Statutory Instrument

S.I. No. 425 of 2003

EUROPEAN COMMUNITIES (MANUFACTURE, PRESENTATION AND SALE OF TOBACCO PRODUCTS) REGULATIONS 2003

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European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003

I, Micheál Martin, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Directive 2001/37/EC[1] of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, hereby make the following regulations:-

PART 1

Preliminary

1. These Regulations may be cited as the European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003.

2. (1) In these Regulations:-

"Act of 1999" means the Health (Eastern Regional Health Authority) Act 1999 (No. 13 of 1999);

"Area Health Board" means an Area Health Board established by section 14(1) of the Act of 1999;

"authorised officer" means an authorised officer appointed under Regulation 9;

"Authority" means the Eastern Regional Health Authority established by section 7 of the Act of 1999;

"designated analyst" means an analyst designated by the Minister pursuant to Regulation 12;

"designated laboratory" means a laboratory designated by the Minister pursuant to Regulation 12;

"Directive" means Directive 2001/37/EC[2] of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws,

[1] OJ L 194, 18.7.2001, p. 26.
[2] OJ L 194, 18.7.2001, p. 26.

regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products;

"functional area" means -

- in relation to the Authority, the functional area of the Authority as specified in section 7(4) of the Act of 1999,

- in relation to an Area Health Board, the functional area of each Area Health Board as specified in section 14(4) of the Act of 1999,

- in relation to a health board established under section 4 of the Health Act 1970 (No. 1 of 1970), the functional area of the health board as specified in the Health Board Regulations 1970 (S.I. No. 170 of 1970);

"functions" includes powers and duties and references to the performance of functions include references to the exercise of powers and the performance of duties;

"health board" means either -

(a) a board established under section 4 of the Health Act 1970 (No. 1 of 1970), or

(b) the Authority,

or both;

“import” means importation from a third country;

“ingredient” means any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives;

"Member State" means a Member State of the European Community and shall be construed as including reference to those States that are Contracting Parties to the EEA Agreement;

"Minister" means the Minister for Health and Children;

“nicotine” means nicotinic alkaloids;

“Office” means the Office of Tobacco Control established by section 9 of the Public Health (Tobacco) Act 2002 (No. 6 of 2002);

"place on the market" means -

(a) import,
(b) sell,
(c) offer or expose for sale,
(d) invite the making by a person of an offer to purchase,
(e) distribute free of charge, or
(f) supply for any of those purposes (whether or not for profit)
and cognate words shall be construed accordingly;

"tar" means the raw anhydrous nicotine-free condensate of smoke;

"third country" means a country which is not a Member State;

"tobacco for oral use" means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product;

"tobacco products" means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not.

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

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

PART 2

General Provisions

3. (1) These Regulations concern the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products, taking as a basis a high level of health protection.

(2) A person shall not -

(a) place tobacco products on the market, or

(b) manufacture tobacco products

unless the requirements of these Regulations are complied with.

(3) Notwithstanding the provisions of paragraph (2)(a), tobacco products which do not comply with the requirements of these Regulations may continue to be placed on the market until 30 September 2003.

(4) Notwithstanding the provisions of paragraphs (2)(a) and (3), tobacco products other than cigarettes which do not comply with the requirements of these Regulations may continue to be placed on the market until 30 September 2004.

4. (1) The yield of cigarettes released for free circulation, manufactured or placed on the market in the State shall not be greater than -

- 10 mg per cigarette for tar,
- 1 mg per cigarette for nicotine,
- 10 mg per cigarette for carbon monoxide.

(2) The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

(3) The accuracy of the tar and nicotine indications on packets shall be verified in accordance with ISO standard 8243.

(4) The tests referred to in paragraphs (2) and (3) shall be carried out or verified by a designated laboratory and the results of such tests shall be submitted to the Office.

(5) Tobacco manufacturers or importers shall also carry out such other tests as may be laid down by the Minister in order to asses the yield of other substances produced by their tobacco products on a brand-name-by-brand-

name basis and a type-by-type basis, and in order to assess the effects of those other substances on health, taking into account, *inter alia*, their addictiveness.

(6) Where the Minister lays down other tests pursuant to paragraph (5), such tests shall be carried out or verified by a designated laboratory.

(7) Where the Minister lays down other tests pursuant to paragraph (5), the results of such tests shall be submitted to the Office on an annual basis, or on a less frequent basis with the permission of the Office, where the product specifications have not varied.

(8) The Office shall be informed of changes in the product specifications referred to in paragraph (7).

(9) The Office shall ensure the dissemination, by any appropriate means, of information submitted in accordance with this Regulation with a view to informing consumers and in so doing shall take account, where appropriate, of any information which constitutes a trade secret.

(10) Paragraph (1) shall come into operation on 1 January 2004.

(11) The provisions of the European Communities (Tar Yield of Cigarettes) Regulations 1991 (S.I. No. 327 of 1991) shall continue to apply to any products not complying with paragraph (1) of this Regulation until 31 December 2003.

5. (1) The tar, nicotine and carbon monoxide yields of cigarettes measured in accordance with Regulation 4, shall be printed on one side of the cigarette packet in the English language, so that at least 10% of the corresponding surface is covered.

(2) Each unit packet of tobacco products, except for smokeless tobacco products, must carry the following warnings -

(a) general warnings -

(i) 'Smoking kills', or
(ii) 'Smoking seriously harms you and others around you.'

(b) an additional warning taken from the list set out in Schedule 1.

(3) The general warnings referred to at paragraph (2)(a) shall be rotated in such a way as to guarantee their regular appearance.

(4) The additional warnings referred to at paragraph (2)(b) shall be rotated in such a way as to guarantee their regular appearance.

(5) The general warning referred to at paragraph (2)(a) shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the

exception of additional transparent wrappers, used in the retail sale of the product.

(6) The additional warning referred to at paragraph (2)(b) shall be printed on the other most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

(7) Smokeless tobacco products shall carry the following warning:

'This tobacco product can damage your health and is addictive'.

(8) The warning referred to at paragraph (7) shall be printed on the most visible surface of the unit packet and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

(9) The general warning referred to at paragraph (2)(a) and the warning for smokeless tobacco products referred to at paragraph (7) shall cover not less than 30% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

(10) The additional warning referred to at paragraph (2)(b) shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

(11) Notwithstanding the provisions of paragraphs (9) and (10), in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm^2, the warnings referred to in paragraph (2) shall cover an area of at least 22.5 cm^2 on each surface.

(12) The text of warnings and yield indications required under this Regulation shall be -

(a) printed in black Helvetica bold type on a white background at such a font size as to occupy the greatest possible proportion of the area set aside for the text required;

(b) in lower-case type, except for the first letter of the message and where required by grammar usage;

(c) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;

(d) for products other than those referred to in paragraph (7), surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given;

(e) in the English language;

and such text shall be preceded by the words 'Irish Government Warning' which words shall appear, in the case of products other than those referred to in paragraph (7), outside of the black border referred to at sub-paragraph (d).

(13) The printing of the texts required by this Regulation on the tax stamps of unit packets is prohibited.

(14) The texts required by this Regulation shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet.

(15) In the case of tobacco products other than cigarettes, the texts required by this Regulation may be affixed by means of stickers, provided that such stickers are irremovable.

(16) To ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

(17) The requirements of paragraphs (1) to (16) shall apply in respect of all tobacco products being placed on the market in the State.

(18) The requirements of paragraphs (1) to (16) shall not apply to products manufactured in the State for the purposes of being placed on the market outside the State.

6. (1) Any person manufacturing tobacco products in the State or importing tobacco products into the State, shall submit the following to the Office -

(a) a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type, and

(b) a statement setting out the reasons for the inclusion of such ingredients in those tobacco products, indicating their function and category, and

(c) the toxicological data available to such person regarding such ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, *inter alia*, any addictive effects.

(2) The list referred to at paragraph (1) shall be established in descending order of the weight of each ingredient included in the product.

(3) The information referred to in paragraph (1) shall be provided on a yearly basis.

(4) The Office shall ensure the dissemination of the information provided in accordance with this Regulation by any appropriate means, with a view to informing consumers, and in so doing shall take due account of protection of any information on specific product formulae which constitutes a trade secret.

(5) In particular, the Office shall ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, is made public.

7. (1) With effect from 30 September 2003, and without prejudice to Regulation 5(1), texts, names, trade marks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products.

(2) Without prejudice to the generality of paragraph (1), and with effect from 30 September 2003, the signs listed in Schedule 2 shall not be used on the packaging of tobacco products.

8. (1) A person shall not place tobacco for oral use on the market in the State.

(2) Pending the establishment of the common list of ingredients referred to in Article 12 of the Directive, a person shall not manufacture or place on the market tobacco products containing ingredients which have been identified by the Minister pursuant to Article 13(3) of the Directive as having the effect of increasing the addictive properties of tobacco products.

PART 3

Enforcement

9. (1) The chief executive of the Office shall appoint one or more persons, as he or she considers appropriate, to be an authorised officer or authorised officers for the purposes of these Regulations.

(2) The chief executive officer of a health board shall, in relation to the functional area of that health board, appoint one or more persons, as he or she considers appropriate, to be an authorised officer or authorised officers for the purposes of these Regulations.

(3) The Authority may confer its functions under these Regulations, including its function under Regulation 18, on an Area Health Board pursuant to the Act of 1999 and where it so does, the chief executive officer of such Area Health Board shall, in relation to the functional area of that Area Health Board, appoint one or more persons, as he or she considers appropriate, to be an authorised officer or authorised officers for the purposes of these Regulations.

(4) A person appointed to be an authorised officer under this Regulation shall, on his or her appointment, be furnished -

(a) in the case of a person appointed under paragraph (1), by the Office,

(b) in the case of a person appointed under paragraph (2), by the health board concerned, and

(c) in the case of a person appointed under paragraph (3), by the Area Health Board concerned,

with a warrant of his or her appointment, and when exercising a power conferred by these Regulations shall, if requested by any person thereby affected, produce such warrant to that person for inspection.

(5) An authorised officer may, for the purposes of these Regulations -

(a) at all reasonable times enter, subject to paragraph (7) and (8), 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, exportation, importation, distribution, sale, storage, packaging or labelling of a tobacco product is or has been carried on, or

(ii) records relating to such trade, business or activity are kept,

(b) at such premises inspect and take copies of, any labels, 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 labels, books, records, or 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 examinations, tests, inspections and checks of -

(i) the premises,

(ii) any tobacco product or any article or substance used in the manufacture, processing, labelling, packaging or storage of tobacco products, 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 labels, books, documents or other records (and in the case of documents or records stored in non-legible form, produce to him or her a legible copy 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) take samples of any tobacco product or any article or substance used in the manufacture, processing or storage of tobacco products found at the premises for the purposes of analysis and examination,

(g) direct that such tobacco products found at the premises as he or she, upon reasonable grounds, believes contravene 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 tobacco product, or a substance or article used in the manufacture, processing, labelling, packaging or storage of tobacco products, is found or ordinarily kept, or labels, records, books or 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) take possession of and remove from the premises for examination and analysis any tobacco product or any substance or article used in the manufacture, processing, labelling, packaging or storage of tobacco products found there, and detain them for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations, or

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

(6) When performing a function under these Regulations, an authorised officer may, subject to any warrant under paragraph (9), be accompanied by such number of authorised officers or members of the Garda Síochána as he or she considers appropriate.

(7) 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 (9).

(8) Where an authorised officer in the exercise of the officer's powers under this Regulation is prevented from entering any premises, an application may be made to the District Court under paragraph (9) for a warrant authorising such entry.

(9) On the application of an authorised officer, a judge of the District Court may, if satisfied that there are reasonable grounds for believing that -

(a) a tobacco product or any substance or article used in the manufacture, processing, labelling, packaging or storage of a tobacco product is to be found in any dwelling or premises, or is being or has been subjected to any process or stored in any dwelling or premises,

(b) labels, books, records or other documents (including documents stored in non-legible form) referred to in paragraph (5)(a)(ii) are being stored or kept in any dwelling or premises, or

(c) a dwelling or premises is occupied in whole or in part by an undertaking engaged in any trade, business or activity referred to in paragraph (5)(a)(i),

issue a warrant authorising a named authorised officer accompanied by such other authorised officers or members of the Garda Síochána as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling or premises (as the case may be) and perform the functions of an authorised officer under sub-paragraphs (b), (c), (d), (e), (f), (g), (h), (i) and (j) of paragraph (5).

(10) Any person who obstructs or interferes with an authorised officer or a member of the Garda Síochána in the course of exercising a power conferred on him or her by these Regulations or a warrant under paragraph (9) or impedes the exercise by the officer or member, as the case may be, of such power or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer or member pursuant to this Regulation, or in purported compliance with such request or requirement or in answer to such question gives information to the officer or member that he or she knows to be false or misleading in any material respect, shall be guilty of an offence.

(11) 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 and the address at which he or she ordinarily resides, and, if the authorised officer thinks it necessary, to produce corroborative evidence of his or her name and address.

(12) A person who falsely represents himself or herself to be an authorised officer shall be guilty of an offence.

(13) Where an authorised officer has -

(a) directed that tobacco products not be sold, distributed or moved, pursuant to paragraph 5(g), or

(b) taken possession of and removed any tobacco product pursuant to paragraph 5(i)

he or she may apply to the District Court for an order that any such tobacco product be destroyed, and the judge of the District Court may grant such an order if he or she is satisfied that such product contravenes a provision of these Regulations.

(14) In this Regulation:-
"premises" means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport tobacco products or any article or substance used in the manufacture, processing, labelling, packaging or storage of tobacco products;
"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 of 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 of 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 sub-paragraph (a) applies, a transcript of the sounds or signals embodied therein,

(ii) in the case of a record to which sub-paragraph (b) applies, a still reproduction of the images embodied therein, and

(iii) in the case of a record to which sub-paragraphs (a) and (b) apply, such a transcript together with such a still reproduction.

10. (1) Where the Office is satisfied that an authorised officer appointed by it, or any other member of the staff of the Office has discharged his or her duties in relation to the enforcement of the provisions of these Regulations in a *bona fide* manner, the Office shall indemnify the authorised officer, or such member of the staff of the Office against all actions or claims howsoever arising in respect of the discharge by him or her of his or her duties.

(2) Where a health board is satisfied that an authorised officer appointed by it has discharged his or her duties in relation to the enforcement of the provisions of these Regulations in a *bona fide* manner, the health board shall indemnify the authorised officer against all actions or claims howsoever arising in respect of the discharge by him or her of his or her duties.

(3) Where the Authority has conferred its functions under these Regulations on an Area Health Board and where that Area Health Board is satisfied that an authorised officer appointed by it has discharged his or her duties in relation to the enforcement of the provisions of these Regulations in a *bona fide* manner, the Area Health Board shall indemnify the authorised officer against all actions or claims howsoever arising in respect of the discharge by him or her of his or her duties.

11. (1) Where an authorised officer takes a sample of a tobacco product or a sample of any substance or article used in the manufacturing, processing or storage of tobacco products, he or she shall divide the sample into 3 approximately equal parts, and place each part into separate containers which he or she shall forthwith seal and mark in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied 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 tobacco product, substance or article from which the sample concerned was taken,

(b) retain one of the said sealed containers, and

(c) forward, or cause to be forwarded, one of the sealed containers to a designated laboratory for the purposes of analysis.

(3) Where a tobacco product, or any substance or article used in the manufacturing, processing or storage of a tobacco product is contained in a container and its division into parts is (for whatever reason) not practicable, an authorised officer, who wishes to take samples of such product, substance or article for the purposes of analysis, shall 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.

12. (1) 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 pursuant to Regulation 4 may be carried out (in these Regulations referred to as a "designated laboratory"), 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, and each such person or member is in these Regulations referred to as a "designated analyst"

and the Minister shall monitor the performance of such laboratory.

(2) As soon as practicable after a sample taken by an authorised officer under these Regulations has been received at a designated laboratory it shall be analysed and the composition, the amount and concentration of its ingredients and any other properties of the sample shall be determined by, or under the direction of, a designated analyst at that laboratory.

(3) As soon as practicable after compliance with paragraph (2) a designated analyst engaged in the analysis of samples at the designated laboratory concerned shall forward, or cause to be forwarded, the results of the analysis carried out on the sample concerned -

(a) in the case of a sample forwarded or caused to be forwarded under Regulation 11 by an authorised officer appointed by the Office, to the Office,

(b) in the case of a sample forwarded or caused to be forwarded under that Regulation by an authorised officer appointed by the health board, to the health board concerned, or

(c) in the case of a sample forwarded or caused to be forwarded under that Regulation by an authorised officer appointed by an Area Health Board, to the Area Health Board concerned.

13. (1) In proceedings for an offence consisting of a contravention of these Regulations, a certificate (in the form set out in Schedule 3 to these Regulations or in like form) purporting to be signed by a person employed or engaged at a designated laboratory stating the capacity in which that person is so employed or engaged and stating any one or more of the following, namely -

(a) that the person received a sample submitted to the designated laboratory,

(b) that, for such period as is specified in the certificate, the person had in his or her custody a sample so submitted, or

(c) that the person gave to such other person as is specified in the certificate a sample so submitted,

shall unless the contrary is proved be evidence of the matters stated in the certificate.

(2) In proceedings for an offence consisting of a contravention of these Regulations, a certificate (in the form set out in Schedule 4 to these Regulations or in like form) purporting to be signed by a designated analyst, or by a person acting under the direction of a designated analyst, stating any one or more of the following, namely -

(a) that he or she carried out any procedure for the purpose of detecting the presence of any substance in the sample so submitted, or

(b) that the sample concerned contained such substance or such amount thereof as is specified in the certificate,

shall unless the contrary is proved be evidence of the matters stated in the certificate.

(3) In proceedings for an offence under these Regulations the court may, if it considers that the interests of justice so require, direct that oral evidence of the matters stated in a certificate under this Regulation be given and the court may, for the purpose of receiving oral evidence, adjourn the proceedings to a later date.

(4) In proceedings for an offence under these Regulations, a tobacco product, or a package containing a tobacco product, that purports to bear the name of the manufacturer or importer of that product, shall unless the contrary is proved be evidence that the tobacco product was manufactured or imported, as the case may be, by the person concerned.

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

(6) In this Regulation "trade mark" has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996).

14. (1) It shall be an offence for a person to forge or utter knowing it to be forged a notice, certificate or other document purporting to be issued, granted or given under these Regulations (in this Regulation referred to as "a forged document").

(2) It shall be an offence for a person to alter with intent to defraud or deceive, or to utter knowing it to be so altered a notice, certificate or other document issued, granted or given under these Regulations (in this Regulation referred to as "an altered document").

(3) It shall be an offence for a person to have, without lawful authority, in his or her possession a forged or altered document.

(4) It shall be an offence for a person to aid or abet the commission of an offence under this Regulation.

15. Where a sample is taken by an authorised officer in pursuance of these Regulations for analysis by, or under the direction of, a designated analyst, and where the owner or the person in charge or possession of the product, article or substance being sampled at the time of the taking of the sample, requests in writing the results of such analysis, the request shall be made to the Office, the health board or the Area Health Board concerned and the Office, the health board or the Area Health Board, as the case may be, shall comply with such request.

16. (1) A person who fails to comply with these Regulations shall be guilty of an offence.

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

(3) 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 sub-paragraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation of these Regulations.

(4) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding € 3,000 or at the discretion of the court to imprisonment for a term not exceeding 3 months or both.

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

18. An offence under these Regulations may be prosecuted by the Office or by the health board concerned, or where the Authority has conferred its functions under these Regulations on an Area Health Board pursuant to the Act of 1999, by the Area Health Board concerned.

19. (1) A notice or other document issued pursuant to these Regulations shall be addressed to the person concerned by name, and may be served on or given to the person in one of the following ways -

(a) by delivering it to the person,

(b) by leaving it at the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, at that address,

(c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, to that address, or

(d) where the address at which the person ordinarily resides cannot be ascertained by reasonable inquiry and the notice or other document relates to a place of business, by delivering it to some

person over 16 years of age employed at the place of business or by affixing it in a conspicuous position at or near the place of business.

(2) It shall not be lawful for a person at any time during the period of 12 months after a notice or other document is affixed under sub-paragraph (d) of paragraph (1) to remove, damage or deface the notice or other document without lawful authority.

(3) For the purposes of this Regulation, a company within the meaning of the Companies Acts 1963 to 2001, shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

PART 4

Revocations

20. (1) The European Communities (Tar Yield of Cigarettes) Regulations 1991 (S.I . No. 327 of 1991) are revoked as from 1 January 2004.

(2) Paragraphs (2), (3), (4) and (5) of Regulation 11 of the Tobacco Products (Control of Advertising, Sponsorship and Sales Promotion) Regulations 1991 (S.I. No. 326 of 1991) are revoked.

(3) The Tobacco Products (Control of Advertising, Sponsorship and Sales Promotion) (Amendment) Regulations 1994 (S.I. No. 28 of 1994) are revoked.

(4) Notwithstanding the provisions of paragraphs (2) and (3), those products which are not in compliance with the requirements of these Regulations but which continue to be placed on the market pursuant to paragraphs (3) and (4) of Regulation 3, shall comply with the Regulations revoked under paragraphs (2) and (3) of this Regulation, and for the purposes of this paragraph the Regulations revoked under paragraphs (2) and (3) shall continue to apply as though they had not been revoked.

(5) References to the Regulations revoked under paragraphs (1), (2) and (3) shall be construed as references to these Regulations, as appropriate, and shall be read in accordance with the correlation table in Annex III to the Directive.

Schedule 1

List of Additional Health Warnings [referred to in Regulation 5(2)(b)]

1. Smokers die younger.
2. Smoking clogs the arteries and causes heart attacks and strokes.
3. Smoking causes fatal lung cancer.
4. Smoking when pregnant harms your baby.
5. Protect children: don’t make them breathe your smoke.
6. Your doctor or your pharmacist can help you stop smoking.
7. Smoking is highly addictive, don’t start.
8. Stopping smoking reduces the risk of fatal heart and lung diseases.
9. Smoking can cause a slow and painful death.
10. Get help to stop smoking: Callsave Quitline 1850 201 203.
11. Smoking may reduce the blood flow and cause impotence.
12. Smoking causes ageing of the skin.
13. Smoking can damage the sperm and decreases fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

Schedule 2

List of Prohibited Texts, Names, Trade Marks and Figurative or Other Signs
[referred to in Regulation 7]

Without prejudice to the generality of Regulation 7(1), the following in particular shall not be used on the packaging of tobacco products:-

1. mild
2. ultra mild
3. extra mild
4. super mild
5. light / s
6. lite / s
7. ultra light / s
8. extra light / s
9. super light / s
10. ultimate light / s
11. low tar
12. reduced tar
13. low nicotine
14. reduced nicotine
15. ultra.

Schedule 3

Form of official certificate to be issued by a person employed or engaged at a designated laboratory to the authorised officer who submitted a sample.

European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003

Certificate of Receipt of Sample

To [1] .....

I, the undersigned [2] .....

being a person employed or engaged at a designated laboratory as …… [3], certify that on

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

a sample marked [4] ……

Date .....

Numbers ……..……

Weight or Measure [5] .....….....

was submitted to me by an authorised officer[6] …… and I certify that the sample remained in my custody until the …….. day of …… 20…. when I gave it to …… .

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 authorised officer.

(2) Insert name of person issuing certificate.

(3) Describe position.

(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 designated laboratory carrying out the analysis/examination.

Schedule 4

Form of official certificate to be given by a designated analyst, or by a person acting under his or her direction, following analysis of a sample of a tobacco product or of an article or substance used in the manufacture, processing or storage of tobacco products.

European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003

Certificate of Analysis

To [1] .....

I, the undersigned [2] .....

being a designated analyst for the purpose of the above Regulations, or a person acting under the direction of a designated analyst[3], certify that on

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

a sample marked [4] .....

Date .....

Number .....

Weight or Measure [5] .....

was submitted to me and I certify that the sample was prepared and analysed/examined by me and as a result I am of the opinion that [6]

Observations:[7]

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

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

at [8] .....

Name in BLOCK LETTERS .....

Status .....

Signature .....

_____

Official Stamp

NOTES

(1) Insert the name and address of the Office, health board or Area Health Board, as the case may be (depending on who the authorised officer submitting the sample was appointed by).

(2) Insert name and position within the designated 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 or the weight or measurement is not material to the result of analysis.

(6) Here the designated analyst, or the person acting under his or her direction, should specify the result of the analysis having regard to the provisions of these Regulations.

(7) Here the designated analyst, or the person acting under his or her direction, 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.

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

GIVEN under the Official Seal of the
Minister of Health and Children
this 15th day of September 2003.

L.S.

Micheál Martin, T.D.
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 implement Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

The key measures of the Regulations are summarised below:-

Labelling: Larger health warnings on tobacco products: The area provided for health warnings will be extended to 30% of the external area on the front and 40% of the external area of the back of all tobacco packets and these warnings will be printed in black on a white background. Many of the new warnings, which will be surrounded by a black border, refer to the damage smoking causes to health and to specific diseases caused by smoking.

Cigarette yields: New maximum yields of tar, nicotine and carbon monoxide in cigarettes: As of 1st January 2004, there will be new requirements for the maximum yields in cigarettes which will be 10 mg tar, 10 mg carbon monoxide and 1 mg nicotine. The tar, nicotine and carbon monoxide yields of cigarettes will be printed on one side of a cigarette packet so that at least 10% of the surface area is covered.

Product descriptions: End to "misleading descriptors": As of 30th September 2003, the Regulations prohibit the use of terms to terms such as "low-tar", "mild" and "light" which have the effect of conveying the impression that a particular tobacco product is less harmful than others.

Further product information: The Regulations require tobacco manufacturers and importers to inform the Office of Tobacco Control of all the non-tobacco ingredients by brand, together with relevant toxicological information on an annual basis.

The Regulations will be enforced by authorised officers appointed by the chief executive of the Office of Tobacco Control and by the chief executive officer of a health board. Offences and penalties for non-compliance are provided for in the Regulations.

The Regulations may be cited as the European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003.