



MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES

~ SUMMARY RECORD ~

Date: 13th June 2018

Place: CCAB, Brussels

1. Welcome and Introduction

DG SANTE welcomed all participants to the third Subgroup Meeting on Traceability and Security Features of the year. The Minutes of the last Subgroup were approved by participants and uploaded to the DG SANTE webpage. The chair provided an update concerning upcoming meetings. The agenda of the day was presented, underlining the fact that several MS had submitted questions and points for discussion to DG SANTE. The chair thanked for the transmitted questions and clarified that the answers to those would be provided for during the discussion rounds. The agenda was accepted by all participants and no points were added.

In addition, two participants updated the group on the status of ratification of the FCTC Protocol on Illicit Trade in their countries, indicating that good progress was made.

2. Update from the Commission

DG SANTE updated MS on most important policy issues and recent developments.

2.1. Regional workshops / country visits

DG SANTE informed MS that the fourth Regional Workshop took place in Rome. In addition, COM representatives participated in country visits in PT, EE and SK. The regional workshops and country visits resulted in mainly constructive dialogues and many questions were asked by industry, indicating that the sector was aware of the legislation and that there was a general interest in understanding how to apply it.

2.2. Webinars

DG SANTE organised five sessions of industry webinars in mid-April for manufacturers/importers, wholesalers, distributors and solution providers. It provided answers to questions that were sent in advance by stakeholders, as well as any additional questions raised during the webinar.

2.3. Website

DG SANTE further updated its T&T website with a Stakeholder Manual, a link to the Subgroup minutes, the Implementation Study (carried out by an external contractor, Everis) and a Q&A document. It recommended that Member States refer stakeholders to this page for information.

2.4. Approval/rejection of data storage contracts

DG SANTE reminded that manufacturers/importers must notify their proposed data storage provider and a draft data storage contract between 6 May and 6 July. To date, a number of contracts had already been submitted to DG SANTE. COM has three months from the date of receipt to approve or reject the proposed provider and draft contract. The assessment of providers is subject to the applicable legal rules, in particular on independence from the tobacco industry. Whereas the assessment of the draft contracts takes place based on a pre-defined checklist, which is also based on the requirements of the applicable legal framework: Tobacco Products Directive 2014/40/EU (TPD), Delegated Regulation 2018/573 (on key elements of data storage contracts) and Implementing Regulation 2018/574.

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, EU-CEG). 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 cancellation 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 cancellation 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 supply-chain. 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 pre-define 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:

- i. 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.
- ii. 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.
 - a. 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).
- iii. 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).

- iv. 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.

4. Update from Member States

Member States were then invited to update the group on any developments at national level that took place since the last Subgroup, in the following areas: appointment of ID issuers; designation of competent authority/authorities responsible for the traceability system; appointment of the National Administrator(s); design of security features.

Good progress on the above issues was indicated by Member States taking the floor. In relation to ID issuers, a majority of Member States indicated that a public authority (e.g. a state/national printing house) would be appointed. Certain Member States confirmed that they now intend to use their tax stamps as the security feature, while others confirmed that they had made progress on determining a provisional design of the permitted security feature.

5. AOB

The question of how the cost of traceability equipment is to be distributed amongst manufacturers (as per Article 15.8 of the TPD) was raised and a discussion in the group invited. One Member State informed that it had spoken to some national industry representatives on this and was aware of the potential development of a dedicated scheme. The industry had also raised the possibility of a pan European scheme. COM said it would welcome any update on developments in this respect and would encourage other Member States to inquire with their industries at national level.

DG SANTE also confirmed that it intended to encourage coordination between Member States regarding the length of unique identifier codes and would raise this issue again at the next meetings of the Subgroup.

6. Closing remarks

The chair thanked participants for their input. The main discussion points and answers to MS questions will be summarised in the minutes of the meeting. As always, participants were encouraged to refer stakeholders to the minutes, in particular the discussions and answers that were recorded therein.

The meeting was closed.

Annex I

List of participants

Austria	(Federal Ministry of Labour, Social Affairs, Health and Consumer Protection; Federal Ministry of Finance)
Belgium	(FPS Finances, FPS Health, Food Chain Safety and Environment)
Bulgaria	(National Customs Agency)
Croatia	(Customs Administration of the Republic of Croatia)
Cyprus	(Department of Customs and Excise, Republic of Cyprus)
Czech Republic	(Ministry of Agriculture of the Czech Republic)
Denmark	(Ministry of Health; The Danish Safety Technology Authority, The Danish Ministry of Taxation)
Estonia	(Estonian Tax and Customs Board)
Finland	(Ministry of Social and Health/ Finnish Customs)
France	(Direction Générale des Douanes)
Germany	(Federal Ministry of Food and Agriculture)
Greece	(Independent Authority for Public Revenues)
Hungary	(Ministry of Finance; National Tax and Customs Administration)
Ireland	(Department of Health; Office of the Revenue Commissioners)
Italy	(Custom monopolies agency)
Latvia	(The State Revenue Service of the Republic of Latvia)
Lithuania	(State Tax Inspectorate Under the Ministry of Finance of the Republic of Lithuania)
Luxembourg	(Customs and Excise Administration; Direction de la Santé)
Malta	(Customs Department)
Netherlands	(Permanent Representation of the Netherlands)
Poland	(Ministry of Finance)
Portugal	(Autoridade Tributária e Aduaneira; Imprensa Nacional Casa da Moeda)
Romania	(CN Imprimeria Nationala SA; National Customs Agency)
Slovakia	(Permanent Representation of Slovak Republic to the EU; Ministry of Finance, Financial Directorate)
Slovenia	(Financial administration of the Republic of Slovenia; Ministry of Health of the Republic of Slovenia)
Spain	(Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas; Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas; Fábrica Nacional de Moneda y Timbre)
Sweden	(Public Health Agency of Sweden)
United Kingdom	(H M Revenue&Customs)

Observers

Norway	(Norwegian Ministry of Health and Care Services)
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Commission:

DG SANTE	Thea Emmerling Filip Borkowski Jan Hoffmann Patricia Murray Anna Wartberger Fabian Wenner
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