



EUROPEAN COMMISSION

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Subject: Notification 2023/544/NL

Amendment of the Tobacco and Smoking Products Regulation in connection with establishing a list of additives prohibited for e-cigarettes and tobacco products

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535 of 9 September 2015

Madam,

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535¹, the Dutch authorities notified to the Commission on 19 September 2023 the draft *‘Amendment of the Tobacco and Smoking Products Regulation in connection with establishing a list of additives prohibited for e-cigarettes and tobacco products’* (hereinafter, ‘the notified draft’).

According to the notification message, the notified draft aims to specify the additives prohibited under Article 7(6) of Directive 2014/40/EU for tobacco products and electronic cigarettes. In addition, the list of prohibited additives shall also apply to e-cigarettes without nicotine.

Examination of the notified draft has prompted the Commission to deliver the following comments pursuant to Article 5 (2) of Directive (EU) 2015/1535.

¹ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1.

COMMENTS

Flavouring of electronic cigarettes

Article I of the notified draft amends Articles 2.6, 2.10 and 2.11 of the Tobacco and Smoking Products Regulation (base act), which implement Article 7(6) of Directive 2014/40/EU. In particular, the notified draft introduces Annex 2 to the base act, which specifies the list of additives prohibited under Article 7(6) of Directive 2014/40/EU for tobacco products and electronic cigarettes.

According to Section 2 of the explanatory memorandum accompanying the notification, the list of additives included in Annex 2 is not exhaustive and additives which are not included in Annex 2, but which, in view of their properties, appear to be caught by the prohibition laid down in Articles 2.6, 2.10 and 2.11 of the base act, are prohibited even if they are not yet included in the list in Annex 2.

It should be recalled that Article 7(6) provides the following:

‘Member States shall prohibit the placing on the market of tobacco products containing the following additives:

(a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

(b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives having colouring properties for emissions;

(d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

(e) additives that have CMR properties in unburnt form’.

In order to ensure the correct application of Article 7(6) of Directive 2014/40/EU and to avoid prohibiting additives which do not fall within one of the categories of Article 7(6), points (a) to (e), the Commission would like to remind the Dutch authorities that they should be in a position to clearly justify, and provide adequate evidence, that the additives listed in Annex 2 and any other additional additives which would be prohibited, fall within one, or several, of the categories listed in Article 7(6) of Directive 2014/40/EU.

The Commission invites the Dutch authorities to take the above comments into account.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

For the Commission

Kerstin JORNA
Director-General

Directorate-General for Internal
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