



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

**MEETING OF THE EXPERT-SUBGROUP
ON TRACEABILITY AND SECURITY FEATURES
- SUMMARY RECORD -**

DATE: 17 JANUARY 2019

PLACE: CCAB 3C, BRUSSELS

1. Welcome and introduction

DG SANTE welcomed all participants to the first Subgroup Meeting on Traceability and Security Features of the year. The minutes of the last Subgroup were circulated for comments, which should be made by 25 January. The Chair provided an update concerning upcoming meetings. An additional webinar, linked to the next Meeting of the Subgroup on 14 February, would be organised, in order to address outstanding questions from Member States. Participants were reminded that parts of the meeting in February would also include repository providers and appointed ID issuers, in order to provide a forum for discussion among service providers and regulators.

The Chair reiterated the importance related to the appointment of ID issuers. Commissioner Andriukaitis recently sent a letter to Ministers in which he asked to allocate high priority to the appointment process.

The Chair presented the agenda. The update round would this time focus entirely on the status of appointment and operations of ID issuers in each Member State, and the updates

received would form part of the minutes of the meeting. One Member State asked to add a clarification point on security features and duty free shops to the agenda.

2. Update from the Commission

2.2.Updates on the appointment of the provider of the secondary repository

SANTE updated Member States on the current state of appointment of the provider of the secondary repository. On 21 December 2018, the Commission appointed Dentsu Aegis Network as the provider of the secondary repository. The appointment was also published on the SANTE website. A first meeting with Dentsu had already taken place in which good progress had been reported, in particular on discussions with providers of primary repositories and on the development of technical specifications and a common data dictionary. Dentsu would have to publish the latter no later than 21 February 2019.

2.3.Discussion with AIM Global

SANTE informed Member States that a discussion had taken place with AIM Global regarding the request for a unique identification code (IAC) in the context of the legal framework on tobacco traceability. During that conversation, requested clarifications were provided regarding the legislative framework and the general purpose of requesting IACs for ID issuers.

AIM Global confirmed that the three options of acquiring an IAC, as presented by SANTE during previous Meetings of the Subgroup, were in line with ISO 15459. Furthermore, SANTE was assured that any ID issuer that met the requirements set out in ISO 15459-2 (and -3) would be in a position to receive an IAC. However, SANTE stressed to Member States that the assessment of individual requests would take place without consideration whether the applicant had been appointed as an ID issuer. In light of the tight implementation timeline, SANTE had asked AIM Global for a quick processing and assessment of the requests received.

3. Discussion

3.2.Member State presentations on appointment and operations of ID issuers

Representatives from Denmark and Croatia gave a presentation on the status of affairs of their ID issuer appointment process. Whilst Denmark informed about status and format of their selection process, Croatia presented its current and already operational ID issuer,

including a first set of test UIs that had been generated. SANTE thanked the two Member States for the very interesting and encouraging presentations.

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.

3.5.Follow-up: reading of the term ‘machine’

SANTE recalled the discussion held during the previous meeting on the reading of the term ‘machine’. Member States were invited to express if they had any additional views in addition to the ones discussed previously. The Chair recalled the two preferred readings that had originated from the discussion:

1. View 1: The term ‘Machine’ should be identified as the machine which in the production line is responsible for the core manufacturing process (e.g. cigarette maker), because it is the actual product that is tracked and traced;

2. View 2: The term ‘Machine’ should be identified in the production line as the machine which is used for the packaging process, because tracking and tracing is facilitated through the unique identifier and the latter is applied to the package.

Member States were asked if, provided that no strong views existed, it would be agreeable to decide on one of the two readings, in order to ensure a common approach within the Union. No objections were raised during the meeting in response to this approach. SANTE therefore proposed to hold an informal vote on the two options at the next Meeting of the Subgroup, unless any objections against such procedure would be submitted by a Member State in writing.

One Member State the obligations imposed on Member States under Article 6 of the FCTC Protocol should not overlap with requirements under the traceability regime. SANTE took note of this point and replied that, while it was important to avoid double reporting under different regimes, the scope and objective of Article 6 was both different and arguably also wider than those under the traceability regime. Having said that, the data recorded in the traceability system would contribute to the obligations set out under Article 6 of the FCTC Protocol.

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 secondary repository. 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 equipment (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 re-registration 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.

5. Update from Member States

The Chair reiterated that this agenda point would be entirely dedicated to the status of the ID issuer appointment in Member States. SANTE had stressed and continued to stress the importance of the ID issuer for the overall functioning of the traceability system. Lack of timely appointment and operation of ID issuers bore serious consequences – from a legal and internal market point of view – in particular, given the cross-border dimensions of the traceability regime. While SANTE acknowledged the technical nature of the ID issuer appointment, it believed that the timeframe from the adoption to the application of the secondary legislation was sufficient in order to meet the obligations with respect to the ID issuer appointment. SANTE would also continue to support Member States over coming weeks and months by providing guidance in this process to the extent possible.

During the update round, SANTE presented the answers from Member States to the questionnaire on the ID issuer that had been circulated in the morning. The answers provided at the meeting would be annexed to the summary record of the meeting. On

other aspects (competent authority, UI delivery method, Article 4(1) derogation, etc.), Member States were asked to send any updates that have occurred directly by e-mail. The latter was important in particular with respect to the application of the derogation in Article 4(1) IR for which SANTE intended to make a list available online. This would be especially helpful for stakeholders and ID issuers.

6. AOB

The Chair informed the group that on 28 December 2018 CHAFEA had launched an open call for an expert study on the development and configuration of automatic alerts to be generated by the repositories system (deadline for participation: 15 March 2019).

The AOB point on security features was addressed under agenda point 3.4.

7. Closing remarks

The Chair thanked DK and HR for their presentations on the ID issuer. Participants were reminded about the upcoming meetings. Minutes of today's meeting, including Member State updates on the ID issuer, would be circulated in coming days.

The Chair closed the meeting.

Annex I
Update from Member States on appointment/operation of ID issuers

AUSTRIA	
Name of ID issuer	Monopolverwaltung (state monopoly agency)
Name of subcontracted party (if applicable)	Bundesrechenzentrum (Austrian Federal Computing Center)
Method of appointment	In house
Date of appointment (definite or best estimate)	13.10.2018
Unique identification code	LEAT1
Date of operation (definite or best estimate)	Test phase will start in March 2019

BELGIUM	
Name of ID issuer	INCERT (most possible option)
Name of subcontracted party (if applicable)	No
Method of appointment	Ministerial decree
Date of appointment (definite or best estimate)	April
Unique identification code	
Date of operation (definite or best estimate)	

BULGARIA	
Name of ID issuer	Printing Works of the Bulgarian National Bank
Name of subcontracted party (if applicable)	Yes
Method of appointment	Resolution of the National Assembly
Date of appointment (definite or best estimate)	November 2018 / State Gazette of 27.11.2018
Unique identification code	Not yet
Date of operation (definite or best estimate)	

CROATIA	
Name of ID issuer	Agencija za komercijalnu djelatnost d.o.o. (AKD D.O.O)
Name of subcontracted party (if applicable)	-
Method of appointment	Ordinance
Date of appointment (definite or best estimate)	Date of appointment-Ordinance entered into force on 19.07.2018_State Gazette,No. 61/2018 from 11.07.2018 National application of Article 4(1)-derogation- Ordinance on Amendments of Ordinance- entered into force on 15.12.2018, State Gazette, No. 110/2018, from 7.12.2018.
Unique identification code	LEAKD Information related to unique identification code of appointed ID issuer has been made publically available http://wp1.edifice.org/iso-15459-license-plate-2/list-of-license-plate-codes-assigned-by-edifice/
Date of operation (definite or best estimate)	March 2019

CYPRUS	
Name of ID issuer	Greek ID issuer - General secretariat of information systems
Name of subcontracted party (if applicable)	-
Method of appointment	-
Date of appointment (definite or best estimate)	-
Unique identification code	LE GR 1
Date of operation (definite or best estimate)	-

CZECH REPUBLIC

Name of ID issuer	State printing works of securities
Name of subcontracted party (if applicable)	Atos IT Solutions
Method of appointment	Resolution of the Government of the Czech Republic
Date of appointment (definite or best estimate)	17.10.2018
Unique identification code	LESTC
Date of operation (definite or best estimate)	March 2019

DENMARK	
Name of ID issuer	To be determined
Name of subcontracted party (if applicable)	To be determined
Method of appointment	Public procurement
Date of appointment (definite or best estimate)	21.02.2019 notification winning bidder is informed. Contract signing expected 05.03.2019
Unique identification code	To be determined
Date of operation (definite or best estimate)	No later than 20.04.2019

ESTONIA	
Name of ID issuer	-
Name of subcontracted party (if applicable)	-
Method of appointment	Contract after negotiation
Date of appointment (definite or best estimate)	ASAP and in time
Unique identification code	-
Date of operation (definite or best estimate)	-

FINLAND	
Name of ID issuer	To be determined
Name of subcontracted party (if applicable)	To be determined
Method of appointment	Tender for a concession (procurement process)
Date of appointment (definite or best estimate)	Beginning of April 2019
Unique identification code	To be determined
Date of operation (definite or best estimate)	May 2019

FRANCE	
Name of ID issuer	-
Name of subcontracted party (if applicable)	-
Method of appointment	Decree State Council
Date of appointment (definite or best estimate)	Estimated March 2019
Unique identification code	-
Date of operation (definite or best estimate)	20.03.2019

GERMANY	
Name of ID issuer	Bundesdruckerei GmbH
Name of subcontracted party (if applicable)	-
Method of appointment	Legal act / contract / decree
Date of appointment (definite or best estimate)	Best estimate: In due time
Unique identification code	QCBDR
Date of operation (definite or best estimate)	Best estimate: The ID issuer will be fully operational on 10 th May 2019.

GREECE	
Name of ID issuer	General secretariat of information systems
Name of subcontracted party (if applicable)	Pending
Method of appointment	Ministerial Decree
Date of appointment (definite or best estimate)	26.06.2018
Unique identification code	LEGR1
Date of operation (definite or best estimate)	-

HUNGARY	
Name of ID issuer	ND Nemzeti Dohanykereskedelmi Nonprofit Zrt.
Name of subcontracted party (if applicable)	Still cannot be named (ongoing)
Method of appointment	Decree 72/2018, Government decree
Date of appointment (definite or best estimate)	06.05.2018
Unique identification code	LEHU1
Date of operation (definite or best estimate)	Still depends

IRELAND	
Name of ID issuer	-
Name of subcontracted party (if applicable)	-
Method of appointment	Public procurement
Date of appointment (definite or best estimate)	End of February 2019 (estimated).
Unique identification code	-
Date of operation (definite or best estimate)	To be agreed

ITALY	
Name of ID issuer	Custom Monopolies agency
Name of subcontracted party (if applicable)	-
Method of appointment	National decree
Date of appointment (definite or best estimate)	March 2019
Unique identification code	Not yet
Date of operation (definite or best estimate)	March 2019

LATVIA	
Name of ID issuer	VAS LATVISAS VALSTS RADIO UN TELEVIZIJAS CENTRS
Name of subcontracted party (if applicable)	SIA "ZZ Dats"
Method of appointment	Law
Date of appointment (definite or best estimate)	29.12.2018
Unique identification code	IAC not acquired yet
Date of operation (definite or best estimate)	Best estimate end of March 2019

LITHUANIA	
Name of ID issuer	State tax inspectorate
Name of subcontracted party (if applicable)	Worldline
Method of appointment	Public procurement for subcontractor
Date of appointment (definite or best estimate)	January 2019, finished
Unique identification code	After agreement/contract with company Worldline
Date of operation (definite or best estimate)	As soon as possible

LUXEMBOURG	
Name of ID issuer	Incert G.I.E.
Name of subcontracted party (if applicable)	-
Method of appointment	Ministerial Decree
Date of appointment (definite or best estimate)	23.11.2018
Unique identification code	-
Date of operation (definite or best estimate)	End of March

MALTA	
Name of ID issuer	Opsec
Name of subcontracted party (if applicable)	N/A
Method of appointment	Public negotiation procedure
Date of appointment (definite or best estimate)	13.11.2018
Unique identification code	Now issued through ITSA: WAAØ
Date of operation (definite or best estimate)	End of April 2019

NETHERLANDS	
Name of ID issuer	ATOS
Name of subcontracted party (if applicable)	Worldline
Method of appointment	Concession
Date of appointment (definite or best estimate)	31.01.2019
Unique identification code	Ordered
Date of operation (definite or best estimate)	01.03.19 – pilot 20.03.19 – roll-out phase 20.05.19 – go live

POLAND	
Name of ID issuer	Polish Security Printing Works (PWPWS.A.)
Name of subcontracted party (if applicable)	N/A
Method of appointment	Legislative process is still in progress
Date of appointment (definite or best estimate)	April 2019
Unique identification code	QCPWPW
Date of operation (definite or best estimate)	No later than 15 May

PORTUGAL	
Name of ID issuer	Imprensa Nacional Casa de Moeda - INCM
Name of subcontracted party (if applicable)	N/A
Method of appointment	Decree
Date of appointment (definite or best estimate)	Not officially concluded
Unique identification code	It will be based on GS1
Date of operation (definite or best estimate)	02.05.2019 / Start testing in March

ROMANIA	
Name of ID issuer	Compania Nationala Imprimeria Nationala S.A. , The national printing house of Romania
Name of subcontracted party (if applicable)	N/A
Method of appointment	Government decision (No. 1020/2018 M.O.F 38/15.01.2019
Date of appointment (definite or best estimate)	15.01.2019
Unique identification code	LECNI
Date of operation (definite or best estimate)	Recently appointed, not clear yet.

SLOVAKIA	
Name of ID issuer	Datacentrum (Public Authority under the Ministry of Finance)
Name of subcontracted party (if applicable)	Subject of public procurement
Method of appointment	Legal act
Date of appointment (definite or best estimate)	01.05.2019
Unique identification code	LEDTC
Date of operation (definite or best estimate)	To be determined after appointment

SLOVENIA	
Name of ID issuer	Not yet appointed
Name of subcontracted party (if applicable)	
Method of appointment	Public tender
Date of appointment (definite or best estimate)	
Unique identification code	
Date of operation (definite or best estimate)	

SPAIN	
Name of ID issuer	Fabrica Nacional de Moneda y timbre (www.fnmt.es)
Name of subcontracted party (if applicable)	Not yet decided
Method of appointment	Ministerial order HAC 1365/2018 (BOE OJ nr. 308-22/DEC/18)
Date of appointment (definite or best estimate)	Definite: 23.12.2018 (BOE (OJ) nr. 308 of 22.12.2018)
Unique identification code	Not yet available
Date of operation (definite or best estimate)	Not yet determined

SWEDEN	
Name of ID issuer	Public Health Agency Sweden appointed by 1 March, but actual ID issuer will be procured
Name of subcontracted party (if applicable)	Pending procurement
Method of appointment	Public procurement
Date of appointment (definite or best estimate)	Mid April
Unique identification code	Pending procurement
Date of operation (definite or best estimate)	May 2019

UNITED KINGDOM	
Name of ID issuer	Confidential
Name of subcontracted party (if applicable)	Confidential
Method of appointment	Concession contract
Date of appointment (definite or best estimate)	February
Unique identification code	To be confirmed. As part of the tender process, the candidate outlined a plan to get in time
Date of operation (definite or best estimate)	In time for May

List of Participants

Austria	Ministry of Finance
Austria	Tobacco and Related Products, Alcohol, Behavioural Addictions, International Affairs of Addiction
Belgium	FPS HEALTH
Belgium	SPF Finances Douanes et Accises Expertise Législation et Règlementation
Bulgaria	National Customs Agency
Croatia	Agencija za komercijalnu djelatnost
Croatia	Customs Administration
Cyprus	Department of Customs and Excise, Republic of Cyprus
Czech Republic	CAFIA
Czech Republic	Ministry of Agriculture
Czech Republic	STC
Denmark	Danish Ministry of Health
Denmark	Danish Safety Technology Authority, Ministry of Industry
Estonia	The Ministry of Finance of Estonia
Finland	Ministry of Social Affairs and Health, Supervisory Authority for Welfare and Health
France	French Customs
Germany	Bundesdruckerei GmbH
Germany	Bundesministerium für Ernährung und Landwirtschaft
Greece	Independent Authority for Public Revenues
Greece	Ministry of Finance, General Secretariat for Information Systems
Hungary	National Tax and Customs Administration
Ireland	Department of Health
Ireland	Office of the Revenue Commissioners
Italy	custom monopolies agency
Italy	Società Generale d'Informatica
Latvia	State Revenue Service
Lithuania	State Tax Inspectorate Under the Ministry of Finance of the Republic of Lithuania
Luxembourg	Direction de la Santé
Malta	Customs Department - I/C Tobacco Products Unit

Netherlands	Ministerie van Volksgezondheid, Welzijn en Sport
Netherlands	Belastingdienst
Norway	Norwegian Directorate of Health
Norway	Norwegian Ministry of Health and Care Services
Poland	Ministry of Finance
Portugal	Autoridade Tributária e Aduaneira
Portugal	Imprensa Nacional Casa da Moeda
Romania	National Agency for Fiscal Administration
Romania	C.N. Imprimeria Națională S.A.
Slovakia	SK Perm Rep
Slovakia	Ministry of Finance
Slovenia	Ministry of Health of the Republic of Slovenia
Slovenia	Financial administration of the Republic of Slovenia
Spain	Fábrica Nacional de Moneda y Timbre
Spain	Comisionado para el Mercado de Tabacos. Ministerio de Hacienda y Administraciones Públicas.
Spain	Agencia Tributaria. Ministerio de Hacienda y Administraciones Públicas
Sweden	Public Health Agency of Sweden
United Kingdom	HM Revenues and Customs
European Commission	Filip Borkowski
	Jan Hoffmann
	Sascha Lowenstein
	Anna Mirandola