



Brussels, 7 May 2019
SANTE B2/KB/MF/AK/AS/JL

**MEETING OF THE SUBGROUP ON ELECTRONIC CIGARETTES ESTABLISHED BY THE GROUP
OF EXPERTS ON TOBACCO POLICY**

**7 MAY 2019
MEETING VENUE: CCAB - ROOM: 2.A**

–SUMMARY RECORD–

(1) Welcome and introduction

The Chair welcomed the participants. The agenda was adopted without changes. New participants introduced themselves.

(2) Implementation and Enforcement

SANTE informed the group about the status and progress of the compliance assessment of national transposition measures, including transposition and conformity checks. SANTE informed that bilateral contacts in the framework of conformity checks are taking place and more will follow. No court cases at the Court of Justice related to e-cigarettes are ongoing. Denmark will host a meeting on enforcement on 11-12 June.

(a) EU-CEG

Member States were updated on the functioning of EU-CEG and informed of the trends concerning e-cigarettes. EU-CEG will receive an update (MSREP 2.3) and SANTE took note of Member State recommendations for further developing the system.

(b) Notification of e-cigarettes, ICSMS and RAPEX (Safety Gate)

Member States were reminded of the notification measures under article 20 of the TPD, concerning electronic cigarettes. DG SANTE, DG GROW and DG JUST clarified features of the ICSMS and RAPEX systems (now renamed to ‘Safety Gate’).

DG GROW gave an overview of the IT platform to facilitate communication between market surveillance bodies, which also allows for notification in Safety Gate. Member States were encouraged to use ICSMS¹ for market surveillance to encode all investigations. Involvement of all Member States is essential for efficient exchange of information – all members were invited to register themselves in ICSMS. Member States can contact ICSMS services to help them setting up access to ICSMS for market surveillance authorities by sending an mail to grow-icsms@ec.europa.eu.

DG JUST gave an overview of the Safety Gate notification system concerning measures taken against unsafe products (non-food). According to the provisions of the General Product Safety Directive², a notification must be submitted in the Safety Gate in all cases

¹ Information and communication system for market surveillance: <https://webgate.ec.europa.eu/icsms/>

² Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

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.

where a measure against a dangerous product has been adopted and the other countries of the RAPEX network are required to give follow up to this notification in their territory. Member States took note of the recently published RAPEX guidelines³ which describes the procedures to be followed. The national RAPEX contact points⁴ can be contacted for assistance at national level.

Member States were reminded that where data are available in ICSMS on investigations carried out on a product that needs to be notified in Safety Gate, it is possible to transfer relevant data from ICSMS into Safety Gate, to avoid encoding the same information twice.

DG SANTE, DG GROW and DG JUST clarified features of the ICSMS and RAPEX systems (renamed to 'Safety Gate'). As appropriate, Member States must notify measures taken against dangerous e-cigarette in Safety Gate and are invited to encode all information concerning market surveillance activities they undertake on e-cigarettes in ICSMS. Member States were also encouraged to strengthen national surveillance practices. Member States were also asked to report if they accept sales data submissions outside of EU-CEG and if so how.

(c) Studies

SANTE informed about the planning and timelines for the scientific opinion on electronic cigarettes being prepared by the 'Scientific Committee on Health and Environmental Risks' (SCHEER).⁵

SANTE also informed about the launch of a contract assessing how specific products (water pipes, slim cigarettes, small cigarillos, novel tobacco products and electronic cigarettes) are perceived. This study is also looking into the mapping of consumer preferences and use patterns.

The two studies will tie into the implementation report outlined in Article 28 of the TPD, due in May 2021. In line with that article, Member States are expected to contribute to the report and will be contacted during its preparation (e.g. via questionnaires).

Member States were encouraged to actively contribute to the data gathering exercises that are ongoing in preparation for the report, specified in Article 28 of the TPD.

³ COMMISSION IMPLEMENTING DECISION (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system.

<https://eur-lex.europa.eu/eli/dec/2019/417/oj>

⁴

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/rapex_appointed_authorities_en.pdf

⁵ https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_013.pdf

(3) Member State updates

Member States reported on recent national court proceedings, judgments, and other regulatory issues relevant for electronic cigarettes. They also exchanged views on a range of emerging electronic cigarette matters within and beyond the TPD. This included certain market and use trends, use of cannabidiol (CBD) or cannabinoid liquids, e-liquids without nicotine, internet sales, charging of fees for notification prior to products being placed on the market as well as enforcement activities.

Participants recognised the importance of exchanging information and best practice in order to support the implementation and enforcement of provisions on electronic cigarettes. Member States were encouraged to share in writing relevant regulatory updates with each other and the Commission.

(4) Discussion / update on other e-cigarette matters

(a) JRC overview

JRC gave an overview and update on electronic cigarette standardisation work being carried out in-house and within international fora (CEN and ISO). Member States were also invited to agree on an interpretation of consistent nicotine delivery and on a threshold value for tolerable nicotine contents in nicotine-free e-liquids with a tobacco flavour.

Member States were encouraged to follow the CEN standards development as a reference for measuring consistent nicotine delivery in their market surveillance activities.

(b) Joint Action on Tobacco Control (JATC)

The coordinator for the JATC Work Package 7⁶ gave an update of ongoing work, particularly completion of the first deliverable – the ‘Checklist for e-cigarette product compliance with the TPD’, covering labelling, packaging, health warnings, units and ingredient lists. Deliverables of WP7 can help facilitate enhanced regulation, surveillance and enforcement at national level. Good inputs from Member States are essential for gaining full benefits from the JATC.

Member States acknowledged work of the JATC and thanked for delivery of the check-list, which some have started using. Member States were also encouraged to provide data to the JATC WP7 for analysis.

⁶ Aim of Work Package 7: supporting the Member States in ensuring that only e-cigarettes and refill containers compliant with the TPD are placed on the market.

(5) Any other business

SANTE encouraged Member States to use the Health Policy Platform for informal exchanges within the group. To that end, a specific group had been created on that platform without access for external stakeholders.

Member States were informed of the citizens' initiative titled 'Let's demand smarter vaping regulation!', which was registered by the Commission on 20 February 2019. 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.

Member States were informed of prospective dates for upcoming meetings.

The following meetings are tentatively scheduled:

- Sub-group Ingredients/EU-CEG: June 2019
- Expert group on tobacco policy: October 2019

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

Close of the meeting.

(6) Annex I: List of participants

European Commission:

DG SANTE B2	Thea Emmerling (partially) Katja Broman (Chair) Matus Ferech Agnieszka Kozakiewicz Julia Langer Sascha Löwenstein
DG GROW	Raf Colson
DG JUST	Andre Berends
DG JRC	Thomas Wenzl

Member States:

Austria	(Federal Ministry for Labour, Social Affairs, Health and Consumer Protection)
Belgium	(Federal Public Service Health, Food Chain Safety and Environment)
Bulgaria	(Excused)
Croatia	(Excused)
Cyprus	(Excused)
Czechia	(Ministry of Health)
Denmark	(Danish Safety Technology Authority)
Estonia	(Permanent Representation of Estonia to the EU)
Finland	(Ministry of Social Affairs and Health)
France	(Agency for Food, Environmental and Occupational Health & Safety)
Germany	(Excused)
Greece	(Permanent Representation of Greece to the EU)
Hungary	(National Institute of Pharmacy and Nutrition)
Ireland	(Department of Health)
Italy	(National Institute of Health)
Latvia	(Health Inspectorate)
Lithuania	(Drugs, Tobacco and Alcohol Control Department)
Luxembourg	(Ministry of Health)
Malta	(Ministry for Health)
Poland	(Bureau for Chemical Substances)
Portugal	(Excused)
Romania	(Excused)
Slovakia	(Ministry of Health)
Slovenia	(Excused)
Spain	(Ministry of Health, Consumer and Social Welfare)
Sweden	(Public Health Agency)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Medicines and Healthcare products Regulatory Agency)
Norway (observer)	(Norwegian Medicines Agency)
Iceland (observer)	(Ministry of Health)