



STATUTORY INSTRUMENTS.

**S.I. No. 440 of 2013**



EUROPEAN UNION (COSMETIC PRODUCTS) REGULATIONS 2013

## EUROPEAN UNION (COSMETIC PRODUCTS) REGULATIONS 2013

I, JAMES REILLY, Minister for Health, 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 full effect to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009<sup>1</sup>, Commission Regulation (EU) No. 344/2013 of 4 April 2013<sup>2</sup> Commission Regulation (EU) No. 655/2013 of 10 July 2013<sup>3</sup> and Commission Regulation (EU) No. 658/2013 of 10 July 2013<sup>4</sup>, hereby make the following regulations:

PART 1  
PRELIMINARY

*Citation*

1. These Regulations may be cited as the European Union (Cosmetic Products) Regulations 2013.

*Interpretation*

2. (1) In these Regulations—

“Act” means the Irish Medicines Board Act 1995, as amended by section 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and the European Communities (Amendment of the Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);

“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 chemist or analyst appointed by the Board;

<sup>1</sup>OJ No. L 342, 22.12.2009, p. 59.

<sup>2</sup>OJ No. L 114, 25.4.2013, p. 1.

<sup>3</sup>OJ No. L 190, 11.7.2013, p. 31.

<sup>4</sup>OJ No. L 190, 11.7.2013, p. 38.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 26th November, 2013.*

“authorised officer” means—

- (a) a person appointed under Regulation 9,
- (b) a person who was appointed under Regulation 19(1) of the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004), until such time as the said appointment is revoked by a relevant person, or
- (c) an officer of Customs and Excise;

“Board” means the Irish Medicines Board;

“CLP Regulation” means Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008<sup>5</sup>, as amended by Commission Regulation (EC) No. 790/2009 of 10 August 2009<sup>6</sup>, Commission Regulation (EU) No. 286/2011 of 10 March 2011<sup>7</sup>, Commission Regulation (EU) No. 618/2012 of 10 July 2012<sup>8</sup>, Commission Regulation (EU) No. 487/2013 of 8 May 2013<sup>9</sup> and Council Regulation (EU) No. 517/2013 of 13 May 2013<sup>10</sup>;

“Commission” means the European Commission;

“compliance notice” means a notice served pursuant to Regulation 12;

“cosmetic product” means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

“distributor” means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the market in the European Economic Area and includes the person engaged in the retail sale or supply of the cosmetic product whether for payment or otherwise;

“end user” means either a consumer or professional using the cosmetic product;

“EU Regulation” means Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009<sup>1</sup>, as amended by Commission Regulation (EU) No. 344/2013 of 4 April 2013<sup>2</sup> and Commission Regulation (EU) No. 658/2013 of 10 July 2013<sup>4</sup>;

<sup>5</sup>OJ No. L 353, 31.12.2008, p. 1.

<sup>6</sup>OJ No. L 235, 5.9.2009, p. 1.

<sup>7</sup>OJ No. L 83, 30.3.2011, p. 1.

<sup>8</sup>OJ No. L 179, 11.7.2012, p. 3.

<sup>9</sup>OJ No. L 149, 1.6.2013, p. 1.

<sup>10</sup>OJ No. L 158, 10.6.2013, p. 1.

“importer” means any natural or legal person established within the European Economic Area, who places a cosmetic product from a third country on the market in the European Economic Area;

“inspect” includes search;

“making available on the market” means any supply of a cosmetic product for distribution, consumption or use on the market in the European Economic Area in the course of a commercial activity, whether in return for payment or free of charge;

“manufacturer” means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

“Minister” means the Minister for Health;

“official laboratory” means—

- (a) Public Analyst’s Laboratory, Cork,
- (b) Public Analyst’s Laboratory, Dublin,
- (c) Public Analyst’s Laboratory, Galway, or
- (d) a laboratory designated by the Board;

“placing on the market” means the first making available of a cosmetic product on the market in the European Economic Area;

“premises” means any place (physical or virtual), ship or other vessel, aircraft, railway wagon or other vehicle or other mobile facility, and includes a container used to transport a cosmetic product or other relevant thing;

“prohibition order” means an order served pursuant to Regulation 13;

“recall” means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;

“record” includes, in addition to a record in writing—

- (a) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in legible or audible form,
- (b) a film, tape or other device in which visual images are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in visual form, and
- (c) a photograph,

and any reference to a copy of a record includes—

- (i) in the case of a record to which paragraph (a) of this definition applies, a transcript of the sounds or signals embodied therein,
- (ii) in the case of a record to which paragraph (b) of this definition applies, a still reproduction of the images embodied therein, and
- (iii) in the case of a record to which paragraphs (a) and (b) of this definition apply, such a transcript together with such a still reproduction;

“relevant person” means—

- (a) the chief executive of the Board, or
- (b) the director general of the Health Service Executive;

“relevant thing” means—

- (a) any cosmetic product, or
- (b) any article or substance used in the manufacture, processing, packaging, labelling, preparation, storage or distribution of any cosmetic product;

“withdrawal” means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain.

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

## PART 2 GENERAL PROVISIONS

### *Responsibility for functions under EU Regulation*

3. (1) The national competent authority for the purposes of the EU Regulation shall be the Board.

(2) The functions of the national competent authority specified in Article 5(2), Article 5(3), Article 6(3), Article 6(5), Article 7, Article 11(3), Article 13(5), Article 23(5), the second paragraph of Article 24, Article 25(1), the first paragraph of Article 25(5), Article 26, Article 27(1) and Article 38 of the EU Regulation may also be performed by the Health Service Executive in accordance with these Regulations.

(3) The Board and the Health Service Executive shall perform market surveillance functions for the purposes of Article 22 of the EU Regulation.

(4) The functions of the State referred to in Article 10(2), Article 20(2), the first, second and fourth paragraphs of Article 22, and Article 35 of the EU Regulation shall be performed by the Board.

(5) The functions of the State referred to in the first paragraph of Article 22 of the EU Regulation may also be performed by the Health Service Executive.

(6) The Board may charge fees for its functions under the EU Regulation in accordance with regulations made under section 13(1) of the Act, read in conjunction with section 4(1)(v) of the Act.

(7) The Board and the Health Service Executive shall agree and submit to the Minister a memorandum of understanding regarding the implementation of the EU Regulation and shall update that memorandum of understanding from time to time.

*Review and assessment of market surveillance activities*

4. (1) For the purposes of compliance with the fourth paragraph of Article 22 of the EU Regulation, the Board shall, with the cooperation of the Health Service Executive, carry out a review and assessment of the functioning of market surveillance activities at least every four years.

(2) The Board shall provide a copy of the results of the review and assessment referred to in paragraph (1) to—

- (a) the Commission,
- (b) the other Member States of the European Economic Area,
- (c) the Minister, and
- (d) the Health Service Executive.

*Poisons centre*

5. For the purposes of the EU Regulation, Beaumont Hospital, Dublin, is the poisons centre in the State.

*Qualifications of person carrying out cosmetic product safety assessment*

6. In carrying out its function, under Article 10(2) of the EU Regulation, of assessing whether persons carrying out a cosmetic product safety assessment, are in possession of evidence of formal qualifications awarded on completion of a course equivalent to one of the courses referred to in that provision, the Board shall assess the evidence on a case by case basis, having regard to the course content and the experience of the person concerned.

*Labelling*

7. (1) Subject to paragraphs (2) and (3), in the case of cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, the information set out in Article 19(1) of the EU Regulation shall appear on the container in which the product is exposed for sale or supply.

(2) In the case of cosmetic products to which paragraph (1) applies, where it is impractical to display the information set out in Article 19(1) of the EU Regulation in the manner provided for in paragraph (1), the information shall—

- (a) be mentioned on an enclosed or attached leaflet, label, tape, tag or card, and
- (b) unless impracticable, be referred to by abbreviated information, or the symbol given in point 1 of Annex VII to the EU Regulation, on the container in which the product is exposed for sale or supply.

(3) In the case of cosmetic products to which paragraph (1) applies, where it is impractical to display the information set out in Article 19(1) of the EU Regulation in the manner provided for in paragraph (1) or (2), the information shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

(4) Subject to Article 19(6) of the EU Regulation, any information required to be displayed in connection with a cosmetic product, whether under this Regulation or under Article 19 of the EU Regulation, shall be in the English language or in both the English language and the Irish language.

*Language of documentation*

8. For the purposes of Articles 5(3), 6(5) and 11(3), the language which can be easily understood by the Board or the Health Service Executive shall be the English language or both the Irish language and the English language.

PART 3  
COMPLIANCE AND ENFORCEMENT

*Authorised officers*

9. (1) For the purposes of ensuring compliance with the EU Regulation and these Regulations, a relevant person—

- (a) may appoint such and so many persons as he or she thinks fit to be authorised officers for the purposes of these Regulations, and
- (b) shall furnish each authorised officer appointed by him or her with a warrant of the authorised officer's appointment.

(2) An authorised officer, other than an authorised officer who is an officer of Customs and Excise, shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of ensuring compliance with the EU Regulation, an authorised officer may—

- (a) subject to paragraph (5), enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he or she has reasonable grounds for believing that—

- (i) any trade, business or activity connected with the manufacture, processing, disposal, export, import, distribution, sale, supply, storage, packaging, labelling or preparation of any relevant thing is or has been carried on, or
  - (ii) books, records or other documents (including documents stored in non-legible form) relating to such trade, business or activity are kept,
- (b) at such premises inspect and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,
- (c) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,
- (d) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—
- (i) the premises,
  - (ii) any relevant thing at the premises, or
  - (iii) any equipment, machinery or plant at the premises,
- as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,
- (e) require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents or records stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under these Regulations,
- (f) purchase or take without payment a sample of any relevant thing found at the premises for the purposes of any test, examination or analysis,
- (g) direct that such relevant thing found at the premises as he or she, upon reasonable grounds, believes contravenes a provision of these Regulations not be sold or distributed or moved from the premises, without his or her consent,
- (h) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records

or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

- (i) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,
- (j) without payment, take samples of any relevant thing, detained pursuant to subparagraph (i), for the purposes of any test, examination, or analysis,
- (k) where the taking of samples of any relevant thing pursuant to subparagraph (f) or (j) is, for whatever reason, not practicable, purchase or take without payment the relevant thing concerned for the purposes of any test, examination or analysis,
- (l) stop any person, vehicle, vessel or container at the premises,
- (m) board and search any such vehicle, vessel or container,
- (n) require the name and address of any person at the premises, including the person to whom a relevant thing is being delivered or who is causing it to be delivered,
- (o) make a record whether in writing, by photography or otherwise,
- (p) inspect and copy or extract information from any data within the meaning of the Data Protection Acts 1988 and 2003,
- (q) require a person, having authority to do so, to break open any container, receptacle or package, or to open any vending machine, or to permit him or her to do so, as he or she may reasonably require for the purposes of his or her functions under these Regulations, or
- (r) require a person, who makes available facilities such as post office boxes, telecommunications or electronic mail addresses or other like facilities, to give him or her such assistance and information as he or she may reasonably require for the purposes of his or her functions under these Regulations in any case where the officer has reasonable grounds for believing that any relevant thing is being supplied by mail.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant under paragraph (6), be accompanied by such number of—

- (a) other authorised officers,
- (b) members of An Garda Síochána, or

(c) persons with expertise relating to any relevant thing,  
as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than—

(a) with the consent of the occupier, or

(b) in accordance with a warrant issued under paragraph (6).

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that—

(a) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(b) a dwelling is occupied in whole or in part by an undertaking engaged in any trade, business or activity referred to in paragraph (3)(a)(i), or

(c) books, records or other documents (including documents stored in non-legible form) referred to in paragraph (3)(a)(ii) are being stored or kept in any dwelling,

may issue a warrant authorising a named authorised officer accompanied by such other authorised officers, members of An Garda Síochána, or persons with expertise relating to any relevant thing, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under paragraph (3)(b) to (r).

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name, date of birth, and the address at which he or she ordinarily resides, and to produce corroborative evidence of same.

(8) Where an authorised officer has reasonable cause to suspect that—

(a) an offence is being or has been committed under these Regulations, or

(b) evidence of an offence or contravention may be, is or has been on or in any premises,

the authorised officer may, in addition to the powers exercisable by him or her under paragraph (3)—

(i) search a person, where the authorised officer considers it necessary,

(ii) seize and detain a vessel, vehicle, container, equipment, machinery or relevant thing, or

- (iii) dispose of a relevant thing, or require the owner or person in charge of or in possession of a relevant thing to deal with or dispose of it (or any other thing used in connection with, or that may have been in contact with, the relevant thing) in a manner that the authorised officer thinks fit.

(9) An authorised officer may dispose of, or cause to be disposed, a relevant thing, or a sample of a relevant thing, taken under this Regulation, in such manner and at such place as the authorised officer considers appropriate in the circumstances of the case.

(10) The costs (including ancillary costs) of any seizure, detention or disposal carried out by the Board or by the Health Service Executive under paragraph (8) or (9) shall be recoverable as a simple contract debt in any court of competent jurisdiction from the manufacturer, responsible person or distributor.

(11) A statement or admission made by a person pursuant to a requirement under paragraph (3) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under Regulation 18(3)(p), (q) or (r)).

(12) Nothing in this Regulation shall be taken to compel the production by any person of a document which he or she would be exempt from producing in proceedings in a court on the ground of legal professional privilege.

#### *Taking of samples*

10. (1) Subject to paragraph (3), where an authorised officer purchases or takes without payment a sample of a relevant thing pursuant to Regulation 9(3)(f) or (j), he or she may—

- (a) divide the sample into 3 approximately equal parts,
- (b) place each part into separate containers, and
- (c) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has divided, sealed and marked a sample of a relevant thing in accordance with paragraph (1), he or she shall—

- (a) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken,
- (b) retain one of the sealed containers, and
- (c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by an approved examiner in an official laboratory or where appropriate for examination by the Board.

(3) Where a relevant thing is contained in a container and its division into parts pursuant to paragraph (1) is, for whatever reason, not practicable, an authorised officer, who wishes to take samples of such relevant things for the purposes of any tests, examination or analysis may take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of paragraph (1), and the provisions of paragraphs (1) and (2) shall apply thereto accordingly.

(4) Where an authorised officer purchases or takes without payment a relevant thing pursuant to Regulation 9(3)(k), he or she may—

- (a) place the relevant thing in a container,
- (b) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that subparagraph, and
- (c) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by an approved examiner.

*Prescribed methods for official testing*

11. (1) The official testing of cosmetic products by, or under the direction of, an approved examiner shall be carried out in accordance with Article 12 of the EU Regulation insofar as the methods referred to in that Article are applicable.

(2) A certificate in the form specified in the Schedule of the results of official testing of cosmetic products carried out in accordance with paragraph (1) shall be provided to—

- (a) the relevant authorised officer,
- (b) the Health Services Executive, and
- (c) the Board.

*Compliance notice*

12. (1) Where an authorised officer is of the opinion that there is non-compliance with a requirement of the EU Regulation, the authorised officer may, following consultation with the chief executive of the Board or the director general of the Health Service Executive, or another officer of the Board or of the Health Service Executive designated for that purpose, serve, or arrange to have served, on the person concerned a notice (“compliance notice”) in accordance with paragraph (2).

(2) A compliance notice shall—

- (a) be signed by the authorised officer issuing it, or the officer consulted in accordance with paragraph (1),
- (b) identify the requirement(s) of the EU Regulation with which there has not been compliance,

- (c) identify the corrective actions to be taken,
  - (d) where appropriate, direct the person on whom the compliance notice is served to ensure that the cosmetic product is not placed or made available on the market until such time as all appropriate measures, including corrective measures, have been taken to bring the product into conformity with the EU Regulation,
  - (e) where appropriate, direct the person on whom the compliance notice is served to inform, without delay, the responsible person designated in respect of the cosmetic product, of the corrective actions to be taken, and
  - (f) give a time period, commensurate with the nature of the risk, within which the responsible person or distributor must take the corrective actions identified in subparagraph (c).
- (3) A compliance notice shall give the person on whom it is served a reasonable period within which he or she may put forward his or her viewpoint on the notice or appeal the notice.
- (4) Where appropriate, the authorised officer shall, without delay, provide a copy of the compliance notice to the responsible person designated in respect of the relevant cosmetic product.
- (5) A compliance notice shall take effect—
- (a) where no appeal is taken, on the expiration of the period referred to in paragraph (3), or
  - (b) where an appeal is taken, on the day next following the day on which the notice is confirmed on appeal or the appeal is withdrawn or on the expiration of the period referred to in paragraph (3), whichever is the later.
- (6) The chief executive of the Board or another officer of the Board designated for that purpose may, for stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the Board.
- (7) The director general of the Health Service Executive, or another officer of the Health Service Executive designated for that purpose, may, for stated reasons, revoke or vary a compliance notice issued by an authorised officer appointed by the Health Service Executive.
- (8) A copy of every compliance notice, and every revocation or variation of a compliance notice, shall be provided within three working days to the Board and to the Health Service Executive.
- (9) In the event of non-compliance or delay by the person on whom a compliance notice has been served, an authorised officer shall, with the approval of the chief executive of the Board, or another officer thereof designated for that

purpose, take whatever measures are considered necessary to ensure compliance with the compliance notice, including the seizure and destruction of the products in question or the making of any arrangements for such seizure or destruction or both.

*Prohibition Order*

13. (1) Where an authorised officer is of the opinion that—

- (a) there is non-compliance with a requirement of the EU Regulation,
- (b) a cosmetic product poses a serious risk to human health, or
- (c) a person has failed to comply with a compliance notice,

the authorised officer may, with the approval of the chief executive of the Board, or another officer of the Board designated for that purpose, serve, or arrange to have served, on the responsible person or distributor concerned an order (“prohibition order”) in accordance with paragraph (2).

(2) A prohibition order shall—

- (a) be signed by the authorised officer issuing it,
- (b) state that the authorised officer is of the opinion that a particular consignment, class, batch of a cosmetic product is not in conformity with the EU Regulation,
- (c) specify the provision or provisions of the EU Regulation with which the cosmetic product is not in compliance and the matters giving rise to the non-compliance,
- (d) where relevant identify the part or parts of the compliance notice with which there has not been compliance, and
- (e) direct the person on whom the prohibition order is served to ensure that the cosmetic product—
  - (i) is not to be placed or made available on the market until such time as all appropriate measures, including corrective measures, have been taken to bring the product into conformity with the EU Regulation,
  - (ii) is prohibited from being placed or made available on the market,
  - (iii) is to be withdrawn or recalled from the market within a specified time-limit, or
  - (iv) is to be destroyed within a specified time limit and in a manner prescribed by the authorised officer or is to be detained for the purposes of destruction by an authorised officer.

- (3) The approval referred to in paragraph (1) may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.
- (4) Where appropriate, the Board shall, without delay, provide a copy of the prohibition order to the responsible person designated in respect of the relevant cosmetic product.
- (5) A prohibition order shall take effect—
- (a) where the prohibition order so declares, immediately the order is received by the person on whom it is served, or
  - (b) in any other case—
    - (i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or
    - (ii) where an appeal is taken, on the day next following the day on which the prohibition order is confirmed on appeal or the appeal is withdrawn or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later.
- (6) The bringing of an appeal against a prohibition order which is to take effect in accordance with paragraph (5)(a) shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the District Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the District Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is disposed of.
- (7) In the event of non-compliance or delay by the person on whom the prohibition order has been served, an authorised officer shall, with the approval of the chief executive or other officer designated in that behalf by the Board, take whatever steps are considered necessary to ensure compliance with the direction given under this paragraph and this may include the seizure and destruction of the products in question or the making of any arrangements for such seizure or destruction or both.
- (8) (a) A person who is aggrieved by a prohibition order may, within the period of seven days beginning on the day on which the prohibition order is served on him or her, appeal against the order to a judge of the District Court in the district court district in which the prohibition order was served in the prescribed manner and in determining the appeal the judge may—
- (i) if he or she is satisfied that in the circumstances of the case it is reasonable to do so, confirm the prohibition order, with or without modification, or

(ii) cancel the prohibition order.

(b) Where on the hearing of an appeal under this paragraph a prohibition order is confirmed, notwithstanding paragraph (6), the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition order for such period as in the circumstances of the case the judge considers appropriate.

(9) A person who appeals against a prohibition order or who applies for a direction suspending the application of the prohibition order under paragraph (6) shall at the same time notify the Board of the appeal or the application and the grounds for the appeal or the application and the Board or the Health Service Executive shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or the application.

(10) The chief executive of the Board may, for stated reasons, revoke or vary a prohibition order made in accordance with this Regulation and the Board shall be notified at the next available meeting of the Board of any such revocation or variation and the reasons therefore.

(11) (a) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application of the Board, by order prohibit the continuance of the activities.

(b) An application to the High Court for an order under this paragraph shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

#### *Emergency measures*

14. (1) Subject to paragraph (2), where the Board is of the opinion that immediate action is necessary in the event of serious risk to human health or where the responsible person or the distributor does not take all appropriate measures in accordance with Article 25(1) or Article 6 of the EU Regulation respectively, it shall, with the assistance of the Health Service Executive, take all appropriate emergency measures to prohibit or restrict the making available on the market of the cosmetic product concerned or to withdraw or to recall the product from the market in the State.

(2) A decision to take emergency measures pursuant to paragraph (1) shall be notified without delay to the responsible person or distributor concerned, stating the exact grounds upon which it is based.

#### *Provisional measures*

15. (1) Subject to paragraph (2), in the case of a cosmetic product made available on the market which meets the requirements listed in Article 25(1) of the EU Regulation, where the Board is of the opinion, or has reasonable grounds

for concern, that the cosmetic product presents or could present a serious risk to human health, it shall, with the assistance of the Health Service Executive, take all appropriate provisional measures in order to ensure that the product concerned is withdrawn or recalled or that its availability is otherwise restricted.

(2) A decision to take provisional measures pursuant to paragraph (1) shall be notified without delay to the responsible person or distributor concerned, stating the exact grounds upon which it is based.

*Maintenance of lists of certain persons and cosmetic products*

16. (1) The Board may, in the interest of public health and consumer protection, keep and maintain lists of—

- (a) the names and addresses of responsible persons, distributors, manufacturers or other persons to whom paragraph (2) applies, together with a description of their trade, business or profession, and
- (b) the names and descriptions of cosmetic products to which paragraph (3) applies.

(2) The persons referred to in paragraph (1) are as follows:

- (a) any person on whom a prohibition order has been served;
- (b) any person placing a cosmetic product on the market in the State in respect of which emergency measures have been taken in accordance with Regulation 14; and
- (c) any responsible person, distributor, manufacturer or person prosecuted for an offence under these Regulations;

(3) The cosmetic products referred to in paragraph (1) are as follows:

- (a) any cosmetic product in respect of which a prohibition order has been served;
- (b) any cosmetic product in respect of which emergency measures have been taken in accordance with Regulation 14; and
- (c) any cosmetic product in respect of which a responsible person, distributor, manufacturer or person has been prosecuted for an offence under these Regulations.

(4) The Board may, at any time and in any form or manner the Board considers appropriate, publish or cause to be published all or any part of the lists referred to in paragraph (1).

*Appeals*

17. (1) A person who is aggrieved by—

- (a) a compliance notice,

- (b) measures taken by an authorised officer pursuant to Regulation 12(9) to ensure compliance with a compliance notice,
- (c) emergency measures taken by the Board pursuant to Regulation 14, or
- (d) provisional measures taken by the Board pursuant to Regulation 15,

may appeal the decision to grant the said notice or take the said measures.

(2) The Board and the Health Service Executive shall jointly publish guidelines in relation to the procedure for appeals under paragraph (1) and shall inform any responsible person, any distributor or any other person who is the subject of a decision in relation to a matter referred to in paragraph (1) of his or her right to appeal and the applicable time limits.

#### PART 4 OFFENCES AND PENALTIES

##### *Offences*

18. (1) A responsible person who—

- (a) makes available on the market a cosmetic product which fails to comply with a safety requirement under Article 3 of the EU Regulation,
- (b) fails to take the corrective measures necessary to bring a cosmetic product into conformity in accordance with Article 5(2) of the EU Regulation, where he or she considers or has reason to believe a cosmetic product that he or she has placed on the market is not in conformity with the EU Regulation,
- (c) fails to—
  - (i) initiate procedures to withdraw a cosmetic product,
  - (ii) initiate procedures to recall a cosmetic product,
  - (iii) ensure that a cosmetic product is withdrawn,
  - (iv) ensure that a cosmetic product is recalled,
  - (v) inform the Board of the initiation of procedures to withdraw a cosmetic product,
  - (vi) inform the Board of the initiation of procedures to recall a cosmetic product,
  - (vii) effectively and accurately inform distributors of the withdrawal of the cosmetic product and the reasons for the withdrawal, or
  - (viii) effectively and accurately inform consumers of the recall of the cosmetic product and the reasons for the recall,

as appropriate, in accordance with Article 5(2) of the EU Regulation, where he or she considers or has reason to believe a cosmetic product that he or she has placed on the market is not in conformity with the EU Regulation,

- (d) fails to inform the Board, where required under Article 5(2), of the details of corrective measures taken in accordance with that provision and the non-compliance in respect of which the measures were taken,
- (e) fails to provide the Board or the Health Service Executive with all required information and documentation following a request by the Board or the Executive under Article 5(3) of the EU Regulation and Regulation 8,
- (f) fails to retain records, in accordance with Article 7 of the EU Regulation, of all distributors to whom a cosmetic product was supplied,
- (g) fails to provide information requested by the Board or the Health Service Executive under Article 7 of the EU Regulation,
- (h) makes available on the market a cosmetic product the manufacture of which did not comply with good manufacturing practice in accordance with Article 8 of the EU Regulation,
- (i) places on the market a cosmetic product which has not undergone a safety assessment in accordance with Article 10 of the EU Regulation,
- (j) places on the market a cosmetic product which is not the subject of a cosmetic product safety report set up in accordance with Annex I to the EU Regulation,
- (k) fails to ensure that the cosmetic product safety report for a cosmetic product which he or she has placed on the market is kept up to date in accordance with Article 10(1)(c) of the EU Regulation,
- (l) fails to keep a product information file, in accordance with Article 11 of the EU Regulation, in respect of a cosmetic product which he or she has placed on the market,
- (m) where the product information file is kept in this State, fails to make it readily accessible to the Board, in accordance with Article 11(3) of the EU Regulation and Regulation 8 of these Regulations,
- (n) fails to perform sampling and analysis of cosmetic products in accordance with Article 12 of the EU Regulation,
- (o) fails to submit information to the Commission, as required under Article 13 of the EU Regulation, before placing a cosmetic product on the market,
- (p) fails to submit information to the Commission, as required under Article 13 of the EU Regulation, in relation to a cosmetic product

which he or she has placed on the market, or fails to provide an update where such information changes,

- (q) fails to submit to the Commission information received from a distributor in accordance with Article 13(4) of the EU Regulation,
- (r) makes available on the market a cosmetic product which contains a prohibited substance listed in Annex II to the EU Regulation except where Article 17 of the EU Regulation applies,
- (s) makes available on the market a cosmetic product which contains a restricted substance listed in Annex III to the EU Regulation, other than in accordance with the corresponding restrictions laid down in that Annex,
- (t) makes available on the market a cosmetic product which contains a colourant other than those listed in Annex IV to the EU Regulation or a colourant listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a colourant,
- (u) makes available on the market a cosmetic product which contains a preservative other than those listed in Annex V to the EU Regulation or a preservative listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a preservative,
- (v) makes available on the market a cosmetic product which contains a UV-filter other than those listed in Annex VI to the EU Regulation or a UV-filter listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a UV-filter,
- (w) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 2, under Part 3 of Annex VI to the CLP Regulation,
- (x) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 1A or 1B, under Part 3 of Annex VI to the CLP Regulation and has not fulfilled the conditions specified in Article 15(2) of the EU Regulation,
- (y) fails to notify the Commission, in accordance with Article 16(3) of the EU Regulation, of a cosmetic product containing nanomaterials he or she has made available on the market, except where—
  - (i) the nanomaterials are used as colorants, UV-filters or preservatives regulated under Article 14 of the EU Regulation,

- (ii) he or she placed the cosmetic product on the European Economic Area market before 11 January 2013 and notified the Commission of the cosmetic product between that date and the 11 July 2013, or
- (iii) the cosmetic product is in conformity with the requirements set out in Annex III to the EU Regulation,
- (z) places on the market a cosmetic product which has not complied with any of the prohibitions related to animal testing contained in Article 18(1) of the EU Regulation,
- (aa) performs within the European Economic Area animal testing of ingredients, combinations of ingredients or finished cosmetic products in order to meet the requirements of the EU Regulation,
- (bb) makes available on the market a cosmetic product which does not comply with any applicable labelling requirement in Article 19(1), (2) or (5) of the EU Regulation or Regulation 7 of these Regulations,
- (cc) makes a cosmetic product available on the market after the date of minimum durability for such cosmetic product, specified in accordance with Article 19(1) of the EU Regulation has passed,
- (dd) makes available on the market, or advertises, a cosmetic product with product claims which do not comply with Article 20 of the EU Regulation or Article 2 of, or the Annex to, Commission Regulation (EU) No. 655/2013 of 10 July 2013<sup>3</sup>,
- (ee) fails to provide the public with access to information, in accordance with Article 21 of the EU Regulation, about a cosmetic product he or she has made available on the market,
- (ff) fails to notify the Board, in accordance with Article 23(1) of the EU Regulation, of any serious undesirable effect connected to a cosmetic product he or she has made available on the market,
- (gg) fails to respond to a reasoned request from the Board in accordance with Article 24 of the EU Regulation,
- (hh) fails to comply with a compliance notice,
- (ii) fails to comply with a prohibition order, or
- (jj) fails to keep readily accessible any information collected pursuant to Article 7a of Council Directive 76/768/EEC of 27 July 1976<sup>11</sup>,

is guilty of an offence.

<sup>11</sup>OJ No. L 262, 27.9.1976, p. 169.

(2) A distributor who—

- (a) makes available on the market a cosmetic product which fails to comply with a safety requirement under Article 3 of the EU Regulation,
- (b) makes available on the market a cosmetic product which is not in conformity with the requirements of the EU Regulation, if he or she considers, has reason to believe, or ought reasonably to know, that the product was not in conformity,
- (c) fails to take the corrective measures necessary to bring a cosmetic product into conformity in accordance with Article 6(3) of the EU Regulation, in respect of a cosmetic product which he or she has made available on the market and which is not in conformity with the EU Regulation,

(d) fails to—

- (i) initiate procedures to withdraw a cosmetic product,
- (ii) initiate procedures to recall a cosmetic product,
- (iii) ensure that a cosmetic product is withdrawn,
- (iv) ensure that a cosmetic product is recalled,
- (v) inform the Board of the initiation of procedures to withdraw a cosmetic product,
- (vi) inform the Board of the initiation of procedures to recall a cosmetic product,
- (vii) effectively and accurately inform other distributors of the withdrawal of the cosmetic product and the reasons for the withdrawal, or
- (viii) effectively and accurately inform consumers of the recall of the cosmetic product and the reasons for the recall,

as appropriate, in accordance with Article 6(3) of the EU Regulation, where he or she considers or has reason to believe a cosmetic product that he or she has placed on the market is not in conformity with the EU Regulation,

- (e) fails to inform, in accordance with Article 6(3) of the EU Regulation, the responsible person and the Board of a cosmetic product which he or she has made available on the market and which presents a risk to human health,
- (f) fails to ensure that a cosmetic product under his or her responsibility is not stored or transported in conditions that jeopardise its compliance with the requirements of the EU Regulation,

- (g) fails to provide the Board or the Health Service Executive with all required information and documentation following a request by the Board or the Health Service Executive under Article 6(5) of the EU Regulation and Regulation 8 of these Regulations,
- (h) fails to retain records, in accordance with Article 7 of the EU Regulation, of—
  - (i) all distributors and responsible persons from whom a cosmetic product was obtained, and
  - (ii) all distributors to whom a cosmetic product was supplied,
- (i) fails to provide information requested by the Board or the Health Service Executive under Article 7 of the EU Regulation,
- (j) fails to submit information to the Commission, as required under Article 13 of the EU Regulation, in relation to a cosmetic product which he or she has placed on the market, or fails to provide an update where such information changes,
- (k) fails to submit information regarding a cosmetic product to the relevant responsible person, as required by Article 13(4) of the EU Regulation,
- (l) makes available on the market a cosmetic product which contains a prohibited substance listed in Annex II to the EU Regulation except where Article 17 of the EU Regulation applies,
- (m) makes available on the market a cosmetic product which contains a restricted substance listed in Annex III to the EU Regulation, other than in accordance with the corresponding restrictions laid down in that Annex,
- (n) makes available on the market a cosmetic product which contains a colourant other than those listed in Annex IV to the EU Regulation or a colourant listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a colourant,
- (o) makes available on the market a cosmetic product which contains a preservative other than those listed in Annex V to the EU Regulation or a preservative listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a preservative,
- (p) makes available on the market a cosmetic product which contains a UV-filter other than those listed in Annex VI to the EU Regulation or a UV-filter listed in that Annex but not used in accordance with

the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a UV-filter,

- (q) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 2, under Part 3 of Annex VI to the CLP Regulation,
- (r) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 1A or 1B, under Part 3 of Annex VI to the CLP Regulation and has not fulfilled the conditions specified in Article 15(2) of the EU Regulation,
- (s) makes available on the market a cosmetic product which does not comply with any applicable labelling requirement in Article 19(1)(a), (e) or (g) or (3) of the EU Regulation or Regulation 7 of these Regulations,
- (t) makes a cosmetic product available on the market after the date of minimum durability for such cosmetic product, specified in accordance with Article 19(1) of the EU Regulation, has passed, or
- (u) makes available on the market, or advertises, a cosmetic product with product claims which do not comply with Article 20 of the EU Regulation or Article 2 of, or the Annex to, Commission Regulation (EU) No. 655/2013 of 10 July 2013<sup>3</sup>,
- (v) fails to notify the Board, in accordance with Article 23(1) of the EU Regulation, of serious undesirable effects connected to a cosmetic product he or she has made available on the market,
- (w) fails to comply with a compliance notice, or
- (x) fails to comply with a prohibition order

is guilty of an offence.

(3) A person who—

- (a) makes available on the market a cosmetic product which fails to comply with a safety requirement under Article 3 of the EU Regulation,
- (b) places a cosmetic product on the market in respect of which a responsible person has not been appointed in accordance with Article 4 of the EU Regulation,
- (c) makes available on the market a cosmetic product which contains a prohibited substance listed in Annex II to the EU Regulation except where Article 17 of the EU Regulation applies,

- (d) makes available on the market a cosmetic product which contains a prohibited substance listed in Annex II to the EU Regulation except where Article 17 of the EU Regulation applies,
- (e) makes available on the market a cosmetic product which contains a restricted substance listed in Annex III to the EU Regulation, other than in accordance with the corresponding restrictions laid down in that Annex,
- (f) makes available on the market a cosmetic product which contains a colourant other than those listed in Annex IV to the EU Regulation or a colourant listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a colourant,
- (g) makes available on the market a cosmetic product which contains a preservative other than those listed in Annex V to the EU Regulation or a preservative listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a preservative,
- (h) makes available on the market a cosmetic product which contains a UV-filter other than those listed in Annex VI to the EU Regulation or a UV-filter listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a UV-filter,
- (i) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 2, under Part 3 of Annex VI to the CLP Regulation,
- (j) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 1A or 1B, under Part 3 of Annex VI to the CLP Regulation and has not fulfilled the conditions specified in Article 15(2) of the EU Regulation,
- (k) places on the market a cosmetic product which has not complied with any of the prohibitions related to animal testing contained in Article 18(1) of the EU Regulation,
- (l) performs within the European Economic Area animal testing of ingredients, combinations of ingredients or finished cosmetic products in order to meet the requirements of the EU Regulation,
- (m) makes available on the market, or advertises, a cosmetic product with product claims which do not comply with Article 20 of the EU Regulation or Article 2 of, or the Annex to, Commission Regulation (EU) No. 655/2013 of 10 July 2013<sup>3</sup>,

- (n) in purported compliance with a request or requirement under these Regulations gives information to the Board or an authorised officer that he or she knows to be false or misleading in any material respect,
- (o) discloses any confidential information to which he or she has access by virtue of these Regulations, otherwise than in accordance with these Regulations,
- (p) obstructs or interferes with the Board, an authorised officer, a member of An Garda Síochána or a person with expertise relating to any relevant thing, in the course of performing a function conferred on him or her by these Regulations or a warrant under Regulation 9(6),
- (q) impedes the performance by a person referred to in subparagraph (p) of such function, or fails or refuses to comply with a request or requirement of, or to answer a question asked by such person pursuant to Regulation 9(3),
- (r) in purported compliance with a request or requirement pursuant to Regulation 9(3), or in answer to a question pursuant to Regulation 9(3), gives information to the officer, member of An Garda Síochána, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,
- (s) falsely represents himself or herself to be an authorised officer,
- (t) 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 (in this Regulation referred to as “a forged document”),
- (u) 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 (in this Regulation referred to as “an altered document”),
- (v) without lawful authority, has in his or her possession a forged document or an altered document,
- (w) tampers with any substance or thing, or
- (x) tampers or interferes with any sample taken under these Regulations

is guilty of an offence.

- (4) A manufacturer of cosmetic products who—
- (a) places a cosmetic product on the market in respect of which a responsible person has not been appointed in accordance with Article 4 of the EU Regulation,
  - (b) makes available on the market a cosmetic product the manufacture of which did not comply with good manufacturing practice in accordance with Article 8 of the EU Regulation,
  - (c) fails to perform sampling an analysis of cosmetic products in accordance with Article 12 of the EU Regulation,
  - (d) places on the market a cosmetic product which has not complied with any of the prohibitions related to animal testing contained in Article 18(1) of the EU Regulation,
  - (e) performs within the European Economic Area animal testing of ingredients, combinations of ingredients or finished cosmetic products in order to meet the requirements of the EU Regulation,
  - (f) makes available on the market a cosmetic product which contains a prohibited substance listed in Annex II to the EU Regulation except where Article 17 of the EU Regulation applies,
  - (g) makes available on the market a cosmetic product which contains a restricted substance listed in Annex III to the EU Regulation, other than in accordance with the corresponding restrictions laid down in that Annex,
  - (h) makes available on the market a cosmetic product which contains a colourant other than those listed in Annex IV to the EU Regulation or a colourant listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a colourant,
  - (i) makes available on the market a cosmetic product which contains a preservative other than those listed in Annex V to the EU Regulation or a preservative listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a preservative,
  - (j) makes available on the market a cosmetic product which contains a UV-filter other than those listed in Annex VI to the EU Regulation or a UV-filter listed in that Annex but not used in accordance with the corresponding conditions laid down in that Annex, including a substance listed in that Annex but not intended to be used as a UV-filter,

- (k) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 2, under Part 3 of Annex VI to the CLP Regulation, or
- (l) makes available on the market a cosmetic product containing a substance which is classified as a CMR substance, of category 1A or 1B, under Part 3 of Annex VI to the CLP Regulation and has not fulfilled the conditions specified in Article 15(2) of the EU Regulation,

is guilty of an offence.

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

(6) 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.

(7) Where the affairs of a body corporate are managed by its members, paragraph (6) applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

#### *Penalties*

19. (1) A person who commits an offence under these Regulations is liable—

- (a) on summary conviction, to a class B fine or imprisonment for a term not exceeding 6 months or both, or
- (b) on conviction on indictment to a fine not exceeding €100,000 or imprisonment for a term not exceeding 3 years, or both.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Board or the Health Service Executive, as the case may be, the costs and expenses, measured by the court, incurred by the Board or the Health Service Executive in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the Board or the Health Service Executive.

(3) On conviction for an offence under these Regulations, the court may, in addition to any other penalty or costs—

- (a) order any relevant thing or any vehicle, vessel or container to which the offence relates to be forfeited to the Board or the Health Service Executive for sale, destruction or disposal as the Board or the Health Service Executive thinks fit, and
- (b) upon application made to it by or on behalf of the Board or the Health Service Executive, order the person convicted of the offence to pay to the Board or the Health Service Executive all or part of the costs of the destruction or disposal of such relevant thing or any vehicle, vessel or container, subject to such conditions, if any, as are specified in the order.

(4) An order for costs and expenses under paragraph (2) or (3) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).

(5) In any proceedings for an offence under these Regulations, where no conviction is recorded, the court may, upon application made to it by or on behalf of the Board or the Health Service Executive, order any relevant thing to which the offence relates to be forfeited to the Board or the Health Service Executive for sale, destruction or disposal.

#### *Proceedings*

20. Proceedings in relation to a summary offence under these Regulations may be brought and prosecuted by—

- (a) the Board, or
- (b) the Health Service Executive.

#### *Evidence in proceedings*

21. (1) In any proceedings for an offence under these Regulations, a certificate in the form specified in the Schedule or a certificate in like form signed by an approved examiner or by an authorised officer of the Board stating the result of any test, examination or analysis of a sample shall, with regard to that sample, be evidence of the matters stated in the certificate unless the contrary is proved.

(2) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who placed that thing on the market, shall, unless the contrary is proved, be evidence that the relevant thing was manufactured or imported, or placed on the market, as the case may be, by the person so named.

(3) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that bears a trademark shall, unless the contrary is proved, be evidence that the thing was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.

(4) In this Regulation, “trademark” has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996).

## PART 5 REVOCATIONS

### *Revocations*

22. The following are revoked:

- (a) the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004),
- (b) the European Communities (Cosmetic Products) (Amendment) Regulations 2005 (S.I. No. 711 of 2005),
- (c) the European Communities (Cosmetic Products) (Amendment No. 2) Regulations 2006 (S.I. No. 64 of 2006),
- (d) the European Communities (Cosmetic Products) (Amendment No. 3) Regulations 2006 (S.I. No. 373 of 2006),
- (e) the European Communities (Cosmetic Products) (Amendment No. 4) Regulations 2006 (S.I. No. 506 of 2006),
- (f) the European Communities (Cosmetic Products) (Amendment No. 5) Regulations 2007 (S.I. No. 235 of 2007),
- (g) the European Communities (Cosmetic Products) (Amendment) Regulations 2008 (S.I. No. 6 of 2008),
- (h) the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2008 (S.I. No. 370 of 2008),
- (i) the European Communities (Cosmetic Products) (Amendment) Regulations 2009 (S.I. No. 191 of 2009),
- (j) the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2009 (S.I. No. 552 of 2009),
- (k) the European Communities (Cosmetic Products) (Amendment) Regulations 2010 (S.I. No. 194 of 2010),
- (l) the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations (S.I. No. 417 of 2010),
- (m) the European Communities (Cosmetic Products) (Amendment) (No. 3) Regulations 2010 (S.I. No. 440 of 2010),
- (n) the European Communities (Cosmetic Products) (Amendment) Regulations 2011 (S.I. No. 723 of 2011),

- (o) the European Communities (Cosmetic Products) (Amendment) Regulations 2012 (S.I. No. 396 of 2012),
- (p) the European Communities (Cosmetic Products) (Amendment) Regulations 2013 (S.I. No. 161 of 2013), and
- (q) the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2013 (S.I. No. 168 of 2013).

*Schedule**Form of official certificate of result of test, examination or analysis of sample*

## CERTIFICATE STATING RESULTS OF TEST, EXAMINATION OR ANALYSIS

This certificate is issued by me, the undersigned, for the purpose of Regulation 11 and 21 of the European Union (Cosmetic Products) Regulations 2013 being—

1. \_\_\_\_\_

I hereby certify that I received on the \_\_\_\_\_ day of \_\_\_\_\_,

from 2. \_\_\_\_\_ of \_\_\_\_\_

a sample of the relevant thing/the relevant thing\*,

being 3. \_\_\_\_\_

for test, examination or analysis; which was undamaged, duly sealed and marked

4. \_\_\_\_\_.

I further certify that the said sample/relevant thing\* has been tested, examined or analysed by me or under my direction and that the results are as follows—

5.

Signature \_\_\_\_\_

Date \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

1. Here insert official title of person signing the certificate.
2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.
3. Here insert the name or description of the relevant thing.
4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.
5. Here insert the relevant results as appropriate.

\* Delete whichever is inapplicable.



GIVEN under my Official Seal,  
20 November 2013.

JAMES REILLY,  
Minister for Health.

EXPLANATORY NOTE

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

These Regulations give full effect to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009, as amended by Commission Regulation (EU) No. 344/2013 of 4 April 2013 and Commission Regulation (EU) No. 658/2013 of 10 July 2013, and to Commission Regulation (EU) No. 655/2013 of 10 July 2013.

These Regulations revoke the European Communities (Cosmetic Products) Regulations 2004 to 2013.

These Regulations may be cited as the European Union (Cosmetic Products) Regulations 2013.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ó  
FOILSEACHÁIN RIALTAIS,  
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2  
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