



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Health in all Policies, Global Health, Tobacco Control

Stakeholder Workshop on implementation of Articles 15 & 16 of Directive 2014/40/EU Summary record

Meeting date: 15 May 2017, 09.30 – 17:00

(1) Welcome and Introduction

The Chair opened the meeting and welcomed all participants, including those joining via web-stream. A brief outline of the general context for the workshop was provided. The task of the Commission to lay down secondary legislation as required under Articles 15 & 16 of the Tobacco Products Directive (TPD) was recalled. The Commission confirmed that the indicative date for adoption of the relevant acts is end 2017. It was explained that the current workshop follows from the first stakeholder workshop held in December, at which the external contractor responsible for carrying out the Implementation Study presented some of its key findings and a number of policy options were discussed. The Chair said that, based on the feedback received, as well as on consultation with Member States and internal and external analysis, a provisional set of 'preferred' policy options had been identified. It was explained that the objectives of the workshop were to present the technical details of these options, and to seek to stakeholder input/comments on their implications. The Chair said the feedback received would provide useful input to the Commission's legal drafting and be used by the contractor to develop the final technical recommendations to be included in the Implementation Study. Finally the Chair reminded that the options to be presented were provisional and stressed that no final decisions had yet been taken.

The Commission's representatives then gave a brief presentation of the provisional options and the resulting general architecture. Following this the external contractor presented the current status of the Implementation Study, explaining that Work Package 3 is now being finalised, the aim of which is to develop a set of technical recommendations for the EU systems of traceability and security features.

(2) Unique Identifier

In relation to the key issue of marking packages with a unique identifier (UI), the Chair explained that the 'mixed' solution had been provisionally identified as the preferred policy option. Under this option, independent third parties – to be appointed by the Member States –

would be responsible for generation of the UI. The industry would then be allowed to carry out the more technical tasks of completing with a timestamp, applying and verifying the UI on packs. It was further explained that the UI would have a block structure with an issuer prefix, thereby allowing for multiple issuers, and that a system of look-up tables would be envisaged, which would allow the required information to be encoded on packs in a manner that minimises its size. As such look-up tables would need to be downloaded at intervals to handheld devices, expected size estimates were requested from participants. It was further clarified that UIs would be necessary at both unit pack and aggregated levels (though there would be differing structure and size for both). Finally it was explained that certain size limitations on individual UI batches (to be delivered upon request to the economic operators), as well as time limits for their use, would likely be required. Feedback on the provisional architecture as well as on certain technical questions posed was then sought from participants.

On the whole, **NGOs** expressed support for the mixed solution and welcomed the concept of generation by independent 3rd parties. One **standards organisation** stressed that overall, use should be made of existing open standards in order to best take the realities of the supply chain into account. **Manufacturers** echoed this and stressed the need to avoid a system that would be overly-complex, as this would result in high costs for them and difficulties to implement the new system on time. Concerns were also expressed that the mixed solution would interfere with production processes. Manufacturers of tobacco products other than cigarettes and roll-your-own stressed that the measures should take into account the complexity of their particular supply chains, which differ e.g. from the FMC supply chain, as well as the low levels of illicit trade in their sector. Representatives of **wholesaler/distributors** echoed concerns relating to potential system complexity and the need to prioritise existing open standards. They expressed concern regarding the need to request UIs for aggregated levels and the potential for supply chain disruption in the case of related delays. A **tax stamp association** stressed that ease of implementation is essential, and added that it believes a fully third-party operated solution is necessary to meet the legal requirements. One **solution provider** echoed this, while others stressed the need to prioritise open standards and simplicity. Some participants stressed the need to ensure both online and offline working possibilities and to avoid over-designing requirements for anti-tampering devices.

The Commission confirmed that the intention is not to opt for an overly complex system but reminded that the basic requirements of the TPD must be met. The Chair confirmed that the Commission is fully committed to respecting the EU's international legal obligations and said that the mixed solution offers the possibility of placing control in the hands of Member States. She said the Commission is fully aware of the challenges for all concerning the timeline but recalled that the deadline is established in the TPD. She confirmed the indicative adoption date of end 2017 remains valid. It was further clarified that the requirement for anti-tampering devices would be in addition to the requirement for manufacturers to verify UIs, but further discussion with Member States on this issue will be required.

(3) Recording and transmission of data

Under this point, the Chair explained that the 'near real-time' policy option is currently the preferred option, but confirmed that the Commission has taken stakeholder concerns in this respect on board. A gradual transition to this requirement, in particular for SMEs, would therefore be likely. The contractor then gave an outline of the main reporting events that it had identified and said that it believes transmissions should take place via secure channels and only by pre-authenticated users. The Commission then provided more details on the types of

events that should be reported, and said that 3 events are currently foreseen for the reporting of transactional information (as required under Article 15(2)(k)): issuance of purchase order, of invoice and receipt of payment. It was further clarified that in a limited number of cases (such as dispatch), reporting prior to the event may be required.

Wholesaler/distributors raised questions regarding the costs of implementing such reporting requirements, in particular for SMEs. They said further clarification regarding event triggers would be needed and raised specific questions on reporting requirements, in particular in relating to trans-loading. They also asked whether the installation of temporary buffers would be a technical requirement. It was pointed out that reporting of transactional information prior to dispatch would be difficult as invoices are often only issued following dispatch. **Manufacturers** said that reporting of transactional information is not likely to be straightforward as one product movement can have several financial flows and e.g. as products are often produced to stock. One **standards organisation** also stressed that clarification on event triggers is essential, and said that transactional data would need to be treated with caution. One **solution provider** asked for clarification of the extent to which retailers will be implicated in the system and others said that too many reporting points is likely to increase risks.

Regarding event triggers and what events need to be reported, the Commission reminded that Article 15(5) of the TPD is quite explicit, requiring reporting of entry into possession, exit and all intermediate movements. In general it was also pointed out that there is a need to distinguish between the recommendations of the Implementation Study, which adopts a more advisory approach, and the requirements that will feature in the legal acts, which are likely to be less technically prescriptive. It confirmed that the concerns of SMEs are being taken into consideration, as illustrated by the possible transition arrangements under consideration. It was further clarified that the trigger to report a transactional event comes with the occurrence of the event itself, e.g. the issuance of an invoice (whenever this may take place), but said it had noted the points raised relating to dispatch/invoice sequences. It was confirmed that the aim of allowing for reporting of unit pack UIs via aggregation and disaggregation is to reduce administrative burden, but there is no obligation to re-aggregate following disaggregation.

(4) Processing, storing and accessing data

The Commission explained that this point relates to the question of where the data should be stored in order to best meet the requirements of Article 15. It said that the option currently preferred is for a combined data storage model. The contractor then outlined additional details relating to this option, explaining it would be composed of multiple decentralised repositories, selected by each manufacturer/importer, and a common data repository, hosting a copy of all data stored in the decentralised repositories and guaranteeing access and a global overview of the supply chain for authorities and the Commission. It added that the proposed architecture would include a 'router', via which events transmitted by distributors/wholesalers would be routed to the relevant decentralised repository, thereby reducing the burden for this sector. The Commission further explained that to facilitate operations, a system of 'registries' – e.g. of manufacturing facilities, economic operators etc. – would need to be established.

NGOs asked why a central storage system had not been preferred and expressed concerns regarding how the provider of the central element would be selected. A coalition organisation also questioned who would run the central element and a tax stamp association expressed a preference for a central system. A standards body stressed the need for robust governance to

determine who can access the potentially sensitive commercial data and for what purpose. **Manufacturers** asked who will be responsible for managing the registries and how it will be possible to avoid double registration of entities. Questions relating to import/export of products to third countries were also posed.

The Commission pointed out that while the combined model would allow manufacturers to select own data storage repositories, it does not exclude that some or all may opt for the same provider. It said it believed the combined model would be capable of offering the required access for authorities as it would receive a full copy of all transmitted information. Regarding the selection of the provider responsible for the central element, the Commission said that further reflection is required, but that it would not necessarily be responsible (one preliminary idea would be for the primary level data storage providers to be responsible). The TPD's explicit requirements relating to independence and auditing of the data storage facilities were recalled. Regarding the registries, the Commission said it may be possible to assign responsibility to the issuers of the UIs. It added that it had noted the point relating to the risk of duplicating entities, and that a clear allocation of responsibility for registration will be needed.

(5) Data carriers

The Commission then introduced the discussion on data carriers, explaining that the option currently preferred would be to allow a limited variety, in order to maximise flexibility whilst ensuring compatibility and readability across the supply chain. The contractor then gave a presentation on the various drivers that it has found may influence the selection of the allowed data carriers, and the Commission presented a list of specific data carriers, as well as certain quality requirements, currently under consideration.

Manufacturers of tobacco products welcomed the details of the presentation including the list of considered data carriers. Clarification on the marking requirements for products for export was also sought, and manufacturers stressed that the additional coding requirements that packs may be subject to in third countries should be taken into account. **NGOs** in general supported the quality requirements outlined and stressed the need to ensure that data carriers are protected against cloning, as well as to ensure that aggregation levels are well protected. One said that it would be important for the time of manufacture to be readable by consumers. One **standards organisation** asked for clarification as to whether GS1 dotcode would be amongst the permitted data carriers, stressing that it has the potential to maximise space. It also drew attention to SSCC label formats for aggregation levels.

The Commission clarified that all tobacco products manufactured in the EU will be required to be marked with a UI, and that all movements until the last event within the Union will need to be recorded, including information on which third country the product is destined for. Movements outside the EU will not, however, be subject to reporting requirements. On whether it should be possible for the time of manufacture to be readable by consumers, it said that further reflection would be required. It nevertheless clarified that under the architecture currently considered, manufacturers would not be required to know the time of manufacture in advance, and that this element would be completed by them upon UI application.

(6) Security features

The Commission introduced the point on security features, explaining that although Article 16 TPD lays down general requirements and characteristics which it will be necessary to comply with, regard must be given to other aspects, including the application methods and the specific type of security feature. It was explained that the current intention of the Commission is to allow for flexibility, as well as to take account of the high degree of innovation that exists in the area of security features. The contractor then presented a list of security feature categories currently on the market, which it would consider suitable, based on its findings to date. The Commission stressed that this list should be considered non-exhaustive and should in no way be regarded as final.

One **NGO** asked why combining the security feature with the UI was not being considered by the Commission. This was echoed by several other participants. One **solution provider** said it welcomed the open approach outlined, while another stressed the need for further concrete details. A separate solution provider organisation said it believes affixing would be the best application method for security features, while a **carton makers association** said that they would advocate for direct printing during pack manufacturing, and that this process should be standardised. One **cigar manufacturer organisation** pointed out that its members produce products in wooden boxes and that an appropriate application method is required for them. Certain other participants provided comments and suggested amendments related to the security feature categorisations outlined.

The Commission said it had taken note of the various points raised and that these would be very useful for the ongoing analysis. It added that the discussion had confirmed that it would be important for flexibility to be taken into account.

(7) Next steps and conclusions

The contractor then briefly presented the outline of its interim report III, which is currently being drafted, and the main aspects that it will cover. It was explained that the input from today's discussion would be used to further inform this work. The Commission then thanked participants for the comments provided, which it said would be further considered by both the Commission and the contractor. The Chair recalled that all options presented were provisional and that the aim of sharing details at this stage had been to ensure transparency and gain feedback. She recalled that the relevant acts of secondary legislation will be published in advance of their adoption, in line with the Commission's Better Regulation agenda. Finally, it was confirmed that participants would have two weeks to send additional comments in writing.

List of Participants:

Stakeholders

British American Tobacco

CECCM (Confederation of European community Cigarette Manufacturers)

Deutscher Zigarettenverband e.V. (DZV)

ESTA (European Smoking Tobacco Association)

Fetabel

HEINTZ VAN LANDEWYCK SàRL

House of Oliver Twist A/S

Imperial Brands PLC

Japan Tobacco International

Karelia Tobacco Company Inc

Philip Morris International Management S.A.

PMI

Scandinavian Tobacco Group

Tobaksindustrien (Tobacco Manufactures Association of Denmark)

Association of Greek Tobacco Industries (AGTI)

European Tobacco Wholesalers Association (E.T.V.)

Federation of German Wholesale, Foreign Trade Services

Handelsverband Deutschland (HDE)

Latvian Traders association

LOGISTA GROUP

SANTELE BVBA

LOGISTA GROUP

Lekkerland AG & Co.AG

Independent Retail Europe

Fiximer Sàrl

National Association of Small and Medium Traders in Romania

Association of European Cancer Leagues ECL

Comité National Contre le Tabagisme

Dutch Cancer Society

ENSP (European Network for Smoking and Tobacco Prevention)

Smoke Free Partnership
Action on Smoking and Health
UEMO – European Union of General Practitioners
European Respiratory Society
Polish Chamber of Commerce
PRO SECURITATE FOUNDATION
Polish Chamber of Trade
Business Europe
Latvian Chamber of Commerce and Industry
Bundesverband der Zigarrenindustrie/ European Cigar Manufacturers Association
ECMA
Joh. Wilh. von Eicken GmbH
CTS cvba
ESTA (European Smoking Tobacco Association)
German Smoking Tobacco Association
AUTHENTIX
Blue-infinity
Coalition Against Illicit Trade (CAIT)
De La Rue International
DOMINO PRINTING SCIENCES
Essentra plc
Arvato Systems GmbH
European Carton Makers Association (ECMA)
Fracturecode Corporation APS
AlpVision SA
GS1
INEXTO
IRPLAST SPA
ITSA (International Tax Stamp Organisation)
LEONHARD KURZ Stiftung & Co. KG
SICPA
SURYS
VERIDOS MATSOUKIS SECURITY PRINTING S.A.
Intergraf

SAP Belgium

SGS

Arvato Systems GmbH

Istituto Poligrafico e Zecca dello Stato (IPZS)

T&T services, Ltd.

Jura JSP GmbH

Kezzler AS

BUNDESDRUCKEREI

Advanced Track & Trace

Honeywell

European Commission and EU Agencies

DG SANTE

CHAFEA

External Contractor

Everis