COMPLIATION OF

QUESTIONS AND ANSWERS

&

EXPERT SUBGROUP DISCUSSIONS CONCERNING

THE EU SYSTEMS FOR TRACEABILITY AND SECURITY FEATURES OF TOBACCO PRODUCTS

This document contains views of the Commission on the operation and requirements of EU systems providing for the traceability of tobacco products and for the application of security features to such products. Please note, however, that only the Court of Justice of the European Union is competent to interpret Union law with final binding authority.

The views expressed in this document are without prejudice to Union legislation, including the provisions of the Union Customs Code.

All references to the legal acts are made to the current versions of these acts.

Contents

Q&A: EU systems for traceability and security features of tobacco products

Brussels, April 2018 -- EU systems for traceability and security features of tobacco products

Q1 *Does the traceability system cover tobacco products that (a) are manufactured in the EU but destined to third countries and (b) products manufactured in third countries and destined for the EU?*

A: Yes. The traceability system applies to all the products manufactured in the Union including where they are destined for export. In addition, it applies to products manufactured outside the Union but destined to be placed on the Union market.

Q2 *My business involves the import of tobacco products into the EU. When should the imported tobacco products be marked with unique identifiers?*

A: Article 6(2) of the Implementing Regulation specifies that the unique identifiers are to be applied on the unit packet before the tobacco product is imported into the Union.

However, Article 2(38) of the Tobacco Products Directive (TPD) specifies that products placed under a customs suspensive procedure or arrangement are not considered to be imported until their release from such a procedure or arrangement.

Q3 *My business involves the transport of tobacco products, but does not handle tobacco products in any other way. Are transport companies like mine subject to the EU traceability system?*

A: The traceability system applies to all stages of the supply chain and to all economic operators involved in tobacco trade from the manufacturer to the last economic operator before the first retail outlet.

However, transport operators will only be required to report incidences of trans-loading, that is, the transfer of tobacco products between vehicles during which tobacco products do not enter and 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.

Q4 *I am in the retail business. Are there any requirements for retailers of tobacco products under the EU traceability system?*

A: If your business is not involved in any other form of tobacco trade than the operation of a retail outlet, i.e. the facility where the tobacco products are made available to consumers, it will only be necessary to obtain economic operator and facility identifier codes. Those identifiers will be required to ensure you can receive deliveries to your retail outlet from other economic operators.

Articles 14(3) and 16(3) of the Implementing Regulation specify that, subject to your consent, the above identifiers can be obtained for you by any other registered economic operator.

See also the responses to questions 7.

Q5 *Could short-term storage be regarded as a part of trans-loading (when such storage occurs for the purpose of a transfer of products between vehicles)?*

A: No, regardless of its duration, storage has to be differentiated from trans-loading.

According to Article 2(19) of the Implementing Regulation, trans-loading is defined as 'the transfer of tobacco products from one vehicle to another during which tobacco products do not enter and exit a facility.'

By contrast, where tobacco products are being stored (which may be the case, for example, when they are left in a warehouse without being handled and no vehicle is present) economic operators will be required to report the arrival of the tobacco products at the relevant storage facility (see 'arrival of tobacco products at a facility' message, Section 3.4 of Annex II to the Implementation Regulation).

Q6 *What is the "first retail outlet" referred to in EU tobacco legislation and how can it be distinguished from retailers in general?*

A: Article 2(3) of the Implementing Regulation defines the first retail outlet as the facility where products are placed on the market for the first time, including vending machines used for the sale of tobacco products.

It is important to note that the term "retail outlet" does not refer to an entity but rather a physical location where the product is placed on the market, i.e. made available to consumers.

Q7 *How can an operator of a retail outlet arrange to have another economic operator register on its behalf?*

A: Article 14(3) of the Implementing Regulation establishes a mechanism by which the operator of a retail outlet can arrange to have its registration with the competent ID issuer carried out by another economic operator.

The economic operator willing to assist the operators of retail outlets must itself be registered with the competent ID issuer. Having obtained the consent of the retail outlet, the economic operator is required to communicate to the ID issuer the information set out in Chapter 2, Section 1 of Annex 2 to the Implementing Regulation. The economic operator that carried out the registration will have to transmit all details received from the ID issuer to the operators of retail outlets in respect of which the registration was completed.

Q8 *I operate a retail outlet. Is it necessary to report the transfer or sale of tobacco products to another retail outlet?*

A: Pursuant to Article 15(5) of the Tobacco Products Directive, reporting obligations arise in respect of the movement of tobacco products through the supply chain from the manufacturer all the way to the first retail outlet. It follows that, in principle, the movement of tobacco products from the first retail outlet to second (or subsequent) retail outlets are not subject to a reporting obligation.

However, it is important to note that the notion of "retail" implies the sale of goods to the public for use or consumption rather than for resale – i.e. 'placing on the market' (see Article 2(40) of the TPD). Consequently, where the transfer of products has the character of trade between economic operators or arises from the internal distribution of products along the supply chain, then such movements fall outside the scope of "retail" and remains subject to a reporting obligation.

An example of a potential scenario in which transfer of tobacco products between retail outlets may take place without giving rise to a reporting obligation is the transfer of products from a first retail – in which they have already been put on sale – to another retail outlet, e.g. because of a shortage of tobacco products in the latter.

Q9 *I operate a facility that, amongst other things, sells tobacco products to individual consumers. Does it mean that my facility has the status of a "first retail outlet" that is exempt from the requirement to report data to the EU traceability system?*

A: If the sales at the facility in question are made only to individual consumers then indeed there will be no need to report any information to the EU traceability system concerning the products delivered to this facility.

However, the existence of sales to individual consumers at a given facility does not automatically mean that all the operations at that facility are excluded from the reporting obligations. In particular, if the facility is involved in the onward distribution of tobacco products, the related product movements. and financial transactions will have to be reported to the EU traceability system.

Q10 *I am an economic operator involved in the trade of tobacco products. Do I need to scan all unit packets of tobacco products for the purposes of the traceability system?*

A: Article 15(5) of the TPD requires that all economic operators, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession.

However, Article 15(5) of the TPD also allows for marking and recording at aggregated packaging level, provided the tracking and tracing of all unit packets remains possible. For example, if 500 packs have been aggregated into 50 cartons, which in turn have been aggregated into a single master case, and if all of these aggregations have been properly marked in accordance with the Implementing Regulation, it will be enough to scan the unique identifier of the master case (instead of the 50 cartons or the 500 packs contained therein) in order to report the movement of all the 500 packs.

Q11 *A part of a stock of products was stolen. Is it necessary to report this fact?*

A: Cases of stolen products are considered as an exit of the products from the economic operator's possession. They must therefore be reported under Article 15(5) of the TPD.

In the event of theft, the economic operator should introduce a request for the deactivation of unique identifiers (UIs) (see message 2.3 in Annex 2 to the Implementing Regulation).

If the economic operator is unable to establish the UIs of the stolen products (at least at their aggregated level), it should turn to the competent authorities with a request for access to the relevant data stored in the repositories system. Article 15(8) of the TPD provides for such a possibility.

Q12 *How should distributors report the delivery of tobacco products when carried out by a vending van ?*

A: The delivery of tobacco products by means of a vending van should generally be reported by transmitting the following sequence of messages (as specified in Annex 2 to the Implementing Regulation) to the repositories system: (i) message 3.3 on dispatch of tobacco products from a facility with value '4' to be indicated in the field 'Destination_ID1'; (ii) for each retail outlet, message 3.7 on the actual deliveries carried out with a vending van; and (iii) for any remaining products, message 3.4 on arrival of tobacco products at a facility with value '1' indicated in the field 'Product_Return'. Apart from the requirement for the above messages to be transmitted in the order of their occurrence, the messages on dispatch and arrival must be communicated within the time-frame for transmission of required information set out in Article 34 of the Implementing Regulation.

Q13 *What is the difference between delivery vans and vending vans?*

A: The term 'vending van' is defined in Article 2(20) of the Implementing Regulation as a vehicle used for the delivery of tobacco products to multiple retail outlets in quantities that have not been predetermined in advance of the delivery. For deliveries carried out with a vending van, the combination of messages 3.3, 3.4 and 3.7 (as specified in Annex 2 of the Implementing Regulation) will be usually required to complete the reporting obligations.

The term 'delivery van' is not defined under the Implementing Regulation. Deliveries by road transport to retail outlets, for which quantities are known before the dispatch, will normally require the transmission of a single message 3.3 for each retail outlet.

Q14 *I am an economic operator involved in tobacco trade. What is required for me to report activities under the EU traceability system?*

A: The requirement depends on the nature of your involvement.

If you are a manufacturer or importer, then first of all, you will be required, pursuant to Article 15(8) of the TPD to conclude data storage contracts with independent third parties. The Delegated Regulation sets out the key elements of these contracts, while Part A of Annex 1 to the Implementing Regulation sets out the procedure applicable to the selection of an independent third party operator. Manufacturers and importers can only start reporting their activities when their contracted data storage facility is operational and integrated within the repositories system.

All economic operators are required to obtain identifier codes which will subsequently be used for communications with the EU traceability system. Depending on the scope of operations, the

following identifiers may be required: economic operator identifier codes, facility identifier codes and machine identifier codes. The requested identifier codes will be issued by the relevant competent ID issuers. The specific provisions relating to identifier codes can be found in Articles 14 to 19 of the Implementing Regulation.

Q15 *Is it necessary to issue a separate invoice for every individual transport of tobacco products dispatched?*

A: No, there is no such a requirement. Message 4.1 in Annex 2 to the Implementing Regulation links the invoice to the UIs of the products covered by the invoice, and not to any specific logistics operation.

In line with Article 34(2) of the Implementing Regulation the time frame for transmission of the relevant information starts to run when the relevant unit packets can be linked to a specific invoice, which, under one possible scenario, may happen at the moment of the dispatch of tobacco products.

Q16 *My business is required to obtain economic operator and facility identifier codes. From where can these identifiers be acquired? How much do they cost?*

A: The ID issuers are tasked with issuing the necessary identifier codes for the purpose of the EU traceability system. In all cases it will be necessary to ensure requests are made to the correct, or 'competent' ID issuer (please see Articles 14(1), 16(1) and 18(1) of the Implementing Regulation for information on this). Economic operators should use the messages set out in Chapter 2, Section 1 of Annex 2 to the Implementing Regulation in order to request these identifier codes from the ID Issuers.

The identifier codes (economic operator, facility and machine identifier codes) will be issued free of charge. ID issuers will be required to finance their operations via the fees collected for issuing UIs to be applied to tobacco packaging.

Q17 *My business trades in cigarettes, roll-your-own tobacco and other tobacco products. Other tobacco products will become subject to the traceability system on 20 May 2024. Does it mean that until then they should be separated from cigarettes and roll-your-own tobacco for the purpose of logistic operations and financial transactions?*

A: No, all these products can be handled together. However, for the first five years of the system's operations, only cigarettes and roll-your-own tobacco will be subject to traceability. Other tobacco products can continue to be manufactured and stored in the same facilities, be a part of the same shipments and appear on the same invoices as cigarettes and roll-your-own tobacco products.

Q18 *What is a difference between a unique identifier and a data carrier?*

A: The unique identifier is an actual code, i.e. a unique sequence of alpha-numeric characters. The data carrier is the form through which the code is expressed in a device-readable format.

Article 21 of the Implementing Regulation lists the types of data carriers permitted for use under the EU traceability system, at both unit packet and aggregated packaging level.

Q19 *Does the introduction of a unique identifier encoded in one of the prescribed data carriers mean that it is no longer possible to use other data carriers, e.g. barcodes with encoded stock keeping units such as EAN-13?*

A: The Implementing Regulation does not contain any provisions that would preclude the placement of other data carriers on unit packets or aggregated packaging. Furthermore, Article 21(6) of the Implementing Regulation permits economic operators to distinguish the traceability data carrier from any other data carriers they may use by adding the marking 'TTT' next to it.

Q20 *Does the EU traceability system meet the requirements of the FCTC Protocol or will it need to be amended once the FCTC Protocol enters into force?*

A: The EU traceability system, as provided for under Article 15 of the TPD and complemented by the Implementing and Delegated Regulation, fully complies with the requirements of Article 8 of the FCTC Protocol. Therefore, when the FCTC Protocol enters into force, the EU traceability system will not require further adjustments.

Q21 *Does a vending machine fall within the definition of a first retail outlet?*

A: Yes, Article 2(3) of the Implementing Regulation specifically mentions vending machines as examples of first retail outlets. The vending machine is considered to be an outlet where tobacco products are placed on the market and made available to consumers.

Q22 *When are service providers for the systems of traceability and security features required to be independent from the tobacco industry?*

A: Under the Implementing Acts the independence requirement applies to four categories of service provider. These are: entities appointed as ID Issuers, providers of data storage, providers of anti-tampering devices and providers of at least one authentication element per security feature. The first three entities are of relevance for the operations of the EU traceability system (see the Implementing

Regulation), while the last one is of relevance for the EU system of security features (see the Implementing Decision).

Q23 *I am a provider of authentication elements that may form part of a security feature to be placed on tobacco products. My type of authentication element does not appear in the Annex to the Implementing Decision. Does it exclude me from supplying authentication elements?*

A: No, the Annex to the Implementing Decision only sets out examples of the types of authentication elements that Member States may include in the combination(s) of authentication elements that are to be used in the security features applied to tobacco products placed on their markets.

Whether a given authentication element will be used in the security features or not is left to the discretion of Member States.

Q24 *What is actually meant by the requirement for the security feature to be irremovable? Can a wrap film meet this requirement?*

A: Article 15(1) of the TPD specifies that all unit packets of tobacco products must carry a tamper proof security feature that must be irremovably printed or affixed, indelible and not hidden or interrupted in any form. These requirements are cumulative.

If a security feature or its element, e.g. a wrap film, can be removed from the packet without leaving any traces of tampering on the packet, such a security feature will have to be considered incompatible with the above regulatory requirements.

Extract of Summary Record of 13 February 2018

[…]

3. Commission report from the 1st Regional Workshop

[…]

- A vending machine making tobacco products available to consumers for the first time should be considered a first retail outlet requiring a facility identifier code. In the case of dispatch to such vending machines, economic operators must set out the unique identifiers (UIs) and the facility identifier codes of the machines in question (see dispatch message, Section 3.3 of Annex II), but it will not be necessary to indicate which UI will be delivered to which machine.

- There are no reporting obligations for retail outlets (e.g. kiosks). Nevertheless, in the case of operators of retail outlets which deliver a certain quantity of their tobacco products to subsequent retail outlets (e.g. vending machines), reporting obligations will continue to apply until the products are placed on the market for the first time.

- In the case of returns of products from first retail outlets to distributors/suppliers, the distributor/supplier in question will be responsible for reporting the return event.

- Registration for relevant identifier codes on behalf of retail outlets may be performed by third party operators (e.g. distributors), provided the operator of the retail outlet has given its consent and is informed of the codes assigned to it.

- Registration for identifier codes should be free of charge for all operators.

The subject of retail outlets located on shipping vessels was also raised. It was clarified that, in the case of deliveries to such retail outlets, where the retail outlet remains closed while the vessel is docked in the harbour, a dispatch message indicating that the products are for export should be reported.

It was also clarified that, in the case of new entities taking over already registered businesses, the new entity should apply for its own economic operator code. If facility codes relating to the old entity exist, the new entity should update the registered information by sending a relevant correction message (see e.g. section 1.5, Annex II).

[…]

In relation to the security features system, the meaning of the term 'irremovable' was discussed. There was a general consensus that this should be read similarly to 'tamperproof', i.e. that any attempted or successful removal of a security feature should be clearly evident (i.e. via damage or tearing to the unit packet).

It was clarified that, while unique identifiers must be applied to unit packets at the time of production (or, in the case of products manufactured outside the EU, before they are imported – see Article 6(2) of the Implementing Regulation and Article 2(38) of TPD), economic operators may choose to apply security features at a later stage in the supply chain, provided that application takes place before the products are placed on the market (see Article 2(40) and 16 of TPD).

[…]

Extract of Summary Record of 12 April 2018

[…]

4. Discussion

[…]

On the unique identifier (UI), the Subgroup discussed encoding requirements, the requirements for exports to carry a UI, the consideration of some Member States to combine the UI and the tax stamp, and the available delivery methods of UIs at unit level. Regarding the encoding requirements, DG SANTE reminded the Subgroup that, within the rules set out in the TPD and the Implementing Regulation, the UI should be as short as possible. In principle, given the single set of rules on the content and structure of the UI, ID Issuers should be able to come up with UIs of similar length. The only limitation in this respect is the size of the market(s) for which each respective ID Issuer will be competent. It was explained that the addition of two alphanumerical characters expends the pool of possible UIs by 1296 times (i.e. 36 to the power of 2). With respect to the delivery method, the Subgroup agreed that electronic delivery). was the default rule but that a Member State could require its ID issuer to offer physical delivery in addition to the electronic one. In cases where a Member State envisaged the combination of UI and tax stamps, the physical delivery was obviously required (without excluding the provision of parallel electronic delivery of UIs). Finally, a Member State asked for further clarification on the fees structure for UIs and the requirements of proportionality and non-discrimination, as required under the Implementing Regulation. DG SANTE reminded that it was for Member States to judge on the proposed fees that are to be charged by the ID issuer appointed by them. As a general rule, a fee should be charged by an ID issuer to economic operators per each UI that is issued to them (proportionate), and that fee should not be different for different economic operators for which an ID issuer generates and issues UIs (non-discriminatory). At a later stage, economic operators would of course also be able to cross-compare the fees applied by different ID issuers. Therefore, DG SANTE suggested that an exchange of information on this matter should continue in future meetings.

On the repository system, the group discussed the approval procedure for data storage contracts, access to information in the repository system for entities other than public authorities (e.g. in the case of an economic operator that needs to acquire information on all UIs recorded to be on stock in its facility, in order to prepare a report on stolen products), and the possible structure/content of

acknowledgment messages, which in case of a negative response, should inform an economic operator as to the nature of the problem with its original message (e.g. the lack of validation due to the incorrectness of specific UIs).

On reporting obligations for economic operators, Member States sought further clarification on the following activities/cases: return of goods from retail outlets, recording of products for which logistic and transactional flows are different ("chain transactions"), transport companies and trans-loading events, and differences between vending vans and vending machines.

With respect to vending machines and first retail outlets, one Member State asked DG SANTE to outline the applicable legal framework. DG SANTE recalled that vending machines fall within the legal definition of 'facility' and 'first retail outlet' and that for the latter definition it was important to consider the location at which a product was intended to be made available to consumers. In this context, it was discussed that the combination of a vending machine that is attached to a shop with direct sales by a shop assistant (thus vending machine and shop are at the same location) might be considered as a single first retail outlet. As such, it would fall under the same rules as other first retail outlets at which the sale of products takes place via sales personnel. It was also stressed that to ensure the effective utilisation of the traceability system and the information contained therein in the fight against illicit trade, it was important that the recording of product movements. along the supply chain and to their final destination took place in the same way across the Union.

One Member State raised the scenario in which two economic operators constituted the manufacturer of one tobacco product. DG SANTE confirmed that, according to the definition of 'manufacturer' laid down in the Tobacco Products Directive, a person who has a product manufactured for himself and markets it under his name, as well as the person who manufacturers that product, both qualified as the manufacturer of the product in question. The legal obligations applicable to manufacturers, including recording obligations, were clearly set out in the secondary legislation. Which obligations applied to a certain type of manufacturer would depend on where the manufacturer was situated in the supply chain. For example, a person who had products manufactured for him would probably not have a manufacturing facility and therefore did not require a machine identifier code and anti-tampering devices. Finally, it was stressed that, in practical terms, it was important that logistic/transactional events were always recorded only one time.

Furthermore, the group discussed the scenario in which logistic and transactional events are different for a certain product, for example because a product moves directly between two economic operators but the financial transactions involve a different or additional entity. In this regard, it was clarified that the recording of logistic and transactional information is treated separate from one another under the legislation. As a general rule, logistic and transactional information would always have to be recorded, in so far that they are linked to tobacco products, even where logistic and financial flows for the products in question were different from one another.

Finally, clarification was sought on recording obligations in the case of return of products from a first retail outlet back to a warehouse facility. DG SANTE explained that the return of such products should be recorded in the form of an arrival message (with indication as Product_Return). The recording obligation would lie with the economic operator who operated the facility at which the product return arrives. If the returned products subsequently would then be moved to another facility, these movements would again be subject to all recording obligations (i.e. dispatch, and possibly trans-loading and arrival messages).

[…]

Extract of Summary Record of 13 June 2018

[..]

2. Update from the Commission

[…]

2.5. Application for an Issuing Agency Code (IAC)

SANTE reiterated the legal requirements provided for in Art. 3 of the Implementing Regulation, particularly regarding the applicability of ISO 15459-2:2015, and also outlined the general approval requirements for Issuing Agencies/ID issuers. COM presented three potential scenarios that may apply regarding the IAC application:

i. the appointed ID issuer is already equipped with an IAC: the IAC of the ID Issuer can also serve as a unique identification code (UIC) required under Art. 3(4) of the Implementing Regulation and in this situation, the UIC equals the IAC;

ii. the appointed ID Issuer is not eligible to apply for an IAC but enters into collaboration with an existing Issuing Agency: the Issuing Agency will have to allocate an "extension code" to the ID Issuer, so the UIC equals the IAC + "extension code"; for example, an UIC may be "101" if GS1 is assumed to be the Issuing Agency (i.e. GS1's IAC is 0 through 9) and it allocates "01" to the ID Issuer appointed in Member State X. If the application identifiers are included in this example, the resulting unique identifier will potentially take the form of (23)101…(01)[GTIN];

iii. the appointed ID Issuer is not eligible to apply for an IAC but enters into collaboration with an Issuing Agency established by a Member State: IACs with first character K are reserved for national public administrations are completed with the relevant alpha-2 country code; for example, if Hungary decides to apply for an IAC, it will be "KHU", then it will be for the Hungarian authority to make any further allocation of "extension codes" to identify its ID Issuer. The ensuing process may be similar to scenario 2 above, although it may be expected to require additional efforts in terms of combining the ID Issuer's unique identifiers with other technical solutions such as data carriers and scanning devices.

3. Discussion

In the first part of this agenda point, SANTE clarified the territorial applicability of Articles 15 and 16 of the TPD (incl. importation/exportation) and gave a presentation based on a table of possible scenarios. In sum, it was concluded that any product that is manufactured or released for free circulation on EU territory, or made available to consumers located on EU territory, is subject to Article 15 (on traceability). Any product that is made available to consumers located on EU territory is subject to Article 16 (on security features).

In this context, it was confirmed that tobacco products sold in duty free shops will be required to carry a security feature. In cases where Member States have designated their national tax stamp as the security feature, a number of approaches were suggested, including a 'zero-value' tax stamp and the designation of alternative combination(s) of authentication elements for exclusive use on duty free products.

In the second part of this agenda point, DG SANTE discussed the questions submitted by Member States in advance of the Subgroup, as well as additional questions posed during the meeting.

On the applicable procedure in cases where a Member State is not in a position to appoint its ID issuer on time: SANTE reminded that Article 4(5) of the Implementing Regulation permits the COM to issue a decision by which it authorises economic operators to turn temporarily to an alternative ID issuer. Such a decision would be made in coordination with all Member States concerned. SANTE also stressed that this provision should be considered as an action of last resort and it encouraged MS to aim for the timely appointment of their ID issuer.

On the link between the traceability system and other existing systems (e.g. EMCS, EUCEG). The obligation of economic operators under the traceability regime to include in their messages information regarding, for example, the TP-ID and the EMCS ARC, will allow Member States to run additional searches on a product in other systems, such as the EU-CEG or EMCS.

On how economic operators could best be made aware of legal provisions that grant a certain level of discretion to Member States, for example, the derogation contained in Article 4(1) of the Implementing Regulation: SANTE said that Member States may communicate the legal option applicable in their country, for instance, by means of a decree. Communication via a dedicated website could be used in addition to the above. In this regard, the group agreed that, at one point, it would be desirable, in particular for small and medium sized operators, to draw up a list outlining the decisions taken by all 28 Member States.

On the scenario in which logistic and transactional events are different for a certain product, DG SANTE referred to the discussion held in the meeting of the subgroup of 12 April 2018.

Another question concerned the scope of the term 'economic operators', as used in the Implementing Regulation, and whether the legislation imposed obligations on any other persons than economic operators. SANTE referred to Article 2(2), which defines economic operators as "any natural or legal person who is involved in the trade of tobacco products, from the manufacturer to the last economic operator". This included, but was not limited, to manufacturers, importers, wholesalers and distributors, as well as transport companies or providers of courier services. In addition, and next to obligations applicable to Member States and the Commission, the secondary legislation also contains obligations directed at other natural/legal persons, notably, operators of first retail outlets, ID issuers, and providers of primary repositories and the secondary repository.

On how economic operators should handle the dispatch of damaged products back to the manufacturer, as well as the possibility to deactivate a UI in the system: SANTE reminded that the Implementing Regulation contained requirements for high readability of data carriers (which embed the UI), as well as the need for each data carrier to include a human-readable code. In addition to that, and provided that information on damaged/stolen UIs cannot be recreated on the basis of previous arrival messages related to the facility concerned, economic operators will have at least two options available to them: either to turn to their upstream business partners in order to inquire the necessary information, or to ask the respective Member State for access to the relevant information, as provided for under Article 15(8) of the TPD.

On the expected activities of the independent provider of security feature solutions: SANTE clarified that the independence requirements, as set out in Article 8 of Implementing Decision 2018/576, as a minimum requirement only relate to the provider of one of the authentication elements included in a security feature. Should one provider supply to manufacturer/importers, or Member States alternatively, the complete security feature, then either that provider itself must meet the independence requirements or it must ensure that one of the authentication elements that it uses to create the final security feature is supplied by another third party that meets the independence requirements.

On whether the applicable legislation contained a minimum retention period for data generated at wholesale level (e.g. messages), which is sent on to the repository system: SANTE explained that the Implementing Regulation set out a retention period of minimum five years for all data stored in the repository system. Pursuant to Article 24 of the Regulation, the repository system is composed of primary repositories, a secondary repository, and a router. While other components did not fall into the scope of the Regulation, it could not be excluded that there existed other (national) data retention rules that would apply to these components nevertheless.

On what type of acknowledgment messages should be sent by the repository system, in particular in the case of errors, the group concluded as follows: while structure and content as such were not regulated, the need for certain general requirements could be derived from the applicable legislation. Taking these into account, the group considered it appropriate that the acknowledgment message should be based on a qualitative check related to the existence of a UI and identifier code, as well as mandatory requirements of fields listed in Annex II. Eventually, the acknowledgment message should tell an economic operator whether or not the reporting activity was successful (positive/negative). And, if negative, what UIs, and preferably also fields, were concerned. The extent to which this is possible will be discussed with the provider of the secondary repository upon its appointment.

On the cancelation of requests for UIs: since manufacturers and importers may cancel their requests within one working day, the group discussed that it may be advisable for ID Issuers to deliver UIs only after this initial time for cancelation has elapsed.

On whether it was necessary to download flat-files created by all ID issuers to the scanning devices used by national enforcement officers: SANTE clarified that flat-files of all ID issuers were necessary for a device to be able to read – in offline mode – the information related to any UI and regardless of the ID issuer that generated it. In this regard, a participant further inquired about the timeframe in which flat-files and registries had to be forwarded by ID issuers to the secondary repository. SANTE referred to Article 20(3) of the Implementing Regulation, which contains the term "up-to-date copy". This wording would suggest that new or updated information should be delivered to the repository system as soon as it became available.

On the obligations of courier services under the traceability regime: SANTE recalled the discussion on transport companies that took place in the Subgroup meeting of 12 April. It was reiterated that

courier services, like transport companies, are economic operators within the meaning of the Implementing Regulation, if they are involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet. SANTE stressed that the reporting obligations of courier services will depend on the actual scope of their logistic operations such as trans-loading or the temporary storage of products at their depots.

On reporting obligations related to the identification of transport vehicles such as lorries: SANTE referred to sec. 3.3 of Annex II to the Implementing Regulation, which requires the identification of vehicles that are used to transport tobacco products along the supplychain. While the description of the relevant field in Annex II left some leeway to economic operators as to what type of identification they could fill in, SANTE pointed out that the core requirement should be that the reported identification number allowed for an unambiguous identification of the vehicle by authorities. In other words, the identification number should be unique in the EU and easily identifiable by all national authorities of Member States, as it is, for example, the case for number plates or plane numbers.

An additional question was raised regarding anti-tampering devices, more specifically, whether the devices could be produced and later installed at a manufacturer's premises using different companies. SANTE confirmed that this was possible, as long as the companies involved met the independence requirements set out in the Implementing Regulation. In this context, a participant furthermore asked whether the data recorded could be stored outside of the anti-tampering device. SANTE replied in the affirmative but reminded that the requirements of Article 7 of the Implementing Regulation related to anti-tampering devices had to be complied with (especially concerning availability of and access to the data).

Another participant asked for clarification as to the last reporting activity that would occur in the case of exports. SANTE replied that the last message would be the dispatch of the product that links to the last transport activity before the product left the Union territory. In the dispatch message, an economic operator had to indicate 'non-EU destination' and provide the destination facility's full address (see sec. 3.3 of Annex II to the Implementing Regulation).

In relation to exports to third countries, DG SANTE explained that discussions with Australia relating to the compatibility between the Australian Tobacco Law and the EU traceability system are

on-going. Furthermore, there would be a possibility to discuss the EU traceability system with other third countries at the FCTC Conference of the Parties that takes place in October.

As regards the level of precision and prescriptiveness of the communication required under Article 3(3) of the Implementing Decision, the group discussed that other Articles of the Implementing Decision, notably Article 7(1), also needed to be taken into account. When establishing (a) combination(s) of authentication elements to be communicated to manufactures and importers of tobacco products, Member States should consider their obligation to be in possession of the means necessary to analyse each permitted combination of authentication elements. Therefore, Member States may need to predefine certain additional parameters of the permitted combination(s) of authentication elements, such as the method of combining various elements or their placement on the package.

As regards Article 4 of the Implementing Decision, the group agreed that any Member State communication to manufactures and importers of tobacco products should occur on a need-to-know basis. For example, in the case of tax stamps that are compliant with all requirements, the communication could be limited to a simple statement of compliance; in this case, it would not be necessary to share any further details.

Finally, the group discussed whether tear tape solutions that are directly applied onto the transparent wrapper of a unit packet could be used as the security feature. In this context, SANTE reminded that Article 16 of the TPD, inter alia, requires a security feature to be applied to the unit packet of a tobacco product. However, neither the definition of 'unit packet', set out in Article 2(30) of the TPD, nor Article 14 regulating the appearance of unit packets, makes reference to transparent wrappers. In addition, the definition of 'outside packaging' in Article 2(29) explicitly excludes transparent wrappers. Reference was furthermore made to health warnings, which were subject to the same requirement as security features in that they must be applied onto unit packets. In this respect, the group agreed that health warnings were always applied under a transparent wrapper and not onto it. In light of these aspects, it was considered doubtful that transparent wrappers form part of the unit packet. Therefore, a security feature, or authentication solution, that is applied onto a transparent wrapper would probably not comply with the requirements of Article 16 of the TPD.

In the third part of this agenda point, MS were then invited to present their national position on a number of open questions:

1. In relation to Article 4(1) of the Implementing Regulation, several Member States indicated that they intend to, or strongly consider, making use of the derogation provided for in the second paragraph (designating competence to the ID issuer appointed for the MS in which products are marketed). The main reasons cited were the possibility to gain better oversight and control of the traceability process at national level, especially from an enforcement perspective, as well as the need for securing the critical mass of UIs to be generated by the national ID Issuer.
2. In relation to the option provided for under Article 9(4) of the Implementing Regulation, a number of Member States confirmed their intention to require ID issuers to offer physical delivery of UIs. Others indicated that this option was still under consideration but would most likely be applied if economic operators expressed a wish to avail of it.
   2.1. In this context, MS were reminded that it had been agreed in the last Subgroup meeting that physical delivery should in all cases be offered in addition to electronic delivery) . Where a MS opted for physical delivery, electronic delivery). as such was still necessary (amongst other reasons, to facilitate the transfer of UIs and identifier codes to the repositories system).
3. Two Member States confirmed their intention to combine unique identifiers with security features (in the case of one of these Member States, only where physical delivery was requested).
4. On the subject of penalties to be imposed in the case of non-compliance by economic operators, some Member States indicated that the legal basis for this is likely to be the same as that for breach of other TPD rules (such as packaging/labelling etc.), but that the possibility to apply other regulatory frameworks (e.g. customs) should be explored. DG SANTE noted that further discussion on this issue would be useful and that Member State feedback would be welcomed in the next Subgroup meeting after the summer.

[…]

Extract of Summary Record of 23 October 2018

[…]

Discussion

[…]

3.2 Unique identifier

The group discussed the importance of coordinating an alignment of the length of unique identifiers (UIs) that were generated by different ID issuers. Participants agreed that the length of UIs was a very important criterion in the selection of the ID issuer and/or, where applicable, subcontractors. In this context, SANTE stressed that attempts to shorten the UI as much as possible should not undermine other applicable requirements (including a sufficiently negligible probability to be guessed, and independence from the tobacco industry). As well as the general consensus of earlier discussions that, as much as possible, all Member States should aim to implement a solution that was based on existing and commonly used international standards.

Participants had also submitted questions asking for clarification of the meaning of Article 8(4) of the Implementing Regulation. SANTE explained that the provision in question asked ID issuers to inform Member States and the Commission of algorithms used for the encryption and/or compression of unit level UIs. These algorithms and compression techniques formed an integral part in securing the integrity of UIs and it was therefore crucial that authorities would take all steps necessary to protect them from access by unauthorised third parties.

[…]

3.3 Secondary repository

[…]

One participant asked whether special hardware were needed for authorities to access the user interfaces. SANTE answered that a computer with network access would normally be sufficient. It also recalled that the modes of accessing the graphical user management interface had to be compatible with the building blocks of the Connecting Europe Facility (e.g. e-delivery).

[…]

3.4 Anti tampering device

[…]

On individual responsibilities of economic operators, the group noted that Article 7(1) of the Implementing Regulation required manufacturers/importers to ensure the verification process of unit level UIs. Given that the anti-tampering device formed an integral part of the verification process, it would follow that manufacturers/importers were responsible for ensuring that such a device was supplied to them and installed on site.

The group furthermore agreed that, in practice, it could make sense to allow that the required written declarations were submitted to the relevant authorities via the manufacturer/importer of the facility at which the device in question had been installed.

Finally the group discussed that it would be sensible for the competent authorities to ask for the records created with the anti-tampering devices installed on non-EU production lines relatively early on after 20 May 2019, in order to verify their proper functioning and the correct structure of the records.

3.5 Payment of scanning devices

The group discussed the obligation of manufacturers to provide all economic operators involved in the trade of tobacco products with the equipment necessary for the recording of products. Questions were raised in particular as to the scope of this requirement and whether it only extended to scanning equipment. SANTE pointed to the last sentence of Article 15(7) of Directive 2014/40/EU, which stated "that equipment shall be able to read and transmit the recorded data electronically to a data storage facility…". It also recalled that the transmission of transactional information could be expected to take place separately and not in the process of scanning of UIs. In light of this, the group considered it reasonable to assume that economic operators had to be provided with more technical equipment than merely scanning devices, in order to record and transmit all relevant data.

[…]

3. Q&A

[…]

On identifier codes, several questions were addressed in relation to the request of codes by economic operators to the competent ID issuers. SANTE recalled the rules set out in Chapter III of the Implementing Regulation.

On the pricing of UI, SANTE referred back to its previous presentation on the calculations in the Implementation Study and the Impact Assessment, which to a large extent relied on the values established in the survey carried out during the Feasibility Study. Fees may also differ dependent on the delivery method chosen, whereas it was reasonable to assume that fees for physical delivery could be slightly higher. Information from the generation and delivery of national tax stamps could be useful as a reference point in this respect.

The group then discussed to what extent UI fees may cover other services related to the UI. It was agreed that also services related to the development of the UI could be recouped through the fees per UI. The same would be true for the generation and issuing of identifier codes, i.e. the costs related to identifier codes could also be included in UI fees.

One participant furthermore asked for an overview of potential relevant criteria that should be used by Member States in the selection of an ID issuer. SANTE replied that all provisions in the Implementing Regulation that referred or related to the ID issuer should be considered (e.g. those relating to ID issuer competence, prefix code, UI structure, request and issuing rules, independence, etc.). In addition, certain other aspects would also be relevant as they had a direct impact on industry operations, notably the length of UIs, estimated fees and the use of commonly used and recognised standards.

On the applicability of the independence requirements to ID issuers, it was clarified that these would also extend to the development of the UI by the ID issuer and any involved subcontractors. It was stressed that independence of the UI development from industry was essential for the overall integrity of the traceability system.

Then a number of points were raised in relation to enforcement. It was acknowledged that Article 15 of Directive 2014/40/EU had a clear cross-border dimension, which relied on the willingness of Member States to act upon the concept of sincere cooperation, in order to ensure effective application and enforcement of the directive across the Union.

On competence of ID issuers, it was confirmed that the derogation in Article 4(1) only applied to unit level UIs.

On the requirements for security features in the context of duty free sales, SANTE recalled the discussion during the last Subgroup meeting. The reference point in the directive was the 'placing on the market' of products, which was the place and time at which a product was made available to consumers, with or without payment. Furthermore, SANTE stressed that the directive sets out the territorial applicability of Article 16 in terms of geographical scope, and that 'territory of the Union' was not to be confused with the concept of customs union. Therefore, duty free shops located in airports of Member States fell under the definition of 'first retail outlet' and tobacco products sold in these shops – regardless of their destination – had to carry a security feature. This equally applied to the sale in ship shops. Here, the group agreed that the determining factor was the geographic location of the vessel at the time when the tobacco product in question would be made available to consumers in the ship shop. With respect to the subject of tobacco product sales on airplanes and the requirement for products to carry a security features, the group decided to have a follow-up discussion during the next meeting in December

On the definition of manufacturer, SANTE recalled the discussions that took place during the last Subgroup meeting and reminded that an entity qualified as manufacturer within the meaning of the directive not only if it manufactured tobacco products, but also if it had products manufactured for it by another entity and marketed those products under its own trademark. While slightly different rules might apply to different types of manufactures dependent on where they were located in the supply chain, in practical terms, it was important that no double recording of logistic and transactional events occurred. In the case of subcontracted manufacturing (i.e. where an entity has products manufactured for it by another entity), SANTE furthermore advised that the entities concerned come to an agreement as to how they will jointly discharge all reporting obligations, including the transmission of relevant data (product movements. and transactional data) to the primary repository.

On the reading of Article 22 of the Implementing Regulation regarding the quality of data carrier, the question was raised whether the referenced ISO standards demonstrated minimum standards. SANTE answered that the reference point was the high readability of permitted optical data carriers that economic operators must ensure. This basic requirement was primarily introduced in order to help all economic operators in meeting their obligation to report all movements of tobacco products

without unnecessary disruptions caused by problems in reading data carriers during their successive scans. In the case of compliance with ISO 15415 (for printed 1D barcodes), or 15416 (for printed 2D barcodes), at a minimum rate of 3.5, a presumption of conformity existed. This did not mean, however, that these ISO standards had to be interpreted as a baseline requirement. Other standards might also be useful as a reference point for high readability, especially in the case of direct marked barcodes that were often used on highspeed production lines. Here the relevant reference point was rather ISO 29158.

Finally, the group discussed scanning activities in the case of physical delivery of the UI. It was noted that, depending on the scanning technology used and the way the time stamp was applied next to the UI, economic operators might be required to do two scanning operations (UI and time stamp separately) in order to transmit the full set of required information on the product movement.

[…]

Extract of Summary Record of 10 December 2018

[…]

3. Discussion

[…]

General scope of Directive 2014/40/EU

The group discussed the scope of Directive 2014/40/EU with respect to tobacco traceability and other customs rules. SANTE recalled that Directive 2014/40/EU applied to the entire territory of the Union, which meant that its geographic scope was wider than this of the Customs Union. All tobacco products that are manufactured on Union territory would fall into the scope of Directive 2014/40/EU and therefore be subject to the rules on tobacco traceability, including cases of export products, even where those products travelled under EMCS. For tobacco products imported to the Union, those products would be subject to the rules of the directive as of the moment that they entered the territory of the Union. Products manufactured in third countries and placed under a customs suspensive procedure ('special procedure') upon their entry into Union territory would however only be considered imported into the Union once they were released from the suspensive procedure ('release for free circulation'). SANTE clarified that the rules on import of products in Directive 2014/40/EU should be read in conjunction with the provisions of the Union Customs Code, especially its Articles 201 and 210.

A number of Member States inquired into the applicability of Directive 2014/40/EU to special territories of the European Union, in particular whether those with special customs and/or VAT status would be subject to tobacco traceability and security features. In light of time constraints, the Chair suggested to discuss this matter more in detail during the next Meeting of the Subgroup.

Territorial requirements for security features

Portugal introduced a table outlining different scenarios of product sales, notably sales in duty free shops, ship shops and on airplanes. The group shortly discussed these scenarios and whether products would be required to carry a security features.

On duty free shops earlier discussions were recalled and the group agreed that for sales in duty free shops located on Union territory the rules on security features applied. With respect to sales on

ships and airplanes, some Member States pointed out that for these types of sales circumstances differed and that it was not always clear whether a security feature would be necessary. SANTE recalled that, according to the applicable legislation, a tobacco product was required to carry a security feature whenever it was made available to a consumer located on Union territory. Whether or not the rules on security features applied therefore depended on the geographic location of consumers at the time a tobacco product was made available to them (e.g. vessel is / is not located in EU waters, airplane is / is not located in EU airspace). One Member State noted that the tabled general scenarios were currently still under internal scrutiny in its ministries, in order to better understand the factual and legal questions that were arising.

Postal services

Austria reported that certain logistic companies, in particular postal services and other type of transport companies, had raised concerns about the implementation of the traceability system. The Austrian representative was therefore wondering whether the Commission and other Member States were aware of these concerns.

SANTE replied that over the past year it had received some general questions as to the applicability of the rules on tobacco traceability to transport companies. Discussions on this had also taken place in previous Meetings of the Subgroup and the group had agreed that these companies would be subject to reporting obligations, however, only if they were involved in transloading activities while handling tobacco products.

[…]

4. Q&A

[…]

On whether all communication from the ID issuer to the secondary repository needed to be in real-time: SANTE noted that, in principle, real-time transfer of data from the ID issuer to the repositories system was necessary in order to ensure, among others, realtime validation of data. Information on time limits applicable to the data transfer were laid down in the different provisions. For example, unique identifiers and identifier codes must be issued and sent electronically within two days. Before they are delivered to the requesting party, unique identifiers / identifier codes need to be transmitted via the router to the relevant repository.

The Commission had been asked to provide clarification about the applicability of rules on traceability and security features in the case of cross-border distance sales. For tobacco traceability, the last recording and transmission event is the dispatch of a product to the first retail outlet, that is the facility where the tobacco product is made available. In the case of cross-border distance sales, this was the dispatch to the shop which would send the product in question to the consumer. For security features, SANTE reminded of Art. 2(40) of Directive 2014/40/EU, which read that "… in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located". As such, the group agreed that the location of the consumer would determine the type of security feature that was required on the product. Some Member States noted concerns with respect to the limited reach of tracking and tracing with regard to the dispatch of products from a shop to consumers. SANTE acknowledged this concern but explained that the scope of the Directive did not allow going further than the first retail outlet. However, the Directive also allowed Member States to prohibit cross-border distance sales.

On whether, following the delivery of tobacco products to multiple vending vans, the remaining stock in the vehicle had to be reported: SANTE answered that the stock that remains after finishing the delivery tour should be recorded in the traceability system by means of an arrival message declared as 'Product_Return'.

One Member State posted a follow-up question related to deliveries that are made for the purpose of supplying both vending machines and point of sales without previous sales order. It was clarified that, in such a case, two different activities existed and therefore two different messages would have to be recorded in the system. First, dispatch to multiple vending machines and second, dispatch to multiple retail outlets via a vending van.

Another Member State asked how facilities should be registered that run different operations within the tobacco trade business (e.g. wholesaler and first retail outlet). It was proposed to declare such a facility as 'other' and to provide further explanation in the description field.

Finally, a question was raised whether reporting obligations existed in cases of product sales where no order existed. SANTE replied that if no order was legally required and also not issued by the vendor, no recording of order information was expected. […]

Extract of Summary Record of 17 January 2019

[…]

3. Discussion

[…]

3.3. Follow-up: applicability of Directive 2014/40/EU to special territories

Following the request of some Member States, SANTE provided clarity regarding the applicability of Art. 15 and 16 of Directive 2014/40/EU to special territories. In accordance with the rules set out in the Treaty on the Functioning of the European Union (TFEU), the so-called Outermost Regions (Guadeloupe, French Guiana, Réunion, Martinique, Mayotte and Saint-Martin (France), the Azores and Madeira (Portugal), and the Canary Islands (Spain)) formed part of the territory of the Union and were subject to the internal market. Therefore, Directive 2014/40/EU applied. Overseas countries and territories, on the other hand, were not to be considered territory of the Union, and consequently Directive 2014/40/EU did not apply to them.

3.4. Security features and duty free shop

One Member State asked about the responsibility to determine the security feature that must be used for products sold in duty free shops located on Union territory. SANTE replied that the permitted security feature was the one that had been determined by the competent authority of the Member State on whose market the duty free shop in question was located. Another Member State then asked for final clarification on the general rules related to security features, in particular also with regards to sales on boats and airplanes. SANTE referred to previous Meetings of the Subgroup during which the topic had been discussed in much detail. These discussions were also reflected in the minutes. To recap, the determining factor to consider was the physical location of the product at the time when it was made available to the consumer (here: location of shop/boat/airplane). If the handing over of the product took place on Union territory, the product in question had to carry a security feature.

[…]

4. Questions & Answers (submitted by Member States)

On whether the secondary repository provider was required to develop a mobile app for enforcement officers to access the traceability data: SANTE explained that the legislation did not contain any reference to the development of a mobile app solution. The provider of the secondary repository will have to develop (non-)graphical interfaces that enable authorities to analyse the traceability data (queries, alerts, reports). SANTE 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. In response to this, some Member States noted that they were either intending or already in the process of developing such technical solution. SANTE welcomed this update and encouraged Member States to follow-up on this topic in coming months. In this respect, participants were also reminded that eventually a mobile app might have to be developed by the EU and its Member States in order to meet their obligations under the Protocol, that is, to enable third countries to have access to certain information encoded in UIs.

On how ID issuers can validate a request for UIs, if the economic operator/facility/machine identifiers codes concerned did not generate from that same ID issuer: it was clarified that the information which are submitted to an ID issuer in the context of requesting an identifier code, as well as the identifier code itself, would form part of a registry that had to be established and managed by each ID issuer. An up-to-date copy of this registry had to be transmitted by the ID issuer via the router to the . In this way, the secondary repository had a complete overview of all identifier codes. It followed that the validation of identifier codes takes place at the level of the secondary repository (before transmission of UIs to the requesting party) and not at the level of the ID issuer.

On the possibility for the tobacco industry to provide equipment to economic operators through financial compensations: DG SANTE recalled previous discussions in relation to scanning equipment. It had been agreed that Article 15(7) TPD referred to the recording of data on both product movements. and transactional activities. Certain information on product movements. (e.g. EMCS), and information related to transactional activities as a whole, could not be recorded and transmitted using handheld devices only. It followed that the provision of equipment alone would not be enough for economic operators to be in a position to transmit a full set of the required data. The latter in itself supported the need for a compensation model to be adopted. The group also agreed that a compensation model made sense from an economic point of view in that certain operators might only require upgrades to existing (hardware/software).

On whether a Member State issued certificate that attests SME status was sufficient to apply the derogation in Article 7 of Implementing Regulation 2018/574 (hereafter: IR): DG SANTE noted that such certificate would be sufficient in providing legal certainty the economic operators, provided that the certification was based on EU Recommendation 2003/361 to which Article 7 made reference. In regards to a follow-up question, SANTE confirmed that there was no need for Member States to send to the Commission each issued certificate.

Another question concerned the method of how a MS should solve the situation where certain products are not marked with a tax stamps (i.e. chewing/nasal tobacco or duty free sales). MS should permit the use of another security feature to be applied to these products For example, a zero-value stamp in the case of duty free products. It should also be remembered that the rules on security features applied to products other than cigarettes and roll-your-own tobacco only as of May 2024.

On whether the requirements of Article 15(6) TPD matched the list of information set out in Chapter VI of the IR: the group discussed that the IR required the recording and transmission of data set out in Annex II. Section 4 of Chapter 2 corresponded to information on order number/payments/invoices, as referred to in Article 15(2) TPD. In addition, however, Art. 15(6) required economic operators (including operators of retail outlets) to maintain complete and accurate records of all relevant transactions (e.g. physical copies of issued and received invoices).

On whether in the case of sales in duty free shops, the competent ID issuer should be determined by reference to Article 4(4) IR: the group agreed that Art. 4(4) IR related to products destined for export, which was not applicable to products sold in duty free shops. Competence would rather have to be determined in accordance with Article 4(1) IR.

Another participant asked about the data retention period for data stored by the ID issuer: SANTE pointed out that the secondary legislation did not set any retention period for data stored by the ID issuer. This was the responsibility of Member States. However, a copy of all relevant information generated by the ID issuer and transmitted to economic operators in line with the IR was stored in the repositories system, and for the latter the retention period was five years. For the avoidance of any doubt, it was also noted that the registries of all the identifier codes generated for economic operators, operators of first retail outlets, facilities and machines, along with the corresponding information, had to be retained as long as necessary for the functioning of the system. Moreover, the

data retention rules should not force any automatic deletion that would lead to the need for reregistration of once registered entities.

On the meaning of vendor: it was clarified that transactional information should always be recorded and transmitted by the entity that legally sold the product in question. For example, this applied to the manufacturer who sold its goods to the distributor. Technically, it was also possible to report on behalf of a business partner (i.e. in the case of sales via an intermediary party). However, this would not relieve the actual vendor from its obligation, particularly in cases of wrong reporting.

With reference to the Implementation Analysis, one Member State asked whether it was necessary for each economic operator to be registered with a username and password, in order to communicate with the competent ID issuer. SANTE recalled that the Implementation Analysis was not a Commission document, therefore also not legally binding. It was for each ID issuer to provide ways in which economic operators could communicate in order to apply for identifier codes and UIs. In terms of security, some form of basic identification would probably be necessary (reference to Article 36 IR). This could be by means of a web-interface (likely requiring username and password), but other technical solutions were also possible (e.g. electronic certificates).

Finally, the group discussed the application for Facility-IDs in situations in which a retail outlet was movable (e.g., a kiosk operated on wheels). In principle, two options existed. First, the retail outlet was always placed at the same event location (e.g. event hall), in case of which the facility address should be the address of the event location. Second, for outlets that moved in-between different locations on a regular basis, a more pragmatic approach might be needed (e.g. address of the entity that operates the movable retail outlet, or reference to the license plate of the vehicle), which should also be described in the registration process (field F_Type_Other). Participants agreed that this matter should be further explored in future meetings.

[…]

Extract of Summary Record of 12 February 2019 (webinar session)

[…]

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 (shortterm) 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 nongraphical 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

[…]

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 154591:2014 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.

[…]

Extract of Summary Record of 14 February 2019

[…]

3. Introduction and feedback from providers of primary repositories

[…]

One repository provider asked whether recalled and non-validated messages would have to be kept in the repository system. SANTE reminded that all information recorded in the system had to be stored in accordance with the applicable retention periods. The legislation required the secondary repository to contain a copy of all data stored in the primary repositories. It followed from this that all messages transmitted to the primary repository, even those that did not pass the validation process, had to be forwarded to the secondary repository. The failed validation had to be appropriately reflected in the records of the concerned repositories.

Another participant raised a question regarding the splitting of transactional information that economic operators transmitted to the router. Splitting would always involve the risk of harming the integrity of the data. SANTE took note of these remarks. In terms of transactional data, it explained that splitting of a message should only take place at the level of the data fields related to the unit level unique identifiers concerned. The latter allowed for identifying the primary repositories to which the transactional information had to be forwarded by the router. Other data fields, such as total net sum, should not be split but a full copy of these data fields should be forwarded to each of the primary repositories concerned.

4. Discussion between public authorities, ID issuers and providers of repository services

One Member State enquired into the possibility to provide national authorities with access to Dentsu's 'knowledge base', which contained the technical documents for ID issuers and repository providers. Dentsu informed Member States that that it would create special profiles for national authorities and for national administrators.

On validation of the information in requests for unit level UIs, in particular the existence of identifier codes (i.e. EOIDs, FIDs and MIDs), the legislation required that this must take place at the level of the secondary repository. More specifically, the router, which will receive each generated UI for validation before it gets transmitted to the primary repository. Upon the request of a number

of Member States, Dentsu offered to provide a separate interface that would allow ID issuers to receive confirmation on the existence of foreign identifier codes (i.e. such that were generated by another ID issuer). For reasons of data protection, this information would be limited to a simple existence check. SANTE clarified that this was an additional feature, not required under the legislation. While it would enable ID issuers (if they wished to do so) to carry out pre-validation checks before generating UIs, it would not remove the obligation of the final and official validation of generated UIs to take place at the level of the router.

One service provider asked for clarification on the application of Article 4(5) of the Implementing Regulation. SANTE reiterated that there was a legal obligation for Member States to appoint an ID issuer and to ensure the operational functionality of that entity in time.

On the deactivation of UIs, it was clarified that the repositories system had to ensure that unique identifiers not used within the six months timeframe of validity were automatically deactivated. In addition, such deactivation could also take place manually and at an earlier point in time, either executed by a national authority (e.g. in the context of an enforcement action) or by the economic operator itself (e.g. where a pre-ordered set of UIs was no longer needed / where it failed validation and could not be used).

Another question concerned an information request regarding the graphical interfaces that would be made available to public authorities. Dentsu thanked for this intervention and responded that it would be happy to engage with Member States in relation to their wishes (e.g. specific automatic query functions). Dentsu promised to look into the possibility of organising a specific meeting with Member States to discuss this matter more in detail. Member States agreed and thanked for this proposal.

One participant noted that it would be desirable to receive further information on the look-up tables, i.e. the flat files. SANTE recalled that each ID issuer would be responsible for preparing and regularly updating the flat files which were necessary for determining the information compressed in the product code (see Article 8(1)(c) of the Implementing Regulation) in the offline mode. In line with Article 20(3) of the Implementing Regulation, the full collection of all the flat files maintained by the ID issuers should be stored with the secondary repository. That will allow the authorities to download the flat files from one place for regular updates of the portable reading devices. SANTE clarified that the flat files should not be mistaken for the registries of all economic operators,

facilities and machines. Information-wise the former overlapped with the latter only insofar as the UIs combined with the flat files were supposed to inform about the mandatory content of message 2.1 of Annex II, including the extraction of information from the concerned identifiers used in that message.

Another Member State asked SANTE whether the competent ID issuer appointed in one Member State only had to register economic operators located on its own territory. SANTE referred to the rules on competence, as set out in Articles 14, 16 and 18 of the Implementing Regulation. Member States should furthermore take into account that rules on the request of identifier codes for importers were different. Some participants noted that they carried out verification checks on requesting entities (e.g. based on the VAT number). During the discussion, the registration obligations for the purpose of issuing identifiers were distinguished from the administrative registration of manufactures and importers that the ID issuer would need to carry out for the purpose of charging the fees for generating and issuing UIs. In response to a follow-up question, SANTE confirmed that the derogation in the second sentence of Article 4(1) of the Implementing Regulation did not affect the rules on competent ID issuers in relation to requests for identifier codes. An ID issuer competent for a Member State, who applies the derogation, therefore may have to process requests for unique identifiers originating from economic operators with identifier codes assigned by other ID issuers.

Finally, one of the participants sought clarification on the data element 'other economic operator ID' in message 1.1 of Annex II. SANTE explained that this information was mainly of use in two specific cases. First, importers who placed their products on more than one national market would receive identifier codes from all competent ID issuers. Second, if an economic operator, who operated under one single legal entity, was responsible for facilities in two or more Member States, it would receive identifier codes from all competent ID issuers. The data element in question would allow for proper linking of all identifiers belonging to the same economic operator. During the discussion, it was underlined that, in most cases, multinational corporations operated through their national subsidiaries, which constituted separate legal entities. Hence, this second example was less likely to occur in practice.

[…]

6. AOB

One Member State wished to clarify whether internal financial transactions taking place within the same company should be recorded. SANTE stressed that the legislation is clear on that point in that every financial event related to an invoice, payment and order needs to be recorded in the system following the occurrence of the event and once it can be linked to the UIs concerned. This also meant that, where no invoice is issued, no transactional data needs to be recorded.

Another Member State enquired whether a harmonisation of UIs at the EU level was foreseen. SANTE explained that the legislation, within its boundaries, leaves a certain degree of freedom to ID issuers who are ultimately responsible for generating and issuing UIs. To that end, Article 8 and Article 11 of the Implementing Regulation set out the required structure and content of unit and aggregated level UIs generated by the ID issuers. Where the UIs are generated by economic operators, Article 10 of the Implementing Regulation specifies that individual codes must be generated in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014. These requirements set out the basis for ensuring uniqueness of the codes. With regard to encoding and reading of UIs in optical format, the legislation stipulates the permitted data carriers. In this regard, the reading of UIs by scanners should furthermore be facilitated by means of integrating data qualifiers and separators into the UI string, in line with ISO/IEC 15459-3:2014, which is intrinsically linked to ISO/IEC 15459-2:2015 referred to in Article 3(4) of the Implementing Regulation.

Several participants raised questions as to the reading of Article 15(7) TPD in relation to the obligation of manufacturers to provide economic operators with the equipment necessary for the recording of tobacco products purchased, sold, stored, transported or otherwise handled. Notably, it was discussed whether this provision should be read as a one-time obligation or rather a continuous obligation. The group agreed that a one-time payment to economic operators would not be compliant with the obligations set out in that provision. In particular, Article 15(7) required that the equipment provided to economic operators must enable them to read and transmit the recorded data electronically to the repositories system. Reading and transmitting of data was an ongoing obligation that applied to economic operators for as long as they would be involved in the trade of tobacco products. The group regarded it was unlikely that any equipment provided would be able to fulfil this obligation over a longer period without requiring maintenance, or even replacement.

One Member State informed the Commission that a manufacturer in their country had not yet notified the Commission about the proposed provider of the primary repository and the related data storage contract, and was wondering whether notifying was still possible. SANTE responded that

every notification received would be treated within the required deadline of three months, as set out in Annex I of the Implementing Regulation. At the same time, SANTE reminded that enforcement of the legislation on tobacco traceability was the responsibility of Member States.

On the deactivation of an economic identifier code by authorities in duly justified cases, SANTE explained to the group that a deactivation of the code would have a 'cascade effect' in that it would lead to the automatic deactivation of all related facility and machine identifier codes (see Article 15(4) and 17(4)). It was reminded that an alert could be introduced in the system in order to avoid that a deactivated economic operator attempts to register a second time.

Finally, the group discussed whether Union legislation on tobacco traceability set out a requirement for manufacturers/importers of tobacco products to reimburse the development of a mobile app, which could be used by national authorities to read the information encoded into UIs. Participants agreed that no such requirement was contained in Union legislation per se. However, Article 8 of the FCTC Protocol stipulated that each Party to the Protocol may require the tobacco industry to bear any costs associated with that Party's obligations under this Article.

[…]

Extract of Summary Record of 12 March 2019

[…]

3. Discussion

3.1. Article 37 of the Implementing Regulation

At the request of some Member States, the Group discussed the reading of Article 37(1) of the Implementing Regulation, which provides for stock exhaustion of cigarettes and roll-your-own tobacco that were manufactured in or imported into the Union before 20 May 2019.

With respect to the terms 'manufactured in the Union' and 'imported into the Union', the following was noted. '[M]anufactured in the Union' refers to the point in time of manufacturing on the territory of the EU, that is, in any of the 28 Member States. '[I]mported into the Union', which should be read in conjunction with Article 2(38) TPD, refers to the point in time when a product enters into the territory of the EU and has been released for free circulation. As such, also taking into account the provisions of the Union Customs Code (UCC), the term relates to products that originate from a non-EU territory and are released for free circulation in the EU (e.g. through the payment of import duties).

The group then discussed two further aspects in relation to this clause. The first aspect relates to the application of Article 37 to products stored in tax warehouses and custom warehouses. The second aspect relates to the enforcement of the provision in Member States.

With reference to the first aspect, there was agreement that based on a reading of the UCC tax warehouses were different from customs warehouses. The latter is used for the purpose of storing products that originated from outside the Union and for which import duty has not (yet) been paid, but this is not the case for tax warehouses, which are used to store products for which (excise) taxes have note (yet) been paid. Therefore, cigarettes and roll-your-own tobacco products, which are manufactured in the Union, or imported into the Union, before 20 May 2019, and are afterwards placed in a tax warehouse located on EU territory, will still benefit from the rules of Article 37(1) of the Implementing Regulation. With reference to the second aspect, the group agreed that certain practical challenges could arise for products manufactured in another Member State. Given that the data of manufacturing currently is not yet visible from the unit packet, the application and enforcement of Article 37 inevitably would require on-site checks in factories. Tax stamps, in

Member States where they are used, may give enforcement officers some indication, but will not provide clarity on the manufacturing date beyond doubt. Cooperation between Member States on this aspect was therefore considered important and should be facilitated whenever necessary and to the extent possible.

3.2. Acknowledgment messages

In light of the stock exhaustion clause, it would be likely that, in the first months after 20 May 2019, aggregated packaging containing both unit packets carrying permitted UIs and packets with non-valid legacy UIs (i.e. UIs generated under the industry's own traceability system, or UIs generated in run-up tests for the EU traceability system) travel along the supply-chain. This leads to a situation where scanning events will capture information relating also to legacy UIs, which are not registered in the traceability system, and send this information, as part of the aggregation message, to the traceability system. These UIs will fail validation in the system. Consequently, the related message from economic operators to the system will receive a negative acknowledgment message, due to the rule that where at least one UI is in error the entire acknowledgement message must be in error. There error message will contain information on the UI(s) concerned as well as the category of error(s) received, therefore allowing economic operators to review the reasons for the (partial) error.

To avoid unnecessary and disproportionate negative impacts on the legal supply chain, the group agreed as follows. In the period until 19 May 2020, messages related to both valid UIs and non-valid legacy UIs should be treated in a way that, despite of sending a negative acknowledgment message, the traceability system will process every existing UI, which forms part of the received message. In such event, the responsibility lies with the economic operator concerned to determine whether the products in question can be moved further in the supply chain despite of a received negative acknowledgment message, because the products benefit from Article 37(1) of the Implementing Regulation. Finally, it was noted that this temporary exception only applied to cases of non-valid legacy UI in the first year after 20 May 2019. All other reasons (e.g. duplicate UI) will impose a prohibition on the product movement. as such, until the error was rectified and the corrected message sent to the system and validated successfully.

SANTE reminded that Member States would be able to configure relevant automatic alerts in the system for these scenarios, in order to support enforcement activities.

3.3 Common security feature for duty free products

Following the request of some Member States, the group re-addressed the possibility to adopt a common security feature for duty free products. Certain stakeholder associations had approached SANTE on this subject matter as well, referring to apparent advantages of a common approach, especially in light of the centralised packaging process of duty free tobacco products in the EU. The Commission Decision on security features does not prohibit the adoption of a common security feature in multiple Member States, yet, at the same time, SANTE stressed that there is no legal basis for the Commission to impose a common security feature. Member States in such a common approach should initiate, and consequently drive, any process.

The group then shortly discussed the necessity of a common security feature for duty free tobacco products. A few Member States indicated that they could be interested in selecting a security feature together with other Member States. However, multiple Member States questioned the rationale behind the need for a common security feature, in particular the assumption of a centralised packaging process. Like any other tobacco product, products sold in duty free shops must carry the combined health warnings, in accordance with the rules of the TPD (i.e. warning in the official language or languages of the Member State on whose market the product is placed). Therefore, individual packaging requirements applied across the Union, including in duty free areas.

[…]

3.5. UI and data qualifiers

SANTE informed the participants that it had received questions related to the use of data qualifiers in UIs. At the outset, SANTE recalled that the rules on ID issuers and generating UIs in the Implementing Regulation referred to ISO 15459-2, and that the latter included a reference to ISO 15459-3 (common rules on unique identification). Therefore, in answering any questions related to the generation of UIs due regard should be given to the Implementing Regulation and ISO 15459. In this respect, SANTE confirmed that Article 8(4) of the Implementing Regulation does not prohibit the use of data qualifiers at the level of the generation of the unique identifier.

[…]

4. Questions & Answers (submitted by Member States)

On the difference between a flat file and the registries, SANTE recalled previous discussions on this topic. Article 2 of the Implementing Regulation defines 'offline flat-files' as 'the electronic files

established and maintained by each ID issuer that contain data in a plain text format allowing for the extraction of information encoded in the unique identifiers (excluding the time stamp) used at the unit packet and aggregated packaging levels without accessing the repositories system'. It follows that flat files enable to decode the information contained in the unique identifiers without having to access the information stored in the repositories system. For enabling competent authorities of Member States to read the information of the unique identifiers in offline mode, regular updates of the flat files must be downloaded onto the portable scanning devices. Registries, on the other side, are the records established and maintained by each ID issuer containing all the identifier codes generated for economic operators, facilities and machines along with the corresponding information. As such, information-wise registries overlapped with flat files only insofar that UIs combined with the flat files inform public authorities about the mandatory content of message 2.1 in Annex II, including the extraction of information from the concerned identifiers used in that message.

On reporting obligations for product movements. between different retail outlets, SANTE note that in principle there are no reporting obligations for products that have already been placed on the market. In line with Article 15(5) of the TPD, the final reporting obligation lies with the last economic operator before the first retail outlet (i.e. message on dispatch to the first retail outlet). However, the group agreed that consistent movements of products between first retail outlets – opposed to single cases – could illustrate a 'pattern'. In this scenario, it is likely that a national authority would investigate the possibility of an attempt to circumvent the rules by declaring a distribution activity as activity of a first retail outlet. Appropriate enforcement of the legislation by that Member State may therefore follow.

A Member State representative intervened to ask on the consequences for a first retail outlet to return to the distributor a tobacco product. SANTE referred to multiple previous discussions on this topic. The obligation to record the product arrival lies with the distributor that receives the product to its facility. Another Member State enquired whether in case of a transloading event the obligation to record the product return falls with the transport company or another economic operator. SANTE clarified that the first reporting obligation remains with the operator of the facility at which goods arrive after dispatch from the first retail outlet, i.e. there is no reporting of potential transloading of the products to be returned on their way from the first retail outlet to the point where the products are first stored upon their return .

On whether ID Issuers could require an entity registered with the ID issuer of another Member State to obtain an EO identifier code before a request for UIs is processed, SANTE specified that every request for UIs must take place in accordance with the rules on competence, as set out in the legislation. Especially where a Member State applies the second sentence of Art. 4(1), it is likely that an ID issuer will receive requests from operators using identifier codes issued by other ID issuers. ID issuers must accept these requests. For that reason, validation of the identifier codes used in messages to request UIs always takes place at the level of the repository system before UIs are transferred to the repository of the requesting party. SANTE recalled the offer of Dentsu to provide ID issuers with an additional interface to carry out verification checks on the existence of foreign identifier codes, as part of a prevalidation check. ID issuers may also put in place procedures to ensure the collection of fees for UIs, which may require the requesting parties to register with the ID issuer. However, such procedures should not be confused with the registration procedure set out in Article 14 of the Implementing Regulation. On the possibility of sending UIs to manufacturers without receiving confirmation of correct validation from the router, SANTE confirmed that this is not permitted. The data flow in the legislation is clear in this regard (see Art. 9(3) of the Implementing Regulation). The ID issuer has to transmit the codes along with the required information (on identifier codes) via the router to the primary repository system. It follows that unique identifiers cannot be sent without being validated first by the router. If the router gives a negative response to the validation, an error message will be sent and the UIs will not be registered in the primary repository as valid.

Another question concerned which identifier code should be used for marking when two or more machines on the production line have different identifier codes. SANTE reminded Member States about the reasons for the earlier vote on the meaning of a machine. According to the Implementing Regulation, only one machine per production line can be registered in the traceability system. In the case that a machine is moved for use across several production lines, each combination of machine and production line must be registered with an identifier code.

The next question concerned the possibility for providers of primary repositories to add to the costs of the secondary repository a mark-up when issuing the respective invoices to manufacturers/importers. The group agreed that, if the mark-up related to aspects such as the invoicing process or general interactions with the secondary repository, these costs would fall within the scope of what the Regulation refers to as 'establishment, operation and maintenance of the

repositories system'. Therefore, the costs should form part of the costs that providers of primary repositories pass on to manufacturers and importers. However, the costs have to remain proportionate to the services rendered and the UIs requested.

On products destined for exports manufactured in one Member State and temporarily stored in a tax warehouse located in another Member State, SANTE recalled that all products manufactured in the Union are subject to the traceability regime. This means that tax warehouses have to register as facilities in the traceability system, and the arrival to and dispatch from these warehouses must be recorded in the traceability system accordingly. This is furthermore supported by the fact that message 1.4 in Annex 2 to the Implementing Regulation allows to specify whether a facility has a tax excise warehouses status.

On validation of the identifier codes sent by ID issuers and UIs, SANTE recalled that validation always takes place at the level of the secondary repository/router. Validation refers to the check of completeness of the information submitted, including their format, as well as to the existence of the UIs/IDs. Verification of company information, such as the correct address of the requesting party, on the other hand, falls into the scope of the business relationship between ID issuer and requesting parties. Therefore, the ID issuer will be responsible for this type of verification, in accordance with its internal procedures and as agreed with the contracting Member State.

On the possibility to use the consignment note instead of the vehicle registration number to identify the transport vehicle in the case of courier companies, SANTE clarified that the objective of this requirement is to allow enforcement officers to identify unambiguously the vehicle used to transport the products in question. The group doubted that a consignment note could allow for this.

Another question referred to aggregated level UIs and the need to transmit additional optional information (e.g. on SSCC) included in the UI to the secondary repository. SANTE recalled Article 11(4) of the Implementing Regulation, which allows economic operators to add additional information to aggregated level UIs, provided that the maximum character limit set out in the legislation is not exceeded. This information would form part of the aggregated level UI string. As such, it must be recorded and transmitted to the traceability system. This is also important in terms of validation when the aggregated UI is scanned throughout the supply chain. The string in the system must match the recorded information. Otherwise, the validation fails.

On identifier codes, a participant asked how, and by whom, the consent of the first retail outlet, referred to in Article 14(3) and 16(3) of the Implementing Regulation, should be verified. SANTE recalled that the Implementing Regulation states that any other registered economic operator may discharge the request of identifier codes for operators of first retail outlets only if the operator of the first retail outlet has given its consent. Having this in mind, from an enforcement perspective, competent national authorities may always request proof of the consent, if deemed necessary in a particular case.

The next point raised by a Member State related to the sale of tobacco products on aircrafts using trolley carts. Tobacco products are loaded onto these carts and then taken onto an aircraft for sale. After the carts have been used on the flight they are locked away with any remaining products staying in the cart. These carts are locked up securely when not on the aircraft, and are identifiable by unique identifiers. In line with previous discussions in the Subgroup on movable retail outlets, the Member State representative wondered whether these carts should be considered as a first retail outlet. The group agreed to this reading. SANTE added that it would be useful for identifying the carts to provide information on the respective 'home airport(s)' and, if applicable, the particular airlines served.

Further clarifications where requested from Member States in relation to the registration process. First, on participant asked whether economic operator identifier codes must be requested by economic operators for each national market in which they place their products. SANTE clarified that this is the rule for importers. All other economic operators and operators of first retail outlets must request an economic operator identifier code from the ID issuer competent for each Member State in which they operate at least one facility. In addition, the group sought clarity about the deactivation of identifier codes (EOID, MIC, FIC) in cases where an appointed ID issuer is replaced by another legal entity. SANTE confirmed that there would be no need for deactivation of identifier codes and therefore no need for a second registration. Data on previous registrations of codes should be maintained in the traceability system and should not be deleted for the duration of the system. Finally, one participant enquired about the validity of UIs before their application to the product. SANTE confirmed that a unique identifier codes remains valid for a period of 6 months starting from the date of receipt of the UI by the economic operator.

[…]

Extract of Summary Record of 12 April 2019

[…]

4. Discussion between public authorities, ID issuers and providers of repository services

4.1. Data protection

The group discussed the applicability of the General Data Protection Regulation (GDPR) to the repositories system. In light of the nature of its different components and the obligations that applied to the different parties, SANTE shared with the group its reading of the situation. Accordingly, it believe that providers of primary repositories and the provider of the secondary repository are data processors within the meaning of the GDPR, whereas a division into processor and sub-processors could be considered. Given the rights and obligations of Member States and the Commission, the parties should act as joint controllers within the meaning of the GDPR. A follow-up on this point would take place in the afternoon session.

Providers of repositories were asked to put in place the required contractual agreement, which, the group agreed, could be annexed to the existing contracts between DENTSU and each primary repository provider.

4.2. Clarification on Article 10(2) IR

In response to a question on the reading of Article 10(2) of the Implementing Regulation, SANTE reminded that this provision allowed for two ways in which aggregated UIs may be generated and issued. Aggregated level UIs may be generated either by the competent ID issuer (in accordance with the rules set out in Article 11), or by means of selfgeneration by economic operators. It was important to note that self-generation is not linked to an appointed ID issuer within the meaning of the Implementing Regulation, but is the responsibility of economic operators who will act as identity issuers on the basis of their own Company Identification Codes (CIN). Self-generation needs to take place in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014 or their latest equivalents.

4.3. Data qualifier

Following a request for clarification by several Member States and stakeholders, the group discussed the use and selection of data qualifiers as part of the UI encoding process. The conclusions of this

discussion would be communicated to Member States and ID issuers (see Annex I) who should share the information with all relevant parties.

[…]

5. Update from the Commission & follow-up discussion

[…]

5.4. Reporting flow

SANTE clarified that different reporting activities may apply to an economic operator where it carried out multiple roles within the meaning of the traceability legislation. For example, C&C markets may act as both distributor and first retail outlet. The same applies to manufacturers/importers, who most of the time ship only their own products from the production facility, but in some instances may also distribute products belonging to different manufacturers/importers.

This meant that different reporting obligations would apply depending on the nature of the products concerned. If the products belonged exclusively to one manufacturer/importer, the reporting information must be transmitted to the primary repository. If the products belonged to different manufacturers/importers, the reporting information had to be transmitted to the router. This is necessary as only the router, containing a global overview of all recorded traceability data, is able to split the products and allocate them accordingly.

[…]

5.6. Registration of economic operators without facilities

Participants discussed the case of entities that were involved in the trade of tobacco products – notably in financial transactions related to the purchasing and selling of products – but did not operate a facility within the meaning of the Implementing Regulation. The group agreed that such entities would qualify as economic operators and should carry out the required reporting obligations. Further considerations should be given to this case and a conclusion on the registration of such entities (i.e. obtaining an EO-ID) would be reached in the next Meeting of the Subgroup.

6. Questions and Answers (tabled by Member States)

On queries via handheld devices, it was noted that the Implementing Regulation does not require DENTSU to develop a mobile app as part of their services on which they must deliver as provider of the secondary repository. At the same time, the secondary repository has to enable public authorities to make any queries on the information stored in the repositories system, including via the use of handheld devices. Any such requests should be processed accordingly by the secondary repository. SANTE stressed the fact that the basic requests generated with handheld devices should be distinguished from analytical searches or queries carried out via the graphical user interfaces. SANTE recalled the importance of National Administrators in this regard. They should ensure that, by granting appropriate access rights to relevant users only, requests to the repositories system are not carried out in a disproportionate manner. This was an important aspect to ensure that the overall functioning of the traceability system is not jeopardised and the confidentiality of traceability data appropriately preserved. At the same time, the Implementing Regulation requires that Member States are able to execute any requests (and receive a reply) which they consider necessary for investigation and enforcement activities. SANTE suggested to follow-up on this discussion in one of the future meetings.

[…]

Annex I

The following sets out the e-Mail of 15 April 2019 from the Commission to Members of the Subgroup on the structure of unit level UIs (after encoding into a data carrier):

As agreed at the Meeting of the Subgroup of 12 April, please see below the points outlining our views on the use of data qualifiers as part of the UI, taking into account Implementing Regulation 2018/574 and the applicable international ISO norms. To facilitate this explanation, please see attached a table illustrating the structure of the UI (after encoding it into a data carrier), and the roles of ID issuers and economic operators in generating / applying the different data elements and, where applicable, data qualifiers.

1. Pursuant to Article 8(1)(a)-(c) of Implementing Regulation 2018/574, the following data elements (strings) should form part of the UI, as generated by the competent ID issuer: - ID issuer identification code (subject to ISO 15459-2 and 3); - Serial number; - Product code.
2. Pursuant to Articles 8(1)(d) and 21(4) of Implementing Regulation 2018/574, manufacturers and importers shall add the time stamp in the last position to the code generated by the ID issuer.

The time stamp can be either encoded into the data carrier or be added separately from the data carrier as a human readable format. The time stamp format must correspond to YYMMDDhh. Regardless of its format, the time stamp remains a part of the UI in the sense of Article 8 of Implementing Regulation.

3. Article 3(4) of Implementing Regulation 2018/574 requires that the ID issuer identification code should be assigned in line with ISO/IEC 15459-2 and the latter should be read in conjunction with ISO/IEC 15459-3 laying down common rules on unique identification and data capture techniques. Accordingly, the ID issuer identification code always must be preceded by a data qualifier, which shall consist of digits and upper cases only. That data qualifier shall be applied, as part of the encoding process, by the economic operator in accordance with the applicable coding structure published by the ID issuer in cooperation with its Issuing Agency.
4. Economic operators may be asked to apply additional ISO/IEC 15459-3 data qualifiers to the code generated by the ID issuer as part of the encoding process into the permitted types of data carriers. The use of these optional data qualifiers should be in line with the applicable coding structure published by the ID issuer in cooperation with its Issuing Agency. To that end, it is important to take into account that the use of data qualifiers may depend on the symbology identifier that is applied in accordance with Article 21(1) of Implementing Regulation 2018/574 (and the ISO norms referred therein). The coding structure of the ID issuer should address this possible interdependency and provide for adequate guidance to economic operators.
5. The potential use of a data qualifier preceding the time stamp will also depend on whether an economic operator decides to rely on Article 21(4) of Implementing Regulation 2018/574. The application of such data qualifier should take place in accordance with the applicable coding structure published by the ID issuer in cooperation with its Issuing Agency.
6. To ensure positive validation by the repositories system, only the following data elements (strings), excluding the symbology identifier and any data qualifiers, should be transmitted by economic operators as part of their recording activity to the repositories system: - ID issuer identification code (without mandatory data qualifier); - Serial number; - Product code; - Time stamp.
7. For the purpose of the explanation above, group separators (/FNC1) are considered in the same manner as optional data qualifiers. Their use depends on the coding structure published by the ID issuer.

8. For aggregated UIs generated and issued by competent ID issuers, the same rules apply on the use of data qualifiers. Self-generated aggregated UIs should be issued in accordance with ISO 15459-1 and -4. Self-generated UIs must only provide for unique identification of the traceable item and as such, any additional information added to the aggregated level UI, as provided for in Article 11(4) of Implementing Regulation 2018/574, must not be transmitted by economic operators as part of their recording activity to the repositories system.

[…]

Extract of Summary Record of 8 May 2019

[…]

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.

[…]

3.5. 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.

[…]

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.

Extract of Summary Record of 24 May 2019

[…]

4. Discussion

4.1 ID issuer competence rules

The Subgroup discussed the application of the competence rules for requesting UIs and identifier codes. The rules on competent ID issuers were clearly set out in Implementing Regulation 2018/574 and the group agreed that conformity of submitted requests with these rules should be ensured through adequate monitoring activities by the competent national authorities. Several Member States noted that appropriate enforcement actions would follow in cases where economic operators requested UIs and/or identifier codes from non-competent ID issuers. The traceability system allows the public authorities to identify these cases.

Following the inquiry by one Member State, DG SANTE explained that the legislation requires ID issuers to deliver UIs electronically within the required deadline of 2 working days from the receipt of the request. The services offered by ID issuers should ensure compliance with the basic rules of delivery, but the legislation does not oblige ID issuers to offer services that go beyond (e.g. API for system-to-system data transfer). This also meant that economic operators could not interpret the absence of certain non-basic services, notably the existence of a system-to-system solution, as a reason to rely on the temporary authorisation decision and turn to other ID issuers.

[…]

5. Questions and Answers

On the recording of product movements. to embassies, DG SANTE reiterated its view that the reporting obligations depended on the territorial status of the embassy. Normally, dispatches to embassies of non-EU countries would be regarded as exports.

On the registration of movable vending machines used at festivals, DG SANTE referred to the previous discussions in the Subgroup on movable retail outlets.

On the validation of UIs, DG SANTE recalled that the validation of each message (i.a. existence of IDs, mandatory fields) took place at the level of the router. Data processing at the level of the primary repositories is also subject to the validation rules.

On the reporting of credit notes or bonuses/discounts, the group agreed that these form part of the transactional information and as such have to be recorded in the system as corrective invoices.

On the execution of queries via mobile apps, DG SANTE noted that the Implementing Regulation required the provider of the secondary repository to make available an API that allows public authorities to connect to the non-graphical interfaces with a system and analytical software of their choice. This included the use of mobile apps.

On whether a cash register document qualifies as invoice, DG SANTE referred to the application of the relevant legislation in this field, e.g. VAT legislation under which the cash register document is considered a simplified invoice.

On the resale of goods that are returned from a retail outlet, the Subgroup agreed that the reporting of a product return (in the form of an 'arrival message') corresponds to the physical arrival of that product to a facility. Consequently, a resale of products should only take place after the product return took place.

Extract of Summary Record of 21 June 2019

[…]

3. Discussion

3.1. Performance of the repositories system

[…]

Afterwards, the Subgroup discussed the receipt of error messages concerning the nonexistence of UIs, which several economic operators had encountered. SANTE explained the most common reasons for why a submitting entity could receive this error message in response to a transmitted reporting message. The reasons are:

- The UI in question is a pre-TPD/legacy UI. Such a UI has never been reported to the router and the secondary repository, and therefore cannot be validated;
- The UI in question is a new UI, but its application has not yet been reported to the router / secondary repository. In this case, economic operators should verify whether earlier reporting activities might still need to be completed. If this is not the case, economic operators should contact the manufacturer/importer of the product at question to seek confirmation as to potential delays in the processing of data at the level of the primary repository;
- The UI in question has not been encoded or decoded in line with the existing formatting instruction. Economic operators should consult the clarifications on the reporting of UIs made available in Dentsu's data centre.

[…]

Finally, SANTE noted that whether an economic operator could continue to trade tobacco products upon the receipt of this specific error message depended on the context, as explained earlier. The assessment was the sole responsibility of the economic operator(s) concerned.

[…]

3.3. Decoding of flat files

In response to a clarification request, SANTE outlined the general requirements on the creation and transmission of flat files. According to Article 20 of Implementing Regulation 2018/574, competent ID issuers are responsible for preparing offline flat files, along with the necessary explanatory notes, and transmit these to the secondary repository. Article 25(1) of the Regulation furthermore empowers Member States to download any set of data from the repositories system, including offline flat files and the explanatory notes. In this regard, SANTE clarified that Dentsu is not obliged to combine all offline flat files into a single encrypted file.

3.4. Registration of economic operators without VAT and TAX number

In the EU, publicly owned entities may engage in the sale of tobacco products and therefore must acquire an EO-ID and F-ID. These public entities normally do not have a VAT or tax number. The Subgroup agreed that, in these cases, when requesting an EOID, it would be appropriate to fill in the following information: VAT_R = '0' (meaning: 'no VAT registration') and TAX_N = 'public entity'. SANTE confirmed that the validation rules at the level of the ID issuer and router should permit this data entry.

3.5. Request of UIs for test products (absence of TP-ID/TP-PN)

SANTE recalled previous discussions in the Subgroup regarding the request for UIs that are applied to test products. In this context, the question on the reporting of TP-ID and TP-PN as part of the request for a UI arose. If test products are not made available to consumers on the territory of the Union, they do not require reporting to the EU-CEG (EU Common Entry Gate). Therefore, these products do not have a TP-ID and PN. The Subgroup agreed that, in these cases, when submitting a request for UIs, it would be appropriate to fill in the following information: TP_ID = '99999-99-99999' and TP_PN = 'test product'. SANTE confirmed that the validation rules at the level of the ID issuer and router should permit this data entry.

[…]

3.8. Sharing of data in the traceability system with economic operators (national enforcement activities)

The Subgroup discussed the scenarios in which Member States may decide to provide an economic operator with an extract of certain data sets in the repositories system, for example, to allow the economic operator to meet its obligations under the legislation (reporting of stolen products, etc.).

SANTE clarified that the sharing of data extracts is subject to the assessment of individual Member States. The sharing of data extracts is not the same as access to the data storages, which, in principle, is limited to Member States, the Commission and approved external auditors.

4. Q & A

One Member State representative inquired into the procedure for economic operators to contact Dentsu in the case of technical problems. SANTE clarified that Dentsu has an online ticketing system in place and that, in principle, submitted inquiries would be treated based on the time of receipt but that the severity of the issue may of course also be taken into account. The Subgroup discussed the registration of logistic terminals in harbours and in which circumstances these terminals required their own F-ID. Several Member States shared the view that terminals operated by the legal entity that also operates and controls the harbour do not require a separate F-ID. It may be appropriate to decide that these terminals are covered by the F-ID that is used to register the harbour facility as a whole. Terminals that are operated by legal entities other than the one operating the harbour must be registered separately. In response to a question from one Member States, it was recalled that if a chain operator of branded shops issues invoices to its affiliated shops with regard to the tobacco products, even if that operator does not physically tackle the products which are delivered to the affiliated shops directly by a specialised distributor, there is a requirement to report on those invoices. In the same manner, that operator has to report on the payments that it receives from its affiliated shops in relation to the invoices.

Extract of Summary Record of 5 September 2019

[…]

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.

[…]

3.5. 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.

[…]

4. Discussion

[…]

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.

[…]

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. 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

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.

Extract of Summary record 7 November 2019

[…]

4. Discussion

[…]

4.2. Release of technical specification version 1.4

One Member State raised practical and legal questions concerning the requirement in the new specification that tobacco products be scanned at the same level of aggregation when they are sent and when they are received. In SANTE's view, the update of the technical specifications does not introduce any additional or unexpected regulatory changes to the traceability system. A number of preventive measures are being taken to limit the market impact as much as possible, including: a soft launch (warning messages in the first month before error messages kick in from 1 February); a generous rollout timeframe (3 ½ months, 1 ½ months longer than legally required); guidance documents and educational efforts by MSs and SANTE. A small correction of the initial release (v. 1.4.1) was necessary to ensure that the receipt of goods that arrive at a facility other than the one initially intended is not blocked by the system.

[…]

4.4. Transloading to vending vans

SANTE referenced discussions on this topic in the 16 October Subgroup meeting, where it was concluded that "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." One economic operator had proposed to insert the word 'many' or 'multiple' in the destination field of transloading messages. Participants agreed that this goes against the idea of reporting on transloading activities and also does not comply with the rules set out in Annex II to the Implementing Regulation.

[…]

5. Q&A

5.1. Timeframe for reporting on payments and invoices

On the timeframe for reporting payments that occurred several days after an invoice had been issued, SANTE noted that payments and invoices should be treated as separate events. The information should be transmitted within 24 hours of the occurrence of the transactional event. The event is deemed to have occurred as soon as it can be linked to the UIs concerned.

Reporting of transactional information in the case of chain transactions and triangular transactions

SANTE recalled previous discussions on this topic, resultant conclusions can be found in the respective summary records. Every transactional event and every logistic event must be recorded and transmitted to the secondary repository. In the case of chain transactions (or the special case of triangular transactions), the supplier must report the dispatch to the recipient and the latter, unless a first retail outlet, must report the arrival. The vendor(s) must report the related transactional information. If, for example, multiple purchasing activities are carried out by different economic operators in the chain, each economic operator is obliged to record and transmit the transactional information for which they are responsible (as a vendor).

5.2. Home-based sales agents

[…]

Dispatches and arrivals must be recorded by the sales agent using the specific vending van message; transactional information must also be recorded. Their home address should receive a Facility ID and their private/corporate car be treated as a vending van.

5.3. Reporting on the return of products

SANTE advised that products can be returned to a facility other than the facility from where it was dispatched. There are no restrictions on the Facility ID in the product return arrival message.

[…]

SANTE noted that the Implementing Regulation provides for a few general exceptions (e.g. stock exhaustion, reporting timeframe, ATD); beyond these exceptions, it is not aware of any additional exceptions granted by a Member State. SANTE recalled the obligation of national authorities to enforce the provisions of the TPD, which includes the recording of movements/transactional information.

[…]

Extract of Summary record 28 January 2020

[…]

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.

[…]

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.

[…]

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.

[…]

Extract of Summary record 24 March 2020

[…]

2. Communication from the Commission

[…]

2.9. Declarations concerning anti-tampering devices under Article 7(2) of Commission Implementing Regulation 2018/574

SANTE recalled the obligation of an independent third party that supplies and installs an antitampering device) at the manufacturers' premises, to provide a declaration to the relevant Member States and the Commission attesting that the installed device meets the requirements of Implementing Regulation 2018/574 (Art. 7(2)).

In this regard, it was pointed out that for several economic operators (not covered with the derogations of Art. 7(6) of the Implementing Regulation and therefore obliged to have installed the anti-tampering device) the obligatory declarations were missing. SANTE added that in one case, anti-tampering device certification documents were submitted instead of the expected declaration.

[…]

4.Q&As / Discussions

[…]

4.1. Third party reporting to T&T system

A Member State asked if third parties that are themselves also economic operators in the sense of the Implementing Regulation can report to the T&T system on behalf of other economic operators. SANTE replied that in principle, there is nothing in the legislation that would prevent a third party (operator A) from providing such a service and reporting into the system on behalf of another economic operator (operator B). However, in such a case, it is important that the identifications (i.e. EOID, FIDs and MIDs) of operator B are used for reporting purposes, since operator A acts as a mere service provider. Operator B also remains legally responsible for the correctness and completeness of reports.

4.2 Deactivation of "expired" UIs

A Member State enquired how non-applied UIs are deactivated after the elapse of six months from their receipt. SANTE clarified that this rule is implemented in the validation layer of the reporting system (point 8.2.4.4 in the technical specifications). This also implies that economic operators will receive an error message from the system if they attempt to report the application of an UI after six months from the date of its receipt.

4.3. Reporting obligations for retail outlets sending tobacco products to selected facilities, where tax inspector renews tax stamps that got out dated

A Member State asked if retail outlets sending the tobacco products that were already placed on the market to other facilities (including facilities that may carry out retail activities), for the purpose of tax-stamp renewal, are obliged to report to the T&T system. After the renewal of tax stamps, the products are to be returned to the original retail outlets. SANTE clarified that retail outlets are not required to report to the system. However, it was also noted that in this scenario, products are sent to a facility where those products are not intended to be placed on the market. The operator of that facility, where the tax-stamp renewal takes place, has to report to the system in line with the rules applying to all other facilities in the distribution chain. The situation in question is similar to the case of cash & carry operators; the fact that some retail operations take place under the same roof does not exempt a given facility and its operator from the reporting obligations as regards distribution activities.

4.4 Marking of double packages

A Member State asked how doubles packages of tobacco products should be marked. SANTE clarified that doubles packages are packages of two unit packets of tobacco products and as such, they fall within the scope of `aggregated packaging` as defined in Article 2(5) of the Implementing Regulation.

SANTE further added that the distinction between `a unit packet` and `an aggregation of unit packages`, as the two types of packaging in which tobacco products are placed on the market, was established in Article 2(29) of Directive 2014/40/EU. It was recalled that Article 15(5) of Directive 2014/40/EU provides for the possibility to mark and record at aggregated packaging level provided that the tracking and tracing of all unit packets remains possible, while Article 10(1) of the

Implementing Regulation further specifies that economic operators shall mark aggregated packages containing tobacco products with an aggregated level unique identifier, where they choose to comply with their recording obligations provided for under Article 15(5) of Directive 2014/40/EU.

SANTE concluded that it is up to an economic operator to mark or not to mark such double packages with aggregated UIs. However, once marked, the aggregated UIs must be used in line with the Implementing Regulation, e.g. in certain situations they may constitute the highest level of available aggregation subject to reporting.

4.5. Reporting of products intended for destruction

A Member State asked how the national competent authorities should handle 'legally marked' tobacco products that were confiscated. SANTE pointed out that in terms of its logistic implications; the situation is analogous to the collection of products for the purpose of lab tests at the government-operated facilities, unless the confiscated products are supposed to be given back to an economic operator. Therefore, the same line as agreed by the Subgroup of 8 May 2019 was proposed: for dispatches to governmental locations, no recording obligations apply. Instead, if it known that the confiscated products are not to be returned (e.g. will be destroyed), economic operators should send a request for deactivation of the products concerned to the traceability system, including a comment that the deactivation concerns products that have been handed over to a national authority. SANTE clarified that in the specific case of confiscated goods, the obligation to send a request for deactivation should fall on the last legal EO known in the traceability system as handling the confiscated goods. The state authorities do not need to report to the traceability system themselves; they just need to check if the EO in question has met its obligations.

A Member State asked if UIs that have been deactivated, can be recalled (e.g. when the police finds stolen tobacco products that have been deactivated and want to return the products to the rightful owner) and if yes, which economic operator should do the recall. SANTE clarified that the reactivation of deactivated UIs is not possible. It was further explained that a product reported as stolen requires the deactivation of the corresponding UI so that when this product eventually reappears (e.g. not stolen but only temporarily lost), a new UI will be required. Only then, the product can be re-introduced into the supply chain.

A Member State asked if products destroyed at the first retail outlet need to be deactivated. SANTE replied that there are no reporting obligations for products that have already been placed on the market. If products are confiscated from or destroyed at a retail outlet and those products have been reported in the system as dispatched to a retail outlet, then there is no need for the UIs of those products to be deactivated.

Finally, a Member State asked if economic operators (i.e. wholesalers, importers or manufacturers) that receive from retail outlets products that are intended for destruction at their level need to deactivate the relevant UIs of those products. SANTE confirmed this, explaining that in this case the economic operator of a facility at which products arrive after their return from a retail outlet, first needs to report the return of those products, and then, after the products are destroyed, needs to transmit a deactivation request.

4.6. Tobacco products intended for exports to Russia: the requirement of two fiscal stamps

A Member State asked if SANTE was aware of problems that small producers of tobacco products face when they export their products to Russia in relation to a requirement for double fiscal stamps that is allegedly related to the T&T systems adopted by the EU and Russia.

It was clarified that the marking of tobacco products with national tax stamps, including potential requirements to combine UIs with a tax/fiscal stamp, is a matter of national competence and if needed, should be addressed to the relevant national competent authorities. However, the Subgroup was not aware of any requirement to include tax stamps for products that are destined for exports.

[…]

Extract of Summary record 9 June 2020

[…]

2. Communication from the Commission

[…]

2.5. Commission Notice on the withdrawal of the United Kingdom and EU rules on Tobacco and related products

SANTE referred to the Commission Notice on the legal situation that is expected to apply to UK and Northern Ireland after the end of the transition period established by the withdrawal agreement signed between the UK and EU. A web-link to the relevant notice was shared with the Subgroup: https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/tobaccoproducts_en_0.pdf.

[…]

2.8. Audit guidelines

SANTE recalled that the Commission Guidelines were published on 15 May, and underlined that the document aims to provide general guidance to an approved auditor on the scope of the audit and the procedure for submitting the annual audit report.

[…]

2.11. Publication of the UI encoding structures

SANTE informed the Subgroup that a full overview of the coding structures of unique identifiers from all the ID issuers is publicly available (see relevant link: https://ec.europa.eu/health/sites/health/files/tobacco/docs/tt_codingstructure_en.pdf).

3. Communication from Member States

3.1. Mobile apps developed at national level to access repository data

An ID issuer presented its mobile application being developed to access the traceability data for control purposes. The application is intended to be made available for use by the competent

authorities of Member States. The functions and objectives of the application as well as its potential for further extensions were explained.

[…]

4. Q&As / Discussions

4.1. Recording returns of products with damages

A Member State asked how to record the return of tobacco products, which have suffered damages (i.e. the UI code is no longer readable). SANTE clarified that there are two available options for the economic operators in this regard: a) to turn to their upstream business partners in order to inquire the missing information, b) to ask the respective Member State to provide them with an extract of the certain data sets in the repositories system to allow them to meet their obligations under the EU tobacco traceability legislation. In the latter case, the sharing of data extracts is subject to the assessment of individual Member States.

[…]

4.2. Reporting on the movement of products to a non-EU military base located in the EU

[…]

SANTE referred to differentiation between test products sent to public authorities and those delivered to third party laboratories that was discussed during the meeting of the Subgroup of 8 May 2019. In particular, SANTE reminded that while movements of test products to nongovernmental facilities are subject to the reporting obligations under the traceability system, 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.

It was underlined that for the discussed scenario, a deactivation message should include a comment that it concerns products to be delivered to a military base, including its address, and such a message should be introduced in the system before products are actually dispatched.

4.3. Error messages while reporting to the T&T system

[…]

SANTE listed the necessary steps the economic operators receiving errors need to follow: a) verify whether their own reporting operations are fully compliant; b) if needed, contact their supplier(s) to verify whether the earlier reporting obligations have been fully and correctly discharged; c) consider launching a support ticket with Dentsu as the router's operator if after contacting their supplier(s) the source of errors cannot be established and eliminated. Finally, SANTE noted that the economic operators may also contact the national competent authorities, who have access to the EU system and, in duly justified cases, may consider verifying the information for economic operators.

4.4 Reporting problems for tobacco importers placing their products on several EU markets

An ID issuer referred to the case where tobacco products imported into the Union are expected to be placed on several EU markets, and reporting problems may result from the assignment of different EOIDs and FID. SANTE stressed that the Implementing Regulation requires importers to be equipped with potentially several EOIDs, i.e. one EOID per ID issuer/intended EU market, but only one FID/MID per non-EU facility/machine. The rule of using one FID/MID should not prevent an importer from placing products on several intended EU markets.

SANTE further added that it pointed at upgrading the VAL_ENT_REL_EOID_FID validation (see Dentsu's technical specifications) by including a check against not only the "main" EOID, but also the "other" EOIDs, i.e. use the information that should be available in the "OtherEOID_N" field (see message 1.1 in Annex 2 to the Implementing Regulation). Dentsu already confirmed that they will include the above fine-tuning to the validation in the next maintenance release and communicate this update to the ID Issuers.

4.5. Commercial vessels and ferries/cruise ships

[…]

SANTE reiterated that the main element to consider is the physical location of a product when the latter is made available to the consumers. On the definition of the EU waters, SANTE replied that the EU waters are considered the EU Member States' territorial waters, whose extension is defined by international conventions and the legislation of the Member States, in general 12 nautical miles.

[…]

A Member State asked which market is considered to be entered as "Intended market" when the delivery is considered an export and the UIs need to be issued in the Member State where the production takes place. SANTE suggested that the intended market should be coded "XZ", which is a free code at the disposal of users of ISO 3166. The same code is tentatively recommended for international waters in a geographic coding scheme developed and maintained by United Nations Economic Commission for Europe (UNECE).

4.7. Clarification on the upUI(s) data type

SANTE clarified that the upUI(s) data type reflects a human readable code that is required under Article 23(1) of the Implementing Regulation. Each ID issuer defines its variant of upUI(s). The adopted format may or may not coincide with the upUI(L) data type after trimming away the time stamp.

Extract of Summary record 8 September 2020

[…]

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).

[…]

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.

[…]

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

[…]

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.

[…]

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.

[…]

4. Q&As / Discussions

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

[…]

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.

[…]

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.

[…]

Extract of Summary record 19 November 2020

[...]

2. Communication from the Commission

2.1. Reporting on the functioning of the system

SANTE provided an overview of the new technical specifications published on 31 October 2020. The overview presented the main changes, in particular the addition of XI (a code distinguishing Northern Ireland from Great Britain) as a new code in the list of country codes (for a detailed description of the technical specifications, click on the link: https://eusecondary.dentsuaegistracking.com/eu-secondary-data-dictionary/.

[…]

2.5. Brexit-related issues

SANTE clarified the implications of Brexit on the EU tobacco traceability system and the EO's obligations set out in the relevant EU legislation.

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

SANTE presented the Commission Decision on the approval of external auditors that was adopted on 26 October 2020. Its scope, addressees and main provisions were detailed.

[…]

5. AOB & Closing remarks

CY introduced a case where tobacco products sold in duty free shops were not compliant with the rules on tobacco traceability and asked whether enforcement actions must be taken in this case. The Subgroup shortly discussed this scenario. SANTE stressed that the directive sets out the territorial applicability of Article 15 in terms of geographical scope, and that tobacco products sold in duty free shops located at the airports of Member States – regardless of their destination – are subject to the tobacco traceability rules.

Extract of Summary record 18 March 2021

(This meeting had three different sessions. IT providers of repositories participated only in session 2 of the meeting)

Session 1 - only Member States' representatives

1. Welcome and introduction

[…]

The Chair referred to the EU Beating Cancer Plan that was presented by the Commission on 3 February 2021, with a focus on the Plan's objectives. In addition, the Chair analysed the contribution of the EU tobacco traceability system to these objectives.

2. Communication from SANTE

2.1. Report of Article 28 of Directive 2014/40/EU

SANTE explained that the Commission is required to submit a report on the Tobacco Products Directive's application by 20 May 2021. The Report's state of play and relevant findings regarding the tobacco traceability system were presented to the Group.

[…]

Session 2 - Member States' representatives and IT providers

[…]

Session 3 - only Member States' representatives

2.6. Brexit-related issues

SANTE informed the Group that the UK, in respect of Northern Ireland, would make use of the derogation of Article 4(1)(2nd subparagraph) of Implementing Regulation 2018/574, namely it designated competence to generate and issue unique identifiers to the UK's competent ID Issuer for the products expected to be placed on the market of Northern Ireland.

In addition, SANTE referred to the issue of goods transported from the EU to Northern Ireland via Great Britain and emphasised that dis-aggregation and re-aggregation of the concerned tobacco products outside the EU system in transit via a third country) is contrary to the applicable rules. Any alternation to the level of aggregation (that is reported at dispatch from an EU facility) during the transit via Great Britain will block the correct reporting of the arrivals of these products at their destination in Northern Ireland. SANTE also presented the state of play as to the discussions with the UK authorities on this issue.

[…]

2.8. Anti-tampering devices: New declaration form

SANTE informed the Group that the declaration form that the independent third parties supplying and/or installing the anti-tampering device need to submit to the Member States and the Commission in accordance with Article 7(2) of Implementing Regulation 2018/574, has been updated. It was explained that the relevant tobacco companies were invited to submit, in collaboration with their supplier/installer of anti-tampering devices, the updated declarations forms.

2.9. Anti-tampering devices: Discussion concerning the overlapping of the anti-tampering device's requirements under the EU and third-country Track and Trace systems

SANTE explained that an anti-tampering device (ATD) provider asked how an ATD could satisfy the parallel requirements resulting from two overlapping T&T systems (i.e. the systems established separately in the country/region of exportation/manufacturing and of importation/consumption). SANTE's preliminary assessment was that it was possible that the same hardware elements of an ATD, such as a camera or a scanner, are used for capturing unique identifiers. However, it was underlined that the actual data logs generated by the ATD should be separate and store only the relevant information for a given jurisdiction. The Member States agreed with SANTE's preliminary assessment.

[…]

3. Q&As / Discussions

[…]

4.2. Returns of products from a first retail outlet to a wholesaler: existing validation controls

One Member State asked which entities were required to report to the system the products' returns from the first retail outlets and what type of validation controls were in place for registering the returns.

SANTE confirmed that in this case, the first reporting obligation lies with the economic operator (distributor/supplier) of the facility at which goods arrive after the return from the first retail outlet. This EO is responsible for reporting (to the router) the return event by indicating in the 3.4 arrival message that the arriving products are a return (following complete or partial non-delivery).

Regarding the applicable validation controls (relating to EO_IDs and F_IDs), SANTE clarified that the system is not checking the EOID in the arrival message (used for the return) against the EOID in the dispatch message (to the first retail outlet), nor the FID of return in the arrival message against the FID of the dispatch message. In other words, a product can be returned to a different warehouse than the one that originally dispatched that product to the retail outlet.

4.3. Uniqueness of the human readable code

One Member State referred to SANTE's email asking all ID Issuers to modify, if necessary, their specifications to make sure that the human-readable code enabling electronic access to the information related to the unique identifiers stored in the repositories system, is unique in itself.

SANTE repeated the obligation stipulated in Article 23(1) of Implementing Regulation 2018/574 and stressed that the human-readable code can lead correctly to the information related to the unique identifiers stored in the repositories system only if it is unique in itself. In a different case, the correct unique identifier cannot be accessed and consequently, Article 23(1) is not respected. SANTE also explained that the lack of uniqueness of the human-readable code undermines the functioning of the system, including for product verification activities when the optical data carrier is damaged or an inspector cannot rely on a scanning device.

The Member States were invited to verify their ID Issuers' practice and any existing documentation for compliance with Article 23(1) of the Implementing Regulation.

4.4. Delivery of products by means of vending vans

One Member State asked how delivery of products by means of vending vans should be reported to the system. SANTE explained that in this case, the concerned economic operators need to submit: (i) message 3.3 on dispatch of tobacco products from a facility with value '4' to be indicated in the field 'Destination_ID1' delivery with VV; (ii) for each retail outlet, message(s) 3.7 on the actual delivery(ies) carried out with a vending van; and (iii) for any remaining products, message 3.4 on arrival of tobacco products at a facility with value '1' indicated in the field 'Product_Return'.

4.5. Tobacco products (other than cigarettes and roll-your-own-tobacco) being subject to the traceability system as of 20 May 2024

SANTE reminded the Subgroup that the Tobacco Products Directive implements the EU's international obligations, i.e. Article 8 of the FCTC Protocol, which requires that the traceability system covers all tobacco products. It was also noted that under Implementing Regulation 2018/574, manufacturers and importers of tobacco products other than cigarettes and roll-your-own tobacco shall notify to the Commission: a) the identity of their proposed primary repository provider; b) a draft data storage contract and c) the necessary declarations (of technical and operational expertise and of legal and financial independence) by 31 December 2022 (see point 6 in Annex I to the Implementing Regulation).

[…]

Extract of Summary record 30 June 2021

[…]

2. Communication from SANTE

2.1. Report on the application of Directive 2014/40/EU

SANTE announced that the Report on the application of Directive 2014/40/EU and the support study that gathered evidence for the Report, were published on 20 May 2021. The Report's relevant findings regarding the tobacco traceability system were presented to the Group.

[…]

2.3. Reporting on the functioning of the system

SANTE provided an overview of Dentsu's new technical specifications that were published on 15 June 2021. The overview presented the main changes related to sequence validations on certain movements of the products (for a detailed description of the technical specifications, click on the link: https://eu-secondary.dentsuaegistracking.com/eu-secondary-data-dictionary/).

[…]

2.7. 1st audit year of the T&T system: Assessment of the audit reports

SANTE presented its assessment of the audit reports that were submitted for the first operational year of the tobacco traceability system. All the Member States took the floor and indicated whether they received the reports from the auditors and whether the Subgroup is the right forum for discussing the reports' content and the corresponding processes.

2.8. 2nd audit year of the T&T system: Submission of the auditors' notifications

SANTE informed the Group that the procedure on the assessment and approval of the notifications of the proposed auditors for the second operational year of the tobacco traceability system is in progress. In this regard, it was highlighted that auditors who were proposed by certain tobacco manufacturers and approved for the purpose of the previous audit year by the Commission, will continue their tasks in the absence of any new notifications that would need to be submitted by the concerned tobacco companies.

2.9. Anti-tampering devices' declarations: findings of the verification exercise and new research

SANTE reminded the Group that as of 21 May 2021 economic operators falling under the definition of small and medium enterprises are also obliged to install an anti-tampering device and consequently, submit the declaration form of Art. 7(2) of the Implementing Regulation. Consequently, only economic operators that follow fully manual production processes, are now exempted from the relevant obligations.

SANTE also presented the results on the review of the anti-tampering devices' declarations that have already been submitted to the Commission. More specifically, SANTE explained that for anti-tampering devices installed in non-EU facilities, certain declarations indicated wrongly the details of the non-EU manufacturer instead of the details of the EU importer(s) who is ultimately responsible for the verification of unit level UIs with an anti-tampering device. It was stressed that this approach goes against Articles 16(4) and 18(3) of the Implementing Regulation, which requires the importer to take responsibility for the registration of non-EU manufacturing facilities and machines.

Other anti-tampering devices' declarations indicated wrongly a MID instead of the relevant FID or two separate FIDs instead of one single FID. It was stressed that this approach goes against Articles 14(1), 16(1) and 18(1) of the Implementing Regulation which establish the compulsory singularity of the identifier codes for economic operators, facilities and machines (i.e. economic operators, EU facilities and machines can have only one identifier code). The cases of non-EU facilities and machines that can be registered independently by different EOs, and cash & carry stores and Spanish local retail-level distributors providing products to vending machines in their neighbourhood and selling directly to consumers, were indicated as exceptions to this rule.

Finally, SANTE presented statistics on the total number of anti-tampering devices used for the verification of unit level UIs as declared by the anti-tampering devices providers/suppliers, the total number of machines registered (active and inactive) by the relevant tobacco companies and the number of active manufacturing machines and the EOID and FID of the same tobacco companies. In this regard, it was emphasised that the number of the AT devices declared should be equal to the number of the (registered) active manufacturing machines. If this is the case, the anti-tampering device declaration that was submitted, is considered complete and no follow-up actions are necessary.

[…]

4. Q&As / Discussions

4.1. Anti-tampering devices: functions and objectives

One Member State asked whether the manufacturers can switch off their anti-tampering devices when they are not producing tobacco products, and instead are producing non-tobacco products on the same production line. SANTE replied in the negative and stressed that the manufacturer should not switch off their anti-tampering devices when the production line is not operated. If switched off, the device cannot adequately protect the verification of the UIs in terms of correct application and readability and as a result, it does not meet the requirements of Articles 2(7) and 7(1) of the Implementing Regulation.

The same Member State also asked whether the manufacturers can use two anti-tampering devices (from the same supplier) on the same production line. SANTE clarified that there is no hindrance of having two anti-tampering devices or a back-up anti-tampering device that can be used to continue the production without disruption if the other fails to operate.

4.2. Financing the Track & Trace system

One Member State raised a question about the scope of the manufacturers' obligation to finance the tobacco traceability system. SANTE stressed that the obligation of the tobacco companies to provide all EOs with the equipment that is necessary for the recording of the tobacco products, should be separated from the obligation of the same companies to cover the costs related to the establishment, operation and maintenance of the repositories system. The first obligation falls within the scope of Article 15(7) of the Tobacco Products Directive and was not specified in the Implementing Regulation. As a result, it is for the Member States to transpose it into their national law. On this matter, SANTE also referred to the previous discussions of the Subgroup according to which a one-time payment to economic operators would not be compliant with the obligations set out in Article 15(7) of the Directive.

4.3. Laboratory equipment sample packs

One Member State asked whether laboratory equipment packs fall within the scope of the tobacco traceability system. SANTE replied in the affirmative and clarified that test products should be tracked and traced as any other tobacco products and referred to the previous Subgroup's discussions on this topic. The Subgroup discussed the case where test products are dispatched to a test lab and expected to be subsequently returned to the concerned manufacturer, and agreed that such a dispatch should not be followed with a deactivation message, because that would block the return of test products to the manufacturer.

The Subgroup discussed the case where test products are dispatched to a test lab and expected to be subsequently returned to the concerned manufacturer, and agreed that such a dispatch should not be followed with a deactivation message, because that would block the return of test products to the manufacturer.

[…]

5. AOB & Closing remarks

[…]

On the reporting of a transit shipment via a third country e.g. from FR to NI via GB, SANTE clarified that these cases should not be treated as exports. This means that the dispatch message that the economic operator in FR should submit to the system, should indicate the NI destination as EU destination (namely message 3.3. of Annex II, Destination ID1 and then value 2-EU destination

other than VM) in order to enable the economic operators in the NI facility to report these arrivals and the system to perform the necessary FIDs' validation controls.

Extract of Summary record 16 September 2021

[…]

Note!
This meeting was divided into 3 separate sessions. The first session was devoted to a discussion between the Commission and the Member States' representatives. The second session was devoted to a discussion between the Commission, the Member States' representatives and the anti-tampering devices' providers. The third session was devoted to a discussion between the Commission andthe Member States' representatives.

[…]

Session 1

2.4. Data quality statistics

SANTE presented Member State by Member State statistics on the supply chain coverage that was focusing on the mismatch between the intended market and actual deliveries of the products for the second and third quarter of 2021. Another research that was based on the retail level data (deliveries per capita in the regions of specific Member States) was also presented to the Subgroup.

The Subgroup discussed the findings of the above statistics. SANTE pointed out that the statistics signal the existence of certain misreporting in a number of Member States, stressed the importance of enforcement actions at national level and invited the concerned Member States to step up the enforcement activities.

One Member State replied that the statistics are used by the competent authorities for the purpose of monitoring the correct application of the relevant legislation at national level.

Session 2

SANTE recalled the main rules on the anti-tampering devices that establish their functions and requirements for the availability and access to the data recorded by these devices during the verification process.

SANTE highlighted the need for the Member States who can request access to the data recorded in accordance with Article 7(5) of Commission Implementing Regulation (EU) 2018/574, to understand the functioning of the existing anti-tampering devices.

Presentations by the anti-tampering devices' providers

The representatives of the relevant companies explained the different components and technical characteristics of the anti-tampering devices, their practical role in the verification of unit level UIs and the different data storage options followed so far.

Exchange of views between the Commission, the Member States and the anti-tampering devices' providers

The representatives of the anti-tampering devices' providers replied to the Member States' questions on the role of the different parts of these devices, their compliance with the requirements of the Implementing Regulation as well as the practical steps for accessing the record of the verification process created by the anti-tampering devices.

[…]

Session 3

Communication from Member States

The issue of granting manufacturers and importers access to the tobacco traceability data in duly justified cases in line with Article 15(8) (subpara 3) of the Tobacco Products Directive was discussed.

One Member State asked if access can be granted in the context of a commercial conflict between two or more economic operators. The Member States which took the floor, explained that the requests for access to the relevant data come usually from police or judicial authorities regarding ongoing legal proceedings against specific economic operators, and access is granted solely to these authorities.

Another Member State raised the issue of misuse/theft of EOIDs. SANTE explained that at the moment, there is no authentication-validation of the EOID and that the authentication exists only for the credentials/client ID of the EO reporting to the system (or the service provider reporting on behalf of the EO). Linking the client ID to each reporting event/product movement was discussed as a solution to this problem.

4. Q&As / Discussions

4.1. Article 9(4) of Implementing Regulation: Physical delivery of unit level UIs

One Member State asked whether in the case of physical delivery of unit level UIs the ID Issuer is the only entity that can deliver the UIs to the requesting manufacturers or importers. SANTE replied in the affirmative and clarified that in this case, only ID Issuers are entrusted with the tasks of delivering and encoding the UIs. However, it was also stressed that nothing prevents the scenario

in which the UIs are delivered electronically, but then the economic operators print them on labels, which in turn are being affixed to products as long as the conditions of Article 15(1) of the Tobacco Products Directive are respected.

4.2. Reporting bulk packaging of tobacco products imported from a third country

One Member State asked for clarification on the obligation of importers to mark with unique identifiers packs of tobacco products resulted from a bulk package of loose tobacco that was imported in the EU. SANTE clarified that according to Article 15(1) of the Tobacco Products Directive, the obligation to mark tobacco products with unique identifiers lies at the level of the unit packet that is defined in Article 2(30) of the Directive as the smallest individual packaging of a tobacco or related product that is placed on the EU market. Regarding tobacco products manufactured outside of the EU, SANTE underlined that this obligation falls on the importer.

4.3. Defining the intended market when requesting unit level UIs

One Member State asked for clarification on the intended market that needs to be reported by manufacturers and importers requesting unit level UIs from the competent ID Issuer. SANTE explained that the Implementing Regulation (Annex II, section 2.1) defines the intended market as the intended country of retail sale. Technically, there is no possibility to update this field and the system does not block the products if they placed on a different EU market than the one that was initially declared. However, SANTE underlined that it is always necessary for manufacturers and importers to know in advance their products' intended market as this will define the language of the mandatory health warnings referred to in Article 8(1) of Tobacco Products Directive.

Extract of Summary record 24 November 2021

[…]

3. Communication from Member States

One Member State presented the procedure and timeline for the application of Article 4(1)(subparagraph 2) of the Implementing Regulation that designates the ID Issuer of this Member State competent for generating and issuing unique identifiers to economic operators who place their products on the national market of this Member State. The same Member State clarified that an inter-ministerial decree modification is necessary so that the above provision can take effect, and provided information about the new fee cost of the national ID Issuer given this development.

4. Q&As / Discussions

4.1. Applying for EOID(s) as EO or importer

One Member State asked about the number of EOIDs manufacturers and importers of tobacco products should apply for and receive. SANTE clarified that regarding economic operators (except for importers), this depends on the Member States in which the economic operators operate at least one facility. If an economic operator operates facilities in several Member States, it has to apply for EOIDs from all competent ID Issuers, namely from all ID Issuers competent for the Member States where these facilities are located.

With regard to importers, the number of the EOIDs depends on the national markets where their products are placed. This means that importers who place their products on more than one national markets need to apply for and receive identifier codes from all competent ID issuers. The importers who have already been allocated an identifier code from one of the competent ID Issuers, need to indicate it in their request for new identifier codes (see fields 'OtherEOID_R' and 'OtherEOID_N' of section 1.1. of Annex II of the Implementing Regulation). This information will allow the system to properly link all identifiers allocated to the same importer.

Another Member State asked whether an economic operator who operate facilities in two Member States, need to apply for two different EOIDs in case the competent ID Issuer of these two Member States is the same. SANTE answered in the affirmative and clarified that this approach ensures the correct application of Article 15(4) of the Implementing Regulation, namely the possibility for one of these two Member States to request, in duly justified cases that are applicable only in this Member State, the deactivation of the EOID (linked to the economic operator's facility that is located at the requesting Member State) without deactivating at the same time also the other EOID.

4.2. Unit level UIs for hand-made cigars

One Member State raised a question about the data fields a producer of hand-made cigars needs to fill in when requesting unit level UIs for their cigars, and in particular, whether the machine identifier code should also be indicated in this request. SANTE clarified that in the case of fully hand made products, the producers do not have to indicate the M_ID since the production process does not involve machinery (see field "process_type" in message 2.1. of section 2 of Annex II to the Implementing Regulation).

The same Member State asked about the location of a UI, in particular whether it has be placed on a box containing unpacked cigars or on each individual cigar. SANTE clarified that in accordance with Article 15 of Directive 2014/40/EU, all unit packets which are defined as the smallest individual packaging of a tobacco or related product that is placed on the market, have to be marked with a unique identifier. However, the Directive does not define the exact content of a unit packet of cigars, namely how many individual cigars a unit packet (of cigars) shall include. SANTE also explained that this question is related to the obligation of a tobacco product to have packaging when being placed on the market. Considering that the traceability obligations apply to the unit packet which is also a type of packaging (the smallest individual), market products can be placed on the market only if they are packaged in accordance with the labelling and packaging requirements described in Chapter II of Directive 2014/40/EU.

4.3. Possibility for EOs who have the dual role of importer and manufacturer in the same MS, to acquire two EOIDs

One economic operator asked whether a company having the dual role of manufacturer and importer (for a non-EU manufacturer) in the same Member State needs to receive an EOID from the ID Issuer in order to route all events related to the imported products to the primary repository of the non-EU manufacturer.

The Group discussed this scenario and agreed that there are two types of of importers: a) importers cooperating with only one non-EU manufacturer and being solely importers, and b) importers cooperating with several non-EU manufacturers and/or being also an EU manufacturer themselves.

As regards the first type of importers, it is acceptable that they co-sign or join a data storage contract for a primary repository together with a non-EU manufacturer. In the regulatory terms, such an arrangement is very similar to the existence of a single data storage contract for the entire group of undertakings, e.g. national subsidiaries of the multinational group.

The same arrangement is not possible for the second type of importers who need to work with their own primary repository. This implies that these companies cannot report information to the primary repository of the non-EU manufacturer. In addition, SANTE clarified that an importer who is also

an EU manufacturer and has thus already received an EOID from the competent ID Issuer, is not permitted to receive another EOID from the same ID Issuer on the basis of their double role as importer and manufacturer in the same Member State.

[…]

Extract of Summary record 24 March 2022

[…]

3. Communication from Member States

One Member State presented information about enforcement activities that took place at national level as a reaction to infringements of Commission Implementing Regulation (EU) 2018/574.

Another Member State raised the issue of security features for tobacco products other than cigarettes and roll-your-own tobacco that will also be subject to obligations concerning traceability and security features from 20 May 2024. DG SANTE referred to the relevant provisions of Directive 2014/40/EU and Commission Implementing Decision (EU) 2018/576.

4. Q&As / Discussions

4.1. EO facilities' relocation: impact on the issued FIDs

One Member State asked about the impact of a wholesaler facilities' relocation on the facility identifier codes that were issued and relate to the old facility that is not used anymore. DG SANTE stressed that in case a wholesaler relocates, the facility identifier code that has already been issued and is linked to the 'old' location will not be valid anymore and needs to be withdrawn. As a result, the wholesaler has to request a new F_ID for the new facility that is associated with the new location and de-register the F_ID linked to the old facility. DG SANTE also clarified that in this case, the wholesaler should also report any movement of tobacco products, which means the reporting of the dispatch of all the existing stocks out of the old facility and of their subsequent arrival into the new location. This means that in the interim period, both old and new F_ID may need to be active.

4.2. Possibility to check FIDs in case of deliveries of unit-level unique identifiers to accredited EOs

One ID Issuer asked about the possibility to examine specific FIDs in case of deliveries of unit-level unique identifiers to accredited EOs. DG SANTE clarified that this information can be obtained from the Member State's competent authority who can retrieve the relevant information from the system.

4.3. Place of installation of anti-tampering devices

One Member State asked whether an anti-tampering device needs to be installed on the machine that is used for the manufacture of tobacco products and has acquired an MID, or on another machine of the production line. DG SANTE stressed that the number of the anti-tampering

devices listed in the declaration of Article 7(2) of Commission Implementing Regulation (EU) 2018/574 should be equal to the number of the (registered) active manufacturing machines. For this reason, anti- tampering devices should be installed on each active manufacturing machine.

Extract of Summary record 29 June 2022

[…]

1. Discussion on the proposed revision of Commission Implementing Regulation (EU) 2018/574

SANTE explained the reasons for the proposed targeted revision of Commission Implementing Regulation (EU) 2018/574, the general procedure for the adoption of Implementing Acts and an indicative timeline for the adoption of the amending Implementing Regulation.

SANTE stressed that the version of the draft Implementing Regulation that was shared with the Member States before the meeting of the Subgroup, is still subject to the formal validation by other Commission services and as a result, certain provisions may change.

SANTE presented all the proposed amendments to Commission Implementing Regulation (EU) 2018/574 together with the relevant rationale for them. The Subgroup discussed the proposed amendments with SANTE and was also invited to submit their written remarks on the text of the draft Implementing Regulation after the meeting.

2. AOB including communication from the Member States

One Member State presented certain enforcement actions that were taken against tobacco companies at national level. SANTE stressed the importance of the enforcement activities for the proper functioning of the T&T system and the relevant exchange of views on these activities during the Subgroup meetings. The Subgroup discussed the case at hand.

Extract of Summary record 22 November 2022

[…]

Q&As/Discussion of the Member States' questions

3.1 Extension of the traceability system's scope to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024

At the outset, SANTE recalled that from 20 May 2024, the scope of the traceability rules will cover all tobacco products. Manufactures and importers will have to notify to the Commission, by 31 December 2022, the identity of their proposed provider and a draft data storage contract.

One Member State asked whether ID issuers are obliged to issue the unique identifier codes for cigars and cigarillos before the deadline of May 2024 if they are requested by manufacturers or importers of these tobacco products. SANTE explained that the ID issuers do not have a legal obligation to issue the codes for cigars and cigarillos before the above-mentioned deadline since Articles 8(2) and 9(3) of Implementing Regulation (EU) 2018/574 need to be interpreted in the light of the higher-ranking norm in Article 15(13) of Directive 2014/40/EU, which provides that paragraphs 1 to 10 of Article 15 only apply to tobacco products other than cigarettes and roll-your-own tobacco as of 20 May 2024. However, SANTE explained that it welcomes the issuing of real UI codes to manufacturers of cigars and cigarillos before the deadline of May 2024 so that they can already prepare for the period after 20 May 2024 when cigars and cigarillos will have to bear an UI code.

In response to a question on the rules concerning the import of hand-made cigars and cigarillos, SANTE explained that if the hand-made cigars and cigarillos are imported into the EU after 20 May 2024, they will need to be marked, at the level of the unit packet, by means of unit level UIs. Regarding the reporting of the movements of these products, SANTE clarified that all the rules of the Implementing Regulation are applicable to importers. The fact that the cigars or cigarillos are fully hand-made makes no difference to the applicability of the rules. The only change is that in the request for unit level UIs the importers need to indicate the products' hand-made character.

SANTE recalled that situation is different with cigars and cigarillos that are imported into the EU before 20 May 2024 and not marked by means of unit level UIs. In this case, the products can remain in free circulation until 20 May 2026 and the importers' reporting obligations are not applicable.

Regarding imported products transported in bulk, before being packaged into unit packets, the UIs

need to be applied at the latest just before importation for products already in unit packets or at the moment of product finalisation, when products are being packaged into unit packets, which may

actually take place after importation, on the Union territory.

One Member State asked when and how the unique identifier (UI) and the security element should be applied on single stick cigars. SANTE referred to Article 6 of Implementing Regulation (EU) 2018/574 and explained that it is the responsibility of the manufacturer (for products manufactured in the EU) to mark these products with unit level UIs. The marking should take place in the manufacturing facility and be directly followed by the verification of those unit level UIs, as explained in Article 7 of the Implementing Regulation. Regarding the security features, economic operators may choose to apply them at a later stage in the supply chain, as long as the application takes place before the product are placed on the market.

For products manufactured outside the EU, SANTE referred to Article 6(2) of the Implementing Regulation which specifies that the unique identifiers are to be applied on the unit packet before the tobacco product is imported into the Union without specifying the exact time or place of the marking procedure. This means that the marking can either take place when the product reaches the customs warehouse or before that moment (e.g. in the manufacturing facility). Verification must be made of the unit level UIs, as explained in Article 7 of the Implementing Regulation.

For products like cigars, where the production process can be a multistage one and even take place in more than one location, the unit level UI should determine as location and time of manufacturing the product process's stage when the unit packet of the tobacco product was created. SANTE stressed that in any case, for tobacco products manufactured outside of the Union and destined to be placed on the Union market, the obligation to mark each unit packet with unit level UIs falls solely on the importer.

Regarding how the unit level UI and security feature should be applied on the unit packet, SANTE referred to the requirements of Article 15(1) and Article 16(1) of Directive 2014/40/EU, which should be respected.

3.2 One FID – One specific location for the facility

The Subgroup discussed the case of facilities' relocation in the context of the ongoing exchange of information between SANTE and specific Member States regarding the change in the location of certain facilities at two different moments.

SANTE recalled that in case an economic operator moves to a new location, the facility identifier code that is linked to the 'old' location needs to be withdrawn and a new F_ID needs to be requested for the new facility associated with the new location (regardless of whether products are moved from one facility to another).

A Member State asked about the possibility to introduce modifications of the information

submitted in the initial application form via message 1.5 of Implementing Regulation (EU) 2018/574. It was discussed that the use of message 1.5 should be limited to rare occasions where an address may change with respect to the same location, e.g. with renaming of a street or a rearrangement of postal codes and their boundaries. Message 1.5 should cover such rare occasions as well as correcting clerical (encoding) errors.

Another Member State asked about the obligation of the retailers in terms of registering their facilities. SANTE replied that according to 16(3) of the Implementing Regulation, the registration is an obligation of the operator of the first retail outlet, even though they do not participate in the reporting on the movements of the products. It was further clarified that in the scenario of product movements from the first to the second retail outlet, in this particular instance, the movement does not need to be reported to the tobacco traceability system.

3.3 Reporting and downloading additional data from the system such as geographical, health and population data

SANTE explained that the data that can be reported to the tobacco traceability system are strictly defined in Implementing Regulation 2018/574. Therefore, under the current rules, there is no such possibility for reporting or downloading additional data.

3.4 Other questions

One Member State inquired about the importer's obligation to contract a primary repository and request the UIs from the ID Issuer of the respective MS where the products are placed on the market. SANTE replied that according to Articles 6(1), 9(1) and 26(1) of Implementing Regulation, the importer has the obligation to establish a primary repository by contracting the primary repository provider and to request and mark the imported tobacco products with UIs. SANTE added that the "importer" is defined in Article 2(39) of Directive 2014/40/EU as "the owner of, or a person having the right of disposal over tobacco or related products that have been brought into the territory of the Union. "Import of tobacco or related products" is also defined in Article 2(38) of the Directive as the entry into the territory of the Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement. This means that products that are placed under a customs suspensive procedure have not entered yet the territory of the Union and as a result, are not considered imported. Therefore, the importer with all the track and trace obligations is the person who owns the products once they have been released from the customs suspensive procedure.

The same Member State asked about the practice of selling individual cigars and cigarillos from an open box. SANTE explained that in this case, the unit packet, namely the smallest individual packaging of the tobacco products that is placed on the market and sold to the consumers is the

individual cigar. As a result, the individual cigar needs to comply with all the necessary requirements of Directive 2014/40/EU and the Implementing Regulation, including the obligation to be marked with a unique identifier. The practice of selling unmarked individual cigars and cigarillos without unit level UIs from an open box is not in line with Directive 2014/40/EU and the Implementing Regulation.

The same Member State also asked for clarification regarding the costs associated with the establishment of a primary repository. SANTE clarified that the Commission is not involved in the determination of the relevant costs which is a contractual issue that needs to be agreed among the private parties (primary repository providers and tobacco manufacturers/importers). SANTE referred to Article 30(1) of the Implementing Regulation, according to which the costs related to the repositories system need to be fair, reasonable and proportionate.

Another Member State inquired about the identifier codes that have already been transmitted to the economic operators in case a new ID Issuer is appointed. SANTE replied that two ID Issuers cannot co-exist at the same time. Each Member State should have only one entity responsible for generating and issuing UIs according to Article 3(1) of the Implementing Regulation. One ID Issuer should be responsible for generating and issuing UIs for products placed on the market until the end of its contract. Finally, SANTE added that the current operator of the secondary repository is finalising a technical document specifying certain technical aspects of the transfer process.

4. AOB & Closing remarks

The Subgroup discussed the reimbursement of equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled and in particular, whether Article 15(7) of Directive 2014/40/EU should be read as a one-time obligation or rather a continuous obligation. SANTE referred to the Subgroup's previous discussions on this issue according to which a one-time payment to economic operators would not be compliant with the obligations set out in Article 15(7).

Glossary