

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES FINAL SUMMARY RECORD

Date: 13 February 2018

Place: Brussels

1. Welcome and Introduction

DG SANTE welcomed the participants and introduced the new Head of Unit with responsibility for tobacco control, Thea Emmerling. It was recalled that this was the first meeting of the Subgroup since the adoption of the three legal acts on tobacco traceability and security features, which took place on 15 December 2017. DG SANTE thanked representatives for their very good collaboration in the months prior to the adoption and in particular for the strong vote in favour of the draft implementing acts returned during the written procedure.

It recalled that the purpose of the Subgroup is to provide a platform for Member States to discuss different aspects of the implementation process related to the new systems and to enable the Commission to provide necessary clarifications related to the legislation. DG SANTE stressed that its main role is to chair and facilitate, and that discussions should be based on input received from Member States prior to and during the meetings. Five meetings of the Subgroup are foreseen for 2018.

2. Update from the Commission

The Commission then provided an update on the status of the secondary legislation. The Implementing Decision on Security Features was notified to Member States on 18 December 2017 and has therefore entered into force. The Implementing Regulation on traceability will be published in the Official Journal jointly with the Delegated Regulation on key elements of data storage contracts, as both contain cross-references. Publication will take place once the European Parliament's review period for the Delegated Regulation has ended (mid-April). The estimated date for entry into force of the Delegated and Implementing Regulations is therefore mid-May.

DG SANTE confirmed that the Commission will closely monitor the status and progress of the technical implementation of systems. It underlined that Member States should endeavour to appoint ID issuers as early as possible and not wait until the 1 year deadline has elapsed. DG SANTE re-confirmed that it will support Member States in this process where possible and will do its utmost to ensure that the process for appointment of the provider of the secondary repository is as efficient as possible.

DG SANTE said that it intends to publish additional dedicated information on the systems via its website, to ensure that stakeholders/authorities/general public are informed. The existing webpage already includes general information, the acts available for download (EN versions) and details on ongoing regional workshops and webinars.

DG SANTE recalled that stakeholders wishing to attend a regional workshop must apply via the attending authorities in the Member State where their business is located. For those stakeholders not in a position to attend, a series of webinars will be held throughout April. Further details are on the website.

In relation to the implementation study (being undertaken by an external contractor, Everis), SANTE confirmed the final report is due to be published on the DG SANTE website in coming weeks. It pointed out that this report may serve as informal technical guidelines for stakeholders.

3. Commission report from the 1st Regional Workshop

General feedback from the 1st Regional Workshop (6 Member States and approximately 60 stakeholders) held in Stockholm in January was then provided. It was agreed that the dialogue was constructive and that there is an interest on the part of stakeholders to better understand how to comply with the legislation.

Some issues of common interest raised in the Regional Workshop were presented and discussed by the Group.

In relation to the **traceability system**, it was confirmed that:

- A vending machine making tobacco products available to consumers for the first time should be considered a first retail outlet requiring a facility identifier code. In the case of dispatch to such vending machines, economic operators must set out the unique identifiers (UIs) and the facility identifier codes of the machines in question (see dispatch message, Section 3.3 of Annex II), but it will not be necessary to indicate which UI will be delivered to which machine.

- There are no reporting obligations for retail outlets (e.g. kiosks). Nevertheless, in the case of operators of retail outlets which deliver a certain quantity of their tobacco products to subsequent retail outlets (e.g. vending machines), reporting obligations will continue to apply until the products are placed on the market for the first time.

- In the case of returns of products from first retail outlets to distributors/suppliers, the distributor/supplier in question will be responsible for reporting the return event.

- Registration for relevant identifier codes on behalf of retail outlets may be performed by third party operators (e.g. distributors), provided the operator of the retail outlet has given its consent and is informed of the codes assigned to it. - Registration for identifier codes should be free of charge for all operators.

The subject of retail outlets located on shipping vessels was also raised. It was clarified that, in the case of deliveries to such retail outlets, where the retail outlet remains closed while the vessel is docked in the harbour, a dispatch message indicating that the products are for export should be reported.

It was also clarified that, in the case of new entities taking over already registered businesses, the new entity should apply for its own economic operator code. If facility codes relating to the old entity exist, the new entity should update the registered information by sending a relevant correction message (see e.g. section 1.5, Annex II).

Member States were also asked whether they believe the format/content of the acknowledgment messages should be laid down. Most respondents indicated they would be in favour of this.

In relation to the **security features system**, the meaning of the term 'irremovable' was discussed. There was a general consensus that this should be read similarly to 'tamper-proof', i.e. that any attempted or successful removal of a security feature should be clearly evident (i.e. via damage or tearing to the unit packet).

It was clarified that, while unique identifiers must be applied to unit packets at the time of production (or, in the case of products manufactured outside the EU, before they are imported – see Article 6(2) of the Implementing Regulation and Article 2(38) of TPD), economic operators may choose to apply security features at a later stage in the supply chain, provided that application takes place before the products are placed on the market (see Article 2(40) and 16 of TPD).

4. Discussion on ID issuer appointment

DG SANTE then gave a brief presentation on requirements and tasks related to the appointment of ID issuers and their subsequent operations. Technical ability, experience, capacity, price and compliance with the independence requirements were suggested as examples of selection criteria that Member States could apply in their appointment processes. Length of the UI was also suggested as a valid criterion, given that Article 8(1) clearly requires the sequence to be as short as possible.

One Member State asked how ID issuers appointed by Member States with no manufacturing or imports from outside the EU will charge fees. It was suggested that such Member States could consider making use of the derogation under Article 4(1) of the Implementing Regulation, or agree with other Member States on joint appointment of an ID issuer.

There was a general agreement that cooperation amongst Member States on the subject of ID issuer appointment would strengthen harmonisation and reduce burden, even if basic interoperability of the system will be ensured via the provisions set out in the Implementing Regulation. DG SANTE re-confirmed that it will closely monitor progress in this process and asked Member States to keep it informed of all developments. It reminded of the possibility for the Commission to make use of its powers under Article 4(5) in the case of temporary absence of a Member State's ID issuer.

5. Update from Member States

A *tour de table* was then held, during which each Member State updated the group on developments at national level in relation to the appointment of ID issuers, designation of national administrators (Article 25(k) of the Implementing Regulation), design and composition of security features and designation of national competent authority/authorities.

Several Member States indicated that they may appoint public authorities as ID issuers, which will likely accelerate the appointment process. A majority of Member States indicated that they intend to make use of their existing tax stamps for the purposes of complying with the requirements relating to security features.

6. Conclusions

The Commission thanked participants for their input. It requested to be informed of any linguistic comments that Member States may have on the translated versions the acts. It said that the next Subgroup would take place on 12 April.

7. <u>Annex I</u>

List of participants

List of participants	
Austria	(Ministry of Labour, Social Affairs, Health and Consumer
	Protection; Ministry of Finance – Tax and Customs
	Administration)
Belgium	(Algemene Adminisratie van de Douaneen Accijnzen; Federal
	Public Service Public Health)
Bulgaria	(National Customs Agency)
Croatia	(Customs Administration of the Republic of Croatia)
Cyprus	(Department Of Customs and Excise)
Czech Republic	(Ministry of Agriculture; Ministry of Finance)
Denmark	(Ministry of Health; Ministry of Taxation)
Finland	(Finnish Customs)
France	(French Customs; Permanent Representation to the EU)
Germany	(Federal Ministry of Food and Agriculture)
Greece	(Ministry of Finance)
Hungary	(National Tax and Customs Administration; Ministry for National
	Economy)
Ireland	(Department of Health; Revenue Commissioners)
Italy	(Italian Customs and Monopolies Agency)
Latvia	(The State Revenue Service of the Republic of Latvia)
Lithuania	(State Tax Inspectorate)
Luxembourg	(Ministère de la Santé; Customs and Excise Administration)
Malta	(Customs Department)
Poland	(Ministry of Finance)
Portugal	(INCM – National Mint and Printing Office; Taxation and
	Customs General Directory)
Romania	(CN Imprimeria Nationala SA; National Agency for Fiscal
	Administration – General Directorate of Customs)
Slovakia	(Ministry of Finance; Permanent Representation to the EU)
Slovenia	(Financial administration of the Republic of Slovenia; Ministry of
	Health of the Republic of Slovenia)
Spain	(AEAT-Agencia Estatal de Administración Tributaria Customs &
-	Excise Department)
Sweden	(Public Health Agency of Sweden; Ministry of Health and Social
	Affairs)
Observers	
Norway	(Norwegian Ministry of Health and Care Services)

Commission:

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