EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES

–SUMMARY RECORD –

Date: 08 May 2019

Place: Brussels

1. Welcome and introduction

The Chair welcomed all Member State participants to the last face-to-face meeting before the launch of the systems. One of the main purposes of the meeting was to address outstanding issues and any remaining questions that participants might have before 20 May. The Chair informed that the next meetings of the Subgroup would take place on 24 May and 21 June.

The Chair presented the agenda of the meeting.

2. Update from the Commission

SANTE informed the group about the technical briefing for stakeholders, which took place on 6 May. In that meeting, the Commission had informed stakeholders about all general aspects related to the launch of the systems for tobacco traceability and security features. The information provided included an explanation of the transitional provisions (stock exhaustion clause) in the two implementing acts, as well as the main characteristics of Commission Decision (EU) 2019/691, which authorises economic operators to use the services of other appointed ID issuers.

In the context of the launch of the system, SANTE explained the need to establish routing services between primary repositories and the secondary repository once manufacturers and importers had received their EO-IDs. Without the routing in place, the router (of the secondary repository) would not be able to allocate requested UIs to the corresponding primary repositories. Dentsu provided support to repository providers on this operational aspect.

SANTE also informed the participants that it has released a communication package on the launch of the systems, including a press memo with Q&A. This package was available on the Commission website and Member States were invited to link to it on their national websites.

3. Discussion

3.1. Commission Decision 2019/691/EU

On 2 May, the Commission adopted Commission Decision 2019/691 authorising economic operators to use the services of other ID issuers. The authorisation decision entered into force on 3 May 2019 by publication in the Official Journal of the European Union. SANTE outlined the main characteristics of the decision. The Decision applies to economic operators, as defined in Implementing Regulation 2018/574, but not to operators of first retail outlets. The application of the Decision is limited to cases in which the competent ID issuer is absent. As soon as a Member State has its ID issuer in place, the decision no longer applies and, in any case, it seizes to apply after 31 December 2019. ID issuers remain free to accept or reject any request that they receive in line with Decision 2019/691. SANTE stressed that the decision does not relieve Member States of their legal obligation to ensure the timely establishment and functioning of ID issuers. In this regard, the group agreed that it is the obligation of each Member State to assess and inform about the possible absence of its ID issuer. In this case, the Member State should inform the Commission and all other Member States.

The group then discussed the fact that, in the absence of a competent ID issuer in a given Member State, numerous economic operators and their facilities in that country would not be able to register in the system (especially first retail outlets but potentially also smaller wholesalers/distributors). At the same time, economic operators dispatching products to such facilities are not in a position to carry out the required reporting obligations. As a temporary practical solution to this problem, Member States and the Commission agreed that a pair of fictitious economic operator and facility identifier code should be issued per each Member State. This 'temporary solution' would provide economic operators dispatching products to unregistered entities/facilities with legal certainty and, at the same time, increase the quality of reporting data in the traceability system by allowing for the completion of the supply-chain reporting cycle. In line with the authorisation set out in Decision 2019/691, a Member State could only share its fictitious economic operator and facility identifier code, if that Member State has declared the absence of its ID issuer. Member States with operating ID issuers in place cannot make use of the codes. The fictitious identifier codes should expire after 31 December 2019.

3.2. Reimbursement of equipment

SANTE informed the group that it had received a letter from a large association in relation to the apparent views advanced by a number of manufacturers with regard to the obligations in Article 15(7) of Directive 2014/40/EU. Some Member States noted that they had received similar letters. The Chair recalled the discussions in the Subgroup on this matter, in particular those that took place in the meeting of 14 February. In the end, it is the obligation of Member States to ensure the sound application of this provision.

3.3. Data protection obligations

SANTE recalled the discussion in the previous meetings and reiterated its internal reading with regard to data controllership. According to this, Member States and the Commission should act as joint controllers, because they determine the purposes and means of the personal data that may form part of the traceability data processed in the repositories system. SANTE stressed that it was important to reach agreement on this

aspect as soon as possible, in order to put the required arrangement in place. Several Member States noted that they required more time to assess this matter together with their data protection experts. One Member State raised initial doubt whether a joint controllership is the appropriate approach.

3.4. Appointment of National Administrators

SANTE recalled that each Member State must designate at least one National Administrator, who will be able to create, manage and withdraw user rights to access the repositories via the available user interfaces. Given the sensitivity of the data in the repositories system, the appointment should follow a sound procedure. SANTE therefore proposed to develop an appointment form by which each national appointing authority (e.g. Ministry) could designate the physical persons in the government who should receive national administrator rights. This form would increase legal certainty and ensure the adequate protection and integrity of the data by setting out general rules and obligations in line with the Implementing Regulation. Several participants spoke out in support of this proposal. One Member State noted that, in light of the different governmental structures in EU countries, a one-fits-all approach may not be desirable and certain amendments could be necessary in the case of some Member States.

3.5. Registration of economic operators – without facilities – who take part in the trade of tobacco products.

SANTE followed up on previous discussions regarding legal entities that are involved in the trade of tobacco products in the EU, but do not operate a facility within the strict meaning of the Implementing Regulation. Even where a legal entity is active in the trade of tobacco products only in terms of financial activities, this entity qualifies as an economic operator. Therefore, the obligations in the Implementing Regulation, including those on registration in the system and reporting on events, should apply. At the same time, the group agreed that Article 14(1) of the Implementing Regulation might not provide sufficient guidance for such entities in terms of requesting EO-IDs.

Taking into account the purpose of registering economic operators in the traceability system by means of an identifier code referred to in Article 14(1), Member States reached the following conclusion. Economic operators involved in the trade of tobacco products, who do not operate a facility on EU territory, shall apply for an economic operator identifier codes from the ID issuer competent for each Member State in which they have a legal seat registered, including their subsidiaries.

3.6. Reporting on the movement of test products

On the obligation to report the movement of test products, the group reiterated the need to differentiate between test products sent to public authorities and those delivered to third party laboratories.

Participants agreed that movements of test products to non-governmental facilities, which often constitute larger product volumes, are subject to the reporting obligations under the traceability system, in order to control their movements. This means that such private laboratories should request an EO-ID and F-ID with the ID issuer competent for the country in which the laboratory is located. For dispatches to governmental locations, no recording obligations apply. Economic operators should instead send a request for deactivation of the products concerned to the traceability system, including a comment that the deactivation concerns test products handed over to a national authority.

3.7. Access to data by industry in duly justified cases.

In response to clarification requests received from some Member States, SANTE recalled the purpose of the third subparagraph of Article 15(8) of Directive 2014/40/EU. This provision provides a legal basis for Member States to share extracts of the traceability data with manufacturers or importers in cases where a necessity to disclose derives from the national legislation in Member states.

SANTE reminded that this provision also formed the basis for OLAF to share extracts of the traceability data with certain tobacco manufacturers. The latter is necessary to enable these manufacturers to meet their obligations (i.a. related to seizures) under the existing agreements. A follow-up discussion on this topic will take place in next week's Expert Subgroup chaired by OLAF.

4. Update from Member States

4.1. ID issuer

SANTE informed Member States about the status update on the test activity of ID issuers, which it had received from Dentsu. Participants were reminded that after the official launch of the traceability system only those entities, which Member States officially confirmed as ID issuer, would be able to communicate with the secondary repository system. To protect the integrity of the system, the Commission will instruct Dentsu to cap any activity that originates from an entity without confirmation by a Member State. Member States remain responsible to ensure that only authorised entities act as ID issuer and transmit data to the secondary repository.

4.2. Tour de table

The group updated the four tables referred to in the introductory part of the meeting (overview of appointment of ID issuers, other implementing measures, application of the second subparagraph of Article 4(1), overview of online information on ID issuers). The tables will be annexed to the summary record of this meeting.

5. Q&A

A question was asked on the registration of facilities with double purpose, such as C&C markets where both wholesale and retail sales take place. For the proper recording of all transactions and product movements in the traceability system, such facilities should acquire two facility identifier codes. For the retail sales, the products have to be first reported as dispatched from the wholesale (F-ID #1) to the retail (F-ID #2) part of the facility. The subsequent retail sale is not subject to reporting obligations in the system.

6. AOB

Representatives from the Czech ID issuer gave a presentation on the establishment of their entity. The presentation covered statistics on the pre-registration of economic operators and facilities, structure of the UI, and lessons learned.

In the follow-up discussion, the Czech ID issuer offered to share its experience with other ID issuers, in particular as regards the secure delivery of codes to economic operators.

7. Closing remarks

SANTE reminder Member States about the particular need to react fast and in a coordinated manner to any developments during the launch phase of the system. The key persons were asked to be on standby over the following weeks.

SANTE thanked Member States for their active participation. Participants were reminded of the upcoming meetings. Member States will receive a draft of the summary record of today's meeting for comments.

The Chair 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	(Bundesdruckerei GmbH and Bundesministerium für Ernährung und Landwirtschaft)
Greece	(Independent Authority for Public Revenues and Ministry of Finance, General Secretariat for Information Systems)
Hungary	(Representatives of minister without portfolio responsible for national propery 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
Thea Emmerling
Jan Hoffmann
Anna Mirandola