EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Cross-border healthcare and tobacco control

MEETING OF THE SUBGROUP ON INGREDIENTS ESTABLISHED BY THE EXPERT GROUP ON TOBACCO POLICY

SUMMARY RECORD

6-7.02.2019

Place: CCAB – ROOM 2D

1. Welcome and Introduction

Thea Emmerling, Head of the Unit "Cross-border health care and tobacco control", welcomed the participants on behalf of DG SANTE and emphasized the importance of interaction of the subgroup with the Joint Action on Tobacco Control (JATC). The meeting was chaired by Katja Bromen, Team Leader of the Tobacco Control Team. The agenda was adopted without changes.

2. Determination of characterising flavours

DG SANTE gave a brief update regarding the procedure and mechanism for determining whether a tobacco product imparts a characterising flavour other than tobacco, as mandated by Article 7(3) TPD and as outlined in Commission Implementing Regulation (EU) 2016/779 and Commission Implementing Decision (EU) 2016/786. The procedure was explained step by step with the emphasis on the initiation of the procedure, the consultation and coordination steps involved, as well as the respective roles of the Independent Advisory Panel on Characterising Flavours (IAP) and the Technical Group providing the panel with an assessment of the sensory and, where appropriate, the

chemical properties of test products. In the coming weeks, the testing of the products identified for two groups of reference products (for cigarettes and RYO tobacco) should be concluded and the methodology to support decisions on characterising flavours finalized in the next months. It was noted that the group of sensory assessors meets regularly for maintenance sessions which might be used for testing of random product samples, including those provided by MSs. A new member of the IAP (Dr. Alberto del Rio, Modena) had been selected from the reserve list.

3. Preparation for discussion with the Joint Action on Tobacco Control

DG SANTE presented to the group the objectives and the structure of the JATC which should support MSs in the implementation of the TPD throughout the 28 EU MS. This involves in particular the assessment of data on tobacco products and e-cigarettes reported via the EU-CEG, by establishing laboratory collaboration and by evaluating the enhanced reports submitted on priority additives. Started in December 2017 and concluding in 2020, this interim meeting is the opportunity to review the progress of the first 16 months and to discuss next steps. As the work areas discussed in the remaining parts of this meeting belong to the JATC key work packages, the focus of the discussion in the subgroup meeting was on regulatory aspects.

a. Priority list of additives

DG SANTE briefly recalled that manufacturers and importers of tobacco products were required to submit their enhanced reports on "priority additives" by 1 July 2018. The participants confirmed that most companies had submitted these reports; however a few cases of non-compliance were observed. The lack of reports on "diacetyl" was of concern and the group agreed to follow up on this by compiling the full overview across the EU including follow-up activities.

It was reported that WP9 had established an assessment framework and guidelines for good experimental practice. An expert panel, established to facilitate the peer review of the submitted information, would meet in person on 8 February 2019.

While the review of the reports is done primarily within WP9, regulators (COM or MSs) may need to request supplementary information from manufacturers and importers. It is in the competence of national regulators to decide whether confidentiality claims of manufacturers and importers are justified, while taking account of the provisions in

Article 6 of Commission Implementing Decision (EU) 2015/2186. However, there was a consensus that most parts of the reports may be published in line with the requirements of Article 5(4) of the TPD.

b. Tobacco product reporting and Assessment

DG SANTE gave an overview of the recent improvements in EU-CEG as well as future developments. A new screen had been introduced, providing a full history of information ("Submitter XML"). Secure bulk data transfer to MSs is now operational via MSREP and full product information was extracted for all MS's in December 2018 and made available for download. A workshop of MSREP users took place in December 2018 allowing the sharing of best practices.

A new feature is being tested for the next MSREP release allowing for JATC data sharing in line with the agreement signed by most MSs. Any data will be extracted at national level in line with justified requests by JATC-participants. This data will be uploaded in the respective national MSREP section for sharing by authorized user with selected users from other MSs.

4. Any other business

The next meeting of the subgroup on ingredients will take place on 27 June. It was agreed to discuss inter alia the application of articles 7.6 to 7.11 of the TPD as well as practical steps to coordinate the determination of tobacco products with characterising flavours.

The next meeting of the subgroup on e-cigarettes subgroup is scheduled for 7 May.

Joint meeting of the Subgroup with the Joint Action on Tobacco Control

Meeting chaired by the JATC Coordinator.

Purpose of the meeting:

a) To provide an update on the tasks performed, the milestones and deliverables that have been met
b) To update on the upcoming work that is in progress and to plan the actions of the next 12 months
c) To facilitate interaction between JATC members and the subgroup on ingredients

Sessions relevant for interaction:

WP5 - EU Common Entry Gate (EU-CEG) data extraction and handling: Presentation of practical aspects of the data sharing, clarification of technical requirements, discussion of the "JATC request" workflow, evaluation of a pilot request (if submitted in advance of the meeting)

WP6 and 7- Tobacco product and E-cigarette evaluation: Presentation of the need assessment questionnaire, prioritisation of products characteristics to be assessed first.

WP8 - Laboratory verification, collaboration and analyses

WP9 - Additives subject to enhanced reporting obligations

WP4 - Integration into national policies and sustainability

PARTICIPANTS

Member States

Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, Austria
FPS HEALTH, Belgium
Croatian Institute of Public Health, Croatia
Ministry of Health, Croatia
Ministry of Agriculture of the Czech Republic
Ministry of Health of the Czech Republic
Danish Safety Technology Authority
Health Board, Estonia
National Supervisory Authority for Welfare and Health, Finland
ANSES, France
Federal Office for Consumer Protection and Food Safety, Germany
Ministry of Human Capacities, Hungary
Department of Health, Ireland
Ministry of Health, Italy
National Institute of Health, Italy
Permanent Representation of Lithuania to the EU
Direction de la Santé, Luxembourg
Ministry of Health, Welfare and Sport, Netherlands
Norwegian Directorate of Health, Norway
Norwegian Institute of Public Health, Norway
Bureau for Chemical Substances, Poland
Direção-Geral da Saúde,Portugal
National Laboratory of Health, Environment and Food, Slovenia
Ministry of Health, Social Services and Equality,Spain
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