

COMMISSION IMPLEMENTING DECISION (EU) 2016/787**of 18 May 2016****laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations***(notified under document C(2016) 2923)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Article 6(1) of Directive 2014/40/EU provides that the Commission shall adopt implementing acts laying down and updating a priority list of additives contained in cigarettes and roll-your-own tobacco. The same article also lays down enhanced reporting obligation for the additives listed in that priority list. Member States are to require manufacturers and importers of cigarettes and roll-your-own tobacco to carry out comprehensive studies on additives contained in those products which have been included in the priority list.
- (2) The priority list should be established on the basis of available data suggesting that an additive may contribute to toxic, addictive or carcinogenic, mutagenic or reprotoxic properties ('CMR properties') of cigarettes and roll-your-own tobacco, result in a characterising flavour, or facilitate inhalation or nicotine uptake.
- (3) The additives laid down in the list should also be amongst the most commonly used in cigarettes and roll-your-own tobacco as reported in accordance with Article 5 of Directive 2014/40/EU. As the reporting obligations referred to in Article 5 will only take effect once Directive 2014/40/EU becomes applicable, it is appropriate to establish the first list of substances on the basis of data received from the Member States under Directive 2001/37/EC of the European Parliament and Council ⁽²⁾.
- (4) In the identification of priority additives to be listed, account has also been taken of a scientific opinion delivered by The Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) ⁽³⁾.
- (5) Additives may exist in several different forms. In order to facilitate their identification, it is appropriate to specify for each additive listed, its chemical formula, where applicable, and the Chemical Abstracts Service (CAS) numbers of the different forms in which the additives may be found in tobacco products.
- (6) In fulfilling their obligation to ensure that manufacturers and importers of cigarettes and roll-your-own tobacco submit comprehensive studies on the additives listed, Member States should be able to require those studies to be presented following a uniform format and methodology. A coordinated approach to the elaboration and presentation of those studies facilitates data analysis and ensures comparability. In order to ensure that Member States are afforded sufficient time to develop study protocols, without limiting the time afforded to manufacturers and importers for carrying out the studies, this Decision should only apply from 1 January 2017. Therefore, in

⁽¹⁾ OJ L 127, 29.4.2014, p. 1.

⁽²⁾ 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 (OJ L 194, 18.7.2001, p. 26).

⁽³⁾ SCENIHR: Additives used in tobacco products. 25 January 2016 http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm

accordance with Article 6(4) of Directive 2014/40/EU, manufacturers and importers should only be required to submit enhanced reports in respect of the first set of identified additives by 1 July 2018.

- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

The priority list of additives referred to in Article 6 of Directive 2014/40/EU is laid down in the Annex to this Decision.

Article 2

Application

This Decision shall apply from 1 January 2017.

Article 3

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 18 May 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

Priority list of additives used in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations

Additive	Chemical formula (if applicable)	CAS number(s) applicable to the substance (not exhaustive)
Carob bean		9000-40-2, 84961-45-5
Cocoa		84649-99-0, 84649-99-3, 95009-22-6, 8002-31-1
Diacetyl	$C_4H_6O_2$	431-03-8
Fenugreek		68990-15-8, 977018-53-3, 84625-40-1
Fig		90028-74-3
Geraniol	$C_{10}H_{18}O$	106-24-1, 8000-46-2
Glycerol	$C_3H_8O_3$	56-81-5
Guaiacol	$C_6H_4(OH)(OCH_3)$	90-05-1
Guar gum		9000-30-0
Liquorice		68916-91-6
Maltol	$C_6H_6O_3$	118-71-8
Menthol	$C_{10}H_{20}O$	2216-51-5, 15356-60-2, 89-78-1, 1490-04-6, 8006-90-4, 68606-97-3, 84696-51-5, 8008-79-5
Propylene glycol	$C_3H_8O_2$	57-55-6
Sorbitol	$C_6H_{14}O_6$	50-70-4
Titanium dioxide	TiO_2	13463-67-7, 1317-70-0