

---

STATUTORY INSTRUMENTS

---

**2016 No. 1127**

**CONSUMER PROTECTION**

The Tobacco and Related Products  
(Amendment) Regulations 2016

<i>Made</i>	- - - -	<i>21st November 2016</i>
<i>Laid before Parliament</i>		<i>25th November 2016</i>
<i>Coming into force</i>	- -	<i>1st January 2017</i>

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(1).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to tobacco, tobacco products, nicotine, nicotine products and herbal products for smoking(2).

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Tobacco and Related Products (Amendment) Regulations 2016.

(2) These Regulations come into force on 1st January 2017.

(3) In these Regulations “the principal regulations” means the Tobacco and Related Products Regulations 2016(3).

**Priority list of additives - enhanced reporting**

2.—(1) The principal regulations are amended as follows.

(2) In regulation 2 (interpretation) at the appropriate place insert—

““CAS Registry number” means the number assigned to a substance by the Chemical Abstracts Service(4);”.

(3) After regulation 20 (sales data and market research information) insert—

---

(1) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act 2006 (c.51) and by section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).  
(2) S.I. 2014/2705.  
(3) S.I. 2016/507.  
(4) Chemical Abstracts Service ([www.cas.org](http://www.cas.org)), is a division of the American Chemical Society.

### **“Priority list of additives - enhanced reporting**

**20A.**—(1) A producer of cigarettes or hand rolling tobacco which contain an additive listed in Schedule 2 must—

- (a) carry out the study specified in regulation 20B in respect of that additive; and
  - (b) on or before the relevant deadline, submit a report on the results of the study to the Secretary of State and to the European Commission.
- (2) The report must include—
- (a) an executive summary;
  - (b) a comprehensive overview—
    - (i) compiling the available scientific literature on the additive concerned; and
    - (ii) summarising the data, whether published or not, which is available to the producer on the effects of that additive; and
  - (c) such supplementary information regarding the additive as the European Commission or the Secretary of State may request.
- (3) The relevant deadline is—
- (a) 1st July 2018 where paragraph (1) applies to a producer on 1st January 2017; or
  - (b) in any other case, 18 months after the day paragraph (1) first applies to a producer in respect of a particular additive.
- (4) A producer must cooperate with a requirement of the Secretary of State or the European Commission for the report submitted under paragraph (1)(b) to be peer reviewed by an independent scientific body.
- (5) This regulation does not apply to a person who produces cigarettes or hand rolling tobacco containing an additive listed in Schedule 2 where—
- (a) the person is a small or medium sized enterprise as defined in the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises<sup>(5)</sup>; and
  - (b) the additive concerned is the subject of a report which has been submitted to the Secretary of State or the European Commission by another producer.

### **Research study into additives**

**20B.**—(1) The study referred to in regulation 20A(1)(a) must be a comprehensive study which examines whether an additive—

- (a) contributes to the toxicity or addictiveness of the product concerned, and whether this has the effect of increasing the toxicity or addictiveness of the product to a significant or measurable degree;
  - (b) results in a characterising flavour;
  - (c) facilitates inhalation or nicotine uptake;
  - (d) leads to the formation of substances that have CMR properties, and if so—
    - (i) in what quantities; and
    - (ii) whether this has the effect of increasing the CMR properties of the product concerned to a significant or measurable degree.
- (2) The study must also—

---

(5) OJ L 124, 20.5.2003, p.36 (in which enterprise categories are determined by staff headcount and financial ceilings).

- (a) take into account the intended use of the product concerned;
  - (b) examine in particular the emissions resulting from the combustion process involving the additive concerned; and
  - (c) examine the interaction of that additive with other ingredients contained in the product concerned.
- (3) Two or more producers who use the same additive in their products, in a comparable product composition, may carry out a joint study.”
- (4) In regulation 25(4) (submission of information) after “regulation 18 (specified information)” insert “ or 20A (priority list of additives)”.
- (5) In regulation 26(b) (use of information)—
- (a) for “(specified information) and” substitute “(specified information),”;
  - (b) after “regulations 18 (specified information)” insert “, 20A (priority list of additives)”.
- (6) In regulation 26(c) after “regulation 18” insert “ and 20A”.

### Priority list of additives

- 3.—(1) The principal regulations are amended as follows.
- (2) Number the Schedule (liability of intermediary information society service providers) as Schedule 1.
- (3) After Schedule 1 (liability of intermediary information society service providers) as numbered by these Regulations, insert—

“SCHEDULE 2

Regulation 20A

Priority list of additives used in cigarettes and hand rolling tobacco subject to enhanced reporting obligations

<i>Additive</i>	<i>Chemical formula (if applicable)</i>	<i>CAS Registry number(s) applicable to the substance (not exhaustive)</i>
Carob bean		9000-40-2, 84961-45-5
Cocoa		84649-99-0, 84649-99-3, 95009-22-6, 8002-31-1
Diacetyl	C <sub>4</sub> H <sub>6</sub> O <sub>2</sub>	431-03-8
Fenugreek		68990-15-8, 977018-53-3, 84625-40-1
Fig		90028-74-3
Geraniol	C <sub>10</sub> H <sub>18</sub> O	106-24-1, 8000-46-2
Glycerol	C <sub>3</sub> H <sub>8</sub> O <sub>3</sub>	56-81-5
Guaiacol	C <sub>6</sub> H <sub>4</sub> (OH)(OCH <sub>3</sub> )	90-05-1
Guar gum		9000-30-0
Liquorice		68916-91-6
Maltol	C <sub>6</sub> H <sub>6</sub> O <sub>3</sub>	118-71-8
Menthol	C <sub>10</sub> H <sub>20</sub> O	2216-51-5, 15356-60-2, 89-78-1, 1490-04-6, 8006-90-4, 68606-97-3, 84696-51-5, 8008-79-5

---

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

---

<i>Additive</i>	<i>Chemical formula (if applicable)</i>	<i>CAS Registry number(s) applicable to the substance (not exhaustive)</i>
Propylene glycol	C <sub>3</sub> H <sub>8</sub> O <sub>2</sub>	57-55-6
Sorbitol	C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	50-70-4
Titanium dioxide	TiO <sub>2</sub>	13463-67-7, 1317-70-0"

Signed by authority of the Secretary of State for Health.

21st November 2016

*Nicola Blackwood*  
Parliamentary Under-Secretary of State,  
Department of Health

---

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Tobacco and Related Products Regulations 2016, the principal Regulations implementing [Directive 2014/40/EU](#) (“the Tobacco Products Directive”).

These Regulations implement Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and hand rolling tobacco subject to enhanced reporting obligations and Article 6 of the Tobacco Products Directive providing for enhanced reporting obligations in relation to the additives on that list.

The effect that these Regulations will have on the costs of business and the voluntary sector was quantified in the Impact Assessment which accompanied the Tobacco and Related Products Regulations 2016. As these Regulations transpose a Directive, a transposition note setting out how the Government has transposed the Directive into UK law has been prepared.

The transposition note is annexed to the Explanatory Memorandum which is available alongside the instrument on the [www.legislation.gov.uk](http://www.legislation.gov.uk) website.