#### STATUTORY INSTRUMENTS

## 2020 No. 1316

## EXITING THE EUROPEAN UNION CONSUMER PROTECTION PUBLIC HEALTH

The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020

Made - - - 18th November 2020 Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 8C(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(1). In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

## Citation and commencement

- **1.**—(1) These Regulations may be cited as the Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020.
  - (2) Regulations 6 and 7 come into force on IP completion day.
  - (3) Otherwise these Regulations come into force immediately before IP completion day.

# Amendment of the Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019

- **2.** The Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019(**2**) are amended as follows.
  - **3.**—(1) Regulation 6 is amended as follows.
  - (2) In paragraph (1), for "Subject to regulation 9, the" substitute "The".
  - (3) After paragraph (1) insert—

<sup>(1) 2018</sup> c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1) and section 8C was inserted by section 21 of that Act.

<sup>(2)</sup> S.I. 2019/41.

## "(1A) After regulation 1, insert—

#### "Extent

- **1A.**—(1) Subject to the following paragraphs, these Regulations extend to England and Wales. Scotland and Northern Ireland.
  - (2) The following provisions do not extend to Northern Ireland—
    - (a) regulation 5A;
    - (b) regulation 7(5);
    - (c) regulation 8(10);
    - (d) regulation 9(12);
    - (e) regulation 10(5);
    - (f) regulation 13(3);
    - (g) regulation 14(5) and (6);
    - (h) regulation 15(3);
    - (i) regulation 16(4);
    - (j) regulation 16A;
    - (k) regulation 20A(6) and (7);
    - (l) regulation 36(11);
    - (m) regulation 37(10);
    - (n) Part 9A;
    - (o) regulations 54ZA and 54ZB.
  - (3) The following provisions extend only to Northern Ireland—
    - (a) regulation 41(3) to (5);
    - (b) regulation 44;
    - (d) regulation 47.
- (4) An amendment made by these Regulations has the same extent as the provision to which it relates"."
- (4) For paragraph (2) substitute—
  - "(2) In regulation 2(1)—
    - (a) after the definition of "emissions", insert—

""GB related product" means a related product which is produced for supply, or is supplied, for consumption in Great Britain or through the GB travel retail sector;

"GB tobacco product" means a tobacco product which is produced for supply, or is supplied, for consumption in Great Britain or through the GB travel retail sector;

"the GB travel retail sector" means retail outlets in Great Britain at which tobacco products or related products may be purchased only by people travelling on journeys to destinations outside Great Britain;";

(b) after the definition of "nasal tobacco", insert—

""NI related product" means a related product which is produced for supply, or is supplied, for consumption in Northern Ireland or through the NI travel retail sector;

"NI tobacco product" means a tobacco product which is produced for supply, or is supplied, for consumption in Northern Ireland or through the NI travel retail sector;

"the NI travel retail sector" means retail outlets in Northern Ireland at which tobacco products or related products may be purchased only by people travelling on journeys to destinations outside Northern Ireland;";

(c) 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;";

(d) for the definition of "travel retail sector" substitute—

""travel retail sector" means—

- (a) the GB travel retail sector, or
- (b) the NI travel retail sector.".".
- (5) For paragraph (3) substitute—
  - "(3) In regulation 3—
    - (a) in paragraph (1)—
      - (i) in the words before sub-paragraph (a), for "the United" substitute "any part of the United";
      - (ii) in sub-paragraph (c), for "the United" substitute "any part of the United";
    - (b) in paragraph (2)(a)(i) and (ii), for "the United" substitute "any part of the United";
    - (c) for paragraph (3) substitute—
      - "(3) In the case of a cross-border distance sale of a product, the product is to be treated for the purposes of these Regulations—
        - (a) where the consumer is located in Great Britain, as supplied, and presented for retail sale in Great Britain;
        - (b) where the consumer is located in Northern Ireland, as supplied, and presented for retail sale in Northern Ireland.";
    - (d) for paragraph (4) substitute—
      - "(4) In these Regulations, "cross-border distance sale"—
        - (a) in relation to Great Britain, means a distance sale to a consumer ("C") where, at the time C orders a product from a retailer, C is located in Great Britain and the retailer is established outside of Great Britain;
        - (b) in relation to Northern Ireland, means a distance sale to a consumer ("C") where, at the time C orders a product from a retailer—
          - (i) C is located in Northern Ireland or a member State, and
          - (ii) the retailer—
            - (aa) if C is located in Northern Ireland, is established in a member State or another country outside of Northern Ireland;

- (bb) if C is located in a member State, is established in Northern Ireland, in a different member State or in a country other than Northern Ireland or a member State
- (5) For the purposes of paragraph (4)(b) a retailer is deemed to be established in a member State—
  - (a) in the case of a retailer who is a natural person, if that person's place of business is in that member State, and
  - (b) in any other case, if the retailer has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that member State."."
- (6) For paragraph (4) substitute—
  - "(4) In regulation 5—
    - (a) for paragraph (3) substitute—
      - "(3) A combined health warning must consist of the relevant smoking cessation information and—
        - (a) for a unit pack or container pack of a tobacco product for smoking which is a GB tobacco product, one of the text warnings with the corresponding colour photograph, as listed in the picture library in Schedule A1, or
        - (b) for a unit pack or container pack of a tobacco product for smoking which is an NI tobacco product, one of the text warnings listed in Annex 1 to the Tobacco Products Directive together with a corresponding colour photograph, as specified in the picture library in Annex 2 to that Directive.
      - (3A) For the purposes of paragraph (3), the relevant smoking cessation information is "Get help to stop smoking at www.nhs.uk/quit"."."
- (7) In paragraph (5)—
  - (a) in the heading for the regulation 5A to be inserted by that paragraph, after "specifications" insert ": GB tobacco products";
  - (b) in the new regulation 5A, to be inserted by that paragraph, in paragraph (b), after "Regulations" insert "as they apply in relation to GB tobacco products".
- (8) For paragraph (6) substitute—
  - "(6) In regulation 6—
    - (a) before paragraph (1), insert—
      - "(A1) A producer of a tobacco product for smoking which is a GB tobacco product (other than an importer) must select the photograph used for the purposes of regulation 5(3)(a) so that each of the 13 photographs appears on between 1/24 to 1/12 of the total number of packs under each brand name produced by that producer within that production year.";
    - (b) in paragraph (1), in the words before sub-paragraph (a)—
      - (i) after "smoking", insert "which is an NI tobacco product";
      - (ii) for "5(3)(a)" substitute "5(3)(b)";
    - (c) for paragraph (2) substitute—

- "(2) An importer of a tobacco product for smoking must use the importer's best endeavours to ensure—
  - (a) where the product is a GB tobacco product, that the obligation in paragraph (A1) is complied with;
  - (b) where the product is an NI tobacco product, that the obligations in paragraph (1) are complied with.";
- (d) in paragraph (3)—
  - (i) in the words before sub-paragraph (a), for "this regulation" substitute "paragraph (1)";
  - (ii) omit sub-paragraph (d);
- (e) after paragraph (3), insert—
  - "(4) In this regulation "production year" means a period of 12 months beginning with 20th May and ending with 19th May."."
- (9) For paragraph (7) substitute—
  - "(7) In regulation 7, after paragraph (4), insert—
    - "(5) Regulations may amend the wording of the information message in paragraph (2)(b) to be carried by a unit pack or a container pack of a tobacco product for smoking which is a GB tobacco product, taking into account scientific and market developments."."
- (10) In paragraph (8), in the new paragraph (10) to be inserted by that paragraph, after "marketed in pouches" insert "which is a GB tobacco product".
  - (11) For paragraph (9) substitute—
    - "(9) In regulation 9, after paragraph (11), insert—
      - "(12) Regulations may amend this regulation as it applies in relation to the production or supply of GB tobacco products, by omitting from paragraph (1) reference to one or more of the products listed in that paragraph if there is a substantial change of circumstances for the product concerned."."
- (12) In paragraph (10), in the new paragraph (5) to be inserted by that paragraph, after "paragraph (2)" insert "to be carried by a unit pack or container pack of a smokeless tobacco product which is a GB tobacco product".
  - (13) For paragraph (11) substitute—
    - "(11) In regulation 13, for paragraph (2), substitute—
      - "(2) For the purposes of this regulation and regulation 14 as they apply in Great Britain, a person ("P") manufactures a product for export if, in the course of a business, other than with a view to the product being supplied for consumption in Great Britain or through the GB travel retail sector, P—
        - (a) manufactures the product, or
        - (b) puts a name, trade mark, or other distinguishing mark on the product by which P is held out to be its manufacturer or its originator.

Such a product is referred to in this regulation and regulation 14 as a "product for GB export".

(3) For the purposes of this regulation and regulation 14 as they apply in Northern Ireland, a person ("P") manufactures a product for export if, in the course of a business, other than with a view to the product being supplied for consumption in Northern Ireland or through the NI travel retail sector, P—

- (a) manufactures the product, or
- (b) puts a name, trade mark, or other distinguishing mark on the product by which P is held out to be its manufacturer or its originator.
- (4) Regulations may decrease the maximum emission levels specified in paragraph (1) in relation to—
  - (a) cigarettes which are GB tobacco products, or
  - (b) cigarettes which are products for GB export,

where this is necessary, based on internationally agreed standards."."

- (14) In paragraph (12), in the new paragraph (5) to be inserted by that paragraph, after "cigarettes" insert "which are GB tobacco products or products for GB export".
  - (15) In paragraph (13), in the new paragraph (3) to be inserted by that paragraph—
    - (a) in sub-paragraph (a), for "a tobacco" substitute "a GB tobacco";
    - (b) in sub-paragraph (b), after "set" insert ", in relation to GB tobacco products,".
- (16) In paragraph (14), in the new paragraph (4) to be inserted by that paragraph, in the words before sub-paragraph (a), after "may" insert ", in relation to GB tobacco products".
  - (17) In paragraph (15), in the new regulation 16A to be inserted by that paragraph—
    - (a) in the heading, after "flavour" insert ": GB tobacco products";
    - (b) in paragraph (1), in the words before sub-paragraph (a), for "a tobacco" substitute "a GB tobacco":
  - (18) After paragraph (15), insert—
    - "(15A) In regulation 19—
      - (a) in paragraph (c), after "of Chemicals", insert "or, in relation to an NI tobacco product, that Regulation as it has effect by virtue of the Protocol on Ireland/ Northern Ireland in the EU withdrawal agreement";
      - (b) in paragraph (d), after "and mixtures", insert "or, in relation to an NI tobacco product, that Regulation as it has effect by virtue of the Protocol on Ireland/ Northern Ireland in the EU withdrawal agreement"."
  - (19) For paragraph (16) substitute—
    - "(16) In regulation 20A—
      - (a) in paragraph (1)(b), for "and to" substitute "and, where the product is an NI tobacco product, to";
      - (b) in paragraph (2)(c), for the words from "European Commission" to the end substitute "appropriate authority may request";
      - (c) in paragraph (4), for "Secretary of State or the European Commission" substitute "appropriate authority";
      - (d) in paragraph (5)—
        - (i) in sub-paragraph (a), after "enterprises" insert, "but, for the purposes of this regulation as it applies in Great Britain, with the modifications in paragraph (7)";
        - (ii) in sub-paragraph (b), for "Secretary of State or the European Commission" substitute "appropriate authority";
      - (e) after paragraph (5) insert—
        - "(6) Regulations may amend the list of additives in Schedule 2 as it applies in Great Britain, which list must contain additives—

- (a) for which initial indications, research, or regulation in jurisdictions outside Great Britain 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 as it applies in Great Britain, the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises 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 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 Great Britain (or any part of it)";
  - (c) in Article 5, in paragraph (b), for "national law" there were substituted "the law of Great Britain (or any part of it)".
  - (8) In this regulation "appropriate authority"—
    - (a) where the product is a GB tobacco product, means the Secretary of State:
    - (b) where the product is an NI tobacco product, means—
      - (i) the Secretary of State, or
      - (ii) the European Commission."."
- (20) After paragraph (16) insert—
  - "(16A) In regulation 21—
    - (a) in paragraph (1)(a), for "the United" substitute "the relevant part of the United";
    - (b) after paragraph (6), insert—
      - "(7) In this regulation "the relevant part of the United Kingdom"—
        - (a) in relation to a tobacco product which is a GB tobacco product, means Great Britain;
        - (b) in relation to a tobacco product which is an NI tobacco product, means Northern Ireland.".".
- (21) For paragraph (17) substitute—

- "(17) In regulation 25—
  - (a) after paragraph (1), insert—
    - "(1A) Information which relates to a GB tobacco product 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) in paragraph (2), in the words before sub-paragraph (a), after "Information" insert "which relates to an NI tobacco product".".
- (22) For paragraph (18) substitute—
  - "(18) In regulation 26, for paragraph (b) (but not the "and" at the end) substitute—
    - "(b) provide the European Commission and the competent authorities of the member States with access to information submitted about any NI tobacco product in accordance with regulation 18, 20A or 21, ensuring that trade secrets and other confidential information are treated in a confidential manner;"."
- (23) For paragraph (19) substitute—
  - "(19) In regulation 31(3), for sub-paragraph (a) substitute—
    - "(a) the name and contact details of—
      - (i) where the product is, or is to be, supplied for consumption in Great Britain or through the GB travel retail sector—
        - (aa) the person who manufactures the product,
        - (bb) the importer of the product (if applicable), and
        - (cc) if neither is based in Great Britain, a responsible person in Great Britain;
      - (ii) where the product is, or is to be, supplied for consumption in Northern Ireland or the NI travel retail sector—
        - (aa) the person who manufactures the product,
        - (bb) the importer of the product (if applicable), and
        - (cc) if neither is based in Northern Ireland or a member State, a responsible person in Northern Ireland or a member State;"."
- (24) After paragraph (19), insert—
  - "(19A) In regulation 32—
    - (a) in paragraph (1)(a), (b) and (c), for "the United" substitute "the relevant part of the United";
    - (b) after paragraph (5), insert—
      - "(6) In this regulation "the relevant part of the United Kingdom"—
        - (a) in relation to an electronic cigarette which is a GB related product, means Great Britain;
        - (b) in relation to an electronic cigarette which is an NI related product, means Northern Ireland."."
- (25) For paragraph (20) substitute—
  - "(20) In regulation 33—
    - (a) after paragraph (1), insert—

- "(1A) Information which relates to a GB related product 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) in paragraph (2), in the words before sub-paragraph (a), after "Information" insert "which relates to an NI related product"."
- (26) For paragraph (21) substitute—
  - "(21) In regulation 34, in paragraph (b)—
    - (a) for "other member" substitute "the member";
    - (b) after "information" insert "in relation to any NI related product".".
- (27) In paragraph (22), in the new paragraph (11) inserted by that paragraph, after "(8)" insert "as they apply in relation to GB related products".
  - (28) In paragraph (23)—
    - (a) for sub-paragraph (a) substitute—
      - "(a) in paragraph (2), for sub-paragraph (g) substitute—
        - "(g) where the electronic cigarette or refill container is an NI related product and the producer is not based in Northern Ireland or in a member State, a contact person in Northern Ireland or within a member State.";";
    - (b) in sub-paragraph (b), in the new paragraph (10) to be inserted by that sub-paragraph, after "(4)" insert "as it applies to unit packets and container packs of GB related products".
  - (29) For paragraph (24) substitute—
    - "(24) In regulation 39—
      - (a) in paragraph (4), for "the competent authority of any other" substitute ", where the product is an NI related product, the competent authority of each";
      - (b) in paragraph (5), for "the competent authority of any other" substitute ", where the product is an NI related product, the competent authority of any"."
  - (30) For paragraph (25) substitute—
    - "(25) In regulation 40, in paragraph (4), at the start insert "Where the matter relates to an NI related product,"".
  - (31) For paragraph (26) substitute—
    - "(26) In regulation 41, in paragraph (2)—
      - (a) for the definition of "the Union market" substitute—

""the Union market" means the market of-

- (a) one or more member States,
- (b) Northern Ireland, or
- (c) Northern Ireland and one or more member States;";
- (b) for the definition of "third country" substitute—

""third country" means a country other than—

- (a) Northern Ireland, or
- (b) a member State.".".

- - (b) in paragraph (3)—
    - (i) after "instituted" insert "in Northern Ireland";
    - (ii) for "a non-UK-EEA-State" substitute "an EEA State";
  - (c) in paragraph (5)—
    - (i) in the words before sub-paragraph (a), for "Paragraphs (1) and (2)" substitute "Paragraph (1) does or, as the case may be, paragraphs (1) and (2)";
    - (ii) in sub-paragraph (b), for "for the Union market" substitute—
      - (i) where the recipient of the service is in Great Britain, for the market in Great Britain;
      - (ii) where the recipient of the service is in Northern Ireland, for the Union market."."
- (34) For paragraph (29) substitute—
  - "(29) In regulation 44—
    - (a) in the heading, after "etc" insert ": Northern Ireland";
    - (b) in paragraph (1)—
      - (i) in the words before sub-paragraph (a), after "person", insert "in Northern Ireland";
      - (ii) for sub-paragraph (a), substitute—
        - "(a) a cross-border event or activity;";
    - (b) after paragraph (1), insert—
      - "(1A) In this regulation "cross-border event or activity" means an event or activity which takes place in or has an effect in—
        - (a) Northern Ireland and one or more member States, or
        - (b) two or more member States.".".
- (35) For paragraph (30) substitute—
  - "(30) In regulation 47—

- (a) in the heading, after "etc" insert ": in and from Northern Ireland";
- (b) in paragraph (1)—
  - (i) in sub-paragraph (a)—
    - (aa) for "the United Kingdom" substitute "Northern Ireland";
    - (bb) for "any other" substitute "a";
  - (ii) in sub-paragraph (b), for "the United Kingdom", in both places it occurs, substitute "Northern Ireland";
- (c) in paragraph (4)(b), for "any other" substitute "any".".
- (36) Omit paragraphs (31) and (32).
- (37) In paragraph (33), in the new Part 9A to be inserted by that paragraph—
  - (a) in the heading for the new Part, after "Fees" insert ": Great Britain";
  - (b) in the heading for the new regulation 53A after "properties" insert ": Great Britain";
  - (c) in the new regulation 53A, in paragraph (1), after "these Regulations" insert "as they apply in Great Britain and in relation to GB tobacco products".
- (38) In paragraph (34)—
  - (a) in the new regulation 54ZA to be inserted by that paragraph, in the heading, after "Regulations" insert ": Great Britain";
  - (b) in the new regulation 54ZB to be inserted by that paragraph—
    - (i) in the words before paragraph (a), for ", Scotland or Northern Ireland" substitute "or Scotland":
    - (ii) at the end of paragraph (a), insert "and";
    - (iii) at the end of paragraph (b), omit "and";
    - (iv) omit paragraph (c).
- **4.** In regulation 7—
  - (a) in paragraph (1), omit "Subject to regulation 9,";
  - (b) after paragraph (1), insert—
    - "(1A) In Article 3(2), omit the second subparagraph.".
- **5.** For regulation 9, substitute—

#### "Transitional provision

- **9.**—(1) The picture warning requirements continue to apply to the supply in Great Britain or through the GB travel retail sector, on or after IP completion day, of a tobacco product for smoking to which paragraph (2) applies as if those requirements had not been amended by regulations 6 and 7 of these Regulations.
- (2) This paragraph applies to a tobacco product for smoking if it was produced, and first supplied in the United Kingdom, before IP completion day.
- (3) For the purposes of paragraph (2), "produce" and "supply" have the meanings given in regulation 3 of the 2016 Regulations, as it had effect immediately before IP completion day.
  - (4) In this regulation—

"the 2016 Regulations" means the Tobacco and Related Products Regulations 2016(3);

"GB travel retail sector" means retail outlets in Great Britain at which tobacco products or related products may be purchased only by people travelling on journeys to destinations outside of Great Britain;

"the picture warning requirements" means—

- (a) regulations 5 and 6 of the 2016 Regulations, and
- (b) Commission Implementing Decision (EU) 2015/1842 of 9 October 2015;
- "tobacco product for smoking" has the meaning given in regulation 2(1) of the 2016 Regulations.".

## Amendment of the Electronic Cigarettes etc. (Fees) Regulations 2016

- **6.**—(1) The Electronic Cigarettes etc. (Fees) Regulations 2016(4) are amended as follows.
- (2) In regulation 1, for paragraph (2) substitute—
  - "(2) In these Regulations—
    - "the 2016 Regulations" means the Tobacco and Related Products Regulations 2016;
    - "GB travel retail sector" and "NI travel retail sector" have the meanings given in the 2016 Regulations (see regulation 2 of those Regulations);
    - "supply" has the meaning that it has for the purposes of the 2016 Regulations (see regulation 3 of those Regulations).
  - (3) For the purposes of these Regulations, the relevant areas are—
    - (a) Great Britain (including the GB travel retail sector), and
    - (b) Northern Ireland (including the NI travel retail sector).".
- (3) In regulation 2, after paragraph (1), insert—
  - "(1A) But only one fee is payable where a person—
    - (a) submits a notification under regulation 31(1) of the 2016 Regulations of the supply, or intended supply, of a product in one of the relevant areas, and
    - (b) submits a notification under regulation 31(1) of the 2016 Regulations of the supply, or intended supply, of the same product in the other relevant area.".
- (4) In regulation 3—
  - (a) after paragraph (1), insert—
    - "(1A) But only one annual fee is payable for a product which is notified under regulation 31(1) of the 2016 Regulations for supply, or intended supply, in both of the relevant areas.";
  - (b) after paragraph (6), insert—
    - "(7) But where a product has been notified under regulation 31(1) of the 2016 Regulations for supply, or intended supply, in both of the relevant areas, the annual fee ceases to be payable only if the Secretary of State is notified under regulation 31(8) of those Regulations that the product has been withdrawn from the market in Great Britain and from the market in Northern Ireland."

<sup>(3)</sup> S.I. 2016/507; there are amending instruments but none is relevant.

<sup>(4)</sup> S.I. 2016/521.

# Amendment of the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017

- 7.—(1) The Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017(5) are amended as follows.
  - (2) In regulation 1, after paragraph (2), insert—
    - "(3) For the purposes of these Regulations, the relevant areas are—
      - (a) Great Britain (including the GB travel retail sector), and
      - (b) Northern Ireland (including the NI travel retail sector).
    - (4) For the purposes of paragraph (3), "GB travel retail sector" and "NI travel retail sector" have the meanings given in the 2016 Regulations (see regulation 2 of those Regulations).".
  - (3) In regulation 2, after paragraph (1), insert—
    - "(1A) But only one annual fee is payable in respect of a variant brand of cigarettes which—
      - (a) is manufactured for supply in both of the relevant areas, or
      - (b) is manufactured for supply otherwise than in the relevant areas.".
  - (4) In regulation 3, after paragraph (2), insert—
    - "(2A) In addition, only one fee is payable where—
      - (a) a producer—
        - (i) submits information in accordance with regulation 18(1) of the 2016 Regulations relating to the supply of a tobacco product in one of the relevant areas, and
        - (ii) submits information in accordance with that provision relating to the supply of the same tobacco product in the other relevant area;
      - (b) a producer—
        - (i) submits a notification in accordance with regulation 22 of the 2016 Regulations relating to the supply of a novel tobacco product in one of the relevant areas, and
        - (ii) submits a notification in accordance with that provision relating to the supply of the same novel tobacco product in the other relevant area.".
  - (5) In regulation 4—
    - (a) after paragraph (1), insert—
      - "(1A) But only one annual fee is payable for a product for which—
        - (a) a submission has been made under regulation 18(1), or a notification has been submitted under regulation 22, of the 2016 Regulations relating to the supply of it in one of the relevant areas, and
        - (b) a submission has also been made, or notification has also been submitted, under either of those provisions relating to its supply in the other relevant area.";
    - (b) after paragraph (5), insert—
      - "(6) But where a submission has been made under regulation 18(1), or a notification submitted under regulation 22, of the 2016 Regulations, relating to the supply of a

product in both of the relevant areas, the annual fee ceases to be payable only if the Secretary of State is notified under regulation 18(5) of those Regulations that the product has been withdrawn from the market in Great Britain and from the market in Northern Ireland."

- (6) In regulation 5, after paragraph (1), insert—
  - "(1A) But only one fee is payable where—
    - (a) a submission is made under regulation 29(1) of the 2016 Regulations in relation to the supply of a product in one of the relevant areas, and
    - (b) a submission is also made under regulation 29(1) of the 2016 Regulations in relation to the supply of the same product in the other relevant area.".
- (7) In regulation 6—
  - (a) after paragraph (1), insert—
    - "(1A) But only one annual fee is payable in respect of a product for which—
      - (a) a submission has been made under regulation 29(1) of the 2016 Regulations in relation to the supply of a product in one of the relevant areas, and
      - (b) a submission has also been made under that regulation in relation to its supply in the other relevant area.";
  - (b) after paragraph (5), insert—
    - "(6) But where a submission has been made under regulation 29(1) of the 2016 Regulations relating to the supply of a product in both of the relevant areas, the annual fee ceases to be payable only if the Secretary of State is notified that the product has been withdrawn from the market in Great Britain and from the market in Northern Ireland.".

Edward Argar Minister of State, Department of Health and Social Care

18th November 2020

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by sections 8(1) and 8C of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16). They deal with matters arising out of, or related to, the Protocol on Ireland/Northern Ireland in the EU Withdrawal Agreement ("the Protocol").

These Regulations amend the Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/41) to take account of the inclusion of Directive 2014/40/EU in Annex 2 to the Protocol. The amendments are needed to ensure that the Tobacco and Related Products Regulations 2016 (which implemented the Directive) (S.I. 2016/507) will continue to function after IP completion day, and also to update the transitional provision made to allow certain products that have been placed on the market in the United Kingdom before IP completion day to continue to be supplied in Great Britain on and after that day.

These Regulations also amend the Electronic Cigarettes (Fees) Regulations 2016 (S.I. 2016/521) and the Tobacco and Related Products (Fees) Regulations 2017 (S.I. 2019/409) so that a single notification and annual reporting fee remains payable if a product is to be supplied in both Great Britain and Northern Ireland.

The net costs imposed on business, the voluntary sector and the public sector by these Regulations have been assessed as being less than £5m in any year and therefore a full impact assessment has not been prepared.