STATUTORY INSTRUMENTS

2016 No. 1127

CONSUMER PROTECTION

The Tobacco and Related Products (Amendment) Regulations 2016

Made - - - -	*21st November 2016*
Laid before Parliament	*25th November 2016*
Coming into force - -	*1st January 2017*

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), 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(**5**); 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).