



Brussels, 30 April 2019
SANTE B2/KB/MF/AK/AS/JH/JL

MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY

21 MARCH 2019

MEETING VENUE: CCAB ~ ROOM: 2.D

–SUMMARY RECORD –

(1) Welcome and introduction

The Chair welcomed the participants. The agenda was adopted with two additional points added under AOB at the request of a Member State. New participants introduced themselves.

(2) Implementation and Monitoring of the TPD

(a) Follow-up on the compliance assessment (transposition/conformity checks)

SANTE informed the group about the status of compliance assessment of national transposition measures, including transposition and conformity checks. Member States were reminded that new transposition measures should be notified to the Commission.

The Commission has closed further infringements for non-communication of national transposition measures. SANTE informed that bilateral contacts in the framework of conformity checks are taking place and more will follow.

(b) Court cases

SANTE informed the group about recent judgments of the Court of Justice of the European Union on the TPD (Case: C-220/17) and the state of play of additional court cases currently pending in the Court (Cases: C-517/18 and T-396/18).

(c) List of competent authorities

Member States noted that the Commission will publish a list of their competent authorities in the Official Journal, as outlined in Article 26 of TPD. A more detailed list will be published on the SANTE website and SANTE will contact Member States with specific information requests.

Remarks:

The meeting is destined for exchange of information on different subjects related to tobacco product and e-cigarette regulation. The meeting will be held in English without translation.

(d) Article 28 report update

SANTE informed about the planning, timelines and preparatory work for the implementation report outlined in Article 28 of the TPD, due in May 2021. As outlined in that article, Member States are expected to contribute to the report and will be contacted during its preparation (e.g. via questionnaires). SANTE also informed that Chafea has launched a study, assessing how specific products (water pipes, slim cigarettes, small cigarillos, novel tobacco products and electronic cigarettes) are perceived. This study will also look into the mapping of consumer preferences and use patterns. The study will also help inform the Article 28 report.

Member States were encouraged to actively contribute to the data gathering exercises that will be carried out in the preparation of the report.

(3) Updates by Member States on relevant regulatory, enforcement and legal developments within and beyond the TPD

(a) Meeting of national enforcement officials

SANTE reminded of provisions in Article 23 of the TPD (cooperation and enforcement) and followed up on the agreement from a previous meeting to exchange on best practices for market surveillance. Denmark announced that they would host a meeting of national enforcement bodies (11-12 June in Copenhagen). Member States were encouraged to nominate persons in charge of enforcement, to actively participate, and to send suggestions regarding the agenda to Denmark who will soon send out the invitations to the other Member States.

Member States were encouraged to actively support and participate in the meeting of national enforcement officials and to identify suitable participants for the meeting.

(b) National court cases, notifications and other regulatory updates

Member States reported on recent national court proceedings, judgments, upcoming notifications and other regulatory issues relevant for tobacco control.

(c) Products containing nicotine but no tobacco

Member States exchanged views on products containing nicotine but no tobacco. Seven Member States have these products on the market or are aware of plans for these products to enter the market. SANTE reminded that the definition of "tobacco products" in the TPD clearly requires tobacco products to consist, even partly, of tobacco, whether genetically modified or not (Article 2(4) of the TPD). The potential applicability of other sectoral legislations was discussed, including on human medicines.

(d) Table of fees charged by Member States

SANTE presented an overview of fee charging practices amongst Member States for tobacco and related products according to the TPD provisions, based on the information provided by Member States. The majority of Member States charged fees for certain activities. There will be an opportunity to further update/refine the information.

As regards point (b) to (d) above, participants recognised the importance of exchanging information and best practice in order to support the implementation and enforcement of the TPD.

(4) Tobacco Product Regulation and Reporting

(a) Joint Action on Tobacco Control and Subgroup on Ingredients meeting

SANTE reported back on the meeting of the Joint Action on Tobacco Control (JATC) and Subgroup on Ingredients (6-7 February), particularly the work on ingredients, updates on data sharing and how the JATC supports Member States in implementing the TPD. The JATC involvement is of particular importance for the assessment of the EU-CEG data and the review of industry reports on the priority additives. Concerning the mechanism for determination of products with characterizing flavours, SANTE updated the group on the ongoing testing of products considered for inclusion in the group of reference products and on the further development of the methodology to support the decision whether a tobacco product has a characterising flavour. Member States were also reminded on the procedure as outlined in the Commission Implementing Regulation (EU) 2016/779.

SANTE further gave an update on product reporting in EU-CEG, and explained new features introduced in the MSREP 2.2 release. While no major MSREP performance issues were experienced, certain MSs reported temporary issues with TESTA NG connection which needs to be addressed through national TESTA NG contact points. In response to a question on the link between EU-CEG and tobacco traceability, SANTE confirmed that the TP-ID and TP-PN number form part of the information in unit level unique identifiers, which are applied to tobacco products intended for the Union market.

Member States reflected on the utility of the JATC and several Member States gave positive feedback, also emphasising that it may be, at this moment, too early to make conclusive assessments on the utility. SANTE gave an overview of timelines for planning actions foreseen for the 2020 Annual Work Programme.

Further assessment and discussion on the utility of the JATC for implementation of the TPD will take place at the next meeting.

(b) Priority additives

Concerning compliance of submissions on priority additives, SANTE confirmed that manufacturers / importers have been, in principle, submitting reports within the submission deadlines, however few reports have been submitted for diacetyl. Work from JATC Work Package 9 and findings of its 'independent interdisciplinary review panel', have identified that industry reports are overall of questionable quality. Member States and SANTE agreed, that in the context of requirements of Article 6 of the TPD the quality of submitted reports is generally poor.

Member States and SANTE agreed that SANTE, in collaboration with WP 9, would prepare a letter requesting supplementary information from manufacturers or importers, in line with Article 6(4) of the TPD. SANTE will also facilitate the development of a standard letter that Member States can address, at the national level, to manufacturers / importers of products containing diacetyl. This would, in particular, refer to Article 23(2) of the TPD calling upon Member States to ensure that tobacco products are not placed on the market if the reporting obligations are not complied with.

SANTE will prepare a draft letter, for approval by the Member States, requesting supplementary information from manufacturers or importers. Moreover, SANTE will facilitate the preparation of a second letter regarding products containing diacetyl, which Member States will send out individually.

(5) E-cigarette regulation and reporting

SANTE informed of the citizens' initiative titled 'Let's demand smarter vaping regulation!' which was registered by the Commission on 20 February. The main objective of the initiators is to repeal Article 20 of the TPD and create legislation separating vaping products from tobacco and pharmaceutical products. SANTE gave an overview of the procedures, which include that 1 million signatures need to be collected within 1-year for the Commission to react with a reasoned reply.

(a) SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) mandate

SANTE informed that the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER Committee) has accepted the mandate for a scientific opinion on certain aspects of e-cigarette use (health effects, cessation, and initiation).

(b) Market surveillance

SANTE reminded of the notification measures under article 20 of the TPD, concerning electronic cigarettes. DG GROW gave an overview of market surveillance via the ICSMS IT-platform, which also allows for notification in RAPEX. Member States were encouraged to use ICSMS for market surveillance to encode all investigations. RAPEX should be used in all cases where a measure against a dangerous product has been adopted in their respective territories. By working in this way, there is no need for the user to encode the same information twice, in both ICSMS and RAPEX.

Member States were informed of the upcoming e-cigarette subgroup meeting which will have a more detailed discussion (7 May).

The e-cigarette subgroup meeting will take place 7 May 2019, addressing a range of issues, including market surveillance IT platforms.

(6) Track and Trace

SANTE gave a horizontal overview and update of the completed, ongoing and upcoming activities on tobacco traceability and security features.

(a) Update on secondary repository

SANTE informed that 'Dentsu' has been appointed as provider of the secondary repository on 21 December 2018. Data storage will be provided via a cloud system operated by Amazon Web Services. The technical specifications, and common data dictionary, were published on 21 February 2019. A complete test environment is available since 20 March 2019. Dentsu agreed to launch the production environment necessary for the request of identifier codes and unique identifiers on 10 May 2019, which is in advance of the legal deadline.

(b) Update on previous Subgroup meetings

SANTE provided feedback on previous Subgroup meetings, which primarily concerned implementation discussions and general questions received from Member States, both of legislative and technical nature. Meetings in February and April were dedicated to discussions between regulators and service providers. One discussion point concerned security features applied to unit packets of tobacco products. This discussion linked to the combined health warnings, as some stakeholders continue to argue that Member States should provide for common security features in the case of duty free sales, because a similar arrangement existed for health warnings. In this regard, SANTE and Member States had agreed on their common understanding that individual Member State labelling requirements also apply in duty free airport shops, requiring the combined health warning to comply with the rules of the Member State on whose market the product is placed (i.e. location of the duty free shop).

(c) Failure to establish an ID issuer in time

Ensuring the appointment and operation of ID issuers is a key obligation for Member States and an important aspect of ensuring the overall functioning of the traceability system. Absence of an ID issuer in one or multiple Member State(s) would likely jeopardise the timely launch of the system, which may have serious consequence from an internal market perspective. SANTE had carried out an internal risk mapping, based on the information received from Member States in the Meetings of the Subgroup of January and February and follow-up communications thereafter. This mapping would be shared with Ministers of competent national authorities as part of a letter to them from Commissioners Andriukaitis and Moscovici.

Member States should give high priority to ensuring timely appointment and operation of ID issuers. Absence of ID issuers in one or multiple Member States can have serious consequences for the internal market. Furthermore, Member States were encouraged to participate actively in future Subgroup discussions.
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(7) Other tobacco control developments beyond the TPD

(a) Tobacco, sponsorship and F1

SANTE asked Member States to be vigilant that EU legislation on advertising, promotion and sponsorship is respected, in particular in the context of upcoming Formula 1 (F1) events.

(b) Customs classification of novel tobacco products

SANTE updated on discussion in the World Customs Organisation (WCO), which is currently reviewing the customs classification for several product categories, including tobacco products (HS 2022 nomenclature). The final decision on creation of a new heading “24.04” (grouping heated tobacco products with nicotine containing e-liquids and nicotine replacement therapies) was taken at the recent meeting of the “Harmonized System Committee” (20 March). SANTE and Member States agreed on the importance of separating this decision from future regulatory decisions regarding novel tobacco products and e-cigarettes in line with existing legislation and work carried out at international level, in particular the FCTC (see decision FCTC/COP8/22)

(c) Smoke-free environments

SANTE informed of the preparation for an upcoming study on smoke-free environments and Member States noted that they will be contacted by a contractor in the near future with questionnaires. Concerning electronic-cigarettes, the majority of Member States informed that electronic-cigarettes were included in their smoke-free environment legislation and a substantial number also included novel / heated tobacco products in their laws.

(d) FCTC and COP8 follow-up

SANTE updated on activities following FCTC COP8, including the process of establishing the Working Group on cross-border tobacco advertising and depiction in the entertainment media as well as of an Expert Group for Articles 9&10. The Netherlands informed about the planned Workshop on Cigarette Ventilation.

(e) Single-use plastics legislation update

SANTE gave an update that the directive will be voted on 28 March and should be approved by the Council on 15 April. 20 days after publication in the Official Journal the legislation will enter into force. Concerning tobacco products, a study is being prepared by DG ENV for the implementing acts, which will further define the labelling requirements and the format for future reporting requirements concerning tobacco products with filters.

(f) Health policy platform

Member States were encouraged to register and test the ‘Health Policy Platform’ as a tool for exchanges between the Member States in the Expert Group (and the Commission as observer).

Member States noted the creation of the ‘Health Policy Platform’ and were encouraged to register and test the internal communication tool.
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(8) Any other business

(a) Menthol as a characterising flavour in novel tobacco products

A Member State raised the case of a novel tobacco product containing menthol. In their view this product is not covered by the characterising flavour prohibition of the TPD. Member States exchanged on the characterising flavour prohibition and SANTE reminded of procedures under Article 7(12) of the TPD, for extending provisions to tobacco products other than cigarettes and roll-your-own tobacco.

(b) Labelling on ‘unit packet’ for e-cigarettes liquids

A Member State raised the issue of labelling on ‘unit packets’ for e-cigarettes liquids. There was an exchange within the group on how different Member States dealt with these provisions and SANTE reminded that the issue has been discussed at the Expert Group meeting in October 2017. It also reminded of the relevant definitions provided in the TPD.

(c) Upcoming meetings / save the date

The next meeting of the expert group will tentatively take place 15 October.

Future meetings in the following subgroups are tentatively scheduled for:

- Tobacco traceability : April 2019
- E-cigarettes : 7 May 2019
- Ingredients/EU-CEG : June 2019

Denmark will also host an enforcement meeting 11-12 June in Copenhagen.

Close of the meeting.

(9) Annex I: List of participants

European Commission:

DG SANTE B2	Thea Emmerling (Chair) Katja Broman Matus Ferech Agnieszka Kozakiewicz Andrea Schwarz Julia Langer Sascha Löwenstein Jan Hoffmann
DG SANTE C1	Marianne Takki Ingrid Keller
DG GROW	Raf Colson

Member States:

Austria	(Federal Ministry for Labour, Social Affairs, Health and Consumer Protection)
Belgium	(Federal Public Service Public Health)
Bulgaria	(Permanent Representation of Bulgaria to the EU)
Croatia	(Ministry of Health)
Cyprus	(Permanent Representation of Cyprus to the EU)
Czech Republic	(Ministry of Agriculture, Ministry of Health)
Denmark	(Ministry of Health, Danish Safety Technology Authority)
Estonia	(Permanent Representation of Estonia to the EU)
Finland	(Ministry of Social Affairs and Health)
France	(Ministry of Social Affairs and Health)
Germany	(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, National Institute of Health)
Latvia	(Ministry of Health)
Lithuania	(Excused)
Luxembourg	(Ministry of Health)
Malta	(Ministry for Energy and Health – Environmental Health Directorate)
Poland	(Bureau for Chemical Substances)
Portugal	(Excused)
Romania	(Ministry of Health)
Slovakia	(Ministry of Health)
Slovenia	(Excused)
Spain	(Ministry of Health)
Sweden	(Ministry of Health and Social Affairs, Public Health Agency)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health)
Norway (observer)	(Ministry of Health)