

S.I. No. 119/2010 — European Communities (Extraction Solvents used in the Production of Foodstuffs and Food Ingredients) Regulations 2010.

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Notice of the making of this Statutory Instrument was published in

“Iris Oifigiúil” of 26th March, 2010.

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 (as amended by section 2 of the European Communities Act 2007 (No. 18 of 2007) and section 4 of the European Union Act 2009 (No. 33 of 2009)) of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009¹ on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients, hereby make the following regulations—

PART 1 Preliminary

1. These Regulations may be cited as the European Communities (Extraction Solvents used in the Production of Foodstuffs and Food Ingredients) Regulations 2010.

2. (1) In these Regulations—

“Act of 1998” means the Food Safety Authority of Ireland Act 1998 (No. 29 of 1998);

“Annex” means Annex I to the Directive;

“approved examiner” means

(a) a Deputy Public Analyst located at a Public Analyst’s Laboratory,

(b) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,

(c) a Public Analyst located at a Public Analyst’s Laboratory,

(d) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 20;

“authorised officer” means an authorised officer appointed under section 49 of the Act of 1998;

“Authority” means the Food Safety Authority of Ireland, established under section 9 of the

Act of 1998;

“Directive” means Directive 2009/32/EC of the Council and of the European Parliament of 23 April 2009¹ on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients;

“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;

“General Food Law Regulation” means Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002² laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety;

“Minister” means the Minister for Health and Children;

“official agency” means an official agency carrying out functions under a service contract and acting on behalf of the Authority pursuant to section 48 of the Act of 1998;

“Official Controls Regulation” means Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004³ on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

“official laboratory” means—

- (a) the Public Analyst’s Laboratory, Cork,
- (b) the Public Analyst’s Laboratory, Dublin,
- (c) the Public Analyst’s Laboratory, Galway,
- (d) a laboratory designated by the Minister pursuant to Regulation 20;

“service contract” means a contract entered into between the Authority and an official agency pursuant to section 48 of the Act of 1998;

“solvent” means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in or on that foodstuff.

(2) A word or expression which is used in these Regulations and which is also used in the Directive or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive or in the General Food Law Regulation.

(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 Regulations 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.

(c) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

(d) A reference in these Regulations to an Article is to an Article of the Directive, unless it is indicated that reference to some other instrument is intended.

PART 2 General Provisions

3. Extraction solvents and any foodstuffs containing any such extraction solvent may be placed on the market only if they comply with the provisions laid down in these Regulations and the Directive.

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.

(4) These Regulations shall apply without prejudice to the provisions adopted under more specific European Union rules.

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, water, to which substances regulating acidity or alkalinity may have been added and other food substances which possess solvent properties may be used as extraction solvents in the manufacture of foodstuffs or food ingredients.

7. The substances and materials listed as extraction solvents in the Annex shall:

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

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

(c) satisfy the specific purity criteria adopted in accordance with Article 4(d) of the Directive.

8. (1) Where the Authority, as a result of new information or of a reassessment of existing information made since the adoption of the Directive, has detailed grounds for establishing that the use in foodstuffs of any substance listed in the Annex, or the level of one or more of the components referred to in Regulation 7 contained in such substances, might endanger human health (notwithstanding that it complies with the conditions prescribed in the

Directive), it may temporarily suspend or restrict the application of the provisions in question in the State. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

(2) In the event that safeguard measures are adopted, same may remain in force until the amendments adopted by the European Commission pursuant to subparagraph 3 of Article 5 (3) of the Directive enter into force in the State.

9. (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 particulars in such a way as to be easily visible, clearly legible and indelible:

(a) the commercial name as indicated 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 European Union;

(e) the net quantity given as units of volume;

(f) if necessary, the special storage conditions or conditions of use.

(2) Notwithstanding paragraph (1), it is permissible that the particulars specified in subparagraphs (c), (d), (e) and (f) of that paragraph appear only 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 European Union provisions regarding weights and measures or provisions applying to the classification, packaging and labelling of dangerous substances and mixtures.

(4) Extraction solvents may not be sold within the State if the particulars provided for in this Regulation do not appear in the English language (unless other measures have been taken to ensure that the purchaser is informed) and such particulars may, in addition, be indicated in the Irish language, or any other language.

10. (1) These Regulations shall also apply to extraction solvents used or intended for use in the production of foodstuffs or food ingredients imported into the European Union.

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

PART 3 Enforcement

11. (1) The enforcement of these Regulations and of the Directive shall be carried out in accordance with the provisions of these Regulations.

(2) These Regulations shall be deemed to be food legislation for the purposes of the Act of

1998.

(3) These Regulations shall be enforced by the Authority or by an official agency acting pursuant to a service contract with the Authority, or by both, and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

12. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of an extraction solvent which is intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent.

(2) An authorised officer may, for the purpose of taking a sample of an extraction solvent intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent, open any receptacle.

(3) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of an extraction solvent intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent, which is suspected by him or her to fail to comply with the provisions of these Regulations, he or she may, by notice in writing to the food business operator, or the person in apparent charge or control of such extraction solvent or foodstuff, prohibit their removal except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding 15 working days from the date of the taking of the sample.

13. Where an authorised officer purchases or takes without payment a sample of an extraction solvent intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent with the intention of having it analysed:

(a) he or she shall notify the food business operator or person in apparent charge or control of the extraction solvent or foodstuff forthwith of his or her intention of having the sample analysed;

(b) he or she shall, in the presence of the food business operator or person in apparent charge or control of the extraction solvent or foodstuff, mark, seal and fasten the sample in such a manner as its nature will permit and in such a way that the integrity of the sample is not compromised and forward it to an approved examiner in an official laboratory for analysis;

(c) as soon as is reasonably practicable after he or she has received such a sample, the approved examiner shall issue to the food business operator or person in apparent charge or control of the extraction solvent or foodstuff a certificate in the form set out in Schedule 1, or a certificate in like form, confirming that the integrity of the sample had been preserved;

(d) the approved examiner or a person acting under his or her direction shall prepare and sub-divide the sample;

(e) the enforcement sample, the trade (defence) sample and the referee sample shall be

marked in such a way as to identify them as a part of the sample taken by the authorised officer and the trade (defence) sample shall be forwarded to the food business operator or person in apparent charge or control of the extraction solvent or foodstuff in such a way that the integrity of the sample is not compromised.

14. Authorised officers and the approved examiners shall take all reasonable steps to ensure that samples taken under these Regulations, and all sub-samples derived from such samples, are stored and transported in conditions that offer adequate protection from contamination and avoid any change in composition of the sample, which might arise during transportation or storage.

15. (1) The approved examiner, or a person acting under his or her direction, shall analyse as soon as possible a sub-sample of the sample submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis.

(2) After the sub-sample has been analysed by the approved examiner, or a person acting under his or her direction, a certificate in the form set out in Schedule 2, or a certificate in like form, shall be completed.

(3) An official certificate given in accordance with this Regulation may be adduced in evidence in a prosecution and shall be *prima facie* evidence of the matters contained therein, until the contrary is proved.

16. (1) Where a sample of an extraction solvent intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, the Authority, or an official agency as the case may be, shall draw up a report in accordance with Article 9 of the Official Controls Regulation.

(2) Where the certificate given in accordance with Regulation 15 indicates that there has been non-compliance with these Regulations, the Authority, or the official agency, as the case may be, shall provide the food business operator or person in apparent charge or control of the extraction solvent or foodstuff with a copy of the report referred to in paragraph (1).

17. (1) An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on an extraction solvent intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent.

(2) An authorised officer may examine any procedure connected with the production of a foodstuff or food ingredient which involves the use of extraction solvents.

18. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of an extraction solvent intended for use in the production of foodstuffs or food ingredients, or any foodstuff containing any such extraction solvent which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator or

person in apparent charge or control of the extraction solvent or foodstuff, or in accordance with an order of a judge of the District Court under paragraph (4) of this Regulation, destroy or otherwise dispose of same so as to prevent the food being used for human consumption.

(3) An authorised officer who has seized, removed, detained or directed the withdrawal from the market of such an extraction solvent or foodstuff in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator or person in apparent charge or control thereof of his or her intention to do so, apply to a judge of the District Court for an order directing that such products be destroyed or otherwise disposed of.

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such an extraction solvent or foodstuff fails to comply with these Regulations, order that it be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order, and an authorised officer shall destroy or dispose of the extraction solvent, or the foodstuff accordingly.

19. In the course of his or her duties, an authorised officer may require a person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

20. The Minister may, for the purposes of these Regulations designate, by notice in writing published in *Iris Oifigiúil*:

(a) a laboratory as a laboratory at which samples taken under these Regulations may be analysed, and testing and verification may be carried out, and

(b) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory, engage in analysis, testing and verification for the purposes of these Regulations.

21. (1) A person is guilty of an offence if he or she fails to comply with these Regulations.

(2) Paragraph (1) shall not apply to an authorised officer or an approved examiner acting in the course of his or her duties pursuant to these Regulations.

(3) A person is guilty of an offence if he or she:

(a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under these Regulations;

(b) fails or refuses to state his or her name or address in compliance with a request under these Regulations;

(c) fails to comply with a request or notice from an authorised officer under these Regulations;

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

(e) gives, in purported compliance with a request under these Regulations, a name, an

address or corroborative evidence which is false or misleading.

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

23. (1) A person is guilty of an offence if he or she forges, or utters knowing it to be forged, a certificate of analysis or other document purporting to be issued, granted or given under these Regulations or required for the purposes of these Regulations (hereafter referred to as “a forged document”).

(2) A person is guilty of an offence if he or she alters with intent to defraud or deceive, or utters knowing it to be so altered, a certificate of analysis or other document issued, granted or given under these Regulations, or required for the purposes of these Regulations (hereafter referred to as “an altered document”).

(3) A person is guilty of an offence if he or she, without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a forged or altered document as the case may be.

(4) A person is guilty of an offence if he or she with the intent to defraud or deceive:

(a) tampers with any substance or thing with the result that a sample taken pursuant to these Regulations does not correctly represent the substance sampled, or

(b) tampers or interferes with any sample taken under these Regulations.

(5) A person is guilty of an offence if he or she falsely represents himself or herself to be an authorised officer.

24. (1) For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation.

(2) A person who is guilty of an offence under these Regulations is liable:

(a) on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 3 months, or both, or,

(b) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

(3) No prosecution on indictment shall be taken on foot of these Regulations in respect of an offence that occurred before the entry into force of these Regulations.

25. Notwithstanding section 57 of the Act of 1998, a summary offence under these Regulations may be prosecuted by:

- (a) the Authority, or
- (b) an official agency.

PART 4 Revocations

26. (1) The European Communities (Extraction Solvents in Foodstuffs and Food Ingredients) Regulations 2000 (S.I. No. 141 of 2000) are 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 1 Form of official certificate to be issued by an approved examiner to the food business operator, or the person in apparent charge or control of such food in respect of which a sample was taken pursuant to these Regulations.

European Communities (Extraction Solvents Used in the Production of Foodstuffs and Food Ingredients) Regulations 2010

Certificate of Integrity of Sample

To (1)

I, the undersigned (2)

being an Approved Examiner for the purposes of the above Regulations, or a person acting under the direction of an Approved Examiner (3) , certify that on

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

a sample marked (4)

Date.....

Number ..

Weight or Measure (5)

was submitted to me by an authorised officer (6) and I certify that the seal has not been tampered with and that it was delivered to this laboratory with its integrity preserved.

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

at (7)

Name in BLOCK LETTERS.....

Status.....

Signature.....

.....

Official Stamp

NOTES

- (1) Insert the name and address of the food business operator.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst's Laboratory).
- (3) Delete as appropriate.
- (4) Insert particulars of marking (e.g. name, date etc.).
- (5) This may be left unanswered if the sample cannot be conveniently weighed or measured.
- (6) Insert the name of the authorised officer who submitted the sample.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.

SCHEDULE 2 Form of official certificate to be given by an approved examiner to an authorised officer.

European Communities (Extraction Solvents Used in the Production of Foodstuffs and Food Ingredients) Regulations 2010

Certificate of Analysis

To (1)

I, the undersigned (2)

being an approved examiner for the purpose of the above Regulations certify that on

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

a sample marked (3)

Date.....

Number.....

Weight or Measure.....

was submitted to me by you and I certify that the sample was prepared and analysed/examined by me or under my direction (4)

and as a result I am of the opinion that (5)

Observations: (6)

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 (7)

Name in BLOCK LETTERS.....

Status.....

Signature.....

.....

Official Stamp

NOTES

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst's Laboratory).
- (3) Insert particulars of marking (e.g. name, date etc.) and the weight or measure (this may be left unanswered if the sample cannot be conveniently weighed or measured or if the weight or measurement is not material to the result of analysis).
- (4) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.
- (5) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.
- (6) Here the approved examiner may insert, at his or her discretion, his or her 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 or she may add any other observations as he or she may consider relevant.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.



GIVEN under my Official Seal,

23 March 2010.

MARY HARNEY,

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 Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. These Regulations revoke and replace the European Communities (Extraction Solvents in Foodstuffs and Food Ingredients) Regulations, 2000, S.I. No. 141 of 2000 .

These Regulations may be cited as the European Communities (Extraction Solvents used in the Production of Foodstuffs and Food Ingredients) Regulations 2010 and they come into effect on the date they were signed.

1 OJ L.141, 06.06.2009, p.3.

2 OJ L 31, 1.2.2002, p. 1.

3 OJ L 165, 30.4.2004, p. 1, as affected by the Corrigendum to Regulation (EC) No 882/2004, OJ L 191, 28.5.2004, p.1.

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