



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: 5 September 2019
Location: CCAB, European Commission

1. Welcome and introduction

The Chair welcomed the participants to the first meeting after the summer break. SANTE gave information about upcoming meetings. The Subgroup approved the agenda.

2. Communication from the Commission

2.1. Short recap from Dentsu workshop

SANTE summarised the main conclusions of the workshop with Member States, which Dentsu organised on the day before the meeting of the Subgroup.

2.2. ID issuer coding structure

SANTE recalled that in order to ensure full compliance each ID issuer should make available a coding structure document. The coding structure is subject to the applicable ISO standards, as referred to in Implementing Regulation 2018/574/EU.

SANTE noted that it was pertinent for ID issuers to publish the coding structure, in order to provide economic operators with the necessary guidance. The appearance of several encoding errors across the market, underlines this necessity. SANTE asked participants to update and inform SANTE about the coding structure of each competent ID issuer.

The Subgroup considers the publication of a list of links to coding structures of all ID issuers.

2.3. Update of technical specifications

The list of technical specifications and the data dictionary will undergo another update and version 1.3. will be published on 16 September 2019, with a 2 month transition period.

Split of address field

The Subgroup discussed the split of the address field for identifier codes and messages) into separate fields, i.e. to separate postal code, street name, house number, and city. This split will help to enhance data quality and ease validation. SANTE noted that Annex II of the Implementing Regulation is very clear as to the information required in the address field and lists all information elements that need to be completed.

A number of ID issuers already applied this split at their level to ensure adequate validation checks. The remaining ID issuers will have to implement the changes accordingly. Where the address field contains complete and well-structured information, ID issuers should be able to perform an automatic split of the information into the subfields.

In cases where a split is not possible, notably because economic operators submitted incomplete information, ID issuers should request economic operators to complete the outstanding information. For that reason, Dentsu is extending the rollout phase for this technical update. SANTE also reminded participants that this matter relates to enforcement and Member States should support ID issuers in this task.

SANTE furthermore explained that this technical change would help to enhance the overall data quality in the traceability system and as such assist enforcement activities.

UTF-8 support

There had been an initially request to support UTF-8 in text fields. However, the additional optional support of this Unicode Standard raised concerns among some ID issuers about additional complexity in data management and exchange. Therefore, it was decided to postpone its implementation. SANTE reminded participants that the legislation required all text fields in the messages to be encoded in Latin alphabet characters (ISO 8859-15). This requirement follows from Annex II of the Implementing Regulation. SANTE urged ID issuers to ensure that they enforce this requirement. The secondary repository will turn on the corresponding validation rules during the course of/in September.

EO CODE

A number of stakeholders asked for the EO-CODE to be added to all logistic and transactional messages as an additional authentication element. This request was rejected for the upcoming technical update, mainly due to the risk of disclosure of the EO_CODE. Future implementation of this request remains under consideration.

2.4. Information on designation of National Administrators, primary repositories and anti-tampering devices

SANTE provided a brief update on appointed primary repository providers, declarations for anti-tamper devices, and on the designation procedure for National Administrators.

On National Administrators, SANTE asked Member States to use the designation form distributed ahead of the meeting and to follow the submission procedure described therein.

Following a question on anti-tampering devices, SANTE clarified that any Member State had the right to request from manufacturers/importers access to the record of the verification process. The information should be provided directly by the provider of the anti-tampering device to Member States.

2.5 Other communication

SANTE updated the participants on an appeal from ITSA against the Order of the General Court of 16 May 2019 by which the Court dismissed ITSA's application for the annulment of the three legal acts. The Commission will submit its response to the Court.

The Framework Coalition Alliance (FCA) published a blog post on the EU traceability system, containing several allegations about system, including its alleged non-compliance with the FCTC Protocol. SANTE strongly disagrees with the allegations and will contact the FCA concerning the blog post.

2.6 Technical meeting on exports to Russia

SANTE reported about a technical meeting in Berlin between the German Printing House (BDR), the ID issuer of the Russian traceability system, and SANTE. The meeting concerned the marking of tobacco products to be exported to Russia. SANTE noted that any technical solution would have to comply with EU legislation and the WHO FCTC Protocol. The Subgroup will be informed of any progress on this issue.

3. Reply to Member State questions

3.1. Transfer of identifier codes from temporary ID issuers to Romania's competent ID issuer

Temporary ID issuers should transfer relevant identifier codes to Romania's competent ID issuer. Transfers should take place at the request of the competent ID issuer, once it has become operational. SANTE had already shared a possible transfer schedule with Romania.

It is important to ensure smooth transfers and avoid any double competence scenarios. Temporary ID issuers should update their registries by removing any transferred identifier codes. The competent ID issuer will add the transferred identifier codes to its registry and upload the registry to the secondary repository.

3.2. Incorrect reporting of TP-ID

Some Member States noted that a few economic operators had submitted invalid TP-ID information in their requests for UIs. SANTE replied that this was a case of incorrect reporting, which should be enforced by Member States. For export products, TP-ID entry is not required but some economic operators nevertheless submitted '00000-00-00000'. Such cases were not considered problematic.

3.3. Deactivation of UIs

Implementing Regulation 2018/574 allows for economic operators to send deactivation of issued UIs requests to the traceability system. In the event of non-compliance issues, Member States could direct economic operators to send a deactivation request. The Regulation does not differentiate between applied and non-applied UIs. SANTE received

confirmation from Dentsu that it is possible to deactivate non-applied UIs. Manufacturers/importers should ensure that providers of primary repositories allow for such deactivation request as well.

3.4. Sharing of SF with the Commission

According to Commission Decision 2018/576 on security features Member States shall require manufacturers to supply them, upon written request, with sample products of products placed on the market. Based on the Decision, the Commission may ask Member States to make any received samples available to it.

3.5. Reporting in cases of C&C

SANTE referred to the summary records of the Subgroup of 8 May 2019, and of the Subgroup of 12-14 February 2019 (webinar session), which already addressed the reporting requirements in cases of C&C. SANTE clarified that the retail part of the C&C business activity should be registered as a retail outlet.

3.6. In-flight and on-board sales

The Subgroup concluded its discussion regarding traceability and security feature requirements in relation to in-flight sales and sales on-board commercial vessels / cruise ships. The conclusions are set out in Annex I to the summary record.

4. Discussion

4.1. Data quality issues

SANTE recalled previous discussions. Review of the initial data recorded in the traceability system indicates sub-optimal data quality.

SANTE, together with Dentsu, intends to develop a guidance document for economic operators on data quality. The document will outline common reporting mistakes in order to assist economic operators in meeting their legal obligations.

SANTE intends to translate the document into all EU languages, publish it online and forward it to Member States. Member States should help to ensure that the sector is informed accordingly about the data quality issue and common mistakes concerned, for example by publishing the document on their websites and/or by providing a link to the Commission document.

In view of the natural learning curve, the general trust in efforts by the legal supply chain to comply with the new set of rules, not all of the possible validation rules have been turned on in the initial months of the system's operation. The Subgroup agreed that following a transition period of four weeks after the publication of the guidance document, SANTE will request the secondary repository turn on the full validation of messages received from economic operators in line with Article 25(1)(g) of the Implementing Regulation. As of that moment, the reporting mistakes indicated in the guidance document will result in the receipt of error messages.

A follow-up discussion on this topic will take place in the next meeting of the Subgroup.

4.2. *User access rights policy*

On access rights, the Subgroup discussed the categorisation of user rights, based on a proposal presented by SANTE. A number of comments were made and SANTE will share an updated version with Member States, which will be subsequently shared with Dentsu to inform their further technical work on the interface for access rights administrators.

4.3. *Manufacturer and request for additional repository services*

The Subgroup discussed a request for additional primary repository services, as submitted by one manufacturer.

4.4. *Registration of facilities – type “others”.*

SANTE recalled its former communication to Member States in which it noted a considerable volume of facilities declared as facility type ‘others’.

This facility type should only be used in special cases (e.g. the wholesale part of a cash and carry). Member States should monitor any potential abuse and take necessary measures accordingly. Excessive use of this facility type undermines the quality of query results and other reports.

4.5. *Transloading activities – van to sales van/mobile retail outlets.*

The Subgroup discussed a scenario in which products are shipped from a facility and directly transloaded from a van/truck to a vending van supplying retail outlets. Very few Member States noted that they are aware of such activities.

Annex II of the Implementing Regulation does not foresee reporting of transloading activities directly to a vending van. The transloading message requires a Facility ID for destinations in the EU.

Economic operators should be advised to register a facility indicating the (geographic) location at which products are shifted/moved from a van/truck to a vending van. An arrival message referencing the F-ID of that location will be required. It must be followed by a dispatch message for each vending van.

Where a delivery (a movement of product) takes place from a van/truck to a sales van (a mobile retail outlet), the sales van should be registered as the first retail outlet. Such a delivery should be reflected in a dispatch message from the (warehouse) facility to the sales van, which should contain the Facility-ID of the sales van (the retail outlet) and identify the van/truck as the transport vehicle.

4.6. *Re-entry of stolen products into the legal supply chain*

A product reported stolen requires the deactivation of the corresponding UI. Where the product eventually reappears (e.g. not stolen but only temporarily lost), it requires a new UI. Only then can the product be re-introduced into the supply chain. The reactivation of deactivated UIs is not possible.

4.7. *Scanning equipment*

Test facilities

SANTE recalled the conclusions of previous meetings on the requirement to report dispatch movements to test facilities (tobacco laboratories) operated by non-governmental parties.

Operators of such test facilities do not fall within the definition of economic operators because they are not involved in the trade of tobacco products. Therefore, it is not required to record the arrival of products to such test facilities.

In order to enable dispatches to test facilities, operators of test facilities require an EO-ID and F-ID. Otherwise, the dispatch cannot be recorded in the system.

Conclusively, where Member States require the recording of dispatches to test facilities, the operators of these facilities must be required to request EO-ID and F-ID.

Absence of scanning equipment

SANTE informed Member States that several economic operators have pointed to delays in obtaining the required scanning equipment. SANTE recalled previous discussions, in particular the obligation that Directive 2014/40/EU imposes on the manufacturers vis-à-vis other economic operators in terms of the provision of and other scanning equipment.

In this context, an economic operator enquired as to whether it was permitted to dispatch products to another economic operator despite possibly being aware that the other economic operator did not possess the necessary scanning equipment.

SANTE noted that each economic operator must ensure that it complies with the specific obligations that the legislation imposes on them. Where products are not recorded correctly, or recorded at all, the economic operator in question violates its obligation under the legislation and runs the risk that a Member State may seize the products and/or apply penalties. Each economic operator along the supply chain must take first and foremost its own responsibility which does not extend to other economic operators.

To avoid any doubt, the non-compliance of another economic operator does not free a given economic operator of its own obligations. For example, subject to the full validation rules, a non-reported dispatch will prevent the next operator from accepting the goods because they will be unable to correctly report the arrival of those goods and hence discharge its own obligations.

5. AOB

One of the participants tabled a question about the reporting obligations of ship suppliers. Another Member State representative noted that, in accordance with Articles 269 and 270 UCC, ship suppliers move tobacco products directly from the warehouse to the vessel. Intermediate stops are not permitted. SANTE explained that ship suppliers who merely transport products between warehouses and vessels, and do not engage in any transloading activities, do not have any reporting obligations. However, ship suppliers may also operate the warehouses from which products are dispatched to vessels. In such cases, the ship suppliers must report on the arrival to and dispatch from these warehouses. Therefore, they must also obtain the relevant economic operator and facility identifier codes.

6. Closing remarks

The Chair thanked the participants for their input and closed the meeting.

Annex I

1.) On rules regarding tobacco traceability

Aircraft:

Union legislation permits in-flight sales of tobacco products only while the plane is outside of EU airspace.¹ Therefore, tobacco products made available during in-flight sales should be considered as an export.

The ‘final destination address field’ in the corresponding dispatch message should include information on the aircraft identification and the airport from where the plane takes off (or, alternatively, the home airport of the aircraft).

It is common procedure that the transport of tobacco products from the distribution centre to planes takes place in locked trolleys/carts. The Subgroup agreed that, from a traceability point of view, it would be beneficial to require these trolleys/carts be indicated and identified in the dispatch message via the fields transport mode (= ‘other’) and transport vehicle identification number (= ‘trolley/cart number’).

Commercial vessels / cruise ships:

The economic operator responsible for making tobacco products available to consumers on vessels/ships is responsible for determining whether a product will be placed on the Union market, as defined in Article 2(40) of Directive 2014/40/EU.

Where it is determined that the product will be placed on the Union market (e.g. shops on cruise ships that operate exclusively in EU waters), a dispatch message with destination ‘retail outlet’ must be recorded in the traceability system and the vessel/ship shop must acquire a Facility-ID (type: ‘retail outlet’). In this context, several Member States noted that in certain situations it might not be possible for manufacturers (and economic operators) to determine the competent ID issuer because a ship shop opens several times during one cruise and the ship travels through territorial waters of different Member States. As a solution, manufacturers (and economic operators) should turn to the ID issuer competent for the Member State on whose territory the tobacco products are loaded onto the vessel / cruise ship.

Where it is determined that the product will be made available to consumers outside of EU waters, a dispatch message for exports must be recorded in the traceability system and there is no need for the vessel/ship shop to acquire a Facility-ID. The ‘final destination address field’ in the corresponding dispatch message should include the vessel / cruise ship identification and the port from where the vessel / ship departs (or, alternatively, the homeport of the vessel / ship).

Returned products

For products that return from a plane or vessel/cruise ship and enter back into the supply-chain, the Subgroup agreed that those products are subject to the rules on traceability.

2.) On rules regarding security features

¹ Representatives of France and the Netherlands noted that, by derogation to the general rule, the sale of duty free tobacco products is also permitted on flights between the mainland and their Outermost Regions (OMR), but only while the airplane flies through international airspace.

Aircraft:

As concluded in the discussion on traceability, tobacco products made available during in-flight sales should be considered as an export. Therefore, Directive 2014/40/EU does not oblige Member States to require that such tobacco products carry a security feature.

Commercial vessels / cruise ships:

The economic operator responsible for the handing-over of tobacco products to consumers on commercial vessels / cruise ships should determine whether the products in question are placed on the Union market. All products placed on the Union market must carry the required security feature.

Several Member States noted that, in situations where it is determined that a tobacco product must carry a security feature, a pragmatic approach might be necessary to determine the permitted national security feature. This is necessary, for example, where a ship shop opens several times during one cruise and the ship travels through territorial waters of different Member States. In such a situation, it may not be feasible for the economic operator to determine in advance the exact Member State territory on which the product is made available to consumers. As a solution, economic operators should apply the security feature permitted by the Member State on whose territory the tobacco products are loaded onto the vessel / cruise ship.

One Member State said that it considered requiring the placing of a security feature on all products that are loaded onto vessels / ships departing from its territory.

List of participants

Austria	(Federal Ministry of Labour, Social Affairs, Health and Consumer Protection; State Monopoly)
Belgium	(Excise & Customs and FPS HEALTH and Food Chain Safety and Environment)
Croatia	(Agencija za komercijalnu djelatnost and Customs Administration)
Czech Republic	(Ministry of Agriculture; State Printing Works of Securities)
Denmark	(Danish Safety Technology Authority and Danish Ministry of Health)
Estonia	(Ministry of Social Affairs of Estonia; Permanent Representation)
Finland	(National Supervisory Authority for Welfare and Health; Customs Authority)
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	(Government office of the Prime Minister, Ministry without portfolio responsible for national property management, the National Tax and Customs Administration & ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság)
Ireland	(Department of Health and Office of the Revenue Commissioners)
Italy	(Customs Monopolies Agency)
Latvia	(State Revenue Service of Latvia)
Lithuania	(State Tax Inspectorate under the Ministry of Finance of the Republic of Lithuania)
Luxembourg	(Customs and Excise Administration ; Direction de la santé; INCERT Luxembourg)
Malta	(Customs Department)
Netherlands	(Ministerie van Volksgezondheid, Welzijn en Sport and Belastingdienst)
Poland	(Ministry of Finance; Polish Security Printing House)
Portugal	(Autoridade Tributária e Aduaneira)
Romania	(General Directorate of Customs)

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

Slovenia (Ministry of Finance of the Republic of Slovenia)

Spain (Comisionado para el Mercado de Tabacos; Ministry of Finance; FNMT)

Sweden (Public Health Agency Sweden)

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