



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: 8 September 2020
Location: Video-conference

1. Welcome and introduction

The Chair welcomed the participants, reminded them about the basic rules as to participation in discussions via video-conference and introduced the meeting's agenda as well as its indicative timing. The Subgroup approved the agenda.

2. Communication from the Commission

2.1. Reporting on the functioning of the system

SANTE provided an overview of the additional technical measures announced in mid-June 2020 and put into effect on 1 September 2020 to assist the stakeholders to bring their reporting activities into full conformity with the applicable rules and specifications (for a detailed description of the measures, click on the link: https://ec.europa.eu/health/sites/health/files/tobacco/docs/20200615_tt_news_en.pdf).

The overview first presented the recent technical errors that resulted in misreporting, e.g. delayed transmission of messages to the secondary repository affecting the subsequent events in the products' distribution chain and having created the need for new measures.

The group was then informed about Dentsu's latest update on the deployment of the new measures and their impact on the system.

SANTE expressed its hope that thanks to the additional measures, the IT problems will be eliminated and avoided in the future and that it will become more straightforward for the

competent national authorities and economic operators to identify the causes and entities responsible for any potential errors that may occur due to reporting mistakes.

In the context of an email from a Member State referring to error messages that were observed at national level, SANTE distinguished between the IT-related errors, which had been addressed with the recent technical measures, and other errors that may occur because of non-respect of the applicable rules on reporting by the economic operators. The latter type of errors should not be linked to the architecture and functioning of the system. To the contrary, the errors sent in response to the instances of misreporting show that the system fulfils its enforcement functions. While asking the concerned Member State for the re-assessment of the situation in one month time, SANTE undertook to discuss the reported problems with Dentsu. *Statistics on traceability system*

SANTE presented an overview of general statistics on the application and movement of UIs, total numbers of economic operators, facilities and machines, packet level UIs and aggregated level UIs, router's and portal's monthly response time as well as monthly uptime of the secondary repository.

2.2. Use management statistics

SANTE reported on Dentsu's statistics concerning support activities during August 2020.

2.3. Joint Controllorship Arrangement with regard to the processing taking place in the context of EU tobacco traceability system

SANTE informed the Subgroup that their comments on the draft Joint Controllorship Arrangement have been received and carefully examined. The Commission is currently discussing internally the necessary next steps in view of its data protection obligations. The Subgroup will be informed in writing of the Commission's decision on this matter.

2.4. Approval of external auditors proposed to audit the activities of primary repositories: state of play

SANTE presented an overview of the number of valid data storage contracts, tobacco companies which notified the Commission of their proposed auditors, external auditors notified so far and tobacco companies which still need to send the relevant notifications.

It was underlined that the tobacco companies which were active during the first year of the tobacco traceability system and have not yet notified the Commission of their proposed auditor, are in breach of the relevant tobacco traceability obligation and need to take immediate actions to prevent a further delay in the process.

SANTE informed the Subgroup that the Commission's assessment on the suitability of the proposed auditors will shortly be finalised. The Commission will subsequently notify the relevant Decision on the approval or rejection of the proposed auditors to the addressees, i.e. notifying tobacco companies.

On the notification of the Decision that is expected to be adopted, it was stressed that the Decision needs to be notified for its entry into force. Notification of adopted acts generally takes place via courier service. However, due to the covid situation, the Decision will be notified electronically (by email) to its addressees. Once notified, the relevant tobacco companies will be asked to confirm (by email) the receipt of the document.

2.5. Disclosure of data storage contracts

The Subgroup was updated on the progress regarding the disclosure of approved data storage contracts (between manufacturers/importers and providers of primary repositories) to Member States for enforcement purposes.

2.6. Overview of the production machines declared in the system

SANTE presented an overview of production machines per Member State. The overview distinguished the active from the registered machines. Emphasis was put on the machines' average activity. The machines were divided into three groups according to average capacity utilisation.

3. Communication from Member States

Member States did not suggest any topic for discussion/presentation.

4. Q&As / Discussions

4.1. Brexit: Code for Northern Ireland from 1 January 2021

A Member State asked how Northern Ireland is expected to be distinguished from the rest of UK from 1 January 2021 (i.e. after the end of the transition period that the withdrawal agreement between the EU and UK established) in cases where Northern Ireland is reported as the intended market in the tobacco traceability system.

SANTE recalled that according to the Protocol on Northern Ireland the EU rules incl. the Tobacco Products Directive will continue to apply in the United Kingdom in respect of Northern Ireland and the latter will continue to follow the Internal Market rules after the end of the current transition period. It was also reminded that Implementing Regulation 2018/574 requires manufacturers and importers to indicate the intended market when submitting a request to the competent ID issuer for unit level UIs. SANTE thus accepted that Northern Ireland's different treatment from 1 January 2021 will necessitate the use of a separate identifier code for Northern Ireland to differentiate it from the rest of the UK. At this point, SANTE clarified that the code currently used for Northern Ireland is GB which is also the code used for the rest of the UK. SANTE announced that the most likely candidate for Northern Ireland's new identifier code is "XI", which is a user-assigned, non-reserved code in the decoding table of ISO 3166-1 alpha-2 codes. The Subgroup did not raise any objection to this suggestion and asked SANTE to document it in the meeting's minutes.

4.2. Traceability obligations when products are stored at the EU MS' free zones

A Member State inquired about the traceability obligations of economic operators handling tobacco products that are manufactured in the EU, exported to a non-EU country and reimported into the EU to be temporarily placed at the free economic zone of an EU Member State. SANTE underlined that for the discussed scenario, the fact that these products were manufactured in the EU cannot be altered because they passed through a third country before being reimported. It was concluded these products must be tracked and traced (i.e. their movements must be reported) whenever they are handled on the Union territory, regardless of their customs status.

Another Member State asked whether tobacco products (cigarettes and roll your own tobacco) manufactured in the EU before 20 May 2019 and not marked by means of unit level UIs can be exported to third countries. SANTE replied in the negative clarifying that the deadline of 20 May 2020 established by Article 37 of Implementing Regulation 2018/574 had already expired and that all products manufactured in the EU and destined for exports must be marked with a unique identifier. Otherwise, these products cannot be exported.

5. AOB & Closing remarks

Finally, the Subgroup discussed the possibility of inviting primary repositories' representatives to one of the next Subgroup's meetings. The invitation would concern their participation in a specific session(s) that would be of interest to them. The Member States were asked to inform SANTE of their views on this matter.

The Chair thanked the participants for their active contribution to the meeting and looked forward to the next meeting in mid/late November.

List of participants

| | |
|----------------|---|
| Austria | (Ministry of Finance - Tax and Customs Administration, State Monopoly Agency, Ministry of Social Affairs) |
| Belgium | (Customs and Excise Administration and FPS Health, Food Chain Safety and Environment) |
| Bulgaria | (National Customs Agency) |
| Croatia | (AKD - Commercial Services Agency, Ltd., Customs Administration) |
| Cyprus | (Department of Customs and Excise) |
| Czech Republic | (Ministry of Agriculture, Czech Agriculture and Food Inspection Authority, State Printing Works of Securities) |
| Denmark | (Danish Safety Technology Authority) |
| Estonia | (Ministry of Finance, Ministry of Social Affairs, Tax and Custom's Board) |
| Finland | (Customs, National Supervisory Authority for Welfare and Health) |
| France | (Customs) |
| Germany | (Bundesdruckerei GmbH, Federal Ministry of Food and Agriculture) |
| Greece | (Independent Authority for Public Revenue, Ministry of Digital Governance) |
| Hungary | (Government office of the Prime Minister, Ministry without portfolio responsible for national property management, National Tax and Customs Administration, ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő Részvénytársaság) |
| Iceland | (Ministry of Health) |
| Ireland | (Department of Health, Office of the Revenue Commissioners) |
| Italy | (Ministry of Health, Customs and Monopolies Agency) |
| Latvia | (State Revenue Service) |
| Lithuania | (State Tax Inspectorate under the Ministry of Finance) |
| Luxembourg | (Customs and Excise Administration, Direction de la santé) |

| | |
|-------------|---|
| Malta | - |
| Netherlands | (Customs Department, Ministry of Health) |
| Norway | (Ministry of Health and Care Services, Directorate of Health) |
| Poland | (Chamber of Tax Administration in Katowice, Ministry of Finance, Revenue Administration Regional Office in Katowice, Polish Security Printing Works) |
| Portugal | (Tax and Customs Authority) |
| Romania | (Customs National Agency) |
| Slovakia | (Financial Directorate under the Ministry of Finance) |
| Slovenia | (Ministry of Finance, Financial Administration of Republic of Slovenija) |
| Spain | (Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas, Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas, FNMT-RCM, Ministry of Finance) |
| Sweden | (Public Health Agency) |

European Commission

| | |
|----------|--|
| DG SANTE | Filip Borkowski Dimitrios Apostolou Melina Ballario Nicolle Monica Dimitriu |
| OLAF | Clare Twomey |