NOTE FOR THE ATTENTION OF
MS LOWRI EVANS, DIRECTOR-GENERAL
DG INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs

Subject: Notification N° 2015/490/FI - Tobacco Act
Comments (Article 8 § 2 of Directive 2015/1535/EU)

DG SANTE assessment of certain provisions of the notified draft - addressed to the Commission services

The purpose of this Note is to set out DG SANTE’s analysis of the notified draft legislation and to propose some limited comments.

I. THE NOTIFICATION

In the context of the notification procedure under Directive 98/34/EC (from 7 October 2015, Directive 2015/1535¹), on 20 August 2015 the Finnish authorities notified a draft Tobacco Act which aims at transposing Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products² and implements various other measures aimed at preventing tobacco initiation and nicotine addiction, promoting the cessation of tobacco and similar products and protecting the public from exposure to tobacco smoke. The notification clarifies that parts of the draft law are notified under Article 24(3) of Directive 2014/40/EU (thereafter ‘TPD’) which allows Member States to ban certain product categories under stringent conditions.

The notification concerns different types of provisions: 1) provisions that merely aim at transposing the TPD; 2) provisions that are adopted on the basis of the TPD (introducing a ban of certain product categories) and 3) provisions that are outside the scope of the

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Directive. Within the last type of provisions there are different subcategories: a) product regulations (in particular flavours for nicotine-free or nicotine-containing e-cigarettes), b) sales arrangements and other non-product specific legislation (including age limits, distance sales, smoke-free environment etc.) and c) provisions that have no impact on intra-Community trade such as imports from countries outside the EEA.

This note only deals with the provisions falling into category 2) and category 3)a). The other provisions are not considered relevant when assessing compatibility with the free movement rules.

II. ASSESSMENT AND POSSIBLE REACTIONS

1) Ban on 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. The key provisions read:

'S 57 Sales prohibition of smokeless tobacco products
Smokeless tobacco products may not be sold or otherwise supplied.'

'S 66 Ban on import of smokeless tobacco products
The import of smokeless tobacco products is prohibited. The ban on import also applies to acquiring or receipt of smokeless tobacco products by mail or by comparable means from countries outside Finland.'

The second paragraph provides for certain derogations for private persons.

In the assessment of DG SANTE the draft legislation should not be assessed under Directive 98/34/EC, but under Article 24(3) TPD. Art. 24(3) TPD has created a separate legal framework for assessing the ban of certain categories of tobacco products, which is considered to be lex specialis. This is evidenced by the fact that the time frame for the assessment is different (six months). Also the assessment criteria deviate from those in Directive 98/34/EC. Finally, within the Commission DG SANTE is chef de file for this type of notification.

In this light it is recommended to inform the Finnish authorities that the Commission considers the envisaged ban of smokeless tobacco products to fall within the scope of Article 24(3) TPD and that the Commission will – if necessary - revert to Finland at a later stage.

2) Ban on flavouring substances and flavouring additives

The notified draft envisages the prohibition of flavours in e-liquids containing nicotine and the prohibition of sales of all flavourings that can be added to nicotine-containing e-liquids. The relevant rules read:

§ 25 Requirements regarding nicotine-containing liquids

Nicotine-containing liquids intended for use in electronic cigarettes may be sold or supplied to consumers only:
5) If no flavouring substances were added to the liquid.

§ 58 Sales prohibition of flavouring additives

Flavouring additives intended for nicotine-containing liquids may not be sold or otherwise supplied to consumers.

Pursuant to the Impact Assessment accompanying the notification, the aim of those provisions 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.

As the TPD makes clear in its recital 47, the regulation of flavours in e-liquids is a non-harmonised area outside of its scope, and therefore left to MS to regulate:

"the responsibility for adopting rules on flavours remains with the Member States."

It should nevertheless be noted that it specifically recommends that they bear in mind the effect that flavours in these products may have on children and non-smokers when regulating them:

"In doing so, they 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".

At the outset it should be noted that DG SANTE shares the health objectives and the grounds for the proposed measures set out in the notification. We would however appreciate if the Finnish authorities could be invited to better explain why all flavours are attractive to young people. Also, the Finnish authorities could be invited to review the situation on the basis of new evidence that has become available, after a given time period, e.g. five years.

As the rules on flavours seem to apply also to nicotine-free e-cigarettes, the same comment could be made for these products.

Signed in ARES

C.c.: (GROW) (AGRI) (SANTE)