EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Health in all policies, global health, tobacco control

Brussels, 02 December 2016

SANTE B2/MF/mp ARES(2016)

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

SUMMARY RECORD

Date: December 2 2016

Place: CCAB – ROOM AB-2B

1. Welcome and Introduction

DG SANTE welcomed the participants and the agenda was adopted without changes.

2. Priority list of additives

DG SANTE informed the group about the status of the SCHEER-opinion that was in the process of being finalized following the public consultation, held from 22 July to 22 September 2016. DG SANTE also informed about the work of the external contractor, DIRECT, that had assessed the data submitted as part of the reporting obligations under Directive 2001/37/EC and provided methodological guidance.

DG SANTE informed that Art. 6 provisions are directly applicable without any further conditions from 1 January 2017 and that SCHEER/DIRECT reports, expected to be published soon aim to provide high level methodological guidance. However their availability does not impact on the legal obligations to request/perform the studies within 18 months.

Following a question from a MS, DG SANTE clarified that the opinion issued by SCHEER is not binding and that MS are responsible for implementing its legal obligation to require manufacturers and importers to carry out comprehensive studies. Moreover, DG SANTE encouraged MS collaboration in the context of the Joint Action on Tobacco Control for a coordinated approach in requesting and assessing the studies from manufacturers.

3. Determination of characterising flavours

DG SANTE informed the group that they are currently evaluating the applicants to the Independent Advisory Panel assisting MS and the Commission in determining whether tobacco products have a characterising flavour. DG SANTE also gave an update regarding the establishment of the technical group and encouraged the MS to distribute the information on the call for establishing the technical group to their networks once it will be launched.

MS gave a brief update regarding the national implementation of the TPD concerning the ban of the products with characterizing flavours. MS confirmed that several brands with characterizing flavours have been taken out from the market. On the other hand appearance on the market of devices that can modify flavour of tobacco products was signalled (i.e. flavour sticks).

4. TNCO measurement

4.1. Verification - approved laboratories

DG SANTE informed that the list with approved laboratories would be published shortly after the meeting and stated that all approved laboratories are equivalent with regard to the objective assessment of the product. DG SANTE informed that about half of the MS do not have approved laboratories.

Several MS presented the way in which national authorities deal with the verification of TNCO levels. Generally, the verification procedure varied between MS regarding the frequency and the sample used for verification (i.e. all products, randomly selected products).

Following a question from one of the MS, DG SANTE mentioned that verification should apply to products produced on the national market and those imported.

DG SANTE encouraged MS without approved laboratories to find solutions for the verification (i.e. use of approved laboratories in other MS). DG SANTE also stated their support for verification to be mutually accepted between MS.

4.2. Measurement methods

One MS raised the issue of adapting the measurement measures in order to be more sensible to the toxic and addictive substances in cigarettes inhaled by consumers.

MS taking the floor acknowledged that each of the known methods has its advantages and disadvantages and modification of the method would imply re-discussing the current emission thresholds. In this context MSs admitted that it would be premature to make changes in the recently adopted legislation.

DG SANTE reminded that that during the discussions in the Council Working Group on Public Health for the preparation of the 6th Conference of the Parties (COP6) to the WHO Framework Convention on Tobacco Control (FCTC) (October 2014), several MS had expressed concern regarding a recommendation by the FCTC WG on Articles 9 & 10 suggesting concomitant use of two different measurement methods (ISO and Canadian Intense).

DG SANTE stated that the Commission does not foresee the development of a delegated act under 4.3 at the moment, but will consider this in future discussions. Furthermore, in accordance with Article 28, the Commission will report by 2021 on the application of the TPD, including on the development of internationally agreed rules and standards on tobacco and related products. The report shall be followed up by proposals for amending the Directive, which the Commission deem necessary.

5. Reporting of ingredients and notification of e-cigarettes

5.1. Update on EU Common Entry Gate (EU-CEG)

DG SANTE gave an update on the EU-CEG. During the two weeks preceding the legal deadline of 20th of November 2016 for the notification of products already placed on the

market by 20th of May 2016, the EU-CEG system received a high volume of submissions (87.000 tobacco products and e-cigarettes, the majority a few days prior to the deadline).

In response to MS questions on the delays in response messages and the system's accessibility, DG SANTE explained that the high volume of product data submitted (twice higher than expected) inevitably caused the system to take more time than usual to process and validate all product information. Having said this, DG SANTE stressed that the EU-CEG system had been stable throughout the period, accepting submissions continuously since June 2016. Moreover, DG SANTE informed that the time at which a submission reached the EU-CEG would be made visible in MSREP. Several technical questions raised by MS were discussed (success/error message, XLM creator etc.)

DG SANTE explained that it is MS responsibility to apply and reinforce the law regarding the deadline of 20th of November 2016 and reminded that a common approach on applying the deadline is not possible and offered to assist MS in this process by providing information available in the system on specific submissions.

5.2. Future steps in EU-CEG

DG SANTE gave a presentation on MSREP and an update on the next release.

MS asked for some additional features to be implemented in MSREP in order to allow efficient extraction and use of the data in EU-CEG. This data extraction was considered important both for administrative purposes (e.g. fees) and for making available product data to the general public. DG SANTE requested MS to send in writing a list of fields/information that they would like to have extracted. DG SANTE further encouraged MS to discuss the issue of confidentiality and to agree on key principles guiding the publication of data in the context of the Joint Action on Tobacco Control.

5.3. Initial experience with assessment of product information

Several technical questions raised by MS were discussed (i.e. notification of non-compliant products, manufacturer's proof of notification for importer, searchable fields in MSREP, importance of sub-brand name).

A few MS presented their approach regarding notification of aromas/flavours. DG SANTE reminded that the TPD requires all ingredients to reported/notified, and that this takes place at common level and not at product presentation level. This means, the format

and extent to which ingredients are notified is sent to all MS equally. It became clear that most MS applied a literal meaning of Art. 20 (i.e. "information on all ingredients").

5.4. Languages (studies and specific ingredient information in national language)

DG SANTE reminded that based on past discussions prior to the development of EU-CEG it had been SANTE's understanding that MS would accept common data reporting in English. EU-CEG has been designed to accommodate a single product description complemented with country specific presentation information. In this respect, most of the fields allow only a single value which, in most cases, is either numeric or selected from a dropdown menu. At the same time, a number of fields allow upload of multiple attachments. If Member States required certain information in their national language this could be facilitated to a certain extent by using the comments field at product presentation level or, otherwise, such submission had to take place outside the EU-CEG process.

6. Strengthened Cooperation - Tobacco Control Joint Action

DG SANTE presented the Joint Action on Tobacco Control and described its Working Packages: four horizontal and five substantive (EU-CEG, Tobacco, E-cigs, Labs, Priority) packages. Following the implementation of the comments received as part of the evaluation, the Tobacco Control Joint Action is expected to be launched in spring.

DG SANTE encouraged MS to be active in the discussion within the Tobacco Control Joint Action whose main aim it will be to facilitate the implementation of the TPD.

DG SANTE took note of the MS request to invite the coordinator of the Tobacco Control Joint Action during one of the next expert group meetings.

7. Any other business

One MS described the presence on the market of individual containers of pure nicotine and flavours commercialized in the same unit pack. A few MS stated that depending on the concentration of nicotine the product may fall under medical legislation or the TPD. DG SANTE reminded that the purpose of the use of the product and not the way in which

the product is marketed should be taken into account when assessing this situation. Also the topic of labelling such type of products was addressed.

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Agency for Consumer Affairs, food Safety and Nutrition, Spain

Anses, France

Bundesministerium für Gesundheit

Bureau for chemical substances, Poland

Croatian Institute of Public Health

Danish Health Authority

Danish Safety Technology Authority

Department of Health, Ireland

Estonian Health Board

FPS Public Health, Belgium

General Directorate of Health, Portugal

Health inspectorate of Latvia

HSE Ireland

Ministry of Health, Czech Republic

Ministry of Health, Luxembourg

Ministry of Health, Slovakia

Ministry of Health, Social Services and Equality, Spain

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