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

Date: June 6 2018

Place: CCAB – ROOM 0 B

1. Welcome and Introduction

DG SANTE welcomed the participants and the agenda was adopted without changes except for the order of points.

2. Priority list of additives

DG SANTE briefly recalled that manufacturers and importers of tobacco products are required to submit enhanced reports on all additives they use that are included in the 'priority list' laid down in Commission Implementing Decision (EU) 2016/787 of 18 May 2016. Deadline for submission is 1 July 2018. DG SANTE emphasised that after review of the documents, both COM and MSs may request supplementary information from manufacturers and importers. They may further require these reports to be peer reviewed by an independent scientific body, in particular regarding their comprehensiveness, methodology and conclusions. As foreseen by Article 6(4) TPD, proportionate fees may be charged for these reviews.

The leader of Work Package (WP) 9 of the Joint Action on Tobacco Control (JATC) gave an overview on how this WP can support MSs in reviewing and assessing the industry reports received. In this respect, WP9 is in the process of establishing an assessment framework and guidelines for good experimental practice. This will involve a

panel of 12 experts established to facilitate the peer review of the submitted information - MSs are welcome to suggest additional candidates by 15 June 2018. Nevertheless, the JATC's resources are limited and in this respect DG SANTE encouraged MSs to set up their own review mechanisms while avoiding duplication of work at the EU level.

Further, it was clarified that it is in the competence of national regulators to decide on a case-by-case basis scenario whether confidentiality claims made by manufacturers and importers are justified by trade sensitivity of the concerned information. The assessment of the information contained within the industry's reports should provide the basis for further steps in line with the provisions of articles 6, 7 and 28 of the TPD.

3. Determination of characterising flavours

DG SANTE gave a brief update regarding the procedure for determining whether a tobacco product imparts a characterising flavour other than tobacco, as mandated by Article 7(3) TPD. In accordance with Commission Implementing Decision (EU) 2016/786 of 18 May 2016, the Independent Advisory Panel (IAP) has been established, with a first meeting having taken place 1 June 2017. The IAP can request input from a Technical Group of sensory and chemical assessors, i.e. the Consortium EUREST-Flavour, which was established via a public procurement procedure and began its work on 21 February 2018. The mandate of the Technical Group is to provide the panel with an assessment of the sensory and, where appropriate, the chemical properties of test products. Currently, the main tasks of the group is to establish two groups of reference products (for cigarettes and RYO tobacco) for product testing, to further specify a methodology to support decisions on characterising flavours and to establish, train and maintain a group of sensory assessors. Together, the IAP and Technical Group aim to develop a scientifically robust process that allows MSs to take decisions in accordance with Article 7(1) of the Directive and withstand possible Court challenges.

The Technical Group informed MSs about the establishment of the reference groups consisting of both "top-market" and "niche" products. In this respect, MSs were asked for their input on the draft list presented by the Technical Group.

4. Interaction of the Subgroup with the Joint Action on Tobacco Control

DG SANTE informed the MS about the current status and rationale of the JATC. Started in December 2017 and concluding in 2020, the individual WPs are now consolidated and ready to perform their tasks. Their main goal is to provide support for the implementation

of the TPD throughout the 28 EU MS, in particular through assessment of EU-CEG data submitted for tobacco products and e-cigarettes, by establishing laboratory collaboration and by evaluating the enhanced reports on priority additives.

The JATC WP7 leader introduced a common questionnaire to collect feedback from EU MS regulators on key issues of TPD implementation that should be addressed within the remit of the JATC. The JATC WP6 leader described the potential analysis of tobacco product-related data in light of the obligations laid down by the TPD. Particular emphasis was put on the validation and cleaning of the EU-CEG data as a precondition for a proper assessment. DG SANTE pointed out that the experience gained from the process of data cleaning may allow improving EU-CEG and providing guidance for the industry.

5. Product reporting/notifications

DG SANTE gave an overview of the recent improvements in EU-CEG as well as future developments. In particular, system capacity (so far, almost 200,000 products have been submitted) and search/filtering tools have been improved. A new screen has been introduced, providing a full overview of files on priority additives submitted at least for one product in the concerned MS. DG SANTE is also exploring options for secure bulk data transfer to MSs, either via MSREP or eTRUSTEX. DG SANTE encouraged MSs that experiences on how to best extract and clean raw xml-files should be shared as best practices, with DG SANTE as a potential hub for the exchange. Possible clarifications of the data dictionaries may be useful for measurement units and identification of ingredients (CAS numbers should avoid ambiguity). It was clarified that, for security reasons (one-way data flow), industry has no access to data stored in eTRUSTEX and MSs cannot contact manufacturers via eTRUSTEX when confidential matters are concerned.

While the industry has the right to flag any sort of information as confidential in its submissions, it is in the competence of national regulators to ultimately decide whether a confidentiality claim is justified or not under their national legislation. Moreover, Article 6 of Commission Implementing Decision (EU) 2015/2186 would provide guidance on this matter. DG SANTE and JATC suggested that the JATC could work on an appropriate output format (possibly in consultation with the industry, as it was the case under the earlier reporting system EMTOC).

6. TNCO measurement methods

The Netherlands presented results of an experiment conducted by RIVM depicting differences between the ISO and the Canadian intense methods. In this respect, the ISO values for tar, nicotine and carbon monoxide (TNCO) would not reflect the actual user's exposure to these emissions. While the participants generally agreed that the ISO method is misleading, no immediate action was agreed at this stage. Moreover, none of the currently established emission measurements of TNCO would reflect the actual user's exposure to these emissions. DG SANTE reminded that, under the revised TPD, the ISO values of cigarettes are not printed on unit packets and thus consumers normally are not directly exposed to them. However, relevant data in relation to filter ventilation was reported under the EU-CEG and would allow for data analysis on this issue.

7. Any other business

DG SANTE briefly reported on the results of the addictiveness reduction workshop in Berlin from 15 to 16 May 2018 and previewed the COP8 in Geneva (October 2018). The next meeting of the subgroup was foreseen for early 2019 and MSs were encouraged to cooperate with JATC.

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
Ministry of Human Capacities, Hungary
Department of Health, Ireland
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
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Joint action on Tobacco Control

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