



Brussels,
SANTE B2/

MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY

02 DECEMBER 2021

**MEETING VENUE: ONE-DAY WEBINAR 9:30 –
17:00**

– SUMMARY RECORD –

1. Welcome and introduction

The Chair welcomed the participants and explained the rules for the online WebEx meeting. The Chair introduced the team and himself as acting head of unit. The agenda was presented and adopted without changes.

2. Update on the implementation and monitoring of the TPD

DG SANTE updated the MSs on the implementation and monitoring of the TPD and presented the findings of the report on the application of the Directive (see below).

A few MSs asked about the procedure and planning of the revision of the EU tobacco control regulatory framework. DG SANTE referred to the recently published roadmap in the context of the Europe's Beating Cancer Plan¹.

2.1. The TPD Application report (Article 28)

DG SANTE outlined the key elements of the report on the application of the Directive prepared in line with Article 28 of the TPD and adopted by the Commission in May 2021. The report examines the progress achieved so far, namely that the TPD contributed to the reduction of tobacco consumption and generated positive outcomes for public health, while

¹ https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/2021-2025_cancer-roadmap_en.pdf

addressing the Directive's strengths and weaknesses and indicating elements requiring adaptation. The report was supported by a number of preparative studies, which are also published.

Overall, the application report concluded that the TPD had enhanced tobacco control and its validity had been upheld in courts. The TPD had contributed to the improvement of public health, provided added value and MSs could not have accomplished the same objectives alone. In general, the TPD was considered to be consistent internally, but due to market developments there is scope for improvement in certain essential areas. According to the report, compliance of national laws with the TPD and their harmonised application varies and many MSs lack adequate enforcement resources. In particular, the new functional systems (EU-CEG, IAP, traceability) are relatively resource-intensive.

2.2. SCHEER opinion

DG SANTE informed the MSs on the SCHEER opinion on e-cigarettes and the important role they play in smoking initiation, as well as the weak available evidence to support their role in helping smokers to quit. In addition, SCHEER concluded that flavours in e-cigarettes strongly influence young people by decreasing harm perception and increasing will to try.

2.3. Court Cases

DG SANTE updated the MSs about the court proceedings, including the recent decision in Case C-176/21 P and state of play of requests for the preliminary ruling: Case C-370/20 (Germany) - judgement scheduled for 9 December, Case C-160/20 (Netherlands) and Case C-452/20 (Italy).

DG SANTE also pointed out to the communication sent by one MS to the Members of the Expert Group informing about a national court case on classification of novel tobacco products.

2.4. Compliance assessment

DG SANTE informed the MSs that the conformity checks of the national transposition measures of the TPD are ongoing and bilateral meetings between the MSs and the Commission are continuing.

DG SANTE reminded the MSs to notify the new national transposition measures to the Commission.

3. Update on determination of characterizing flavours in tobacco products

DG SANTE updated the MSs regarding ongoing requests to consult the independent advisory panel (IAP) for determination of characterising flavours. The MSs were informed about practical aspects of the procedure and some related issues. The MSs were informed that the procedures were ongoing and only limited information might be shared at this stage.

Subsequently, the MSs had an opportunity to share their own experience with the procedure. One MS updated the Expert Group on potential procedural aspects of the withdrawal of products under investigation. For example, a manufacturer has been repeatedly withdrawing and re-launching very similar products under new TP-IDs in the EU-CEG database. Similar practices have been also identified in several other MSs.

The technical group, assisting the IAP in its assignments, has faced issues with shipments of products across borders, both to the UK but also within the EU.

DG SANTE noted that the frequency of new notifications has lowered since the last year and invited the MSs to share their experience as regards market developments. Some new cases of potentially flavoured products were raised.

The IAP will continue to work on the pending opinions in its upcoming meeting of 7 December.

4. Substantial change of circumstances

DG SANTE informed the MSs that the observed market developments concerning heated tobacco products constituted a substantial change of circumstances as defined in Article 2(28) of the TPD. The general conditions that trigger the application of the relevant provisions as well as their scope and legal implications were presented to the Expert Group.

DG SANTE clarified that the substantial change of circumstances concerning heated tobacco products will have to be established in a Commission Report. The relevant statistics and findings to be included in the report were also presented to the Expert Group.

The report will provide a basis for the Commission to adopt a delegated act to withdraw the exemption from the prohibitions of Article 7(1) and (7) of the TPD for heated tobacco products and, where applicable, the MSs' possibility of granting exemptions to heated tobacco products from certain labelling requirements laid down in Articles 9(2) and 10 of the TPD. In due time, DG SANTE will have to organise a separate *ad-hoc* meeting of the Expert Group to discuss in detail the provisions of the draft delegated act with the MSs.

Finally, in response to the MSs' questions, DG SANTE clarified that the delegated act is likely to include a brief transitional provision concerning the stock exhaustion of heated tobacco products. The act should cover solely heated tobacco products, excluding other novel tobacco products.

5. Nicotine pouches and other emerging products

DG SANTE informed MSs about the findings of an informal consultation related to nicotine pouches within the context of the medicinal products legislation. MSs expressed concerns about these products because while they pose a serious public health threat, they remain unregulated on many national markets. In the survey, most MSs have called for a legislative

initiative at EU level that would regulate these products (including banning nicotine pouches). A few MSs informed the Expert Group that they categorised nicotine pouches as food products or plan to do so, and a few MS reported regulating these products as tobacco surrogates. Asked for its opinion DG SANTE stressed that only the Court of Justice has the ultimate word on the interpretation of the EU legislative framework.

6. 9th Conference of the Parties to the WHO Framework Convention on Tobacco Control report

DG SANTE informed the MSs of the WHO FCTC COP9 developments. As it was a virtual COP, it faced many challenges but in the end had a successful outcome. Inter alia, the Parties decided to move forward with the development and launch of an investment fund, which will offer a third source of support to help global tobacco control efforts. The next COP and MOP will take place in November 2023 and will be hosted by Panama².

7. Launch of Joint Action on Tobacco Control 2

DG SANTE informed the MSs about the launch of JATC-2, a kick-off meeting and the next steps. The grant agreement was signed on 20 September 2021, while the actual work started on 1 October 2021. The JATC-2 has a wider policy scope comparing to JATC-1. The leaders of work packages 5, 6 and 7 introduced the priorities of their work and encouraged the MSs to follow-up their progress.

It was noted that with regard to the EU-CEG data publication, more specific technical specifications are needed to provide for efficient export of non-confidential fields. Also, a dedicated training session was considered a useful idea as many current users joined their competent authorities after the initial training at the time of the EU-CEG launch.

8. Tobacco advertising and smoke free environments study

DG SANTE informed the MSs on the state of play regarding the advertising/smoke free study. The study was expected to be published on 10 December and then to serve as the key input for the evaluation of the advertising provisions of the TAD and the TPD as well as for extending the scope of Council Recommendation on smoke-free environments (2009/C 296/02). DG SANTE informed about the challenges that emerged due to new products and new types of advertising and about some of the recommendations of the consultant to tackle those challenges.

² <https://fctc.who.int/who-fctc/governance/conference-of-the-parties/ninth-session-of-the-conference-of-the-parties>

9. Tobacco advertising on motorsports events

DG SANTE informed the MSs of its experiences and actions regarding advertising, promotion and sponsorship in the Formula 1 and MotoGP events of 2021. Concerned MSs also provided a brief update. A few MSs were faced with advertising in these races. They reacted with sending letters to the companies in question to remind or even beforehand to inform them of the advertisement ban.

10. Revision of the Tobacco Taxation Directive

DG TAXUD informed the MSs on the progress and key areas of the revision. The revision of the Directive 2011/64/EU on excise rules for tobacco is ongoing. The external study has now been finalized. The next steps are an impact assessment and a Commission proposal to be adopted in 2022. The Impact Assessment will look at the minima rates for manufactured tobacco products, the possibility to extend the scope of the Directive to heated tobacco products, e-cigarettes, and new products, as well as to raw tobacco. The increasing production of illicit cigarettes in clandestine factories within the EU highlighted the need to control the cross border movements of raw tobacco.

11. Any other business

A few MSs raised the issue of the Single Use Plastic Directive marking requirements in the context of plain packaging. DG SANTE referred to the presentation to the Expert Group meeting in November 2020 and to the relevant discussions in DG ENV Waste Technical Adaptation Committee in September 2021. The importance of coordination among national authorities responsible for various policy areas was also highlighted.

One MS informed the other MSs about its experiences with the menthol ban on the basis of Article 7(6) of the TPD. Ingredients analogue to menthol and geraniol were also included in the ban. There is an ongoing court case for suspension of this ban. Other MSs were also confronted with similar challenges. One MS is working on an additives list and asked other MSs to work together on such a list.

Annex I

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 Safety Technology Authority)
Finland	(Ministry of Social Affairs and Health)
France	(Ministry of Social Affairs and Health, Ministry of Europe and Foreign Affairs, French Agency for Food, Environmental and Occupational Health and Safety (ANSES))
Germany	(Federal Ministry of Food and Agriculture, Federal Office of Consumer Protection and Food Safety)
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	(Permanent Representation)
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)