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"I/A" ITEM NOTE

From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

Subject: Proposal for a Directive of the European Parliament and of the Council 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 (**first reading**)

- Adoption of the legislative act (**LA + S**)
- = Statements

Statement by the Commission

As regards Articles 10 and 16, the Commission understands that these provisions are intended to address specific needs of the Member States. The Commission recalls that the application of these provisions has to take account of the high level of health protection already achieved by this Directive and has to comply with the Treaty.

Statement by the Commission

When revising the text warnings in ANNEX I, the Commission will take into account established and available scientific findings accordingly, including as regards the risks of second hand smoke.

Statement by the Commission

on the procedure of adoption of implementing acts

The Commission underlines that it is contrary to the letter and to the spirit of Regulation 182/2011 (OJ L 55 of 28.2.2011, p. 13) to invoke Article 5 § 4, subparagraph 2, point b) in a systematic manner. Recourse to this provision must respond to a specific need to depart from the rule of principle which is that the Commission may adopt a draft implementing act when no opinion is delivered. Given that it is an exception to the general rule established by Article 5 § 4 recourse to subparagraph 2, point b), cannot be simply seen as a "discretionary power" of the Legislator, but must be interpreted in a restrictive manner and thus must be justified.

Statement by the Commission

The Commission will undertake to request the appropriate scientific committee to examine the issue of Polonium 210 in tobacco products, in particular regarding its carcinogenic effects, on the basis of available scientific and other relevant data.

Statement of Hungary

Hungary expresses its concerns that the provisions on e-cigarettes, especially those related to nicotine content and refill containers, may lead to serious public health risks. Hungary is of the view that e-cigarettes with a 20 mg/ml nicotine concentration could put the health of their users at risk, as a 2 ml cartridge or tank can contain as much as 40 mg nicotine which may cause serious, even potentially lethal poisoning in cases where this amount of nicotine is inhaled by a child or an adolescent. There is statistical evidence that young people who never smoked tobacco have already consumed nicotine containing e-cigarettes. Consequently, we have every reason to consider electronic cigarettes as a tool of reformulating smoking behaviours. Therefore, Hungary is going to take all measures possible under the Directive to protect public health in this regard. Furthermore, Hungary is going to make full use of the provisions included in Article 20, paragraph 1, second subparagraph of the Directive.

Statement of Sweden

Concerning the Directive of the European Parliament and of the Council 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

Sweden strongly supports obligatory health warnings on tobacco packages, but the proposed increase in size of these warnings may pose great difficulties in terms of compatibility with the Swedish constitution.

The transposal of a directive with health warnings covering more than the size of the warnings stipulated in the current directive (2001/37/EC) might be incompatible with the Swedish constitution.

Consequently, in respect of the provisions relating to the size of health warnings (articles 9 and 10, in conjunction with article 8.6, of the proposed directive), it is not certain if or how Sweden can implement the Directive. In any case, Sweden will require additional time for the implementation of the directive. Currently, Swedish constitutional rules concerning freedom of the press and freedom of expression are being examined regarding text warnings, contents declarations and similar product information.

Furthermore, the transposal of the provisions on e-cigarettes that do not fall under the scope of the Directives [2001/83/EC](#) and [93/42/EEC](#) might be incompatible with the Swedish constitution. Consequently, it is not certain if or how Sweden fully can implement article 20. In any case, Sweden will in this respect require additional time for the implementation of the directive.