#### STATUTORY INSTRUMENTS

## 2002 No. 3041

# The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002

#### Citation and commencement

- 1. These Regulations may be cited as the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 and shall come into force—
  - (a) for the purposes of regulations 3 (maximum tar, nicotine and carbon monoxide yields of cigarettes) and 6(1)(a) (procedure for determining yields of tar, nicotine and carbon monoxide),—
    - (i) as to cigarettes which are or are to be supplied in the United Kingdom or another EEA State and the manufacture of such cigarettes, on 1st January 2004,
    - (ii) as to cigarettes which are or are to be supplied for export outside the European Economic Area and the manufacture of such cigarettes, on 1st January 2007;
  - (b) for the purposes of regulation 11 (product descriptions) on 30th September 2003;
  - (c) for the purposes of regulation 16(a) (revocations) on 1st January 2004;
  - (d) for all other purposes on 31st December 2002.

## Interpretation

- 2.—(1) In these Regulations—
  - "1991 Regulations" means the Tobacco Products Labelling (Safety) Regulations 1991(1);
  - "EEA State" means a State which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(2) as adjusted by the Protocol signed at Brussels on 17th March 1995(3);
  - "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;
  - "ISO4387" means the International Standard entitled Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical cigarette-smoking machine ISO4387: 2000 third edition published by the International Oganisation for Standardisation on 6th April 2000;
  - "ISO8243" means the International Standard entitled Cigarettes—Sampling ISO8243: 1991 second edition published by the International Organisation for Standardisation on 15th October 1991;
  - "ISO8454" means the International Standard entitled Cigarettes—Determination of carbon monoxide in the vapour phase of cigarette smoke—NDIR method ISO8454: 1995 second

<sup>(1)</sup> S.I.1991/1530, amended by S.I. 1993/1947.

<sup>(2)</sup> OJNo. L1, 3.1.94, p.3.

<sup>(3)</sup> OJ No. L1, 3.1.94, p.572.

edition published by the International Organisation for Standardisation on 15th November 1995;

"ISO10315" means the International Standard entitled Cigarettes—Determination of nicotine in smoke condensates—Gas-chromatographic method ISO10315: 2000 second edition published by the International Organisation for Standardisation on 30th March 2000;

"maximum permitted yield" has the meaning set out in regulation 3(2);

"most visible surface", in relation to a rectangular cigarette package, means that surface of the packet which is, or is equal in area to, the largest surface and either—

- (a) faces a person opening that packet; or
- (b) where no surface faces a person opening the packet, carries most prominently the name, trademark or other distinguishing mark of the brand of cigarettes,

and in relation to other packets for tobacco products means the most conspicuous surface;

"nicotine" means nicotinic alkaloids;

"other most visible surface", in relation to a rectangular cigarette packet means the side opposite to the most visible surface;

"packet", in relation to a tobacco product, means any box, package, container, wrapping or other receptacle which contains the product, and in which the product is, or is intended to be, presented for retail supply, excluding any additional transparent outer wrapping which may be discarded on opening and excluding any wrapping of individual cigars or cigarillos, and where any such receptacle is or is to be contained in another receptacle (excluding such outer wrapping), includes each such receptacle;

"producer", in relation to a tobacco product, means a person who in the course of a business—

- (a) manufactures it,
- (b) puts a name, trademark or other distinguishing mark on it, by which he holds himself out to be its manufacturer or originator, or
- (c) imports it into the United Kingdom,

with a view to the product being supplied for consumption in the United Kingdom or through the travel retail sector; and "produce" shall be construed accordingly;

"rectangular", in relation to a packet of cigarettes, denotes a packet having only rectangular surfaces:

"supply", in relation to a tobacco product, means the supply of, or offer or agreement to supply, the tobacco product or the exposure or possession for supply of the tobacco product;

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

"tobacco for oral use" means any product made wholly or partly of tobacco which is—

- (a) intended for oral use, unless it is intended to be smoked or chewed; and
- (b) either—
  - (i) in powder or particulate form or any combination of these forms, whether presented in sachet portions or porous sachets or in any other way, or
  - (ii) presented in a form resembling a food product;

"tobacco product" means a product consisting wholly or partly of tobacco, whether genetically modified or not and intended to be smoked, sniffed, sucked or chewed;

"travel retail sector" means retail outlets in the United Kingdom at which duty free tobacco products may be purchased only by people who are travelling on journeys to destinations outside the European Community; "yield" means the smoke yield per cigarette as determined using ISO4387, ISO8243, ISO8454 and ISO10315 as appropriate and for carbon monoxide allowing a measurement tolerance of plus or minus 20 per cent subject to a minimum measurement tolerance of plus or minus 1 mg.

- (2) In these Regulations—
  - (a) any reference to a Standard is a reference to that Standard as it has effect on the date on which these Regulations are made (including any amendment to that Standard taking effect on or before that date); and
  - (b) where any Standard mentions relevant requirements by reference to another Standard, that reference is to be construed for the purposes of these Regulations as a reference to that other Standard as it has effect on the date on which these Regulations are made (including any amendment to that other Standard taking effect on or before that date).

## Maximum tar, nicotine and carbon monoxide yields of cigarettes

- **3.**—(1) No person shall manufacture or supply any cigarette the yield of which exceeds the maximum permitted yield of tar, nicotine or carbon monoxide.
  - (2) "Maximum permitted yield" means, in the case of—
    - (a) tar, 10 milligrams per cigarette,
    - (b) nicotine, 1 milligram per cigarette, and
    - (c) carbon monoxide, 10 milligrams per cigarette.

## Statement of yields on packets of cigarettes

- **4.**—(1) Subject to the following provisions of these Regulations, a producer of cigarettes shall ensure that each packet of cigarettes which he produces carries a statement of the tar, nicotine and carbon monoxide yields of the cigarettes contained in it.
  - (2) The statement—
    - (a) as to the tar yield shall be shown as a figure rounded to the nearest whole number and expressed in the form "x mg tar";
    - (b) as to the nicotine yield shall be shown as a figure rounded to one decimal place and expressed in milligrams in the form "x.y mg nicotine";
    - (c) as to the carbon monoxide yield shall be shown as a figure rounded to the nearest whole number and expressed in the form "x mg carbon monoxide".
  - (3) The statement of the yields shall—
    - (a) be printed on one side of the packet;
    - (b) cover an area amounting to at least 10 per cent of that side of the packet; and
    - (c) comply with the provisions of regulation 9.

## Testing of cigarettes, samples and information

- **5.**—(1) The Secretary of State may test cigarettes for the purposes of establishing their tar, nicotine and carbon monoxide yields and the accuracy of the statement of those yields on any packet of cigarettes; and in testing the cigarettes the Secretary of State shall select samples in accordance with ISO8243 and conduct the tests in accordance with ISO4387, ISO8454 and ISO10315.
- (2) For the purposes of enabling the Secretary of State to perform his functions under paragraph (1), a producer of cigarettes shall—
  - (a) provide the Secretary of State with such samples, at such times and intervals, and from such sources, as the Secretary of State may reasonably require;

- (b) within the period of one week beginning with the date on which he first supplies a new brand in the United Kingdom notify the Secretary of State of the tar, nicotine and carbon monoxide yields shown and expressed as specified in regulation 4(2);
- (c) before 1st October in each year notify the Secretary of State—
  - (i) of the names of all brands of cigarettes produced and to be produced by him during the 12 months preceding that 1st October and of the tar, nicotine and carbon monoxide yields determined by the producer and shown and expressed as specified in regulation 4(2), and
  - (ii) of the renaming or discontinuance of any brand produced by him within the 12 months preceding that 1st October.
- (3) In this regulation "new brand" includes a brand of cigarettes which has the same composition as, even if it has a different name from, a brand previously produced, and includes a brand which, though having the same name as one previously produced, has a specification which is sufficiently different to bring about a different yield of tar, nicotine or carbon monoxide.

## Procedure for determining yields of tar, nicotine and carbon monoxide

- **6.**—(1) Where the Secretary of State considers, having tested cigarettes in accordance with regulation 5(1) that either—
  - (a) the yield of tar, nicotine or carbon monoxide exceeds the relevant maximum permitted yield; or
  - (b) the tests do not confirm the accuracy of the yield of tar, nicotine or carbon monoxide notified to him by the producer in accordance with regulation 5(2)(b) or (c),

he may notify the producer of that opinion and the yields of tar, nicotine and carbon monoxide he considers to be accurate.

- (2) A producer may within one month beginning with the date on which he receives notification under paragraph (1) inform the Secretary of State in writing that he does not agree with the accuracy of the yields notified to him by the Secretary of State, and where he does so he may make representations with a view to agreeing the correct yield with the Secretary of State.
- (3) Where a producer receives notification under paragraph (1)(b) that the Secretary of State's tests do not confirm the accuracy of the yield of tar, nicotine or carbon monoxide, and he does not inform the Secretary of State in accordance with paragraph (2) that he does not agree with the accuracy of the yields so notified he shall, with effect from the date of expiry of the period of three months beginning with the date on which he receives that notification, provide, as the information which he is required by regulation 4 to provide on packets of those cigarettes, a statement of the tar, nicotine and carbon monoxide yields as notified by the Secretary of State under paragraph (1).
- (4) Where a producer informs and makes representations to the Secretary of State in accordance with paragraph (2) and—
  - (a) they reach agreement within the period of nine months beginning with the date on which the producer received notification under paragraph (1)—
    - (i) the producer shall provide, with effect from three months after the date of the agreement, as the information he is required by regulation 4 to provide, the statement of the tar, nicotine and carbon monoxide yields as so agreed, and
    - (ii) in any proceedings to enforce these Regulations it shall be presumed until the contrary is proved that the tar, nicotine and carbon monoxide yields of cigarettes of the same composition are the yields as so agreed;
  - (b) they fail to reach agreement within the period of nine months beginning with the date on which the producer received notification under paragraph (1), the producer shall provide,

within three months after the date of expiry of that period, as the information which he is required by regulation 4 to provide, the statement of tar, nicotine and carbon monoxide yields as notified by the Secretary of State under paragraph (1), or if different, the statement of tar, nicotine and carbon monoxide yields most recently notified to him before the expiry of that period by the Secretary of State.

## Warnings on tobacco products

- 7.—(1) A producer of a tobacco product other than tobacco for oral use and smokeless tobacco products shall ensure that each packet carries—
  - (a) on the most visible surface, one of the following warnings—
    - (i) "Smoking kills",
    - (ii) "Smoking seriously harms you and others around you"; and
  - (b) on the other most visible surface, an additional warning from the list set out in the Schedule.
- (2) A producer of a tobacco product intended only for supply in the travel retail sector may use the warning "Get help to stop smoking: consult your doctor or pharmacist" on that product instead of the warning numbered 10 in the Schedule.
- (3) A producer of a brand of a tobacco product other than tobacco for oral use and smokeless tobacco products shall ensure that—
  - (a) each of the warnings in paragraph (1)(a) appears on between 47.5 per cent and 52.5 per cent; and
  - (b) subject to paragraphs (2) and (4), each of the warnings set out in the Schedule appears on between 4.16 per cent and 8.33 per cent,

of the total number of packets of tobacco products of that brand which he produces over any period of 12 months.

- (4) In the case of packets other than the packet which immediately encloses the tobacco products, the period for measuring the frequency of the warnings set out in the Schedule as set out in paragraph (3)(b) shall be three years.
- (5) A producer of a smokeless tobacco product shall ensure that its packet carries, on the most visible surface, the warning: "This tobacco product can damage your health and is addictive".

## Size of warnings

- **8.**—(1) Subject to paragraph (2), the warnings required in accordance with—
  - (a) regulation 7(1)(a) and (4) shall cover an area amounting to at least 30 per cent of the external area of the most visible surface of the packet;
  - (b) regulation 7(1)(b) shall cover an area amounting to at least 40 per cent of the external area of the other most visible surface of the packet.
- (2) Where the area of the most visible surface of the packet of a tobacco product other than cigarettes exceeds 75 cm<sup>2</sup> the warnings required in accordance with regulation 7(1)(a) and (b) shall each cover an area of at least 22.5 cm<sup>2</sup>.

## Appearance of warnings and yield statements

- **9.**—(1) On each packet of a tobacco product the text of the yield statements required in accordance with regulation 4 and of the warnings required in accordance with regulation 7 shall be—
  - (a) indelible;

- (b) legible;
- (c) printed in black Helvetica bold type on a white background;
- (d) in a font size consistent throughout the text which ensures that the text occupies the greatest possible proportion of the area specified for the relevant statement or warning in regulation 4(3) or 8;
- (e) in lower-case type, except for the first letter of the text;
- (f) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;
- (g) surrounded by a black border outside the area specified for the relevant statement or warning in regulation 4(3) or 8 which shall—
  - (i) be not less than three millimetres and not more than four millimetres in width, and
  - (ii) not interfere with the text of the yield statement or warning;
- (h) subject to paragraph (2), irremovably printed on the packet.
- (2) In the case of tobacco products other than cigarettes the warnings required in accordance with regulations 4 and 7 may be affixed to the packet by means of an irremovable sticker.
  - (3) The yield statements and warnings shall not—
    - (a) be printed on the tax stamps on any packet of a tobacco product;
    - (b) be hidden, obscured or interrupted by—
      - (i) other written or pictorial matter, or
      - (ii) the opening of the packet.

## **Product identification markings**

- **10.**—(1) A producer of a tobacco product other than tobacco for oral use shall ensure that each packet of that product carries a code marking, whether by batch numbering or otherwise, whereby—
  - (a) the place; and
  - (b) the date; and
  - (c) in the case of a product other than cigars, the time,

of its manufacture may be determined.

(2) A producer of a tobacco product shall provide to the Secretary of State such information as he shall require to enable him to interpret the code marking on that tobacco product for the purpose of any of his functions under these Regulations.

#### **Product descriptions**

- 11.—(1) No person shall supply a tobacco product the packaging of which carries any name, brand name, text, trademark or pictorial or any other representation or sign which suggests that that tobacco product is less harmful to health than other tobacco products.
- (2) Paragraph (1) does not apply where a tobacco product is or is to be supplied for consumption outside the United Kingdom.

## **Provision of further product information**

- **12.**—(1) A producer of tobacco products shall, before 1st October in each year, provide to the Secretary of State for each tobacco product he produces by brand name—
  - (a) a list of all the ingredients of that product which shall—

- (i) include the quantities of those ingredients, and
- (ii) be drawn up in descending order of the weight of those ingredients;
- (b) a statement of the reasons for the inclusion of those ingredients which shall indicate for each ingredient—
  - (i) its function,
  - (ii) its category;
- (c) all toxicological data available to him concerning the ingredients of that tobacco product—
  - (i) in the case of products intended to be burnt, burnt and unburnt,
  - (ii) in the case of products not intended to be burnt, unburnt

which shall for each ingredient—

- (iii) refer in particular to their effects on health,
- (iv) include any effects produced in combination with any of the other ingredients of that product that are not produced by that ingredient alone, and
- (v) take into account any addictive effects;
- (d) information concerning the renaming or discontinuation of any brand produced by him within the 12 months preceding that 1st October.

## **Products imported from other member States**

- 13. A person who imports tobacco products of any brand into the United Kingdom from another EEA State with a view to them being supplied for consumption in the United Kingdom shall be regarded as complying with the requirements of—
  - (a) regulation 3, if it complies with Article 3,
  - (b) regulations 4, 8, 9 and 10, or any of them, if the packet complies with Article 5,

of 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(4) and with any requirements imposed by that EEA State pursuant to that Directive.

#### Prohibitions on supply of non-compliant tobacco products

- **14.**—(1) No person shall supply any tobacco product in respect of which the producer has not complied with any requirement of regulations 4 to 10 which relates to that product.
- (2) Except in relation to products intended for the travel retail sector, paragraph (1) does not apply where a tobacco product is or is to be supplied for consumption outside the United Kingdom.
- (3) Where in relation to a brand of cigarettes the producer is required by regulation 6 to provide on the packet a statement of tar, nicotine and carbon monoxide yields notified to him by, or agreed with, the Secretary of State, the producer shall not, after the expiry of a period of three months beginning with the date of expiry of the period of nine months mentioned in regulation 6(4)(a) or (b) or the date of the agreement, supply a packet of cigarettes which does not provide that statement.

## **Enforcement and penalties**

15.—(1) Notwithstanding that they are made partly in exercise of powers other than those conferred by section 11 of the Consumer Protection Act 1987, these Regulations shall be regarded

for the purposes of enforcement (whether by criminal proceedings or otherwise) as safety regulations as defined in that Act(5) and except as provided by paragraph (2) any provision of these Regulations made under those other powers shall be regarded for those purposes as a safety provision as defined in that Act(6).

- (2) Where a person contravenes the prohibition in regulation 3 on manufacturing cigarettes which exceed the maximum permitted yields that person shall be guilty of an offence and the enforcement provisions of Part IV of the Consumer Protection Act 1987 shall apply to that manufacture as they apply to supply in contravention of a prohibition in safety regulations.
- (3) Subject to paragraph (4) the requirement of regulation 5(2) to provide samples shall, for the purposes of section 12(4)(a) of the Consumer Protection Act 1987, be treated as though it were a requirement to give information.
- (4) A person guilty of an offence under paragraphs (2) or (3) shall be liable on summary conviction to imprisonment for a term not exceeding three months or to a fine not exceeding level 5 on the standard scale.

#### Revocations

- **16.** The following regulations are revoked—
  - (a) the Cigarettes (Maximum Tar Yield) (Safety) Regulations 1992(7);
  - (b) the Tobacco Products Labelling (Safety) Regulations 1991(8);
  - (c) the Tobacco Products Labelling (Safety) Amendment Regulations 1993(9).

## Savings and transitional provisions

- 17.—(1) Regulation 5(2)(c) shall have effect, in relation to the year ending 31st December 2002, for the purposes of the notification by a producer of the carbon monoxide yields of cigarettes produced by him as if, for the words—
  - (a) "before 1st October in each year", there were substituted the words "as soon as reasonably practicable after 30th December 2002, and in any event no later than 28th February 2003"; and
  - (b) "preceding that 1st October" in both places where they appear, there were substituted the words "preceding 31st December 2002".
- (2) Regulation 11 shall not apply to the supply of a tobacco product other than cigarettes produced before 30th September 2003 where the supply takes or is to take place before 30th September 2004.
- (3) Regulation 12 shall have effect, for the purposes of tobacco products produced during the 12 months preceding 1st October 2002, as if, for the words "before 1st October in each year", there were substituted the words "as soon as reasonably practicable after 30th December 2002, and in any event no later than 28th February 2003".
- (4) Regulation 14 shall not apply to the supply of a tobacco product produced before 31st December 2002 where the supply takes or is to take place—
  - (a) in the case of cigarettes, before 30th September 2003;
  - (b) in the case of other tobacco products, before 30th September 2004,

<sup>(5)</sup> See sections 11(1) and 45(1) of that Act.

<sup>(6)</sup> See section 45(1) of that Act.

<sup>(7)</sup> S.I. 1992/2783.

<sup>(8)</sup> S.I. 1991/1530.

<sup>(9)</sup> S.I. 1993/1947.

provided that, notwithstanding regulation 16(b), such cigarettes and other tobacco products comply until those dates with the relevant provisions of the 1991 Regulations, and for the purposes of this paragraph the 1991 Regulations shall continue to apply as though they had not been revoked.

(5) Notwithstanding regulation 16(b), where on 30th September 2003 the procedure set out in regulation 10 of the 1991 Regulations for determining the statement of tar and nicotine yields on cigarette packets has been commenced in relation to a brand of cigarettes by notification by the Secretary of State to its producer, regulation 10 of the 1991 Regulations shall continue to apply to the determination of the tar and nicotine yields of that brand of cigarettes until the statements of tar and nicotine yields are agreed or notified in accordance with regulation 10(3) of the 1991 Regulations as though it had not been revoked.

Signed by authority of the Secretary of State for Health

Hazel Blears
Parliamentary Under Secretary of State,
Department of Health

10th December 2002