



Brussels, 03 July 2015

MEETING WITH STAKEHOLDERS ON SUBMISSION OF INFORMATION UNDER ARTICLE 5 OF DIRECTIVE 2014/40/EU

SUMMARY RECORD

Date: 29 June 2015

Place: CCAB-2C

Background

The meeting was focused on the technical solutions for submission and storage of information under Article 5 of the Tobacco Products Directive 2014/40/EU (TPD) and to gather feedback from stakeholders, in particular concerning:

- the architecture and feasibility of the technical solutions being proposed by the Commission
- interest in participation in an industry ad-hoc technical working group with possible subsequent involvement in pilot testing

Introduction

DG SANTE welcomed the participants and introduced the Commission's team. The Chair underlined that the purpose of the meeting was not to discuss the legality or the interpretation of the TPD, given that it has already been adopted and that court cases are pending

DG SANTE then briefly outlined the state of play regarding the common reporting format for tobacco to be established by means of an implementing act according to Art. 5 (5) TPD. An external study was launched in May 2014, carried out by the EUREST consortium. One of the key deliverables of the project is the data dictionary (draft reporting format). This document is being finalised taking into account input from stakeholders and Member States. On this basis a pilot reporting platform is being developed. The adoption of the implementing act on the reporting format is foreseen for Q4 2015.

One of the key concerns expressed by stakeholders following the January meeting was fragmentation of the reporting process throughout 28 Member States using different

technical solutions. In this regard, and to ensure that harmonised data sets are transferred to Member States, DG SANTE reviewed the data dictionary and considered a possibility to centralise the data submission via a European Common Entry Gate (EU-CEG). Such a system would also limit the administrative burden for manufacturers, importers and national regulators and facilitate comparison of data.

To respond to request from some Member States, DG SANTE considers offering a data storage facility for Member States. Member States which are interested would be able to rent server capacity from the Commission by signing a Service Level Agreement. In this scenario the data would be stored by Member States in a national data repository hosted by the Commission. The alternative would be storing the data at national data repositories hosted by the Member States.

The Commission would fund the development and maintenance of the EU-CEG. However responsibility for data processing remains with Member States which may charge proportionate fees to manufacturers and importers of tobacco products may according to Art. 5 (8) TPD.

General comments

Overall, stakeholders welcomed the approach and the development of a common entry gate for submission of data.

Discussion Points:

1) Submission and identification of confidential data

Some stakeholders asked how confidential data will be identified. DG SANTE clarified that the data dictionary provides the company with the possibility to label data as confidential. However, requests to keep data confidential would need to be justified and it is ultimately for Member States to ensure that relevant non-confidential data is made publically available according to TPD. Stakeholders representing SMEs drew special attention to their concerns that trade secrets are not the same for all products and companies. Moreover some stakeholders expressed a preference for reporting formats with two separate tables, one with data for the regulators (full reporting) and one with data for the public (grouping of flavourings, therewith not revealing quantities below certain thresholds), like it is done today. DG SANTE explained that this issue will require reflection when establishing the IT system.

2) Special impacts of the reporting format for SMEs

Some stakeholders raised the issue that the IT system should not create an obstacle to trade for SMEs because of the technical complexity and language requirements. Stakeholders argued that it should be taken into account that the reporting would have a different impact for SMEs than for big companies. DG SANTE pointed out that they are aware of these differences and consider a workable system also for SMEs. For example, companies will have a choice between submitting data system-to-system interface or using a graphical tool for submission, for example active PDF files.

3) Correction and validation of submitted data

Regarding the uploading of information, stakeholders were interested if there would be a validation when submitting the data online and asked whether it would be possible to make corrections if a submission had been made that contained an error. DG SANTE described how the technical submission process could work and explained that corrections can be made by resubmitting via EU-CEG. The option to receive a “frozen” copy of the PDF to verify what has actually been submitted will be examined.

Also, the division of tasks and the need for clear responsibility between the two help desk functions – one at the Commission and one at the Member States – was raised in the discussion.

4) Pilot reporting platform and industry ad-hoc technical working group

DG SANTE introduced the idea of an ad-hoc technical working group with industry as well as a pilot testing of the notification format for stakeholders and explicitly invited smaller operators to participate because it is also a good opportunity for SMEs to express their concerns and provide feedback before actual notification is needed. The meetings of the ad-hoc technical working group will be held via web conferences so that there will not be a need to travel. DG SANTE indicated that invitations to participate in the technical ad-hoc working group and the pilot testing will be sent and stakeholders should let DG SANTE know if they would like to participate in both or one of the options.

In general, stakeholders welcomed the industry ad-hoc technical working group as a great idea and most of the industry representatives expressed interest in participating in this ad-hoc technical working group and in the pilot testing which is foreseen for the first half of 2016.

TPD implementation on ingredients update

DG SANTE gave a short overview of the current state of play on the TPD implementation on ingredients. Regarding the priority list of additives (Art. 6 (1) TPD) SCENIHR will organise a public consultation over the summer period in July/August 2015. An external study (DIRECT) has also been launched to work on toxicological data. The adoption of the implementing act on priority additives is foreseen for Q1 2016. On determining whether tobacco products have characterising flavours DG SANTE is assisted by an external contractor, the HETOC consortium. A study was launched in August 2014 and stakeholders have been involved in the work.

Conclusions

DG SANTE thanked stakeholders for their input and asked them to submit any additional comments relating to the proposed EU-CEG ideally within one week of the meeting and at the latest within two weeks. During the same time period stakeholders should inform DG SANTE if they like to participate in the technical ad-hoc working group and the pilot testing.

Annex I

List of participants

Stakeholders:

Agio Cigars	Bas de Jager
Austria Tabak	Alexander Pokorny
British American Tobacco	Darren Harris
British American Tobacco	Anne Schramm
Bulgartabac	Mima Kraeva Kraevska
CECCM	Antonella Pederiva
	Cynthia Fürste
ESTA	Peter van der Mark
	Vlad Olteanu
European Cigar Manufacturers Association	Marcel Crijnen
House of Oliver Twist	Lisette Pelck Albrecht
Imperial Tobacco	Jonathan C. Davis
JTI	Julia Wolf
Karelia Tobacco Company	Vlachos Panagiotis
Landewyck Tobacco	Pedro Marques
Philip Morris International	Karsten Merkel
Pöschl Tabak	Patrick Preissler
PT Djarum	Ariant Hendrata Tjan
	Sonny Bohang
Scandinavian Tobacco Group	Bob van Mierlo
Swedish Match	Thomas Södermann
	Cecilia Kindstrand

Commission:

DG SANTE D4	Dominik Schnichels (chair)
	Anna-Eva Ampelas
	Katja Broman
	Matus Ferech
	Herman Brand
	Markus Kalliola
	Kerstin Selbach