EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

Brussels, 19 January 2015

MEETING WITH TOBACCO INDUSTRY STAKEHOLDERS ON DEVELOPMENT OF A COMMON REPORTING FORMAT

SUMMARY RECORD

Participants: **Dominik Schnichels, Katja Bromen, Matus Ferech, Anna Eva Ampelas, Ingrida Pucinskaite-Kubik, Patricia Murray (DG SANTE D4);**

Michael Lauterbach, Michelle Dowle (BAT); Elitsa Lozanova, Mima Kraevska (Bulgartabac); Antonella Pederiva, Cynthia Fürste (CECCM); Marcel Crijnen, Bob van Mierlo (ECMA); Peter van der Mark, Vlad Olteanu (ESTA); Inge Delfosse, Amanda Gunarrson (ESTOC); Petra Taschner, Jon Davis (Imperial Tobacco); Dr Thilo Paschke, Dr Julia Wolf (JTI); Nikolaos Stamatiou (Karelia Tobacco Company); Pedro Marques, Marc Scharfe (Landewyck Tobacco); Lisette Pelck Albrecht (Oliver Twist); Karsten Merkel, Andrea Gontkovicova (PMI); Patrick Preissler, Tina Wildhack (Poeschl Tabak); Annica Hedin, Cecilia Kindstrand Isaksson (Swedish Match).

Observers: **EUREST**

Date: **19 January 2015**

Place: **CCAB-3B**

Background

The meeting was organized upon the initiative of DG SANTE with the following objectives:

1) To inform industry stakeholders about the upcoming implementation tasks under the Tobacco Products Directive 2014/40/EU (TPD) with a focus on the development of a common reporting format for information on ingredients and emissions as set out in Article 5 of Directive 2014/40/EU.

2) To present a draft data dictionary developed by the EUREST consortium under a request for service under Framework Contract EAHC/2013/Health/23 and gather feedback.

Introduction

DG SANTE provided an overview on the upcoming implementation tasks in the area of ingredients and clarified that the purpose of the meeting was not to discuss Directive 2014/40/EU (TPD) as such and its implementation in general or related legal matters, but rather to focus on the development of a common format for ingredients reporting. More specifically, the aim was to provide industry stakeholders with an opportunity to present their views on the draft data dictionary being developed by the EUREST consortium for the purpose of the common reporting format circulated before the meeting.

Industry representatives thanked DG SANTE for the opportunity to provide feedback. They also agreed to the proposed rules of transparency (publication of minutes on the DG SANTE website).

The ongoing work of EUREST including the draft data dictionary was presented to participants. DG SANTE outlined the main sections of the draft data dictionary and explained the information likely to be requested under the new reporting format. Finally, DG SANTE highlighted a number of points for discussion, reminding participants that the document is still an early draft.

General comments

Stakeholders acknowledged the comprehensiveness of the draft data dictionary produced by EUREST and highlighted the need for a workable reporting format. Although they understood the aim of the data dictionary to enable regulators to effectively use the collected data for the EU-wide regulation of tobacco products, some recommended that there was a need for simplification and that some information may go beyond the scope of the TPD.

Stakeholders emphasised that it is more beneficial to have one reporting system instead of 28 national systems (per Member State). The new tool should fulfil the objective of the TPD to harmonise reporting regimes and allow for automatic processing of the data. Preference for use of English was expressed. At the same time some essential issues were raised, including the location and ownership of the database and data security.

Stakeholders called upon DG SANTE to make use of the existing reporting platform (EMTOC) or develop a new solution based on the experience up to date. Any new platform should be simple, secure and reliable.

The specific considerations for SMEs were brought up in the discussion, as well as costs related to reporting. Some stakeholders also enquired about the possibility of a trial to test data compatibility and the establishment of a helpline supporting the implementation of the new reporting format, in particular for SMEs.

DG SANTE expressed understanding for the specific situation of SMEs as well as the specificity of certain types of tobacco products, while at the same time underlining the need to respect the relevant requirements of the legislation. Regarding the costs for manufactures/importers, DG SANTE stressed that the contractor is tasked to assess this issue in the next phase of the project.

Discussion Points

Manufacturer/Importer identification

Some stakeholders suggested that each product should only be reported once, and when repeating a notification or completing it in a different Member State, a reference to the original notification should suffice (in the case that central submission is not possible).

DG SANTE said such a view is understandable but may be difficult to implement in practice, in particular as importers may not have an overview of what others have notified, and the data storage is in any case Member State-based. It added that, ultimately, reporting will be facilitated through the use of codes and numbers to submit the data, and EUREST clarified that it will be possible to do mass batch uploads.

Most of the large companies seem to have a global reporting function and suggested that this entity should report and be accountable for submitted information. It was also stressed that certain trade sensitive information might not be available to all entities within the same group of companies. DG SANTE explained that the aim is to make a link between various entities of a single company/group of companies operating across borders. The stakeholders were asked to further reflect on this point and on the definition of parent company.

In the case of cigars, stakeholders suggested that, as these may be produced in bulk outside the EU and subsequently packaged individually in a factory located in the EU, the EU-based factories should be considered as manufacturing sites. DG SANTE clarified that the TPD defines importers as those importing from third countries.

Unique identification of a product

DG SANTE underlined the need to link products placed on different Member States' markets or across years, in particular in cases where the same product is marketed under different names. Stakeholders pointed out that a centralised system would help achieve this. At the same time, companies operating in multiple Member States would welcome the possibility of a single submission when a product is marketed in multiple Member States. Technical aspects, advantages and disadvantages of various product identification codes proposed in the data dictionary (EAN, SKU…) were discussed. Without a unique EU-wide identification code, a reference to a notification submitted elsewhere would be the only option as some products may be marketed under various brand names in various Member States and the regulators should be in a position to link such products.

Furthermore several practical aspects of product identification were discussed, including mandatory/optional submission of a product picture, measurement of product diameter, submission of annual sales data, price information and market research studies.

Identification of ingredients

Representatives agreed that the data dictionary should build on the CAS number (whenever available) as the main unique identification of an ingredient. However, various solutions were discussed for additives with multiple CAS codes or additives without CAS code where the FEMA number seems to be most useful.

The contractor explained that the CAS parent number, to be used as a single CAS for the given ingredient, should be the earliest noted CAS number. A supportive reference was made to the current EMTOC platform, which has integrated an ingredient list allowing selection from a drop box.

Ingredient quantity

Stakeholders acknowledged comprehensiveness of the category and function reference tables. Various views were presented concerning the need for continuous adjustment of ingredients' quantities for batch homogenisation to compensate for natural variations in the properties of supplied tobacco leaves and whether this would be considered a substantial modification of a product. DG SANTE explained that the aim is to offer a mechanism for which would combine the recipe value (with a justified variation

range) and retrospective reporting of actually used values allowing verification whether a company obeyed to indicated recipe values. In this regard an

appropriate reporting frequency should be established which may be linked to fixed time period or fixed quantities.

The discussion further addressed the use of complex flavour mixtures purchased from third parties and reporting of ingredients' toxicity classifications. It was considered useful if the IT system would provide for automatic completion of certain fields for ingredients previously submitted by manufacturers.

Some stakeholders considered the proposed approach for reporting of tobacco ingredients (tobacco leaf/ reconstituted/expanded tobacco) too complex and possibly beyond the scope of the TPD. DG SANTE invited the representatives to propose solutions in writing.

Trade sensitive information

Stakeholders highlighted the need to preserve a high level of trade secrets' protection and referred to the current practice outlined in DG SANTE practical guide. Nevertheless further discussion on possible adjustment was not excluded (differentiation between tobacco and non-tobacco ingredients was suggested). Some stakeholders said they would welcome the possibility to indicate which data are considered confidential, while it was assumed that non confidential data would be published.

Beyond specific thresholds to be agreed, it was mentioned that there are also other aspects of trade sensitivity to be considered.

It was considered that duplication of data reporting (e.g. for sales data) should be avoided.

Conclusions

DG SANTE thanked the industry representatives for their attendance and input. Any additional comments should be submitted in writing within two weeks after the meeting. DG SANTE also indicated that the contractor would contact stakeholders at a later stage with a questionnaire regarding costs and impacts associated with the reporting format.

DG SANTE explained that information on the expected publication of implementing legislation can be found in the implementation plan published on the DG SANTE website, and updated regularly.