EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

MEETING OF THE EXPERT SUBGROUP ON TRACEABILITY AND SECURITY FEATURES (WEBINAR SESSION)

~ SUMMARY RECORD~

Date: 12 February 2019

SANTE.B2 welcomed all participants. The purpose of the webinar session was to discuss a number of outstanding questions related to the systems of tobacco traceability and security features. The webinar session was organised as an extension to the Subgroup of 14 February 2019.

The group addressed the following questions:

Q1: Is there a dedicated mechanism in the Track & Trace system that will allow to solve a human error enabling the product to be sold again? (e.g. instead of giving a scanned product to the customer, the product delivered is another pack which has not been scanned)

A: In case of a human error, (Section 5, Annex II, of the Implementing Regulation) the system provides for the possibility to recall a message previously sent to the repositories. In the 'Recall Reason 1' field, economic operators are given the choice to insert a reason why the message has to be recalled. Among the three different options, it is possible to select: "1 - reported event did not materialise…". If this option is applied, it is recommendable for the submitting party to provide explanations regarding the reasons for recalling a message, as foreseen under the field 'Recall_Reason3', and thus provide further clarity to authorities. Any potential return of a product along the supply-chain must be recorded in the system accordingly (i.e. as product return in the arrival message). There is also no need to apply a new unit level unique identifier to the product.

Q2: In which place do we have to scan products which are returned from customer through ex-van sales representatives?

A: When a product is returned from a customer to a facility by means of a vending van, the delivery of the product is considered an 'arrival'. The obligation to report on this arrival lies with the economic operator operating the facility to which the product arrives first. The arrival message must be transmitted to the repository system via message 3.4, declaring it as product return.

Q3: If tobacco products is returned from a customer to a cross-dock, but has to stay overnight, do we need to scan it in at the cross-dock?

A: Yes, in this case tobacco products have to be scanned at the facility.

In this respect, it was important to note the difference between transloading and (short-term) storage events. According to Article 2(19) of the Implementing Regulation, transloading is defined as '*any transfer of tobacco products from one vehicle to another during which tobacco products do not enter or exit a facility'*. By contrast, a situation where tobacco products are left in a warehouse without being handled and no vehicle is present should be considered as storage. Therefore, economic operators will be required to report the arrival of the tobacco products at the relevant storage facility.

Q4: If tobacco products are delivered to a cross-dock for transloading and there is force-majeure, or any other situation, that prevents the goods from being moved without intermediary storing, is there an obligation to report on arrival and dispatch of the goods? How should the reporting be handled, if the cross-dock does not have a facility ID?

A: In the event of force-majeure that prevents the goods from being transloaded, products have to be scanned at the cross dock facility and be reported as an arrival (see also Q3), and later on as dispatch. In order to handle the occurrence of such events, it is advisable that cross-docks are registered with a facility ID, also considering that no costs are involved in requesting a facility ID code from the competent ID issuer (see Article 3(9) and Article 16 of the Implementing Regulation).

Q5: Is there a mechanism to check the status of a UID?

A: Yes. Member States will be able to verify the status of the UID via the use of their scanners or mobile apps. Access to the information in the repositories system will be

facilitated using either an online connection to the repositories system or the flat files (in the case of offline use). Member States will also be able to conduct a real-time status check of a UID, including further detailed analyses via with the help of graphical and non-graphical user interfaces, which the secondary repository provides for.

Q6: When delivering products to economic operators who have centralized warehouses, is there an obligation to report on product movements from the central warehouse to different stores?

A: Yes. Pursuant to Article 15(5) of Tobacco Products Directive 2014/40/EU (TPD), reporting obligations arise in respect to all movements of tobacco products from the manufacturer to the last economic operator, before the first retail outlet. It follows that any dispatch from a warehouse to a retail outlet, including internal distribution of products within one legal entity, subject to all reporting obligations.

Q7: Is it possible to change data (e.g. customer name) in an already reported message on transactional information? If yes, what is the procedure to do so?

In principle, this is possible. There are several possible scenarios depending on the nature of the error, for example:

a) An invoice was issued erroneously and the error was detected immediately or with some delay. The erroneous invoice is replaced with a new one;
b) An invoice was contains mistakes and the error is not immediately detected but only after several days or even weeks. Given the nature of the error, the erroneous invoice is corrected with a separate correction invoice.

In scenario a), the Implementing Regulation provides the possibility to send a recall message (see section 5 of Annex II). The relevant reasons for the recall must be selected. Preferably, additional explanation should be added to the message.

In scenario b), the Implementing Regulation provides the possibility to transmit a correction invoice in question. For this invoice, the 'correction' value should be selected under 'Invoice_Type1' in section 4.1 on 'Issuing of the invoice'.

Q8: What are the time-frames for posting information to the router (when executing normal processes and also in case of mistakes, discrepancies in tobacco products and etc.)?

A: Article 34 of the Implementing Regulation provides the timeframe period for transmission of information on product movements and transactional data. Within 3 hours from the occurrence of the event, economic operators are required to transmit the following events: application of unit level and aggregated level UIs; arrival of tobacco products at a facility; disaggregation (where UI is intended for reuse); delivery to multiple retail outlets via a vending van; transactional events. This 3 hours period will apply only from 20 May 2028; until then a 24 hours rule applies. Conversely, for transloading activites or dispatches of tobacco products from a facility, the event has to be recorded in the traceability system within the 24 hours window prior to the occurrence of the event. Mistakes, stolen or destroyed products and alike, should be reported to the system as soon as possible after detection.

Q9: In case we hire a transport company to deliver our tobacco products, should the transport company scan-in the products to prove that the tobacco products is in their position and in transit?

A: No, the Implementing Regulation does not foresee this requirement. Transport companies are only required to report events of transloading, that is, the transfer of tobacco products from vehicles during which tobacco products do not enter or exit a facility. Other logistical operations, in particular dispatches and arrivals, are to be reported by the operators of facilities from which the tobacco products are dispatched or to which they arrive.

Q10: What do we do and how do we report a system failure if this is due to a fault of the primary or secondary repository?

A: The Implementing Regulation provides several provisions which aim at guaranteeing the continues and uninterrupted operation of the repositories, in order to avoid any loss of data and/or interruption of supply-chain activities. These include the necessity for the repositories system to ensure continuous availability of all components and services with a monthly uptime of at least 99.5% and sufficient back up mechanisms (Article 25).

In this regard, it was also important to differentiate at which level the failure takes place. Primary repositories are governed by the contractual relationship between providers and the respective manufacturers/importers. The secondary repository, including the router, is

governed by the contractual relationship between its provider and the providers of different primary repositories.

Q11: In case we receive tobacco products in our central warehouse and we further divide the tobacco products and transport them to our first retail outlets, do we need an ID for each location (warehouse and every store)? Do we have to report the transportation from our warehouse to our stores or to another of our warehouses?

A: Yes, all products movements between facilities, including transloading events, must be recorded into the system and transmitted to the system within the required time-frame. It follows that all facilities, which handle tobacco products, require a facility ID code and their operators an EO-ID. See also Q6 on this point.

Q12: What procedure should be followed in the case that during a transport tobacco products are destroyed/damaged and the products must therefore be returned to the warehouse?

A: Destroyed products must also be recorded as they are considered an exit of the products from the possession of the economic operator. The economic operator concerned should introduce a request for the deactivation of the UIs (section 2.3 of Annex II).
See also Q1 and 2 on returns.

Q13: Does the Commission provide a mobile application to read UIs or should Member States develop an application themselves?

A: Reference was made to the discussions in the Meeting of the Subgroup of 17 January. The Implementing Regulation not contain any reference to the development of a mobile app solution. It was agreed, however, that it could be useful to explore the possibility of taking a more common approach among Member States in developing a mobile app solution for enforcement officers.

Q14: What is the role of competent authorities with regard to tobacco products placed on one's market, which carry a UI not issued by the competent ID issuer?

A: Unless covered with the transitional provision stipulated in Article 37 of the Implementing Regulation, this would constitute a violation of the provisions of the Implementing Regulation. Pursuant to Article 23 of the TPD, enforcement of the legislation is the competence of the competent authorities of Member States. This question

therefore constituted a matter of national enforcement that must be addressed at national level.

Q15: How should the economic operator and the competent authority deal with the situation of lost or stolen tobacco products?

A: As touched upon in Q12, these events must be recorded in the traceability system, as they are considered an exit of the products from the possession of the economic operator. The economic operator should introduce a request for the deactivation of the UIs concerned. To that extent, the economic operator may have to cooperate with its business partners from whom it received the products in question. Moreover, Article 15(8) of the TPD also provides for the possibility that, in duly justified cases, Member States may grant manufacturers and importers access to the relevant stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and national law.

Q16: According to Art. 14(5), the relevant operator notifies to the ID issuer any modification of the information submitted in the initial application form and any cessation of the operator activities. Who is the relevant operator in case that the initial application was submitted by another registered economic operator? Who is responsible for notifying the modifications?

A: Article 14(3) and 16(3) of the Implementing Regulation specify that, subject to the consent of the operator of the first retail outlet, i.e. the facility where tobacco products are made available to consumers for the first time, any other registered economic operator can obtain for them economic operator and facility identifier codes.

Apart from this provision, the Implementing Regulation does not contain any further provisions that would preclude the possibility for the operator of the first retail outlet (whose identifier codes have been registered by a third party) to directly notify to the competent ID issuer any modifications that would occur to its identifier codes (i.e. economic operator, facility). The responsibility always remains with the concerned operator, in this case the operator of the first retail outlet.

Q17: We would welcome further information regarding the last sentence of Article 7 (2) of the Commission Decision, in particular, the specification of cases, reasons, amount of requested samples and requests frequency (estimate) of the Commission.

A: Pursuant to Article 7(2), Member States shall require manufacturers and importers of tobacco products located on their territory to provide, upon written request, samples of tobacco products currently placed on the market. The necessity and number of samples would be determined on a case-by-case basis. For example, samples could be asked once in a while, on a random rotation, to verify that products placed on the market are in line with the legislation. Products may also be requested for further analysis, for example by TOBLAB.

Q18: In particular cases, could tobacco companies charge money for the sample to be provided to Member States (taking into account an usual price and value of excise duty)?

A: Article 5 of the Treaty of the European Union as well as Article 296 of the Treaty of Functioning of the European Union are straightforward in this regard '*The use of Union competences is governed by the principles of subsidiarity and proportionality'.* This means that under EU law disproportionate measures are not allowed. If samples are required for enforcement purposes, the sample asked will be limited to the quantity necessary to determine its characteristics, for example in order to establish the authenticity of the product.

Additionally, it is important to note that Article 7, paragraph 2, of the Implementing Decision imposes an obligation. Its wording clearly specify that '*Member States* ***shall*** *require manufacturers and importers of tobacco products located on their territory to provide samples of tobacco products currently placed on the market'.* No compensation could therefore be expected.

Q19: What are duly justified cases in which the Member State should require the ID issuer to deactivate identifier codes?

A: As stated previously, the enforcement of the legislation is solely the responsibility of Member States (see Article 23 of the TPD). Whether or not a particular case constitutes a 'duly justify case' therefore needs to be established by each Member State. Possible examples may include the finding of criminal activity, the loss of necessary licences, or the seizure of a machine. In such cases, preventative measures, such as the deactivation of identifier codes, may be justified.

In this regard, it may be advisable for Member States to configure the automatic alert rules related to the deactivation of identifier codes. On the possibility to prevent the re-

registration of an economic operator whose identifier code was deactivated, it was advised to configure, for example, an additional alert linked to that entity's VAT number.

Q20: How should a facility be registered that operates as a wholesaler and as a first retail outlet?

A: In case that a facility runs different operations within the tobacco trade business (e.g. it is both a wholesaler and a retail outlet, as may be the case for C&C markets), that facility should be registered as type 'other'. Further information should be provided in the description field (see section 1.4 of Annex II).

Q21: Is there a timeline specified for the registration of EOs?

A: There is no timeline for the registration of economic operators in the traceability system. However, without economic operator and facility identifier codes, it is not possible to record product movements and transactional information, nor is it possible for first retail outlets to receive products.

Q22: For Member States that select their ID issuer by means of a procurement procedure. What are the options in case that there is no interest from potential contractors?

A: A list of ID issuers already appointed by several Member States can be found in the minutes of the latest Meeting of the Subgroup of 17 January 2019. This list will be updated during each Subgroup meeting. For Member States without production facilities, it is strongly recommended to apply the second sentence of Article 4(1) of the Implementing Regulation. Otherwise, there may be indeed very little economic incentive for an entity to assume the operation as ID issuer, because no fees can be charged for the issuing of identifier codes.

Q23: In relation to possible frauds during registration of economic operators, is there a need for verification during the registration process? Should this take place ex-post or ex-ante?

A: In principle, the enforcement of the legislation is the competence of Member States. With regard to ex-post and/or ex-ante verifications, a few important considerations should be taken into account. In the initial period, there will be a significant number of operators which will require registration, which could make ex-ante checks a very burdensome

exercise. Furthermore, the legislation imposes a time limit of two working days for generating and issuing identifier codes (see Article 9(3) of the Implementing Regulation). However, there is nothing in the legislation that would prevent ex-post checks to be exercised by ID issuers that may be tasked accordingly by Member States.

Q24: Can you please clarify the concept of 24 hours in case of dispatch of products?

A: Article 34 of the Implementing Regulation sets out that the recording and transmission of transloading and dispatch events must take place within the 24 hours window prior to the occurrence of the event. As an example, if the goods have to be dispatched on Monday at 8AM, the recording of the event can take place as of 8AM on Sunday even until 7:59AM on Monday. The logic behind this rule is that the product should not be moved before the event is successfully recorded in the system. The economic operators may also want to program certain operations earlier than 24 hours ahead the event in their internal IT systems. In this context, it is recalled that the Implementing Regulation only prescribes the time window for reporting.

Q25: Can products be moved without acknowledgment message?

A: No, without positive acknowledgment message products cannot be moved. Pursuant to Article 32(7) of the Implementing Regulation, the information concerning the event shall be deemed to have been transmitted correctly upon the positive acknowledgement sent by the primary repository or the router. It follows that if there is no acknowledgment message, there is no reporting. If there is no reporting, goods cannot be moved. Article 34(3) of the Implementing Regulation further clarifies that the recording of product movements should be done within 24 hours prior to the occurrence of the event.

Q26: Manufacturing facilities located outside the Union are registered by the importer in the Union with any ID issuer competent for the market they place their products. Does this mean that a facility can have multiple identifier codes?

A: EU facilities can only have one facility identifier code, generated by the competent ID issuer. The situation is, however, different for non-EU facilities. As the obligation to record facility identifier codes lies with the EU importer, it is possible that a non-EU facility cooperates with several EU importers. It follows that the facility can be registered independently by different economic operators and, as consequence, will have multiple identifier codes under the traceability system. In this case, the other identifier codes need

to be listed in the request for an identifier code (see 'OtherFID_N' in section 1.4 of Annex II).

Q27: With reference to the recall message, how should a "working day" be interpreted – as 24 hours from the request or as end of the business day? Additionally, is it acceptable to implement a mechanism where the requester deliberately agrees to refuse on the recall right?

A: Article 2 of the Implementing Regulation defines 'working day' as every day of work in the Member States for which the ID issuer is competent. Therefore, the interpretation of working day should take place in accordance with national law. It would also be advisable for each ID issuer to publish information on working days / holidays that is accessible to all economic operators, in order to provide them with legal certainty. In principle, a day should be considered as lasting for 24 hours. A message transmitted at 10AM on Monday can be recalled until 10AM on Tuesday.

The right to recall is enshrined in the Implementing Regulation and therefore economic operators could not be deprived of it per se.

Q28: Can you confirm that the unique identification code (UIC) assigned to our ID issuer is correct?

A: The Implementing Regulation stipulates that the UIC should be compliant with ISO/IEC 15459-2 (and implicitly -3). Therefore, any UIC that was issued in accordance with this ISO/IEC norm will be compliant. In case of doubt, the Registration Authority with competence for ISO/IEC 15459 should be consulted (i.e. AIM Global).

Q29: Are importers distinguished from manufacturers in the traceability system?

A: The legislation does not distinguish between manufacturers and importers. Both are considered as economic operators (see section 1.1. of Annex II). Nonetheless, importers would be identifiable in other ways, as for instance at the moment in which they will have to send a request for unit level UIs. Section 2.1., field 'Import' requires the submitting party to indicate whether the UI will be applied to a product that is imported into the Union.

Q30: What are the requirements for the data element "P_brand" in the messaging requirements?

A: The description should allow for the identification of the product (on trade item level). It can be reasonably assumed that therefore brand and sub-brand name are at least required.

Q31: Does the relocation of a machine to another facility require the issuance of a new machine identifier code? Does a modification of the data also suffice?

A: If there is a relocation of a machine from one facility to another under the responsibility of the same economic operator, the event can be registered in the system by means of a correction to the previously submitted information in line with the requirements foreseen in point 1.8 of Annex II.

Please note that, in line with the legislation, the repository system will store data on identifier codes for the lifetime of the traceability system.

Follow-up questions

The group afterwards discussed a number of follow-up questions. One Member States asked for clarification regarding the rules on disaggregation. SANTE replied that reporting on disaggregation is required only in cases where an aggregated UI is intended for reuse. Reuse of UIs is only permitted in the case of self-generation in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459:4:2014.

One Member State asked for the possibility to have a common security feature design to be used in duty free shops. SANTE clarified that there is no legal base for the Commission to impose the use of a common security feature. In line with the Implementing Decision, the obligation to determine the combination of authentications elements, which make up a security feature, falls within the responsibility of each Member State. This was also in line with the fact that Member States have to ensure that they possess the means necessary to analyse the combination of authentication elements to be used to develop a security feature (see Article 7 of the Implementing Decision).

Another Member State inquired into the registration of planes and vessels and whether these could be identified as a ‘facility’ or ‘first retail outlet’. SANTE referred to previous discussions in the Subgroup. Shops on planes and vessels can be considered as a ‘retail outlet’

if products are placed on the market in these shops (i.e. made available to consumers on Union territory). The obligation to request a facility identifier code lied with the operating legal entity.

On the scenario of insolvency of a legal entity, where that entity ceases to exist or where its operations are taken over by another legal entity, the group agreed that this would normally require deregistration, or correction, of the economic operator identifier code. At the same time, it was acknowledged that other, more specific, scenarios of insolvency can occur, which may require a case-by-base assessment. In the case of doubt, economic operators should therefore turn to competent authorities in Member States, which are ultimately responsible for the application and enforcement of the rules on tobacco traceability.

Final remarks

SANTE thanked Member States for their active participation. Minutes of the webinar session will be circulated as part of the minutes of the physical Meeting of the Subgroup on 14 February 2019.

The Chair closed the webinar session.