EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

Brussels, 8 January 2015

MEETING WITH STAKEHOLDERS ON

PROCEDURES TO DETERMINE TOBACCO PRODUCTS WITH CHARACTERISING FLAVOURS

SUMMARY RECORD

Participants: **Dominik Schnichels, Katja Bromen, Matus Ferech (DG SANTE D4);**

Dr Dirk Minkner, Michelle Dowle (BAT); Elitsa Lozanova, Mima Kraevska (Bulgartabac); Antonella Pederiva, Cynthia Fürste (CECCM), Peter van der Mark, Vlad Olteanu (ESTA); Petra Taschner, Walter Van Hove (Imperial Tobacco); Dr Thilo Paschke, Ivan Marinov (JTI), Asterios Athanasiou (Karelia Tobacco Company); Koen Roelstraete, Dr Marc Scharfe (Landewyck Tobacco); Anne May, Andrea Gontkovicova (PMI)

Observers: **HETOC**

Date: **8 January 2015**

Place: **Rue Belliard 232, 8/120**

Background

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

1) To inform industry stakeholders about the upcoming implementation tasks on ingredients under Directive 2014/40/EU with a focus on developing the procedures to determining tobacco products with characterising flavours.

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

Introduction

SANTE provided an overview on the upcoming implementation tasks on this topic and the ongoing work conducted by HETOC. Drafts of the literature review and the proposed approaches had been shared with the industry in advance of the meeting together with specific questions. SANTE thanked representatives for comments received. SANTE underlined that the purpose of the meeting was not to discuss Directive 2014/40/EU, its implementation in general and related legal matters. Instead, the meeting should provide an opportunity to industry to present their views on the proposed methodological

approach. This approach would be further discussed and adapted in an upcoming seminar organized by HETOC with scientific experts and regulators.

Industry representatives thanked SANTE for the information provided and for the opportunity to provide feedback on the methodology proposed. They agreed with the rules of transparency proposed (publication of minutes on the SANTE-website).

General comments

Industry representatives acknowledged the high quality of the working documents (literature review, draft methodology) produced by HETOC even though they considered the draft methodology too generic to be applied in practice. They stated that the literature review provided an encompassing overview on currently existing sensory methods to assess flavours in consumer products, but that none of these methods were designed to determine whether a product had a characterising flavour. Industry representatives also stated that there is currently no established methodology to determine if a tobacco product has a characterizing flavour as defined by the Directive.

A representative from ESTA asked that a distinction be made between factory-made cigarettes and fine-cut tobacco as flavour intensity in fine-cut tobacco products would depend on a variety of intrinsic features such as the tobacco varieties used, the blending methods used, and the individual consumer transforming a semi-finished product into a finished one (i.e. a smoking article).

All industry representatives agreed that the procedure to be developed should work in practice and should lead to robust, reliable and reproducible results. Several stakeholders emphasized their readiness to comply with the provisions on products with characterising flavours and indicated a willingness to take all the necessary steps to do so.

Discussion Points

Sensory testing: Expert versus consumer panel

Industry representatives recommended that the evaluation should be done by consumers. The level of sensitivity of experts would be too high and not representative. It would be difficult to find experts suitable for this task, and expert panels would be too costly and difficult to maintain. However, it was not fully clarified whether consumer panels could obtain robust, reliable and reproducible results in the same way as expert panels and if so how.

Panel composition

Regarding the composition of the testing panel, representatives emphasized that the number of panellists on a consumer panel should be at least 150 persons to ensure sufficient statistical power. One panel for the EU would be sufficient as national and cultural preferences are not relevant for the question whether a product has a characterising flavour. They recommended to only include adults into the panel as all products were aimed at adults and to involve men and women in a representative spilt (in line with the population consuming the respective product). It was mentioned that not all countries would allow the testing of tobacco products.

Product assessment

Industry representatives favoured to carry out the assessment both through smelling and smoking. They claimed that assessment of the product through smelling tobacco products in an unburned form alone was not sufficient. The smelling of pads was considered

inadequate due to the loss of volatile components. The possibility of carrying out the tests in a stepwise approach (first smelling then smoking) was considered but no clear recommendation was provided. Some representatives however mentioned that they were not in favour of this approach. As the result of the testing experiment would lead to regulatory decisions, the controlled environment of on-site testing was considered more reliable and thus preferred over testing at home.

Determination of baseline or reference

Industry representatives acknowledged the challenge to select a suitable reference. In their view the term "other than tobacco" was difficult to qualify as there were hundreds of different varieties and sub varieties of tobacco products with different flavours. Furthermore the flavour of tobacco was affected by the type of tobacco leave as well as the curing and fermentation processes. Representatives considered natural tobacco without any flavourings not a suitable reference. Instead, traditional blended cigarettes or different blends of tobacco used in commercial cigarettes and roll-your-own products without characterizing flavour should serve as a reference. The "ellipse" approach (plotting various reference products representative for blend types onto a sensory map and assessing through sensory testing how a test product is positioned relative to the ellipse) was proposed by the industry.

Statistical methods

Industry representatives indicated that the statistical method should be suitable for assessing the question (yes/no decision) and that in line with their recommendation to employ a consumer panel, the check all that apply (CATA) method should be used.

Sensory testing versus instrumental (machine) testing

Industry representatives said that sensory methods were preferable to chemical analysis for determining products with characterising flavours as such flavours could be created by different additives and by different combinations of additives/ingredients resulting in the same odour. For this reason, industry representatives also highlighted that the use of a flavour library setting upper limits for individual flavourings alone would not allow products which impart a characterizing flavour to be identified and would carry the risk of banning products with additives which do not contribute to a characterizing flavour when used in traditional blended cigarettes. It was also stressed that TPD article 7(1) is an output, not an input regulation.

General discussion/conclusions

Upon request of the industry representatives, it was agreed to set the deadline for additional comments on the working documents to 22 January 2015. This would include, as appropriate, the sending of additional relevant scientific articles not included in the literature review as well as considerations on the appropriate baseline and statistical methods.

SANTE explained the next steps and referred in particular to the implementation plan which will be updated regularly. SANTE also indicated that the industry may be contacted again during the assessment of economic impacts.