EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 16 January 2020
SANTE B2/KB/MF/AK/AS/JL/LP/AM

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

28 NOVEMBER 2019
MEETING VENUE: CCAB - ROOM: 2.D

– SUMMARY RECORD –

(1) Welcome and introduction

The Chair welcomed participants. The agenda was adopted, with one point added under the AOB point concerning reporting under the regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP). New participants introduced themselves.

(2) Implementation and Enforcement

(a) Product safety and reporting systems

Member States discussed the latest development on adverse incidents and deaths linked to e-cigarette use in the USA. Adverse incidents suspected to be linked to e-cigarette use have emerged within a few EU Member States. Investigations of the suspected cases are ongoing at national level.

While notification systems are increasingly used by Member States for information and exchange, SANTE urged Member States to report adverse events, any suspected cases as well as non-compliant products through the reporting systems available. In particular, Member States were reminded of their obligation under article 20(11) to inform the Commission and other Member States if an e-cigarette or refill container could present a serious risk to human health and to require that, in line with article 20(9), manufacturers, importers and distributers of electronic cigarettes and refill containers have a system to collect information on suspected adverse events in place.

Member States were reminded to use ICSMS for market surveillance to encode all relevant investigations on non-compliance and Safety Gate (RAPEX) for cases where a measure against a dangerous product has been adopted in their respective territories. The Early Warning Rapid Response System (EWRS) for serious cross-border threats to health should be used for suspected cases under investigation (email: SANTE-EWRS@ec.europa.eu). Additionally, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)'s Early Warning System Network and Reitox National Focal Points should be used for reports linked to suspected new drugs (e.g. synthetic cannabinoids) or unusual toxicity (email: ews@emcdda.europa.eu).

One Member State updated the group on a recent death in their territory, possibly linked to use of an e-cigarette (non-nicotine e-liquid containing CBD) and shared how the case

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.

was followed-up at national level with local authorities. The case was still being investigated by national competent authorities.

Through a tour-de-table, Member States further reported on measures being taken at national level. Several Member States informed the group that CBD is not permitted in e-liquids containing nicotine under article 20(3)(c) (cross-reference to article 7(6)). In particular, there was a wide agreement among participants that CBD could create the impression that a product has health benefits. For e-liquids without nicotine, some Member States pointed out that there is a legal gap for these products since those are not covered by the TPD.

Possible cases of adverse incidents linked to the use of e-cigarettes have emerged within a few EU Member States, with investigations still ongoing. SANTE and Member States agreed to continue to monitor the situation very closely, and to report any suspected cases through the reporting systems available. SANTE and Member States agreed to collaborate closely, with the overarching aim of protecting human health.

(b) Non-compliant products reported to EU-CEG

SANTE updated the group on the functioning of the EU-CEG system and informed of the trends concerning e-cigarettes. Member States were provided with an overview of products in EU-CEG possibly containing substances within the scope of article 7(6). Member States reminded that only submitters are in a position to withdraw their products from EU-CEG and, currently, there is no other mechanism to deactivate products in EU-CEG. SANTE is investigating possible solutions internally and the issue will be discussed in the next EU-CEG webinar.

Member States were encouraged to make full use of EU-CEG and participate in the next EU-CEG webinar to discuss possible new use cases in more detail.

(c) Article 28 report on the application of the Directive

Member States were informed of the planning and timelines of the upcoming studies preparing for the article 28 report on the application of the Directive, in which e-cigarette will also be addressed. Member States were reminded of their legal obligation to contribute to the report, e.g. via questionnaires.

SANTE urged Member States to actively support and take part in the preparations for the article 28 report.

(d) SCHEER scientific opinion

Member States were updated on the status of the ongoing SCHEER Committee work and timelines. Their mandate is to deliver a scientific opinion on e-cigarettes (health effects, cessation and initiation) and their work is well underway. A final opinion is expected in September/October 2020. SANTE encouraged Member States to share relevant national studies with the Committee through SANTE.

(e) Product perception study

SANTE informed the group of the preliminary findings from the ongoing product perception study. Their task is to assess how specific product categories (water pipes, slim cigarettes, small cigarillos, novel tobacco products and e-cigarettes) are perceived by the public, as well as mapping consumer preferences and use patterns of these

products. It will also feed into the article 28 report on the application of the Directive. The final study report is expected early 2020.

(f) European Citizens Initiative "Let's demand smarter vaping regulation!"

Member States were updated on the follow-up to the Expert Group discussion addressing concerns that certain aspects of the Initiative might breach relevant TPD provisions on e-cigarette advertising, promotion and sponsorship. As agreed by the Expert Group, the Commission sent a communication to the organisers of the Initiative outlining those concerns.

(3) Member State updates

(a) Best-practice exchange: Child-proofing of e-cigarettes and refill containers

One Member State presented to the group their approach and experiences in developing guidelines for child-proofing e-cigarettes and refill containers.

(b) Further exchanges and regulatory updates

Member States shared information on relevant e-cigarette issues, including new regulatory aspects, market developments and other cooperation activities. Examples mentioned were the regulation of flavours, considerations on plain packaging, inclusion in smoke-free environment, regulation of nicotine-free products and licensing regime for retailers.

(4) Updates on other e-cigarette matters

(a) Joint Research Centre (JRC) overview and update on standardisation work

JRC provided the group with an overview of e-cigarette standardisation work being followed within international standardisation fora (CEN and ISO). Member States were further informed of a recent ANEC position paper addressing substances in e-liquids.

Member States were encouraged to use the CEN standards for measuring consistent nicotine delivery in their market surveillance activities.

(b) Joint Action on Tobacco Control (JATC)

WP7 leader of the JATC updated the group on recent activities related to e-cigarettes, including the sharing of EU-CEG data within JATC. WP7 leader urged those Member States which have signed the legal agreement to share their EU-CEG data with the JATC, if this had not yet been done. A checklist to assess e-cigarettes compliance with the TPD was presented once again and its use for enforcement discussed among Member States. The MSs were also updated on the progress of the public/confidential field status assessment facilitating publication of EU-CEG data.

SANTE informed Member States on the progress of the 2020 Annual Work Programme of the Health Programme and invited them to reflect on their involvement in a potential JATC-II, if adopted.

SANTE highlighted the importance of the JATC for the implementation of the Directive, and urged Member States to use the deliverables of the JATC such as the checklist for market surveillance activities in order to ensure TPD compliance at the national level.

(c) Studies on second-hand exposure to emissions from e-cigarettes

Member States were updated on the main findings from the TackSHS project on exposure to second-hand emissions from e-cigarettes.

(d) EMCDDA overview on psychoactive substances in e-cigarettes

Member States were informed of ongoing activities by the EMCDDA on new psychoactive substances in e-cigarettes, particularly in regards to cannabis extracts and the development of new cannabis products. SANTE urged Member States to make contact to those engaged with drug issues nationally or directly with the EMCDDA under ews@emcdda.europa.eu .

(5) Any other business

(a) E-liquids and CLP regulation

One Member State pointed to a partial overlap between the notification requirements set under the CLP regulation article 45 for poison centre notifications (PCN) and the submission requirements under the TPD. Article 45 of the CLP regulation aims primarily at collecting information to meet a medical demand in case of emergency, and to undertake statistical analysis to improve risk management measures. Certain duplication was identified also in other areas (e.g. biocides, plant protection products or cosmetics). ECHA addressed this issue in their Guidance for poison centre notification[1] and further alignment would likely require amendments to the legislation.

(b) Upcoming meetings

- Article 28 Report, Tobacco Stakeholder Dialogue: 10 December 2019
- Subgroup on Ingredients / JATC: February 2020
- Expert Group on Tobacco Policy: March 2020

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Guidance on harmonised information relating to health emergency response - Annex VIII to CLP (§ 1.6.2)
https://echa.europa.eu/documents/10162/13643/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11

Annex I: List of participants

European Commission:

DG SANTE B2	Katja Bromen (Chair)
	Antti Maunu
	Julia Langer
	Matus Ferech
	Agnieszka Kozakiewicz
	Andrea Schwarz
	Sascha Loewenstein
	Laerke Engell Petersen
	Sevasti Skeva
	Veronica Miller
DG JRC	Thomas Wenzl
EMCDDA	Michael Evans-Brown

Member States:

Austria	(Federal Ministry for Labour, Social Affairs, Health and Consumer Protection)
Belgium	(Federal Public Service Public Health)
Bulgaria	(Excused)
Croatia	(Excused)
Cyprus	(Excused)
Czech Republic	(Ministry of Health, Permanent Representation of Czech Republic to the EU)
Denmark	(Danish Safety Technology Authority, Danish Health Authority)
Estonia	(Excused)
Finland	(National Supervisory Authority for Welfare and Health)
France	(French Agency for Food, Environmental and Occupational Health & Safety)
Germany	(Federal Office of Consumer Protection and Food Safety)
Greece	(Excused)
Hungary	(National Institute of Pharmacy and Nutrition)
Ireland	(Department of Health, Health Service Executive)
Italy	(Ministry of Health)
Latvia	(The Health Inspectorate of Latvia)
Lithuania	(Ministry of Health, Drug, Tobacco and Alcohol Control Department)
Luxembourg	(National Health Directorate)
Malta	(Ministry of Health, Ministry of Finance)
Poland	(Bureau for Chemical Substances)
Portugal	(General Directorate of Health, Ministry of Health)
Romania	(Ministry of Health)
Slovakia	(Excused)
Slovenia	(National Laboratory of Health, Environment and Food)
Spain	(Ministry of Health, Consumer Affairs and Social Welfare)
Sweden	(Public Health Agency)
The Netherlands	(Ministry of Health, Welfare and Sport, The Netherlands Food and Consumer Product Safety Authority)
United Kingdom	(Medicine and Healthcare Products Regulatory Agency)

Norway (observer)	(Norwegian Medicines Agency)
Iceland (observer)	(The Consumer Agency)