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: 28 January 2020
Location: CCAB, European Commission

1. Welcome and introduction

The Chair welcomed the participants to the first meeting of 2020, and introduced both departing and new members of the Track & Trace team. SANTE informed those gathered about planned Subgroup meetings for 2020. The Subgroup approved the agenda.

2. Communication from the Commission

2.1. Statistics on the traceability system (supply chain activity & use management)

SANTE presented an overview of statistics (monthly generation and application of UIs, etc.). As overall usage of the system is stabilising, it is becoming possible to identify trends and possible anomalies. SANTE invited Member States to use the data to inform their enforcement activities. Statistics on warning messages were also presented. SANTE emphasised the need for economic operators to be ready for the new technical specification.

The Chair noted that the majority of errors are caused by misreporting by economic operators, reminding that the responsibility to transmit information correctly lies with economic operators and recalling the actions taken by SANTE to date to counter this, namely: publishing the common mistakes document and the information sheet for distributors in all EU languages, providing examples of real mistakes to the four largest tobacco manufacturers.

2.2. Technical specifications 1.4.2 – state of play

SANTE presented a timeline for the rollout of specification 1.4.2, starting with a one-month transition period from 1 March 2020, with full validation, including hard warnings, for new products as of 1 April 2020. SANTE explained the validation rules, in particular sequence checks for dispatches and arrivals, the possibility to deliver products to a facility other than the intended one and the possibility of product returns from retail outlets. SANTE noted that the split address field has already been implemented (version 1.3), effective as of 1 January 2020, which enables the running of geographical controls.

2.3. Project on automatic alerts

SANTE thanked Member States who have provided input/feedback to Sopra Steria. The first data analysis session is due to take place soon on Commission premises under the supervision of Commission staff, following the first bulk download of data to SANTE's cloud.

The Chair advised that SANTE hopes to provide a progress update at the next subgroup meeting.

2.4. WHO FCTC Working Group on Track & Trace (Panama)

OLAF briefed the participants on the proceedings at and outcome of the first meeting of the WHO FCTC Working Group on Track & Trace, which was attended by a team from both OLAF and SANTE. The main achievements of the meeting, in line with the EU objectives were: A mandate (as Key Facilitator) to draft a proposal for how a Global Information Sharing Focal Point could be established; A mandate was adopted to compile a report on good practices on track and trace systems, for which a questionnaire has been created. OLAF is drafting a joint reply, collating all EU and national measures, which will be shared with the subgroup.

2.5. Inspection mobile application

SANTE recalled that Dentsu offered to make an inspection management application available to Member States and the Commission. The app is due to be provided free of charge for the duration of the concession contract. SANTE advised that it received written confirmation from Dentsu that the first version of the app will be delivered by the end of Q1/2020. SANTE underlined that this proposal does not prevent the Commission and/or a Member State from developing and using their own app, connecting at no additional costs to the existing application programming interface (API) of the secondary repository.

2.6. UID fees

SANTE advised that the Commission continues to receive complaints from some manufacturers, including one of the big four, regarding the fees charged by certain ID issuers. Recalling earlier discussions, SANTE noted that responsibility for controlling the fees charged by ID issuers lies with Member States, through national-level agreements or legislation, adding that the implementing regulation requires that the fees are proportionate to the services delivered.

The Chair undertook, at the invitation of the Member States, to review the data available on the fees charged and calculate a weighted average.

2.7. Audit guidelines

SANTE recalled that Article 15(8) of the Tobacco Products Directive (TPD) requires that all primary repositories and their providers be audited annually; noting that the auditors must be approved by the Commission.

SANTE advised Member States that it had issued an initial communication to all manufacturers informing them of the approval process, including necessary declarations on the part of potential auditors.

The Chair undertook to circulate the communication to manufactures via the subgroup mailing list.

SANTE advised that it will also publish guidelines on the scope of the annual audits and the format the reports should take, to ensure the right focus and consistency between different reports to enable easy comparison. SANTE added that the guidelines will be based on the ISO 27001 standard, and as such will not be legally binding; it is intended that the first audit reports will be submitted by the end of October 2020 (and each year thereafter).

The Chair advised that the guidelines are expected to be published around the end of Q1 2020.

2.8. Verification check for existence of UIDs and ID codes

SANTE informed the meeting that some manufacturers had requested approval for the repository providers to provide them with technical information on the existence of UIDs and identifier codes. SANTE confirmed to the repository providers that it was possible to provide such technical information to manufacturers, noting that it was strictly limited to 'yes or no' verification checks.

2.9. Reporting invoices

SANTE recalled previous discussions about the reporting of transactional events, noting that the Implementing Regulation requires that all transactions related to tobacco products be reported to the traceability system. SANTE informed the meeting that it continues to receive questions on the reporting of invoices, including cases where wholesalers assert that they cannot meet this reporting obligation due to not possessing information on UIs. SANTE described a scenario where a wholesaler sells products to first retail outlets but another distributor carries out the actual delivery of the products. SANTE advised that the distributor should share the necessary information on UIs with the wholesaler, cautioning that failure to do so could potentially impede the wholesaler from meeting its regulatory obligations. SANTE underlined that a list of the UIs delivered can easily be extracted from the dispatch message, so providing such information to the wholesaler should not prove burdensome for the distributor.

A Member State referred to another scenario in which an EU manufacturer ships its products outside the single market but the transaction is arranged via a separate trader company, which is

not directly involved in the logistics. SANTE explained that in this scenario a dispatch to a third country should be notified by the manufacturer, with an invoice from the manufacturer to the trader also notified to the system; subsequently, the trader should report an invoice issued to the non-EU buyer. To report this invoice the trader will need a list of the UIs dispatched by the manufacturer to the non-EU buyer. The same logic applies to other transactional events, i.e. orders and payments.

2.10. Compliance checks Article 15 and 16 TPD

SANTE briefed the subgroup on the status of the compliance checks carried out by the Commission, explaining that it is a two-stage exercise, consisting of a transposition check followed by a conformity check. SANTE informed that bilateral contacts within the framework of the conformity checks were continuing. SANTE reminded Member States of the importance of notifying the Commission, via the National Measures of Execution (MNE) system, of national legislation introduced to implement the TPD, to ensure the completeness of the assessment. SANTE advised the subgroup participants, if in doubt, to contact the international relations department of their ministry to determine how the MNE system is administered in their Member State.

2.11. ID coding structure

SANTE presented a table listing by Member State links to the encoding and decoding instructions for unique identifiers. SANTE took the opportunity to invite any Member States who had not yet provided a link to do so as soon as possible to ensure the publication of a complete list.

2.12. Subgroup position on movements to vessels / planes

SANTE recalled the subgroup's position on the reporting of movements to vessels/planes.

The Chair took the opportunity to invite Member States to share the outcome of the discussion on the issue of dispatches to vessels, which was annexed to the minutes of the previous subgroup meeting, with their colleagues, especially those working in ports. SANTE noted that not all customs officials operating on the ground seem to be are aware of the view taken at that subgroup, as ship suppliers continue to raise the issue.

3. Communication from Member States

3.1. Reporting mistakes – national actions

SE presented its enforcement actions taken since May-June 2019, including against one manufacturer that had reported the wrong brand name in the unit level UIs for cigarettes and roll-your-own tobacco products, which resulted in a ban on the sale of these products. SE further advised that manufacturers have been contacted in relation to the discovery of TP-IDs not reported in the EU-CEG system and TPIDs with null values and went on to describe a supervisory case opened against a wholesaler. SE concluded that the traceability system is

proving to be a useful tool in carrying out enforcement tasks. SE cautioned that in order to be effective, data quality in the system needs to improve, adding that further data cross-checking mechanisms required.

The Chair thanked SE for its presentation and stressed the importance of national authorities' enforcement activities.

3.2. Data quality issues

AT informed the subgroup meeting about actions it has taken to improve data quality in the traceability system. AT provided examples of best practice to eliminate common reporting mistakes, including: checking data recorded in the secondary repository against random product purchases; using the secondary repository's interfaces to check for reporting errors. AT explained that it had also contacted the companies concerned to inform them of its findings.

AT detailed another initiative undertaken to ensure that the correct brand names were used by economic operators, describing how first a definitive list of brand names was established by cross-checking three different data sources before emailing all economic operators a request to use the correct brand names.

The Chair thanked AT for its presentation and suggested the subgroup consider organising an enforcement workshop after the updated specifications becomes fully applicable (see point 2.2 above).

SANTE informed the meeting about crosschecks of the TPIDs registered in the EU Common Entry Gate (EU-CEG) system against those reported in the traceability system; where issues were discovered reports were sent to Member States concerned in late December. The Chair advised that SANTE would continue to carry out similar checks but underlined that responsibility for enforcement rests with Member States.

3.3. Communication with third-country ID issuers

Member States updated the subgroup on recent interactions with the operator of the Russian traceability system. SANTE recalled its position from previous subgroup meetings.

3.4. Adjustment to UID fees and primary repository fees

The Chair explained the background to this agenda item, namely some ID issuers and primary repository providers have asserted that the changes required under technical specification versions 1.3 and 1.4 make an increase in fees necessary. The Chair noted that the Commission has no role as fees form part of the agreement between ID issuers and the appointing national authority, and between primary repositories and the contracting manufacturer.

Recalling that technical specifications are a technical document that may be updated over time (Article 28(3) of the Implementing Regulation), the Chair invited the subgroup participants to take the floor.

A number of Member States took the floor and advised that there was no intention to renegotiate or retender for contracts with ID issuers as an increase in fees would only be justified if there were a change in the law that required major technical updates.

4. Discussion

4.1. Reporting imported products

SANTE presented three scenarios and invited the subgroup participants to share their perspectives.

The first scenario concerned importations from non-EU countries, and specifically the use of bonded warehouses. A number of Member States made interventions and the consensus reached in the room was that import products that reach EU territory only become subject to the traceability rules once they have been released for free circulation. There may be cases of goods brought into the EU but not cleared for import and then re-exported, therefore there is no requirement to notify to the traceability system.

The second scenario concerned products dispatched from the EU to another territory in the EU via a third country. A number of Member States made interjections and the consensus reached in the room was that such cases should be deemed to be exportation and re-importation in terms of logistic operations, with corresponding notifications to the traceability system (for further discussion on marking, see point 4.2 below).

The final scenario concerned importation where release for free circulation happens at a retail outlet. It was considered that such a facility would be serving both as a retail outlet and a bonded warehouse and would therefore require two F-IDs.

Finally, the Chair emphasised that for imported products, there must always be an arrival message at a facility where a release for free circulation takes place, as that constitutes the starting point in terms of logistic movements to be reflected in the traceability system..

4.2. Dispatch of products via non-EU countries

The subgroup discussed a scenario whereby products manufactured in one Member State but intended for another EU market are dispatched via a non-EU Member State. It was discussed that, in terms of UIDs, such cases should not be treated as an export. The competent ID issuer is determined in accordance with Article 4 of the Implementing Regulation, it does not require the relabelling of the packet with a new UID. The importer to the final EU destination is not required to contract with a separate primary repository if the tobacco products in question are manufactured by a manufacturer that already has notified the Commission of its primary repository.

4.3. Reporting products intended for destruction

SANTE introduced a scenario whereby economic operators dispatch products to a waste processing facility, noting that the waste processing company does not qualify as an economic operator within the definition given in the Implementing Regulation as it is not involved in the trade of products. A number of Member States made interventions, with one stating that they adopt a similar approach as for when products are sent to testing facilities. Recalling the previous decision by the subgroup in respect of tracking movements to test labs/facilities, which normally do not qualify as economic operators but a manufacturer can apply on their behalf for a F-ID at no cost, SANTE suggested that Member States may adopt a similar approach in this scenario.

4.4. Receipt of non-compliant products

The subgroup discussed steps to be taken by an economic operator if it receives non-compliant goods due to a mistake made by the previous economic operator.

The subgroup agreed that the received non-compliant products should not be dispatched further as any further movement would trigger an error message from the traceability system. Instead, the economic operators should contact the responsible business partner to inform them that they did not comply with their reporting obligations and that the products can therefore not be moved further.

SANTE reminded the subgroup about the 24-hour window during which the business partner should try to rectify the situation by satisfying its reporting obligation, most likely by sending a missing dispatch message to the system; this should enable the economic operator to carry out its own reporting within the prescribed deadline.

4.5. Reporting in the case of receipt of lost products (for aggregated packaging)

SANTE informed the subgroup that economic operators had complained about receiving aggregated packaging missing some packets, for example, a palette missing two master cases. The matter was followed up by email after the meeting (see annex).

4.6. Reporting interface for stolen products

SANTE recalled previous discussions on the possibility of introducing an interface in the traceability system that would facilitate economic operators to notify of stolen goods. A number of subgroup participants commented on the proposal.

The Chair undertook to circulate some scenarios for how such an interface could function and requested that the subgroup participants consider them and provide feedback on their preferred option. SANTE underlined that the availability of an interface does not obligate a Member State to use it.

4.7. Sharing data on the traceability system

In response to the request of one Member State, SANTE reminded that the TPD stipulates that Member States and the Commission should have full access to all data and recalled previous

discussions in the subgroup on the subject, specifically the categorisation of access rights to ensure that staff members only have access to the information strictly required for their function. SANTE further noted that the use of the data is restricted to the purposes of the Directive and Implementing Regulation, i.e. it cannot be used for other reasons, in particular, for commercial purposes.

5. Q&A

5.1. Specification 1.4.

One Member State informed the subgroup that they had been contacted by stakeholders who are concerned that specification 1.4. introduces restrictions in terms of sequence checks that should not come into effect until 2028. This view was rejected by the subgroup, with SANTE citing relevant sections of the Directive and Implementing Regulation.

5.2. Downloads from EU-CEG

One Member State queried whether it would be possible to update the EU-CEG roadmap to enable automatic downloads from the database.

The Chair undertook to consult with colleagues on the matter.

6. AOB

6.1. Inclusion of exports in the instruction provided by Article 15(1) TPD

One Member State took the floor to raise the issue of the inclusion of exports in the EU tobacco traceability system. SANTE stressed that Commission Implementing Regulation 2018/574 was adopted on the basis of article 15(11) of Directive 2014/40/EU and was intended to give effect to the latter which makes clear that following the movements of tobacco products that are manufactured in the EU but intended for export to a third country is a sine qua non element of the EU tobacco traceability system. SANTE further advised that neither the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products nor the Directive can be interpreted in a way that implies a different approach could be taken where tobacco products are intended for export to a third country, irrespective of whether said country has a functioning tracking and tracing system for tobacco products or otherwise.

6.2. Trainings for users from the competent authorities

The subgroup discussed potential trainings for users from the competent national authorities. The Chair noted the request for exploring options for such trainings.

7. Closing remarks

The Chair thanked the participants for their active contribution to the meeting and looked forward to the next meeting in March.

Annex: Post-meeting discussions

In the week of 17 February 2020, the subgroup discussed, by email, an approach to be advised to economic operators who may receive partial deliveries of tobacco products, where some of the goods have been lost in transit. If the economic operators concerned (sending and receiving party) establish that the missing goods were stolen, SANTE recommended that a receiving party should first report the complete arrival of goods to a destination facility (message 3.4 in Annex II to the Implementing Regulation) and only then send a request for the deactivation of UIs (message 2.3) for the products that were stolen on the way to the given facility. Explanations concerning the nature of theft, i.e. goods stolen during transportation to a given facility, should be provided in the optional data field "Deact_Reason3" available in message 2.3. In this scenario, SANTE did not see any need to physically return the remaining (non-stolen) goods to the dispatching facility.

One Member State commented that this approach should be only used if one is certain that the goods are stolen and referred to a filing of a police report of stolen goods.

List of participants

Austria (Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, Ministry of Finance - Tax and Customs Administration, State Monopoly Agency)

Belgium (Customs and Excise Administration and FPS Health, Food Chain Safety and Environment)

Croatia (Agencija za komercijalnu djelatnost and Customs Administration)

Cyprus (Department of Customs and Excise)

Czech Republic (Ministry of Agriculture, Czech Agriculture and Food Inspection Authority)

Denmark (Danish Safety Technology Authority)

Estonia (Ministry of Social Affairs)

Finland (Customs)

France (Customs)

Germany (Bundesministerium für Ernährung und Landwirtschaft and Bundesdruckerei GmbH)

Greece (Independent Authority for Public Revenue and Ministry of Digital Governance - General Secretariat of Information Systems for Public Administration)

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)

Lithuania (State Tax Inspectorate under the Ministry of Finance)

Luxembourg (Direction de la santé)

Malta (Customs Department)

Netherlands	(Customs and Ministerie van Volksgezondheid, Welzijn en Sport and Belastingdienst)
Norway	(Ministry of Health and Care Services and Directorate of Health)
Poland	(Ministry of Finance, Revenue Administration Regional Office in Katowice and Security Printing Works)
Portugal	(Tax and Customs Authority)
Romania	(Customs General Directorate)
Slovakia	(Financial Directorate under the Ministry of Finance and Slovak Permanent Representation)
Slovenia	(Ministry of Finance)
Spain	(Agencia Tributaria. Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas and Fábrica Nacional de Moneda y Timbre.)
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