



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation  
**Cross-border healthcare and tobacco control**

**EXPERT GROUP ON TOBACCO CONTROL**  
**MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES**

— SUMMARY RECORD —

**Date:** 24 May 2019  
**Location:** CCAB, European Commission

## **1. Welcome and introduction**

The Chair welcomed the participants to the first meeting after the launch of the system and thanked Member States for their support and the good cooperation that had taken place over the past months and years in the Subgroup. At the same time, it was important to note that the launch of the system did not mean the end of this project. A number of important steps remained ahead and some outstanding matters still required attention over the coming weeks and months.

The meeting agenda included follow-up discussions on some of these outstanding matters, notably the operations of ID issuers, data protection obligations, and the designation of National Administrators. The group approved the agenda without additional points under AOB.

## **2. Update from the Commission**

### *2.1 Performance of the repositories system*

DG SANTE provided a short update on the overall performance of the repositories system. The system has been working without major issues or interruptions since its official launch on 20 May. By now, more than 370,000 EO-IDs, 630,000 F-IDs, and 860 M-IDs have already been registered in the system. The total number of upUIs registered in the secondary repository amounted to almost 900 million UIs. These statistics confirmed the successful establishment and overall functioning of the system.

DG SANTE noted that the repositories system indicated activity by the majority of ID issuers, while a few entities had not yet transferred any real-life data. Member States were asked to revert to their ID issuers in order to ensure that the connectivity with the repositories system is established and working.

Regular discussions continued to take place between DG SANTE and Dentsu, and Member States will be informed about any important updates related to the performance of the traceability system.

## 2.2 Court cases

In 2018, an association had launched a request with the Court of Justice of the European Union for the annulment of the implementing and delegated acts on traceability and security features. DG SANTE informed the Subgroup that the Court had rejected the request on grounds of non-admissibility. The Court's decision sends a strong signal in support of the Union legislation, which Member States and the Commission have jointly worked on over the past years.

## 2.3 Data storage contracts

In the meeting of March, several Member States asked the Commission to receive a copy of the approved data storage contracts between manufacturers/importers and repository providers, in order to enable Member States to carry out their enforcement obligations under Directive 2014/40/EU. DG SANTE is in the process of consulting all manufacturers/importers about the full disclosure of their contracts and provide them with a possibility to indicate any redaction of information that they consider legally justified. These justifications must be communicated to DG SANTE in writing, who will share them with the relevant Member States together with the redacted version of the contracts. Member States will be kept updated about the process.

## **3. Feedback from Member States**

A number of Member States noted that they had received overall positive feedback from economic operators, indicating that the registration process worked well. Some Member States explained that a high number of requests for identifier codes had posed certain challenges in the days before and after 20 May.

Romania informed the Subgroup that it had officially communicated to economic operators the absence of its ID issuers. Economic operators were therefore advised to rely on Commission Decision (EU) 2019/691 (temporary authorisation decision), as well as the fictitious identifier codes. All other Member States confirmed the operational functionality of their ID issuers.

One Member State raised the point of fees for generating and issuing of UIs. A number of Member States took the floor to provide indications as to the fees charged by their ID issuers. A follow-up on this topic was agreed to take place in the next meeting of the Subgroup.

Another Member States provided feedback on an issue in the registration process regarding the address field of facilities. The ID issuer of the Member State required economic operators to fill in the address of facility in a free text field. This made it more difficult to identify cases in which economic operators provide incomplete address information (e.g. no ZIP code/city).

The Member State and ID issuer were working on adjusting their registration form to split the different elements of the address into individual data fields. The group thanked the Member State for sharing this practical experience.

## **4. Discussion**

### *4.1 ID issuer competence rules*

The Subgroup discussed the application of the competence rules for requesting UIs and identifier codes. The rules on competent ID issuers were clearly set out in Implementing Regulation 2018/574 and the group agreed that conformity of submitted requests with these rules should be ensured through adequate monitoring activities by the competent national authorities. Several Member States noted that appropriate enforcement actions would follow in cases where economic operators requested UIs and/or identifier codes from non-competent ID issuers. The traceability system allows the public authorities to identify these cases.

Following the inquiry by one Member State, DG SANTE explained that the legislation requires ID issuers to deliver UIs electronically within the required deadline of 2 working days from the receipt of the request. The services offered by ID issuers should ensure compliance with the basic rules of delivery, but the legislation does not oblige ID issuers to offer services that go beyond (e.g. API for system-to-system data transfer). This also meant that economic operators could not interpret the absence of certain non-basic services, notably the existence of a system-to-system solution, as a reason to rely on the temporary authorisation decision and turn to other ID issuers.

### *4.2 Follow-up: data protection obligations*

The Subgroup followed-up on the data protection obligations with regard to the repositories system. DG SANTE provided a short update on the implementation of the obligations of data processors into the contract with Dentsu, and the contracts between Dentsu and primary repository providers.

On the subject of data controllership, some Member States noted that the matter was still under review at national level. In this context, Member States asked for a more thorough written explanation from DG SANTE that could facilitate the discussion at national level.

### *4.3 Follow-up National Administrators*

The Subgroup followed-up on the discussion concerning a template form for the designation of National Administrators by competent national authorities. DG SANTE recalled that the use of such a form would provide higher certainty to public authorities, as well as to Dentsu, who has to create the credentials for National Administrators. In this regard, the use of a designation form would strengthen the verification process to prevent unauthorised access to the traceability system.

At the request of the Subgroup, DG SANTE presented its initial ideas of key elements that should be included in the appointment form (i.a. information on designating authority, identity of National Administrator(s), responsibilities and tasks of National Administrator(s), rules on communication). The participants thanked for the presentation and welcomed DG SANTE's readiness to submit a draft form to Member States for comments. Participants noted that the mode of government in some Member States (e.g. federal and regional governments) might require certain deviations from the standard template.

## **5. Questions and Answers**

On the recording of product movements to embassies, DG SANTE reiterated its view that the reporting obligations depended on the territorial status of the embassy. Normally, dispatches to embassies of non-EU countries would be regarded as exports.

On the registration of movable vending machines used at festivals, DG SANTE referred to the previous discussions in the Subgroup on movable retail outlets.

On the validation of UIs, DG SANTE recalled that the validation of each message (i.a. existence of IDs, mandatory fields) took place at the level of the router. Data processing at the level of the primary repositories is also subject to the validation rules.

On the reporting of credit notes or bonuses/discounts, the group agreed that these form part of the transactional information and as such have to be recorded in the system as corrective invoices.

On the execution of queries via mobile apps, DG SANTE noted that the Implementing Regulation required the provider of the secondary repository to make available an API that allows public authorities to connect to the non-graphical interfaces with a system and analytical software of their choice. This included the use of mobile apps.

On whether a cash register document qualifies as invoice, DG SANTE referred to the application of the relevant legislation in this field, e.g. VAT legislation under which the cash register document is considered a simplified invoice.

On the resale of goods that are returned from a retail outlet, the Subgroup agreed that the reporting of a product return (in the form of an 'arrival message') corresponds to the physical arrival of that product to a facility. Consequently, a resale of products should only take place after the product return took place.

### **Any other business**

No additional discussion points.

## **6. Concluding remarks**

The Chair thanked participants for the constructive discussion and closed the meeting.

## List of participants

Austria	(Federal Ministry of Labour, Social Affairs, Health and Consumer Protection and Ministry of Finance - Tax and Customs Administration)
Belgium	(Excise & Customs and FPS HEALTH FPS Health and Food Chain Safety and Environment)
Bulgaria	(National Customs Agency)
Croatia	(Agencija za komercijalnu djelatnost and Customs Administration)
Czech Republic	(Ministry of Agriculture and STC)
Denmark	(Danish Safety Technology Authority)
Estonia	(The Ministry of Finance of Estonia)
Finland	(Supervisory Authority for Welfare and Health)
France	(FRENCH CUSTOMS)
Germany	(Bundesministerium für Ernährung und Landwirtschaft; Bundesdruckerei GmbH)
Greece	(Independent Authority for Public Revenues and Ministry of Finance, General Secretariat for Information Systems)
Hungary	(Representatives of minister without portfolio responsible for national property management, the National Tax and Customs Administration and ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság)
Ireland	(Department of Health and Office of the Revenue Commissioners)
Italy	(Ministry of Health)
Latvia	(State Revenue Service)
Lithuania	(State Tax Inspectorate Under the Ministry of Finance of the Republic of Lithuania)
Luxembourg	(Customs and Excise Administration and ID issuer Luxembourg)
Malta	(Customs Department)
Netherlands	(Ministerie van Volksgezondheid, Welzijn en Sport and Belastingdienst)
Poland	(Ministry of Finance)
Portugal	(Imprensa Nacional Casa da Moeda)

Romania (C.N. Imprimeria Națională S.A. and National Agency for Fiscal Administration)

Slovakia (Ministry of Finance, Financial Directorate and Slovak Permanent Representation)

Slovenia (Ministry of Health of the Republic of Slovenia)

Spain (Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas and Ministry of Finance.)

Sweden (Public Health Agency Sweden)

United Kingdom (HM Revenues and Customs)

**Observers:**

Norway (Norwegian Ministry of Health and Care Services and Norwegian Directorate of Health)

**Commission:**

DG SANTE

Filip Borkowski  
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