Subject: Notification 2015/490/FIN

Draft Government bill to Parliament regarding an amendment to the Tobacco Act and certain related acts

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

Sir,

Within the framework of the notification procedure laid down by Directive 98/34/EC, repealed and replaced as of 7 October 2015 by Directive (EU) 2015/1535\(^1\), the Finnish authorities notified to the Commission on 20 August 2015 the draft Government bill to Parliament regarding an amendment to the Tobacco Act and certain related acts.

Pursuant to Article 5(2) of Directive 2015/1535/EU, examination of the draft has prompted the Commission to deliver the following comments.

1. Liquids other than those containing nicotine, flavours in e-liquids containing nicotine and flavourings

The Commission notes that the notified draft, inter alia:

(i) envisages the prohibition of flavours in e-liquids containing nicotine - Section 25 'Requirements regarding nicotine-containing liquids';
(ii) envisages the prohibition of sales of all flavourings that can be added to nicotine-containing e-liquids - Section 58 'Sales prohibition of flavouring additives'.
(iii) regulates also liquids other than those containing nicotine intended for use in electronic cigarettes. Those products are subject to provisions in, inter alia, Sections 23 'Manufacturers’ or importers’ responsibilities'; 26 'Requirements regarding other liquids intended for vaporising by means of electronic cigarettes' referring to requirements in Section 25(1)(2)-(5); 33 'General provisions for unit packets', which is part of Chapter 5 'Unit packets'; 83 'Supervision tasks of Valvira'; 102 'Sales prohibition'; and 109 'Appeals in Market Court matters'.

With regard to the free movement of goods, any national measure which has been the subject of exhaustive harmonisation at EU level must be assessed in the light of the provisions of those harmonising measures and not those of primary law, in particular Articles 34 and 36 TFEU (See Case C-309/02 Radlberger [2004] ECR I-11763, paragraph 53).

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It is noted that, first, Directive 2001/37/EC on tobacco products\(^2\), which will be repealed as from 20 May 2016, does not cover electronic cigarettes (either with or without nicotine). Second, flavours in e-liquids containing nicotine, flavourings and liquids other than those containing nicotine intended for use in electronic cigarettes are not within the scope of the Tobacco Product Directive 2014/30/EU\(^3\). It follows that provisions stipulated in the notified draft on those products are to be assessed under the Treaty rules relating to the free movement of goods. It also appears that the notified draft regulates the objective characteristics of those products, and thus falls within the principle of product requirements established in Cassis de Dijon (Case 120/78 Rewe-Zentral [1979] ECR 649).

Recital 47 of Tobacco Directive states that "the responsibility for adopting rules on flavours remains with the Member States..." which "... should be mindful of the potential attractiveness of such products for young people and non-smokers. Any prohibition of such flavoured products would need to be justified and notification thereof submitted in accordance with Directive 98/34/EC of the European Parliament and of the Council ". The Commission notes, that pursuant to the Impact Assessment accompanying the notification, the aim of the provisions concerning flavours is to make electronic cigarettes less appealing to children, prevent cases of nicotine poisoning and prevent the products from becoming a gateway to nicotine addiction for minors. The provided justification could further benefit from a clarification on why all flavours are attractive to young people. Also, the Commission invites the Finnish authorities to take into consideration undertaking a review of the situation on the basis of new evidence that has become available, after a given time period, e.g. five years. For products/flavours for which no adequate justification is provided the mutual recognition principle applies.

2) Smokeless tobacco products

The notified draft envisages a prohibition on the sale and import of a certain category of tobacco products, namely smokeless tobacco products (Section 57 'Sales prohibition of smokeless tobacco products' and Section 66 'Ban on import of smokeless tobacco products').

The Commission notes that the Finnish authorities also notified their draft pursuant to Art. 24(3) TPD under which Member State "may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive." According to Article 24(3) TPD "the Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States."

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In this respect, the Commission would like to inform the Finnish authorities that – if necessary – the Commission might revert to the Finnish authorities at a later stage under this notification procedure.

Yours faithfully,

For the Commission

Lowri Evans
Director-General