Extraction Solvents in Foodstuffs) Regulations, 1993.
2. These Regulations shall come into operation on the 31st day of December, 1993.
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 in the course of a business 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, 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.

4. (1) Subject to sub-article (2) of 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;

(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.

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 Ethylmethylketone 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 acyclic 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.

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.

7. (1) Substance 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.

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.

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 foodstuff containing that extraction solvent in order to protect public health.

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.