S.I. No. 141/2000 — European Communities (Extraction Solvents in Foodstuffs and Food Ingredients) Regulations, 2000

Statutory Instrument

S.I. No. 141 of 2000

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I, Micheál Martin, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No 27 of 1972), and for the purpose of giving effect to Council Directive 88/344/EEC[1] of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients, as amended by Council Directive 92/115/EEC[2] of 17 December 1992, Directive 94/52/EC[3] of the European Parliament and of the Council of 7 December 1994 and Directive 97/60/EC[4] of the European Parliament and of the Council of 27 October 1997, hereby make the following Regulations:

1. These Regulations may be cited as the European Communities (Extraction Solvents in Foodstuffs and Food Ingredients) Regulations, 2000.

2. (1) In these Regulations -

"the Act of 1998" means the Food Safety Authority of Ireland Act, 1998 (No.29 of 1998) ;

"Annex" means the Annex to the Directive;

"authorised officer" means a person appointed as an authorised officer under Regulation 15;

"the Directive" means Council Directive 88/344/EEC[1] of 13 June, 1988 on the approximation of the laws of the Member States on extraction solvents

used in the production of foodstuffs and food ingredients, as amended by Council Directive 92/115/EEC[2] of 17 December 1992, Directive 94/52/EC[3] of the European Parliament and of the Council of 7 December 1994 and Directive 97/60/EC[4] of the European Parliament and of the Council of 27 October 1997;

"extraction solvent" means a solvent which is used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which is removed but which may result in the unintentional, but technically unavoidable presence of residues or derivatives in the foodstuff or food ingredient;

"functional area" in relation to a health board established under section 4 (1) of the Health Act, 1970 (No. 1 of 1970) , means the functional area of the health board as specified in the Health Board Regulations, 1970 (S.I. No. 170 of 1970) and in relation to the Eastern Regional Health Authority established under section 7 of the Health (Eastern Regional Health Authority) Act, 1999 (No. 13 of 1999) ("the Act of 1999"), means the functional area of the Authority as specified in section 7(4) of the Act of 1999;

"health board" means a health board established under section 4 (1) of the Health Act, 1970 (No. 1 of 1970) and the Eastern Regional Health Authority established under section 7 of the Act of 1999;

"solvent" means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff;

"to market" includes to supply (whether or not for profit), offer for sale, expose for sale and have in possession for sale, and cognate words shall be construed accordingly.

(2) A word or expression that is used in these Regulations and that is also used in the Directive, has, unless the context otherwise requires, the same meaning in these Regulations that it has in the Directive.

(3) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulation is intended.

(b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

3. (1) Subject to paragraph (2), the extraction solvents to which these Regulations apply and any foodstuffs containing any such extraction solvent may be marketed only if they comply with the provisions laid down in these Regulations and the Directive.

(2) Extraction solvents to which these Regulations apply and any foodstuffs containing any such extraction solvents placed on the market or labelled before the 27th April, 1999, and not complying with these Regulations and

the Directive may be marketed until stocks are used up.

4. (1) Subject to paragraph (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 Annex.

(3) Notwithstanding paragraph (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. Only those substances and materials listed in the Annex may be used as extraction solvents in the manufacture of foodstuffs or food ingredients, under the conditions of use and where appropriate within the maximum residue limits therein specified.

6. Without prejudice to Regulation 5, the Food Safety Authority of Ireland may, on application made to it in writing in that behalf, authorise the use of substances used for diluting or dissolving flavourings as solvents for the extraction of flavourings from natural flavouring materials.

7. Without prejudice to Regulation 5, water, to which substances regulating acidity or alkalinity may have been added, other food substances which possess solvent properties and ethanol may be used as extraction solvents in the manufacture of foodstuffs or food ingredients.

8. The substances and materials listed as extraction solvents in the Annex shall satisfy the following purity criteria:

(a) they shall not contain a toxicologically dangerous amount of any element or substance;

(b) subject to any exceptions deriving from the specific purity criteria referred to in paragraph (c), they shall not contain more than 1 mg/kg of arsenic or more than 1 mg/kg of lead;

(c) they shall satisfy the specific purity criteria determined in accordance with Article 4 of the Directive.

9. Where the Food Safety Authority of Ireland considers that the use in foodstuffs of any extraction solvent listed in the Annex, or the level of one or more of the components referred to in Article 3 of the Directive contained in such extraction solvent, may endanger human health (notwithstanding that it complies with the conditions prescribed in these Regulations), it may take such measures as it considers appropriate, including the temporary suspension or restriction of trade in that extraction solvent or in any foodstuff containing that extraction solvent or component.

10. (1) The substances listed in the Annex and intended for use as extraction solvents in foodstuffs shall not be marketed unless their packaging, containers or labels carry the following information in such a way as to be easily visible,

clearly legible and indelible:

(a) the commercial name as given in the Annex;

(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) Notwithstanding paragraph (1), the information specified in sub- paragraphs (c), (d), (e) and (f) of that paragraph 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) This Regulation is without prejudice to more precise or more extensive Community provisions regarding weights and measures or provisions applying to the classification, packaging and labelling of dangerous substances and preparations.

(4) The information required in this Regulation shall be given in the English language (unless other measures have been taken to ensure that the purchaser is informed) and may, in addition, be given in the Irish language or any other language.

11. (1) These Regulations shall apply equally to extraction solvents used or intended for use in the production of foodstuffs or ingredients imported into the Community.

(2) These Regulations shall not apply to extraction solvents or foodstuffs intended for export outside the Community.

12. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998 and the enforcement provisions contained in that Act shall accordingly apply for the purpose of ensuring compliance with these Regulations.

13. (1) Without prejudice to Regulation 12, the powers contained in the European Communities (Official Control of Foodstuffs) Regulations, 1998 (S.I. No. 85 of 1998), as amended, may be exercised for the purpose of ensuring compliance with these Regulations.

(2) An official certificate given in accordance with sub-article (1) of article 14 of the said Regulations of 1998, as amended, may be adduced in evidence in a prosecution under these Regulations and shall be prima facie evidence of the matters contained therein, until the contrary is proved.

14. Without prejudice to Regulations 12 and 13, before entry into a service contract by a health board with the Food Safety Authority of Ireland under the Act of 1998, the powers contained in Regulations 15 to 19 may be exercised for the purpose of ensuring compliance with these Regulations.

15. (1) The Chief Executive Officer of a health board may appoint in writing such and so many officers of the health board as he or she thinks fit to be authorised officers for the purposes of ensuring compliance with these Regulations in the functional area of the health board.

(2) A person appointed as an authorised officer under the Health (Extraction Solvents in Foodstuffs) Regulation, 1995 (S.I. No. 283 of 1995) and holding office as an authorised officer immediately before the making of these Regulations shall continue in office as if appointed under this Regulation.

(3) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and, when exercising any power conferred on an authorised officer under these Regulations, shall, if requested by any person affected, produce the certificate to that person.

16. (1) An authorised officer may for the purpose of ensuring that these Regulations are being complied with -

(a) require any employee of the health board, a former employee of the health board or any person otherwise currently or previously retained by the health board, or any person who carries or has carried on any trade, business or activity to which these Regulations relate or any person currently or previously employed in connection with that trade, business or activity to produce to him or her such records, and in the case of such information in a non-legible form to reproduce it in a permanent legible form, or to give him or her such information, as the officer may reasonably require in relation to any entries in such records,

(b) at all reasonable times enter any premises, subject to paragraph (2), at which there are reasonable grounds to believe that any trade, business or activity in connection with the production, processing, disposal, manufacture, exportation, importation, storage, distribution, sale, marketing or labelling for the purposes of marketing of any extraction solvent or foodstuff to which these Regulations apply is or has been carried on, or that records in relation to such trade, business or activity are kept, and search and inspect the premises and any extraction solvent, foodstuff, label or records found in or on the premises,

(c) secure for later inspection any premises or any part thereof in which such extraction solvent, foofstuff, label or records are kept or there are reasonable grounds for believing that such extraction solvent, foodstuff, label or records are kept,

(d) require any person in charge thereof or so employed therein, to produce to the officer such records and to give to the officer such information as the officer may reasonably require in relation to any entries in such records,

(e) inspect and take copies of or extracts from any such records (including in the case of information in a non-legible form a copy of or extract from such information in a permanent legible form),

(f) remove and retain the said extraction solvent, foodstuff, labels or records for such period as may be reasonable for further examination or until the conclusion of any legal proceedings,

(g) as regards any extraction solvent or foodstuff or any article or substance used in the manufacture or preparation of a extraction solvent or foodstuff the officer finds at or in a premises, require any person in charge thereof or any person who appears to the officer to be in possession of the extraction solvent or foodstuff or the article or substance, to supply without payment, for test, examination or analysis sufficient samples thereof,

(h) require any person to afford the officer such facilities and assistance within his or her control or responsibilities as are reasonably necessary to enable the officer to exercise any of the powers conferred on an authorised officer under this Regulation,

(i) require a person referred to in subparagraph (a) to give to the officer any information which the officer may reasonably require in regard to the trade, business or activity or in regard to the persons carrying on such trade, business or activity or employed in connection with that trade, business or activity,

(j) require any person referred to in subparagraph (a) by or on whose behalf data equipment is or has been used in relation to a business within the meaning of subparagraph (b) or any person having charge of, or otherwise concerned with the operation of, the data equipment or any associated apparatus or material, to afford the officer all reasonable assistance in relation to its use thereto,

(k) summon, at any reasonable time, any other person being or having been an employee of the health board or retained or having been retained by the health board or employed in connection with the trade, business or activity under examination by the health board to give to the officer any information which the officer may reasonably require in regard to that trade, business or activity and to produce to the officer any records which are in that person's power or control;

(l) examine any procedure connected with the manufacture of an extraction solvent or foodstuff, and

(m) exercise such other powers as may be necessary to ensure that these Regulations are being complied with.

(2) An authorised officer shall not, other than with the consent of the occupier, enter a private dwelling unless he or she has obtained a warrant from the District Court under paragraph (5) authorising such entry.

(3) Where an authorised officer in the exercise of the officer's powers under this

Regulation is prevented from entering any premises an application may be made to the District Court under paragraph (5) for a warrant authorising such entry.

(4) An authorised officer where he considers is necessary, may be accompanied by a member of the Garda Síochána when performing any powers conferred on an authorised officer under this Regulation.

(5) If a judge of the District Court is satisfied on the sworn information of an authorised officer that there are reasonable grounds for suspecting that there is information required by an authorised officer under this Regulation held on or in any premises [or any part of any premises or there is a product which an authorised officer requires to inspect for purposes of these Regulations or that such inspection is likely to disclose evidence of a contravention of these Regulations], the judge may issue a warrant authorising an authorised officer, accompanied, if appropriate, by other authorised officers or by a member of the Garda Síochána, at any time or times within one month from the date of issue of the warrant, on production, if so requested, of the warrant, to enter, if need be by reasonable force, the premises and exercise all or any of the powers conferred on an authorised officer under this Regulation.

(6) An application under paragraph (5) shall be made to the judge of the District Court in whose district court district the premises is situated.

17. (1) Where a sample of any product, article or substance is supplied pursuant to paragraph (1)(g) of Regulation 16 and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into not more than three approximately equal parts each of which he shall mark in such a way as to identify it as a part of the sample taken by the officer. The authorised officer shall mark, seal and fasten each part in such a manner as its nature will permit, forward one part to a laboratory approved under the European Communities (Official Control of Foodstuffs) (Approved Laboratories) Order, 1998 (S.I. No. 95 of 1998), where it may be tested, examined or analysed for the purposes of these Regulations by an approved examiner, within the meaning of the European Communities (Official Control of Foodstuffs) Regulations, 1998, as amended, give or send one part to the seller, owner or person in apparent charge or control of the product, article or substance and retain the third part.

(2) Where an authorised officer takes a sample consisting of a product, article or substance contained in unopened containers and its division into parts—

(a) is not reasonably practicable, or

(b) might affect the composition or impede the proper analysis of the sample,

the provision of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1).

18. (1) The approved examiner within the meaning of Regulation 17(1) or a person

under his direction shall analyse as soon as possible any sample of a product, article or substance submitted to him in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him the result of such analysis. If the sample is found to be diseased, contaminated or otherwise unfit for human consumption, the form of certificate set out in the Schedule to these Regulations or a certificate in like form shall be used.

(2) An official certificate given in accordance with paragraph (1) may be adduced in evidence in a prosecution under these Regulations and shall be *prima facie* evidence of the matters contained therein, until the contrary is proved.

19. Where a sample of a product, article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the seller, owner or person in apparent charge or control of such item requests in writing the results of such analysis, the request shall be made to the health board in whose area the sample was taken and the health board shall comply with such request.

20. (1) A person who fails to comply with Regulation 3 shall be guilty of an offence.

(2) A person who falsely represent himself to be an authorised officer shall be guilty of an offence.

(3) A person who -

(a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under Regulation 16, or

(b) fails to comply with a request from an authorised officer under Regulation 16, or

(c) makes a statement to an authorised officer which the person knows is false or misleading,

shall be guilty of an offence.

(4) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,500 or at the discretion of the Court to imprisonment for a term not exceeding six months, or both.

21. Where an offence under these Regulations is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to be attributable to any neglect on the part of any director, manager, secretary or any other officer of such body or a person who was purporting to act in any such capacity, such person shall also be guilty of an offence and shall be liable to be proceeded against and punished as if he were guilty of the first-mentioned offence.

22. An offence under these Regulations may be prosecuted by the health board in whose functional area the offence was committed.

23. (1) The Health (Extraction Solvents in Foodstuffs) Regulation, 1995 (S.I. No. 283 of 1995) are hereby revoked.

(2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations, as appropriate.

Schedule

Form of official certificate to be given by an approved examiner to an authorised officer.

European Communities

(Extraction Solvents in Foodstuffs and Food Ingredients)

Regulations, 2000

Certificate of Analysis

To (1) .....

I, the undersigned (2) .....

being the Approved Examiner for the purpose of Regulations 17 and 18 of the above Regulations certify that on

the ..... day of .....20.....

a sample marked (3) .....

Date .....

Number .....

Weight or Measure (4) .....

was submitted to me by you and I certify that the sample has been analysed/examined by me or under my direction (5) and as a result I am of the opinion that (6)

Observations : (7)

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this ..... day of ..... 20.....

at (8) .....

Name in BLOCK LETTERS ..... Status .....

Signature .....

Official Stamp

NOTES

GIVEN under my official seal this 25th day of May, 2000

Micheál Martin

_____

Minister for Health and Children

Explanatory Note

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations give effect to Council Directive 88/344/EEC of 13 June 1988 as amended by Council Directive 92/115/EEC, Directive 94/52/EC and Directive 97/60/EC which lay down specific provisions for extraction solvents used or intended for use in the production of foodstuffs or food ingredients.

These Regulations revoke the Health (Extraction Solvents in Foodstuffs) Regulation, 1995 (S.I. No. 283 of 1995).

1 [1] OJ No. L157, 24.6.88, p.28

2 [2] OJ No. L409, 31.12.92, p.31

3 [3] OJ No. L331, 21.12.94, p.10

4 [4] OJ No. L331, 3.12.97, p.7

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(1) Insert the name and address of the person submitting the sample for analysis.

(2) Insert description (i.e. officer of Health Board etc.)

(3) Insert particulars of marking (e.g. name, date etc.)

(4) This may be left unanswered if the sample cannot be conveniently weighed or measured or the weight or measurement is not material to the result of analysis.

(5) State whether the analysis was carried out by an approved examiner or under his direction by deleting appropriate words (“by me” or “under my direction”).

(6) Here the approved examiner should specify the result of the analysis having regard to the provision of relevant legislation.

(7) Here the approved examiner may insert, at his discretion, his opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign

matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he may add any other observations as he may consider relevant.

(8) Insert the name and address of the laboratory carrying out the analysis/examination.