EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Cross-border healthcare and tobacco control

Brussels,
SANTE B2/DA(2022)

MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY

09 February 2022

MEETING VENUE: WebEx, 9:30 – 12:00

– DRAFT SUMMARY RECORD –

1. Nature of the meeting

The meeting was non-public. It took place via videoconference.

2. Welcome and introduction

The Chair welcomed the participants and explained the rules for the online WebEx meeting. He stressed that the meeting focuses on the preparation of the draft Delegated Directive with regard to exemptions for heated tobacco products.

The Chair presented the role of the Expert Group in the process concerning the adoption of the Delegated Directive. It was underlined that the consultation of the Expert Group is in line with the Inter-institutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law Making, in particular the Commission's commitment to gather, prior to the adoption of a delegated act, all necessary expertise through the consultation of Member States' experts. The Chair also stressed that the members of the Expert Group will not be asked to deliver a formal opinion on the adoption of the Delegated Directive.

Finally, he explained the role of the European Parliament and the Council of the European Union in the process concerning the adoption and entry into force of the Delegated Directive. In particular, it was stressed that the Delegated Directive will be officially transmitted to the European Parliament and to the Council upon its adoption by the Commission. The two institutions will then be able to exercise the rights provided for in Article 290 TFEU within the time limits laid down in Article 27(5) of Directive 2014/40/EU.

3. Presentation by the Commission of the draft Report on the establishment of a substantial change of circumstances for heated tobacco products

DG SANTE presented the underlying data and findings that are included in the draft Report on the establishment of a substantial change of circumstances for heated tobacco products.

4. Presentation by the Commission of the draft Delegated Directive with regard to exemptions for heated tobacco products

DG SANTE presented the draft Delegated Directive with regard to exemptions for heated tobacco products.

Regarding the scope of the draft Delegated Directive, DG SANTE clarified that it does not concern all novel tobacco products but only a particular category of them, the heated tobacco products. It was indicated that the definition of heated tobacco products is based on the WHO definition of such products.

DG SANTE described the amendments that need to be made to Article 7(12) and Article 11(1) of the Tobacco Products Directive: a) the heated tobacco products should be listed, together with cigarettes and roll your own tobacco, in Article 7(12), as the tobacco products that cannot be exempted from the characterising flavour and flavourings prohibition of Article 7(1) and 7(7) of the TPD, b) the heated tobacco products should be listed, together with cigarettes, roll-your-own-tobacco and waterpipe tobacco that cannot be exempted from the obligations relating to tobacco products for smoking to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10.

Regarding the deadline for the transposition of the Delegated Directive by the Member States, DG SANTE explained that a six-month period after the entry into force is proposed. DG SANTE emphasised that a single date of application at the end of the transposition period should also be introduced in order to prevent the creation of barriers because of potential differences in the application dates.

5. Discussion with the Member States on the draft Delegated Directive with regard to exemptions for heated tobacco products

The Member States were invited to express their comments on the draft Delegated Directive in the form of *tour the table*.

The majority of the Member States welcomed the draft Delegated Directive and expressed their support for its main provisions and the amendments put forward by it.

Timeline on the adoption and entry into force of the Delegated Directive

Several Member States raised the question on the procedure and timeline for the adoption and entry into force of the Delegated Directive. Some Member States expressed their support for a fast timeline.

One Member State asked DG SANTE to clarify the period concerning the scrutiny period for the European Parliament and the Council.

Another Member State stated that the Expert Group on Tobacco Policy should meet to discuss the draft Delegated Directive only after the publication of the Report on the establishment of a substantial change of circumstances for heated tobacco products.

DG SANTE explained that the next step in the adoption procedure will be the formal internal validation of the draft Delegated Directive by the Commission services. It was clarified that the Expert Group will be provided with the opportunity to discuss the text, if its material content is changed after this internal procedure. Then, the adoption of the Delegated Directive by the Commission, preceded by its translation into all EU official languages, will follow. DG SANTE pointed out that this is tentatively expected to take place before the summer break. DG SANTE also explained that the adoption of the Report will precede that of the Delegated Directive.

As soon as the Delegated Act is adopted, the Commission will notify it simultaneously to the European Parliament and the Council that have the right to scrutinise the adoption of the Delegated Directive within a period of two months of notification of that Directive to them. DG SANTE added that this period can be extended by two more months at the initiative of the European Parliament or the Council. After the expiry of the scrutiny period, the Delegated Directive will be published in the Official Journal of the European Union and enter into force after twenty days from the publication. The deadline for the transposition of the Delegated Directive will then start. The transposition period is not expected to be less than six months. Taking the above into consideration, the Chair foresaw that the Delegated Directive is very unlikely to produce its market effects in less than a year time from this Expert Group meeting.

Definition of heated tobacco products

Some Member States raised concerns over whether the Commission is empowered to introduce a definition of a new category of tobacco products in a Delegated Act. A few Member States claimed that the new definition could only be in the main act, namely Directive 2014/40/EU.

DG SANTE assured the Member States that the Commission does not intend to act outside the scope of the delegated powers granted to it in Directive 2014/40/EU. DG SANTE explained that the introduction of this new definition in the Delegated Act is absolutely necessary in order to: a) give effect to Articles 7(12) and 11(6) of Directive 2014/40/EU which aimed at ensuring that the tobacco legislation is dynamic, as reflected in the presence of the "novel tobacco products" category and the "substantial change of circumstances" provision, and stays up to date with market developments, and in particular enable the Commission to comply with its obligations mentioned therein, b) limit, in line with the principle of proportionality, the withdrawal of exemptions only to heated tobacco products and not extend it to the general category of novel tobacco products.

One Member State stated that the definition proposed is problematic as it suggests that all heated tobacco products are tobacco products for smoking. Another Member State expressed concerns on the application of Article 1 in Member States where smokeless tobacco is banned.

DG SANTE indicated that in accordance with Article 1 of the draft Delegated Directive, heated

tobacco products are defined as novel tobacco products. As a result, all the provisions of the Tobacco Products Directive 2014/40/EU that apply to novel tobacco products, including Article 19(4), apply to heated tobacco products, which can be either smokeless tobacco products or tobacco products for smoking. The definition was tailored to reflect a possibility that further types of heated tobacco products might enter the market, which will have to be classified as smokeless or for smoking depending on their individual characteristics.

One Member State raised concerns on the use of the terms "containing nicotine and other chemicals" in the definition of Article 1, notably on whether this requirement will make difficult the task of proving that products fall under the definition of heated tobacco products.

DG SANTE clarified that there would be nicotine or other chemicals in any product of thermodynamic reaction to which tobacco inserts are subject inside the device and as a result, the proof of this element is simple and does not require any hard laboratory effort.

Another Member State asked whether the definition of Article 1 covers also the device that heats the tobacco, besides the tobacco insert. The same Member State claimed that the tobacco insert and device should be treated as a whole and not separately by the Delegated Directive.

DG SANTE underlined that the draft concerns tobacco products that are heated to produce an emission, and there is no possibility to heat the insert without the device.

Heated tobacco products as smokeless tobacco products or tobacco products for smoking

Several Member States asked whether heated tobacco products should be classified as smokeless tobacco products or tobacco products for smoking. The Member States also inquired about Article 2(2) of the draft Delegated Directive, notably whether, in accordance with this provision, the heated tobacco products should always be classified as tobacco products for smoking.

One Member State suggested that Article 2(2) of the draft Delegated Directive should be deleted as it wrongly classifies heated tobacco products as tobacco products for smoking.

A few Member States pointed out that the existing heated tobacco products that are placed on their markets, are smokeless tobacco products and as a result, follow the labelling rules for smokeless tobacco products.

DG SANTE clarified that the provisions of the draft Delegated Directive do not aim at classifying the heated tobacco products as either smokeless tobacco products or tobacco products for smoking. DG SANTE added that this decision is entirely up to the Member States on the basis of the heated tobacco products' characteristics and in line with Article 19(4) of the TPD.

Finally, DG SANTE stressed that Article 2(2) of the draft Delegated Directive is not applicable in the Member States where heated tobacco products are classified as smokeless tobacco products. In this case, the amendment put forward by the above provision will not take effect as long as those products are classified as smokeless tobacco products.

Transposition period

Some Member States considered the six months deadline for the transposition of the Delegated Directive to be short and suggested a longer transposition period. There was no agreement amongst Member States on the duration of an appropriate transposition period. The same Member States called for an additional transition period after the end of the transposition period so that the tobacco industry can adapt to the new rules and sell their stocks of flavoured heated tobacco products.

One Member State welcomed the proposal of a single date of application of the Delegated Directive that requires the Delegated Directive to produce its full legal effects at the same time in all Member States.

DG SANTE stressed that the transposition period should be short, namely not longer than six months considering that the amendments put forward by the draft Delegated Directive are of a very limited character. However, DG SANTE indicated that the Member States' calls for a longer transposition period will be taken into account in the preparation of the final draft that will be subject to the Commission internal validation procedure. The Chair also emphasised that given the overall time expected to elapse before the intended measures will produce their market effects, i.e. about a year time from this meeting, an additional transition period would be at odds with: a) the claims made by the sector in the context of the tobacco traceability system as to its self-classification as part of the fast-moving consumer goods sector, and b) the fact that the amendments put forward by the draft Delegated Directive were foreseeable under specific condition clearly described in Directive 2014/40/EU.

Applicability of Commission Implementing Regulation (EU) 2016/779 to heated tobacco products

One Member State asked whether the procedure concerning the determination of characterising flavours in tobacco products that is described in Commission Implementing Regulation (EU) 2016/779, will also apply to heated tobacco products.

DG SANTE answered the question in the affirmative and clarified that the relevant procedure applies to all tobacco products, including heated tobacco products which form part of the category of novel tobacco products.

Additional questions

One Member State inquired about the parties consulted in the drafting process. DG SANTE clarified that except for the members of the Expert Group on Tobacco Policy, the amendments of the Delegated Directive were also discussed in a general manner with the representatives of the European Confederation of Tobacco Retailers.

Finally, DG SANTE stated that for transparency purposes, the draft Delegated Directive is expected to be published on its website once it is adopted by the Commission as soon as the scrutiny period starts.

6. Conclusions and next steps

Several Member States' delegates expressed their support for the draft Delegated Directive with regard to exemptions for heated tobacco products. Questions and concerns were raised by a number of Member States. DG SANTE provided answers and clarifications.

DG SANTE will launch soon the procedure for the internal validation of the text by the Commission services. If the material content of the draft Delegated Directive is changed after this procedure, DG SANTE will consult again the Expert Group on the draft Delegated Directive. If the Commission internal validation procedure does not result in significant changes to the text, the Commission is expected to adopt the Delegated Directive and send it to the European Parliament and the Council for their scrutiny period before the Delegated Directive's publication in the Official Journal and entry into force.

Annex

List of participants

Member States:

Austria	(Federal Ministry of Social Affairs, Health, Care and Consumer Protection)
Belgium	(Federal Public Service Public Health, Food Chain Safety and Environment)
Bulgaria	(Ministry of Economy, Tobacco and Tobacco Products Institute)
Croatia	(Ministry of Health, Institute of Public Health)
Cyprus	(Ministry of Health – Medical and Public Health Services – Health Services)
Czech Republic	(Ministry of Agriculture, Ministry of Health)
Denmark	(Ministry of Health, Danish Health Authority)
Finland	(Ministry of Social Affairs and Health)
France	(Ministry of Social Affairs and Health, Ministry of Europe and Foreign Affairs)
Germany	(Federal Ministry of Food and Agriculture, Ministry of Food, Rural Affairs and Consumer Protection, Baden-Wuerttemberg)
Greece	(Ministry of Health)
Hungary	(Ministry of Human Capacities – Focal Point on Tobacco Control)
Ireland	(Department of Health, Tobacco and Alcohol Control Unit)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Lithuania	(Ministry of Health of the Republic of Lithuania)
Luxembourg	-
Malta	(Ministry for Health, Environmental Health Directorate)
Poland	(Ministry of Health, Bureau for Chemical Substances)
Portugal	(General Directorate of Health)
Slovakia	(Public Health Authority of the Slovak republic)
Slovenia	(Ministry of Health, National Laboratory of Health, Environment and Food)
Spain	(Ministry of Health)
Sweden	(Ministry of Health and Social Affairs, Public Health Agency)
The Netherlands	(Ministry of Health, Welfare and Sport, Permanent Representation of the Netherlands)
Iceland (observer)	(Ministry of Welfare)
Norway (observer)	(Ministry of Health)

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