



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY

16 MAY 2022

MEETING VENUE: CCAB 10:00–17:00

– SUMMARY RECORD –

1. Welcome and introduction

DG SANTE welcomed the participants and explained the technical arrangements for the physical meeting and hybrid connection/online rules. The Commission reminded the group of the last relevant meetings, namely, the Expert Group on Tobacco Policy meeting that took place on 02/12/2021, the Expert Group on Tobacco Policy meeting with special focus on the substantial change of circumstances of heated tobacco products that took place on 09/02/2022 and finally, the Tobacco Traceability Subgroup meeting that took place on 24/03/2022.

DG SANTE presented the draft agenda, which was adopted without changes.

2. Update by the Commission and Member States on the implementation and monitoring of the TPD

DG SANTE updated Member States about court proceedings, notably judgements in Case C-370/20 (Germany), Case C-160/20 (Netherlands) and Case C-452/20 (Italy).

DG SANTE gave an update on the status of conformity checks of the national transposition measures, which continue for further Member States. This is followed by structured bilateral meetings which, for the moment, continue in the virtual format. However, DG SANTE aims at starting face-to-face meetings whenever possible. Further bilateral meetings are planned.

DG SANTE updated the group on the status of compliance assessments of national transposition measures, including transposition and conformity checks. Member States were informed that the last infringement for non-communication of the transposition measures has just been closed.

DG SANTE informed that bilateral contacts in the framework of the conformity checks continue and further structured bilateral meetings took place since the last Expert Group and more are planned via teleconferences. Member States were reminded of their obligation to notify new transposition measures to the Commission. DG SANTE also reminded about the principle of close cooperation in the context of post-bilateral communications.

This was followed by a tour de table including Member States' updates on national court cases, imminent notifications under Directive 2015/1535, and other regulatory and enforcement updates relevant for tobacco control in the context of the TPD and beyond.

3. Evaluation of the Legislative Framework for Tobacco Control

DG SANTE updated Member States on the most recent developments regarding the evaluation of the legislative framework for tobacco control, namely in the context of Europe's Beating Cancer Plan and its implementation roadmap. DG SANTE also explained the evaluation process under Better Regulation, including the call for evidence planned to be published as a part of this process. DG SANTE has created a new website dedicated to this evaluation, where it will update stakeholders on different steps, as well as inform them of any relevant events, including public and targeted consultations. The current evaluation will inform the Commission on the need for a revision subsequent to an impact assessment.

To support the evaluation process, DG SANTE is in the course of contracting a supporting study. DG SANTE presented the task description in line with the procurement request and described the study's timelines and deliverables. Additionally, the study will also include a task related to smoke-free environments that will support the planned update of the Council Recommendation on Smoke-free environments. The Commission encouraged Member States' contribution to the study (e.g. in the targeted consultation) and explained that it will instruct the contractor to clearly differentiate between issues reported by Member States' authorities and issues reported by experts/organizations' on their experiences in specific Member States.

4. Substantial change of circumstances for heated tobacco products

DG SANTE updated Member States on the file concerning a substantial change of circumstances for heated tobacco products, including the progress on the adoption of the Report on the establishment of a substantial change of circumstances for heated tobacco products and the Delegated Directive on the withdrawal of certain exemptions in respect of heated tobacco products.

DG SANTE provided a short update on the procedure for the adoption and entry into force of the Delegated Directive. It was stressed that the Commission internal consultation procedure, including the Commission's legal service, had been finalized and resulted in the embargoed version of the draft Delegated Directive that was shared with Member States on 10 May 2022. It was explained that the next steps of the adoption procedure following the meeting's discussion and consideration of Member States' comments would include the translation of the draft Delegated Directive into all EU official languages and the adoption of the Delegated Directive by the Commission. As soon as the Delegated Directive is adopted, the Commission will notify it simultaneously to the European Parliament and the Council. The Delegated Directive will then undergo a two-month period of scrutiny by the two institutions which may request an additional two months of scrutiny time. Once the scrutiny period is over and if no objection has been expressed, the Delegated Directive will be published in the Official Journal of the European Union and enter into force after twenty days from the publication.

DG SANTE then presented the latest amendments to the draft Delegated Directive. Those concerned: a) the addition of a new recital defining the heated tobacco products, b) the new position of the definition of heated tobacco products in the text, c) the introduction of an additional sentence in the definition of heated tobacco products regarding their classification as either smokeless tobacco products or tobacco products for smoking, depending on their characteristics, d) the establishment of an eight-month period that will start after the entry into force of the Delegated Directive, for the transposition of the Delegated Directive into Member States' laws, and e) the establishment of a single date on which the national measures transposing the Delegated Directive should become applicable. This date was set at eleven months after the entry into force of the Delegated Directive.

Following this presentation, DG SANTE invited Member States to submit their comments and questions on the draft Delegated Directive. Most Member States' comments concerned the proposed deadline for the transposition of the Delegated Directive, and the date of application of the national transposition measures. In particular, certain Member States stressed the need for a

longer transposition period and additional transition time after the end of the transposition period so that the tobacco industry can sell their stocks of flavoured heated tobacco products. A few Member States also raised concerns over whether the Commission is empowered to introduce the definition of heated tobacco products in a Delegated Act. One Member State asked the Commission to confirm that the Commission's Legal Service accepted the latest version of the draft Delegated Directive¹.

DG SANTE confirmed to Member States that as part of the standard internal procedures the Commission's legal service was consulted on the latest version of the draft Delegated Directive. All Member States' comments² were duly noted by the Commission and registered for the file.

DG SANTE also confirmed that it will provide Member States with the final version of the draft Delegated Directive as it will be adopted.

5. Update on the revision of the Council Recommendation on Smoke-Free Environments

DG SANTE informed Member States on the intended revision of the Council Recommendation on Smoke-Free Environments, including the publication of the evaluative study, a call for evidence and the publication of the initiative on the 'Have your say' web portal. DG SANTE highlighted that the Commission announced, in the Europe's Beating Cancer Plan, an intention to update this Recommendation. The initiative envisages extending the Council Recommendation to cover emerging products, such as e-cigarettes and HTPs (to address technological developments), as well as to explicitly include certain outdoor and quasi-outdoor spaces in the definition of smoke-free environments, thus removing the need for individual/case-by-case assessment. The existing implementation/evaluative studies, as undertaken in 2013 and in 2021, will be used to assess the expected results of the intended update of the Recommendation. The envisaged consultation activities (namely a call for evidence and a targeted consultation) will allow stakeholders to provide views on this initiative.

6. Advertising, promotion and sponsorship of tobacco and related products

DG SANTE reiterated that the findings of the study reported in point 5 will also feed into the work on the evaluation of the Tobacco Advertising Directive, which is being assessed together with the Tobacco Products Directive in a broader scope defined as "Evaluation of the Legislative Framework on Tobacco Control". The specific work regarding this point and next steps was discussed in detail under point 3 of the agenda.

Within this point, DG SANTE also raised concerns regarding possible challenges to the EU tobacco and e-cigarette advertising and sponsorship bans in the context of Formula 1 and other motorsport events. DG SANTE reminded that the previous season was discussed at the last meeting of the EG, where Member States presented their enforcement actions. DG SANTE invited again the Member States to stay vigilant and undertake the necessary monitoring and enforcement actions in the upcoming events with a view to ensuring that EU and national legislation on TAPS is respected. Member States were also asked to actively exchange information. In the next meeting of the Expert Group, DG SANTE will facilitate another exchange of views and experiences regarding the upcoming season.

7. Emerging products, latest trends and technical developments in tobacco control

¹ The majority of the Member States did not submit any comments or questions on the draft Delegated Directive during or after the meeting.

² Including those that were submitted after the meeting of the Expert Group.

DG SANTE highlighted the increasing requests, among the Member States, for information about emerging products and/or new technical developments and respective regulatory strategies and initiatives. One Member State presented the case of nicotine pouches being more and more used by adolescents in a hidden manner, including putting several pouches in the interdental membranes of the feet. Several Member States mentioned the presence of nicotine pouches in their markets and a few others mentioned the emerging presence of heated herbal products enriched with nicotine.

8. Progress of the Joint Action on Tobacco Control 2 (JATC-2)

DG SANTE informed Member States on the progress of the JATC 2, namely the launch of the initiative in October 2021 with a virtual kick-off meeting in January 2022. It highlighted the successful 2022 events hosted by the Work Packages' leaders, but also the lack of operational website and limited dissemination since the kick-off meeting. DG SANTE also inquired with the participants on how to ensure that the outputs of JATC-2 were assisting the regulators across the EU and invited DK to do a small update from their perspective of a coordinating Member State. DK updated about overall progress and current changes in the team leading the joint action.

9. Update on other EU initiatives relevant in the context of tobacco control

DG SANTE updated Member States on other EU initiatives relevant in the context of tobacco control, namely the SUP Directive, CASP 2021/2022 and Safety Gate, Council recommendation on cancer screening, the Tobacco Taxation Directive and the "One Substance One Assessment" (1S1A) initiative.

a. SUP Directive

One Member State shortly presented the challenges related to a consumer awareness campaign proposed by the tobacco industry in the context of the implementation of the SUP Directive.

DG SANTE reminded that certain concerns relating to the industry's tactics were already raised at the Expert Group meeting in 2020. Member States were encouraged to follow closely the developments in this area since the responsible national environmental services may not be fully aware of the EU tobacco-control regulatory framework and the FCTC provisions, including Article 5.3. The importance of the close collaboration at national level of those responsible for tobacco control and environmental issues was highlighted.

b. CASP 2021/2022 and Safety Gate

DG JUST introduced Member States to the 'Coordinated activities on the safety of products' (CASP), which are activities involving Member States, mostly market surveillance authorities, in which they select categories of products to be assessed for safety. The CASP2021 initiative had a category on electronic cigarettes.

DG JUST also presented in detail the EU rapid alert system for dangerous non-food products, Safety Gate (previously known as RAPEX), including overall purpose, mechanism for reporting and consequent handling of notifications, submission requirements and examples of notifications (namely on e-cigarettes).

c. Council recommendation on cancer screening

DG SANTE brought to the attention of Member States the initiative regarding the update the 2003 Council Recommendation on cancer screening, which is currently considering extending targeted cancer screening beyond breast, colorectal and cervical cancer to include additional cancers, such as prostate, lung and gastric cancer. The call for evidence was published for feedback in the period between 25 January and 22 February 2022. It is planned to be adopted during the CZ Presidency (second half of 2022). Additionally, there is a scientific opinion of the Group of Chief Scientific Advisors of the Commission (established in 2016) from March 2022 on this initiative.

d. Tobacco Taxation Directive

DG SANTE explained that the revision of the Tobacco Taxation Directive is ongoing. TAXUD colleagues are finalising the Commission's impact assessment and the adoption is expected in Q4. The key aspects: raising the minimal rates while considering power purchasing parity, inclusion of emerging tobacco and nicotine products, ongoing discussion on e-cigarettes tax base and inclusion of raw tobacco were confirmed to be in the initiative's scope.

e. "One Substance One Assessment"

DG SANTE highlighted that the IS1A initiative is a follow-up on the chemical strategy with broad objectives of regulating aspects of chemicals across all sectors. It is an opportunity to better understand how tobacco and related products ingredients' assessment could be accommodated following the conclusions of the Tobacco Products Directive application report from May 2021.

10. AOB

In the absence of any AoB proposed by Member States, DG SANTE highlighted that the World No Tobacco day will take place on the 31st of May and that this year's topic tackles "Tobacco: Threat to our environment".

DG SANTE concluded the meeting by thanking all participants for their constructive participation and closed the meeting.

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 and Industry)
Croatia	(Ministry of Health, Institute of Public Health)
Cyprus	-
Czech Republic	(Ministry of Agriculture, Ministry of Health, CAFIA)
Denmark	(Ministry of Health, Danish Health Authority)
Estonia	(Ministry of Social Affairs)
Finland	(Ministry of Social Affairs and Health)
France	(Ministry of Social Affairs and Health)
Germany	(Federal Ministry of Food and Agriculture, Ministry of Food, Rural Affairs and Consumer Protection, Baden-Wuerttemberg)
Greece	(Ministry of Health, Independent Authority for Public Revenue)
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)
Romania	(Ministry 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)
Iceland (observer)	(Ministry of Welfare)
Norway (observer)	(Ministry of Health)

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