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STATUTORY INSTRUMENTS

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**2019 No. 41**

**The Tobacco Products and Nicotine Inhaling Products  
(Amendment etc.) (EU Exit) Regulations 2019**

**PART 3**

Amendment of subordinate legislation

**Amendment of the Tobacco Advertising and Promotion (Brandsharing) Regulations 2004**

**3.—**(1) The Tobacco Advertising and Promotion (Brandsharing) Regulations 2004<sup>(1)</sup> are amended as follows.

(2) In regulation 4, in both paragraph (3)(b) and (7)(b)—

- (a) omit “or has subsequently become”;
- (b) after “European Economic Area”, insert “or which became part of the European Economic Area after that date but before exit day”.

**Amendment of the Standardised Packaging of Tobacco Products Regulations 2015**

**4.—**(1) The Standardised Packaging of Tobacco Products Regulations 2015<sup>(2)</sup> are amended as follows.

(2) In regulation 2—

- (a) in paragraph (1), for the definition of “cross-border distance sale”, substitute—  
““cross-border distance sale”, in relation to a tobacco product, means a distance sale to a consumer where, at the time the consumer orders the product from a retailer, the consumer is located in the United Kingdom and the retailer is established in another country;”;
- (b) in paragraph (7), omit “where the consumer is located in the United Kingdom”.

**Amendment of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015**

**5.—**(1) The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015<sup>(3)</sup> are amended as follows.

(2) In regulation 5(2)—

- (a) in sub-paragraph (a), omit the words “or Article 11” to the end;
- (b) omit sub-paragraph (b).

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(1) [S.I. 2004/1824](#).  
(2) [S.I. 2015/829](#).  
(3) [S.I. 2015/895](#).

**Amendment of the Tobacco and Related Products Regulations 2016**

6.—(1) Subject to regulation 9, the Tobacco and Related Products Regulations 2016(4) are amended as follows.

- (2) In regulation 2(1), for the definition of “retailer”, substitute—
  - ““retailer” means a person who sells, or offers or agrees to sell, a tobacco product or related product to a consumer;”.
- (3) In regulation 3—
  - (a) in paragraph (3), omit “to a consumer located in the United Kingdom”;
  - (b) for paragraph (4), substitute—
    - “(4) In these Regulations, “cross-border distance sale” means a distance sale to a consumer where, at the time the consumer orders a product from a retailer, the consumer is located in the United Kingdom and the retailer is established in another country.”.
- (4) In regulation 5, for paragraph (3)(a), substitute—
  - “(a) one of the text warnings with the corresponding colour photograph, as listed in the picture library in Schedule A1; and”.
- (5) After regulation 5, insert—

**“Revision of text warnings, photographs and technical specifications**

- 5A. Regulations may—
  - (a) amend the text warnings or photographs listed in the picture library in Schedule A1, taking into account scientific and market developments;
  - (b) modify for the purposes of these Regulations the layout, design and proportions specified in the Combined Health Warnings Decision referred to in regulation 5, taking into account different packet shapes.”.
- (6) In regulation 6—
  - (a) omit paragraph (1)(a);
  - (b) in paragraph (1)(b)—
    - (i) for “14”, substitute “13”;
    - (ii) omit “in a specified set”;
  - (c) in paragraph (2)—
    - (i) for “obligations”, substitute “obligation”;
    - (ii) for “are”, substitute “is”;
  - (d) in paragraph (3), omit sub-paragraphs (a) to (c).
- (7) In regulation 7, after paragraph (4), insert—
  - “(5) Regulations may amend the wording of the information message in paragraph (2) (b), taking into account scientific and market developments.”.
- (8) In regulation 8, after paragraph (9), insert—
  - “(10) Regulations may amend paragraphs (5) to (8) as regards the precise position of the general warning and the information message on hand rolling tobacco marketed in pouches, taking into account the different shapes of pouches.”.
- (9) In regulation 9, after paragraph (11), insert—

“(12) Regulations may amend paragraph (1) by omitting reference to one or more of the products listed in that paragraph if there is a substantial change of circumstances for the product concerned.”.

(10) In regulation 10, after paragraph (4), insert—

“(5) Regulations may amend the wording of the health warning in paragraph (2), taking into account scientific developments.”.

(11) In regulation 13, after paragraph (2), insert—

“(3) Regulations may decrease the maximum emission levels specified in paragraph (1), where this is necessary, based on internationally agreed standards.”.

(12) In regulation 14, after paragraph (4), insert—

“(5) Regulations may modify the methods of measurement of tar, nicotine and carbon monoxide emissions from cigarettes, where this is necessary, based on scientific and technical developments or internationally agreed standards.

(6) Any regulations made under paragraph (5) must integrate standards agreed by the parties to the WHO Framework Convention on Tobacco Control<sup>(5)</sup> or by the World Health Organization for measurement methods.”.

(13) In regulation 15, after paragraph (2), insert—

“(3) Regulations may—

- (a) specify whether a tobacco product has a characterising flavour;
- (b) set maximum content levels for additives or a combination of additives that result in a characterising flavour.”.

(14) In regulation 16, after paragraph (3), insert—

“(4) Regulations may—

- (a) specify whether a tobacco product contains additives in quantities that increase the toxic or addictive effect, or the CMR properties of that tobacco product at the stage of consumption to a significant or measureable degree;
- (b) where an additive or a certain quantity thereof has been shown to increase the toxic or addictive effect of a tobacco product, set maximum content levels for that additive.”.

(15) After regulation 16, insert—

**“Regulations: procedures for determining characterising flavour**

**16A.**—(1) Regulations may establish procedures for determining whether a tobacco product—

- (a) has a characterising flavour; or
- (b) contains additives in quantities that increase the toxic or addictive effect, or the CMR properties, of that tobacco product at the stage of consumption to a significant or measureable degree.

(2) Regulations made under paragraph (1) may—

- (a) provide for any determination to be made by—
  - (i) the Secretary of State; or
  - (ii) a person authorised by the Secretary of State for that purpose;

- (b) establish, and provide for the operating procedures of, an independent advisory panel;
- (c) be varied from time to time, including to take account of scientific and market developments in relation to tobacco products;
- (d) make different provision for different cases or descriptions of case, different circumstances, different purposes or different areas;
- (e) be revoked.

(3) Before making regulations under this regulation the Secretary of State must consult such persons (or representatives of such persons) as appear to the Secretary of State to be likely to be substantially affected by them.”.

(16) In regulation 20A(6)—

- (a) in paragraph (1)(b), omit “and to the European Commission”;
- (b) in paragraph (2)(c), omit “the European Commission or”;
- (c) in paragraph (4), omit “or the European Commission”;
- (d) in paragraph (5)—
  - (i) in sub-paragraph (a), after “enterprises”, insert “but with the modifications in paragraph (7)”;
  - (ii) in sub-paragraph (b), omit “or the European Commission”;
- (e) after paragraph (5), insert—

“(6) Regulations may amend the list of additives in Schedule 2, which list must contain additives—

- (a) for which initial indications, research, or regulation in jurisdictions outside the United Kingdom exist suggesting that they have one of the properties set out in regulation 20B(1)(a) to (d); and
- (b) which are amongst the most commonly used additives by weight or number according to the reporting of ingredients pursuant to regulation 18.

(7) For the purposes of this regulation, the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises(7) is to be read as if—

- (a) in Article 2—
  - (i) in paragraph 1, for “EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million” there were substituted “£44,000,000, and/or an annual balance sheet total not exceeding £38,000,000”;
  - (ii) in paragraph 2, for “EUR 10 million” there were substituted “£8,800,000”;
  - (iii) in paragraph 3, for “EUR 2 million” there were substituted “£1,750,000”;
- (b) in Article 3—
  - (i) in paragraph 2(a), for “EUR 1 250 000” there were substituted “£1,100,000”;
  - (ii) in paragraph 2(d), for “EUR 10 million” there were substituted “£8,800,000”;
  - (iii) in paragraph 5, for “by national or Community rules” there were substituted “under the law of the United Kingdom (or any part of it)”;

(6) Regulation 20A was inserted by [S.I. 2016/1127](#).

(7) OJ L 124, 20.5.2003, p. 36.

- (c) in Article 5, in paragraph (b), for “national law” there were substituted “the law of the United Kingdom (or any part of it)”.
- (17) In regulation 25~~(8)~~—
  - (a) for paragraph (2), substitute—
    - “(2) Information must be submitted—
      - (a) in electronic form; and
      - (b) having regard to such technical requirements and procedures as may be specified in guidance issued by the Secretary of State.”;
    - (b) omit paragraph (3).
- (18) In regulation 26~~(9)~~—
  - (a) in paragraph (a), after “Part;” insert “and”;
  - (b) omit paragraph (b).
- (19) In regulation 31(3)(a), for “a member State” (in both places), substitute “the United Kingdom”.
- (20) For regulation 33(2), substitute—
  - “(2) Information must be submitted—
    - (a) in electronic form; and
    - (b) having regard to such technical requirements and procedures as may be specified in guidance issued by the Secretary of State.”.
- (21) Omit regulation 34(b).
- (22) In regulation 36, after paragraph (10), insert—
  - “(11) Regulations may amend the technical standards in paragraph (10) for the refill mechanism required by paragraph (8).”.
- (23) In regulation 37—
  - (a) in paragraph (2)—
    - (i) in sub-paragraph (e), after “toxicity;”, insert “and”;
    - (ii) omit sub-paragraph (g);
  - (b) after paragraph (9), insert—
    - “(10) Regulations may amend the wording of the health warning in paragraph (4) taking into account scientific developments, provided that any such amended warning is factual.”.
- (24) In regulation 39—
  - (a) in paragraph (4), omit “and the competent authority of any other member State in which the product has been supplied or is intended to be supplied;”;
  - (b) in paragraph (5), omit “or the competent authority of any other member State”.
- (25) Omit regulation 40(4).
- (26) In regulation 41—
  - (a) in paragraph (2)—
    - (i) omit the definition of “the Union market”;

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(8) Regulation 25 was amended by [S.I. 2016/1127](#).

(9) Regulation 26 was amended by [S.I. 2016/1127](#).

- (ii) in the definition of “third country”, for “a state which is not a member State”, substitute “a country other than the United Kingdom”;
- (b) omit paragraphs (3) to (5).
- (27) In regulation 42(3)(b), for “Union”, substitute “United Kingdom”.
- (28) In regulation 43—
  - (a) omit paragraphs (2) to (4);
  - (b) in paragraph (5)—
    - (i) for “Paragraphs (1) and (2) do”, substitute “Paragraph (1) does”;
    - (ii) in sub-paragraph (b), for “Union”, substitute “United Kingdom”.
- (29) Omit regulation 44.
- (30) Omit regulation 47.
- (31) In regulation 48—
  - (a) in paragraph (d), after “notifications);”, insert “or”;
  - (b) in paragraph (e), for “, 43 or 44 (advertising and sponsorship); or”, substitute “or 43 (advertising).”;
  - (c) omit paragraph (f).
- (32) In regulation 50(2), for “, 43 or 44 (advertising and sponsorship)”, substitute “or 43 (advertising)”.
- (33) After regulation 53, insert—

## “PART 9A

### FEES

#### **Fees for determining characterising flavour, toxicity, addictiveness or CMR properties**

**53A.**—(1) Regulations may make provision for the charging of fees in connection with the exercise of functions relating to the determination of characterising flavour, toxicity, addictiveness or CMR properties of tobacco products for the purposes of these Regulations.

(2) Regulations made under paragraph (1) may make such provision in relation to fees as may be made by the appropriate authority under paragraph 1(3)(a) or (b) of Schedule 4 to the European Union (Withdrawal) Act 2018 in relation to those functions.”.

- (34) Before regulation 54, insert—

#### **“Regulations**

**54ZA.**—(1) Any power to make regulations under these Regulations—

- (a) is exercisable by the Secretary of State (and in the case of regulations made under regulation 53A, with the consent of the Treasury) by statutory instrument; and
- (b) includes power to make—
  - (i) different provision for different cases or descriptions of case, different circumstances, different purposes or different areas;
  - (ii) consequential, supplementary, incidental, transitional or transitory provision or savings.

- (2) A statutory instrument containing regulations made under—
  - (a) regulation 53A may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament;
  - (b) any other provision of these Regulations is subject to annulment in pursuance of a resolution of either House of Parliament.

**Regulations: duty to consult**

**54ZB.** Where the Secretary of State proposes to make regulations under these Regulations which will apply in Wales, Scotland or Northern Ireland, the Secretary of State must consult—

- (a) the Welsh Ministers, in respect of any proposed application in Wales;
- (b) the Scottish Ministers, in respect of any proposed application in Scotland; and
- (c) such Northern Ireland department as the Secretary of State considers appropriate, in respect of any proposed application in Northern Ireland,

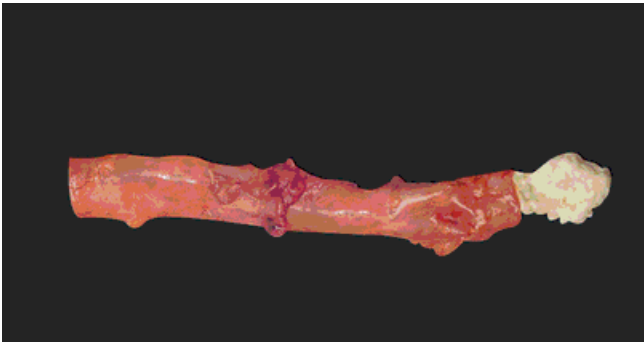
before making such regulations.”.

(35) Before Schedule 1, insert—


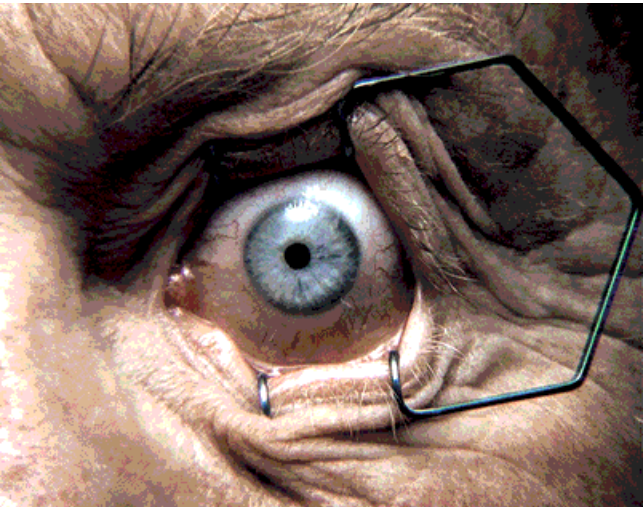
“SCHEDULE A1

Regulation 5(3)(a)

Picture Library (of combined health warnings)

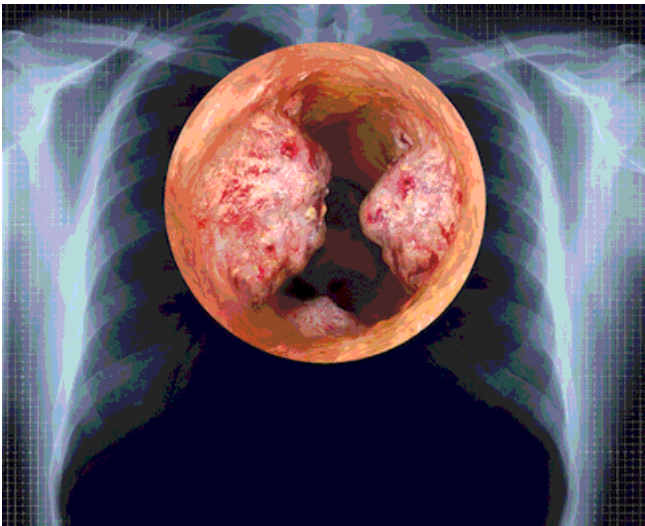
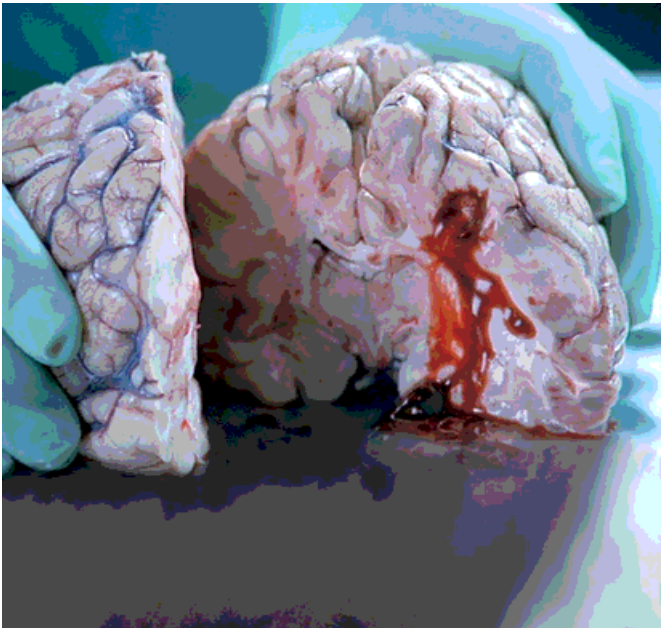
<i>Number</i>	<i>Text Warning</i>	<i>Corresponding Photograph<sup>(NOTE)</sup></i>
1	Smoking clogs your arteries	

**(NOTE)** Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.


Number	Text Warning	Corresponding Photograph <sup>(NOTE)</sup>
2	Don't let children breathe your smoke	 A young girl with long dark hair is lying in a hospital bed, wearing a white hospital gown. She is using a blue nebulizer mask over her nose and mouth. A healthcare professional in a white coat is standing by her side, holding the nebulizer. The background shows a hospital room with a window and curtains.
3	Smoking causes blindness	 A close-up photograph of an elderly person's eye. The eye is heavily cataracted, appearing cloudy and white. The person is wearing black-rimmed glasses. The skin around the eye is wrinkled and aged.

(NOTE) Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.



<i>Number</i>	<i>Text Warning</i>	<i>Corresponding Photograph<sup>(NOTE)</sup></i>
4	Smoking causes lung cancer	
5	Smoking doubles your risk of stroke	




**(NOTE)** Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.

Number	Text Warning	Corresponding Photograph <sup>(NOTE)</sup>
6	Tobacco smoke is toxic	 A photograph showing a person wearing a white lab coat and white gloves. They are holding a clear glass beaker filled with a dark liquid. On the front of the beaker is a yellow triangular warning symbol with a black skull and crossbones and the word "TOXIC" written below it.
7	Smoking harms unborn babies	 A photograph of a newborn baby lying in a hospital bed. The baby is wearing a white oxygen mask over their nose and mouth, secured with white tape. A clear plastic tube is connected to the mask. The baby's face is visible, and they appear to be resting. The background shows a person's hands supporting the baby's head.

(NOTE) Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.


<i>Number</i>	<i>Text Warning</i>	<i>Corresponding Photograph<sup>(NOTE)</sup></i>
8	Smoking causes peripheral vascular disease	
9	Smoking causes emphysema	

**(NOTE)** Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.

Number	Text Warning	Corresponding Photograph <sup>(NOTE)</sup>
10	Quitting will improve your health	 A close-up photograph of a hand lighting a cigarette. The hand is holding the cigarette between the fingers, and a match is being used to light it. The cigarette is held over a clear glass ashtray that contains several other cigarettes. The background is dark, and the lighting is focused on the hand and the cigarette.
11	Smoking damages your gums and teeth	 A close-up photograph of a person's mouth showing severe gum disease and tooth decay. The gums are swollen, red, and bleeding. The teeth are heavily stained with brown and black deposits, and many of the teeth are missing or severely damaged.
12	Smoking damages your gums and teeth	 A close-up photograph of a person's mouth showing moderate gum disease and tooth decay. The gums are swollen and red, and the teeth are heavily stained with brown and black deposits. The teeth are missing or severely damaged.

(NOTE) Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.

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<i>Number</i>	<i>Text Warning</i>	<i>Corresponding Photograph<sup>(NOTE)</sup></i>
13	Smoking causes throat cancer	

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**(NOTE)** Corresponding photographs in numbers 1 to 10 and 13 © Commonwealth of Australia. Corresponding photographs in numbers 11 and 12 © Professor Laurence J Walsh, The University of Queensland.