MEETING OF THE GROUP OF EXPERTS ON TOBACCO POLICY
SUMMARY RECORD

Date: 15 - 16 June 2016

Place: CCAB

1. Welcome and adoption of the agenda

DG SANTE welcomed participants and the agenda was adopted.

2. Transposition and Implementation of the Tobacco Products Directive (TPD)

2.1. Report on Implementation by SANTE

The group was informed that the three remaining Implementing Acts and the Commission Report were adopted on time.

DG SANTE reported on the judgements in three cases (C-547/14, C-477/14 and C-358/14), where the Court of Justice rejected the claims challenging the validity of the TPD.

DG SANTE also explained that as the transposition deadline for the TPD had now passed, there may be less need for subgroup meetings on ingredients and electronic cigarettes. It was however agreed that the Track & Trace subgroup shall meet more regularly in light of the implementing legislation to be adopted in the coming years. Discussions on the common reporting tool (EU-CEG) also need to continue, mainly via webinars.

DG SANTE reminded the group to inform the Commission of their national competent authority (as required by Article 26 TPD).

2.2. State of play of transposition

The group was informed that on 15 June 2016, 17 MS had notified transposition. Of these, 8 MS had notified complete transposition and 9 MS had notified partial transposition.

DG SANTE underlined that it will support MS still working on their transposition of the TPD.

DG SANTE gave a short overview of the infringement procedure in case of failure to notify (or only partial notify) national measures transposing the TPD.

Following this overview, a tour de table on national transpositions was conducted.
3. Ingredients regulation

3.1. Priority additives

DG SANTE informed the group that the Implementing Act specifying fifteen priority additives was adopted on 18 May 2016. The group was also reminded that there is no legal basis for the Commission to formalise the comprehensive studies to be requested by Member States through a legal act or other formal document. However, the Commission will seek to facilitate the coordination and cooperation among Member States, including in the Joint Action. In this context, the Scientific Committee on health, environmental and emerging health risks (SCHEER) and an external contractor (DIRECT) are looking at how best to request adequate comprehensive studies from manufacturers and will publish reports of their findings in order to assist MS.

The approach of SCHEER was presented and discussed. It is foreseen that a preliminary opinion would be issued before the summer break, followed by a public consultation.

3.2. Characterising flavours/ingredients regulation

DG SANTE informed the group that the two Implementing Acts in relation to the identification of tobacco products with characterising flavours were adopted on 18 May 2016.

DG SANTE updated the group on the practical implementation of the two legal acts.

Following a question from one of the members of the group, it was agreed that products that do not consist of tobacco and are placed on the market separately from tobacco products, such as papers or filters, fall outside the scope of the Tobacco Products Directive even if these products have a characterising flavour.

Also, the obligation under TPD Article 4(2) was brought up and it was clarified that Member States shall communicate to the Commission a list of approved laboratories for publication, but that there is no obligation for MS to have an independent laboratory in their countries. They can also use laboratories in other countries.

4. Reporting and notification

4.1. Update from SANTE on EU-CEG

DG SANTE gave a progress report of the work on the IT tool of the common reporting system (EU-CEG) and referred to the webinars organised on 14 June with both national regulators and industry. It was also explained that the pre-stage procedure was mainly designed to prevent any possible negative consequences in terms of the placing on the market of new products. The Group was informed that the pre-notification procedure was officially closed on 8 June.

Furthermore, DG SANTE clarified the different roles of ECAS (to be used for authentication) and SAAS (to be used for authorisation). DG SANTE presented the possibility of providing MS additional training on how to use the reporting tool, including ECAS and SAAS. DG SANTE took note of the request to have an alert mechanism in place for new submissions, but said this is not to be included in the first release.
It was ensured that data would only be visible to the relevant MS where a product is placed on the market and that the system would record any post-modification made by the submitter.

The possibility to publish an information overview regarding the fees charged to submitters by MS was discussed. The group indicated that such an overview could be useful, but no decision was taken.

4.2. Funding of notification and surveillance systems: report from MS

Member States explained their fee systems, i.e. how fee levels are calculated to ensure proportionality as set out in Art. 5(8) and 20(2), including whether fees will be charged by product or by company and how industries are informed of national fee policies.

It was suggested that further discussion on fee structures and their implementation could be a topic for the joint action (JA, see next agenda point).

5. Joint action on tobacco control

DG SANTE gave a presentation on the state of play of the JA preparations and reminded the group that the formal deadline for notifying participation was 16 June 2016. Many MS had already expressed their interest in taking part in the JA.

6. Taxation

DG TAXUD gave a presentation on the possible revision of Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco. Two MS indicated that they would support increased taxation on tobacco and that taxation of electronic cigarettes should be included in the discussion. DG SANTE raised the point that there has already been some cooperation within the framework of the FCTC that should be taken into account.

DG SANTE encouraged the group to take part in the public consultation that will be launched by TAXUD in the second half of 2016.

7. Labelling and Packaging

DG SANTE informed MS that the new combined health warnings had attracted a lot of attention and that it intends to update the website on health warnings to include graphics of the combined health warnings in each MS. In this context MS will be requested to send to DG SANTE their combined health warnings with the cessation information included. A few MS reported that they had received requests to extend the production deadlines in the TPD to allow them to continue to manufacture products with the previous warnings after the 20 May 2016, but had not allowed it. It was a general agreement within the group that such an extension would go against TPD.

MS provided some updates on national plain packaging measures. Additionally one MS gave an overview of its transposition of Article 13 TPD. DG SANTE noted that there seems to be a common interest in national plain packaging measures across a number of MS and encouraged MS to exchange experiences.
8. **Electronic Cigarettes**

MS were asked if they intend to appoint specific surveillance authorities for electronic cigarettes and how they intend to communicate with each other and the Commission on adverse effects and products that pose a serious risk to human health. The group was also reminded that the RAPEX system is already in place to communicate between MS when national authorities take action against dangerous products posing a serious risk to human health. It may, therefore, be that in some instances surveillance authorities could use the already established RAPEX network to communicate their findings to other MS. It was agreed that there should be further reflection on how surveillance is conducted in MS and shared between national authorities.

The labelling requirements on unit packs of e-cigarettes were also discussed. MS shared their interpretations of how information should be printed on packaging and leaflets and on how to comply with the TPD requirements.

One MS asked whether the group considered that Article 20(3)(a) should be read to mean that tanks over 2ml are not allowed. DG SANTE reminded the group that the Expert Subgroup on electronic cigarettes had discussed this issue on 20 November and had concluded that refillable tanks larger than 2ml were not allowed under the TPD.

9. **Novel, herbal and smokeless tobacco products**

DG SANTE informed the group of the requirements for prohibiting certain categories of tobacco or related products under Article 24(3) TPD. It was explained that a ban of a certain category of tobacco can be introduced on grounds relating to "the specific situation in the MS" and the "need to protect public health". MS should clearly outline their reasons for introducing such a prohibition when notifying the Commission. MS were also asked to notify any such measures before their adoption to allow adequate assessment.

The classification of chewing and oral tobacco was also discussed. In this context, one MS presented its transposition of the TPD in relation to the classification of chewing and oral tobacco. It was concluded that in some cases, the marketing of smokeless tobacco products can make it difficult to differentiate between chewing and oral tobacco. DG SANTE reminded the participants of previous discussions in the group and concluded that the basis for assessments should be made on a case-by-case basis, making sure to examine the actual use of the product rather than that indicated by the manufacturer.

10. **Illicit Trade**

DG SANTE provided an update on the state of play of its work on traceability under the TPD, including the timetable for implementation. One MS expressed concern about the tight timelines, designation of competent authorities before the implementing legislation is in place and, once in place, the interoperability of the EU system with existing traceability systems. DG SANTE underlined that it is aware of the issue raised by the MS, but reiterated that it is working towards adoption of the Implementing Acts by Q4 2017.

OLAF informed the group of the Council decision on 17 June 2016 for the EU to ratify the Illicit Trade Protocol. OLAF also explained to the group that the entry into force of the Protocol requires 40 ratifications and urged those MS who had not yet done so to ratify the Protocol. OLAF also underlined that ratification by neighbouring non-EU states is important to tackle illicit trade of tobacco products.
DG SANTE explained it is very important to reflect on the implementation of the Protocol at both EU and national level and that OLAF is an important partner in this context. DG SANTE also stressed that measures against illicit trade are included in both the TPD (Article 15/16) and the Protocol and that both instruments are mutually re-enforceable.

AOB

DG SANTE informed the group that the FCTC Conference of the Parties will take place on 7-12 November in India. A draft agenda has been published on the FCTC website.
Annex I

List of participants

Austria (Federal Ministry of Health)
Belgium (Federal Public Service Public Health)
Bulgaria (Permanent Representation of the Republic of Bulgaria to the EU)
Cyprus (Ministry of Health – Medical and Public Health)
Czech Republic (Ministry of Agriculture; Ministry of Health, Permanent Representation of the Czech Republic to the EU)
Croatia (Permanent Representation of Croatia to the EU)
Denmark (Ministry of Health, Danish Safety Technology Authority)
Estonia (Ministry of Social Affairs)
Finland (Ministry of Social Affairs and Health)
France (Direction Générale de la Santé)
Germany (Federal Ministry of Food and Agriculture)
Greece (Ministry of Health, Permanent Representation of Greece to the EU)
Hungary (National Institute for Health Development)
Ireland (Department of Health)
Italy (Ministry of Health)
Latvia (Permanent Representation to the EU)
Luxembourg (Ministry of Health)
Malta (Environmental Health Directorate Ministry for Energy and Health)
Poland (Ministry of Health)
Portugal (General Directorate of Health)
Romania (Ministry of Health)
Slovakia (Ministry of Health)
Slovenia (Ministry of Health of the Republic of Slovenia)
Spain (Ministry of Health)
Sweden (Ministry of Health and Social Affairs)
The Netherlands (Ministry of Health, Welfare and Sport)
United Kingdom (Department of Health)

Norway (Ministry of Health)

Iceland (Ministry of Welfare)

Turkey (Tobacco and Alcohol Market Regulatory Authority)

fYRoM (Mission of the Republic of Macedonia to the EU)

EFTA Secretariat
Commission:

DG SANTE B2

Anna-Eva Ampélas (chair)
Jerome Boehm
Filip Borkowski
Katja Bromen
Matus Ferech
Jan Hoffmann
Isabel Holmquist
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