

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

MEETING OF THE SUBGROUP ON TRACEABILITY AND SECURITY FEATURES

-SUMMARY RECORD -

Date: 12 April 2019

Place: Brussels, Belgium

1. Welcome and introduction

SANTE welcomed all participants to the fourth Meeting of the Subgroup on Traceability and Security Feature of the year. The Chair informed the group that the minutes of the previous meetings of February and March are available on the SANTE website.

SANTE informed the group about upcoming meetings in May and June. In view of the approaching legal deadline, the Commission will also step up its communication to all concerned parties, including a Q&A press release and organising a technical briefing for stakeholders in the first week of May. Both will be announced in due time.

The Chair outlined that the meeting was divided into an open and a closed session, similar to the meeting in February. Repository providers and ID issuers had been invited to participate in the open part of the session. During the closed session, participation was restricted to public authorities.

The Chair presented the agenda for the open part of the meeting. The group approved the agenda. No additional points were submitted.

2. Presentation by 'Dentsu' on updates regarding the modalities of the secondary repository services

DENTSU gave a presentation on the current state of play of the secondary repository and the router, including feedback from the test run that had started on 20 March. It informed the group that excellent progress has been made, including the system's router and the repositories system. Several ID issuers, providers of primary repositories, as well as other economic operators, were participating in the on-going technical tests with the secondary repository and the router. In this regard, DENTSU informed the group that the central component of the system, i.e. the router, will become available in production on 10 May 2019, i.e. 10 days ahead of the legal deadline for the launch of the system. To assist stakeholders, DENTSU opened a support line for technical questions and established an

online service with the knowledge base containing all the technical information, including the data dictionary and the list of specifications. Stakeholders were invited to register with DENTSU for access to the knowledge base. Finally, DENTSU clarified that the on-boarding/certification environment was ready.

The Chair thanked DENTSU for the presentation and opened the floor for questions and comments. One provider enquired into the existence of an escalation mechanism in case the router will be unable to operate. DENTSU indicated that further information on this will be made available in advance of 20 May. Another provider asked whether stress tests were conducted and their results made available. DENTSU promised to communicate results of the stress test as soon as possible. Regarding the launch of the system, DENTSU confirmed that it will provide further indication of the exact time of the launch on 10 May. On the necessity to obtain certification for the on-boarding process, DENTSU clarified that certification was not mandatory but merely served to provide the users with technical certainty. One participant sought clarification on the possibility to transmit bulk sets of data (e.g. regarding identifier code registrations) to the secondary repository system on the day of the launch of the router. DENTSU replied that this is feasible.

3. Feedback from providers of primary repositories

The Chair invited providers of primary repositories present in the room to provide a short update on the state of play and outcome of the testing period, which had started on 20 March. Overall, providers confirmed good progress in the testing phase and good cooperation with DENTSU. Tests with economic operators were also initiated.

One provider underlined the need for a governance mechanism in order to address upcoming issues in the days before and after the 20 May deadline in a timely manner. DENTSU proposed the creation of a steering committee with primary repository providers. SANTE also reminded that, while Dentsu played a central role in providing clarifications on the existing technical specifications, the Commission will provide further guidance on any outstanding points during additional Meetings of the Subgroup organised in May and June. It strongly encouraged ID issuers that were active in the tests to share their experience with the 'late starters'. If needed, for matters of the highest urgency, the Commission together with the competent authorities of Member States will be ready to provide guidance also in between the Subgroup's meetings. SANTE asked the colleagues from the national authorities to be on a stand-by in case of any unforeseeable, urgent consultations.

Regarding some providers' comments on the specific validation rules in the context of Article 37(1) of the Implementing Regulation, SANTE recalled that the validation schema in question has been introduced as an optional component at the level of the primary repositories. At the level of the router, Dentsu had confirmed that it would put in place the validation rules, in order to limit supply-chain interruptions in the case of aggregated packaging containing valid and non-valid legacy UIs. Therefore, the implementation of these rules facilitates the efficient handling of data traffic received by primary repositories from the respective manufactures/importers.

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 self-generation 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. <u>Data qualifier</u>

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

The Chair announced that the first part of the closed session meeting would be dedicated to updates from the Commission and follow-up discussions. The second part of the meeting would focus on the appointment of ID issuers and on other updates related to implementing measures in Member States.

5.1. *Intro Art.* 4(5)

SANTE informed the group that the Commission was reviewing the possibility of issuing a temporary authorisation, as provided for under Article 4(5) of the Implementing Regulation. This included determining the scope of such authorisation, its format, as well as any legal limitations that may apply. A final decision had not yet been taken and would depend on the status updates received from Member States in today's meeting.

SANTE also reminded Member States that the issuing of a temporary authorisation would serve the purpose of mitigating as much as possible any consequences that may arise from the failure of a Member State to ensure availability of operational ID issuers in time. The application of Article 4(5) should not be seen as relieving Member States from their obligation under Union law. Nor would it change the fact that a Member State failed to meet its legal obligation, which could carry additional consequences.

5.2. Notifications of data contracts on proposed providers of repositories

SANTE recalled that the Commission continues to assess every notification received for proposed providers and related draft contracts within the 3 months' timeframe set out in Annex I to the Implementing Regulation.

Three additional notifications had been submitted to the Commission in March and April. The Commission was in the process of assessing these notifications in view of issuing a decision on approval/rejection in line with the outcome of the assessment. In the case of one notification, the Commission was not in a position to complete its assessment of the proposed provider based on the information available. Therefore, it asked the notifying party to provide further information.

5.3. Enforcement of contracts between manufacturers/importers and providers of repositories (follow-up)

The group followed up on a previous discussion regarding the obligation of Member States to enforce the provisions of the TPD in terms of ensuring that all manufacturers and importers of tobacco products conclude contracts with providers of repositories. To do so effectively, Member States had asked the Commission to provide them with copies of the contracts that the Commission approved.

SANTE informed that it had discussed the request internally. The sharing of the copies will require the consultation of the concerned manufacturers and importers as to any information that they may consider commercially sensitive and that therefore will have to be redacted in the contracts that will be eventually shared with Member States..

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.

5.5. Data protection (follow-up)

The group followed up on the discussion in the morning. SANTE recalled its initial reading of the GDPR with regard to joint controllership of Member States and the Commission regarding personal data processed in the repositories system. It furthermore explained that, in the case of joint controllership, the GDPR required an arrangement to be in place.

Member States and SANTE agreed that follow-up discussions were necessary on this subject matter. Member States were asked to take SANTE's proposed reading of the GDPR under consideration and share their views, preferably, in the next meeting. In this respect, it was also important to agree on the envisaged format of the arrangement. SANTE said that it would be willing to provide a draft of such arrangement, once the group has agreed on the application of the GDPR. All participants agreed that the question of data protection was an important subject matter.

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.

7. Update from Member States on ID issuer

SANTE presented the answers from Member States on the appointment of ID issuer and on other implementing measures (competent authority, UI delivery method, Article 4(1) derogation etc.), which were collected in the morning session. The answers provided in the meeting would be annexed to the summary record.

SANTE noted a visible improvement in terms of formal appointment of ID issuers by Member States. At the same time, the technical report received from DENTSU on the test environment indicated that so far only a few ID issuers had participated actively in

the tests with the secondary repository. SANTE will continue to monitor the situation closely and urged Member States and ID issuers to start testing connectivity and data exchange with DENTSU as soon as possible.

8. AOB

One Member State inquired into contacts between the Commission and third countries concerning tobacco traceability, specifically with the Russian Federation.

Another Member State asked for clarification on access of Member States to the data stored in the repositories system. SANTE confirmed that all Member States had equal access to the collective set of data stored in the repositories system. In this regard, it recalled the role of National Administrators in managing the different levels of access rights in a Member State. The group decided to further discuss this matter in the next Subgroup meetings. In the meantime, SANTE asked National Administrators to be cautious when granting rights to user groups.

9. Closing remarks

The Chair thanked participants for their input and closed the meeting.

List of participants

Austria (Federal Ministry of Labour, Social Affairs, Health and Consumer

Protection and Ministry of Finance - Tax and Customs Administration)

Belgium (Excise & Customs and FPS HEALTH

FPS Health and Food Chain Safety and Environment)

Bulgaria (National Customs Agency)

Croatia (Agencija za komercijalnu djelatnost and Customs Administration)

Czech Republic (Ministry of Agriculture and STC)

Denmark (Danish Safety Technology Authority)

Estonia (The Ministry of Finance of Estonia)

Finland (Supervisory Authority for Welfare and Health)

France (FRENCH CUSTOMS)

Germany (Bundesdruckerei GmbH and Bundesministerium für Ernährung und

Landwirtschaft)

Greece (Independent Authority for Public Revenues and Ministry of Finance,

General Secretariat for Information Systems)

Hungary (Representatives of minister without portfolio responsible for national

propery management, the National Tax and Customs Administration and

ND Nemzeti Dohánykereskedelmi Nonprofit Zártkörűen Működő

Részvénytársaság)

Ireland (Department of Health and Office of the Revenue Commissioners)

Italy (Ministry of Health)

Latvia (State Revenue Service)

Lithuania (State Tax Inspectorate Under the Ministry of Finance of the Republic of

Lithuania)

Luxembourg (Customs and Excise Administration and ID issuer Luxembourg)

Malta (Customs Department)

Netherlands (Ministerie van Volksgezondheid, Welzijn en Sport and Belastingdienst)

Poland (Ministry of Finance)

Portugal (Imprensa Nacional Casa da Moeda)

Romania (C.N. Imprimeria Natională S.A. and National Agency for Fiscal

Administration)

Slovakia (Ministry of Finance, Financial Directorate and Slovak Permanent

Representation)

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 and Ministry of Finance.)

Sweden (Public Health Agency Sweden)

United Kingdom (HM Revenues and Customs)

Observers:

Norway (Norwegian Ministry of Health and Care Services and Norwegian

Directorate of Health)

Service providers:

ALLEXIS

ATOS

AUTHENTIX

BNB PRINT

DE LA RUE

DEMAX

DENTSU

EVERIS

HONEYWELL

IBM

INCERT

MVG

OPSEC SECURITY

WORDLINE

ZETES

Commission:

DG SANTE Filip Borkowski

Jan Hoffmann

Sascha Maria Löwenstein

Anna Mirandola

DG OLAF Clare Twomey

Markus Goerres

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.

Structure of a unit-level unique identifier

(after encoding into a data carrier)

compliant with Implementing Regulation 2018/574 and the applicable international standards

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Unique identifier:	Symbology Identifier	Mandatory Data Qualifier	ID Issuer Identification Code	Optional Data Qualifier	Serial Number	Optional Data Qualifier	Product code	Optional Data Qualifier	Timestamp
Type:	Qualifier	Qualifier	String (<mark>data</mark> element)	Qualifier	String (<mark>data</mark> element)	Qualifier	String (<mark>data</mark> element)	Qualifier	String (<mark>data</mark> element)
Position within the unique identifier:	Fixed	Fixed	Fixed	Free	Free	Free	Free	Fixed	Fixed
Regulated by:	Art. 21(1) and ID issuer's coding structure	Art.3(4), Art.8(1)(a), Art. 21(1) and ID issuer's coding structure	Art.3(4) and Art.8(1)(a)	Art. 21(1) and ID issuer's coding structure	Art.8(1)(b)	Art. 21(1) and ID issuer's coding structure	Art.8(1)(c)	Art. 21(1), Art. 21(4) and ID issuer's coding structure	Art.8(1)(d) and Art.21(4)
Applicable international standards:	ISO/IEC 16022:2006, or ISO/IEC 18004:2015, or ISS DotCode Symbology Spec.	ISO 15459- 2:2015 and ISO 15459- 3:2014	ISO 15459- 2:2015 and ISO 15459- 3:2014						
Process	Applied by EO	Applied by EO	Generated by ID issuer	Applied by EO	Generated by ID issuer	Applied by EO	Generated by ID issuer	Applied by EO	Applied by EO
Transmission to the repositories system	No	No	Yes	No	Yes	No	Yes	No	Yes

Note: For the purpose of the above schema, group separators (/FNC1) are considered in the same manner as optional data qualifiers, i.e. their use depends on ID issuer's coding structure.

<u>Annex II</u> <u>Update from Member States on appointment/operation of ID issuers</u>

AUSTRIA		
Name of ID issuer Monopolverwaltung (state monopoly agency)		
Name of subcontracted	Bundesrechenzentrum (Austrian Federal Computing Center)	
party		
(if applicable)		
Method of appointment	In house	
Date of appointment	13.10.2018	
(definite or best		
estimate)		
Unique identification	LEAT1	
code		
Date of operation	Internal test started in March 2019 :	
(definite or best	with operators and DENTSU will start on 23.04.2019	
estimate)	operational start on 20.05.2019	

BELGIUM		
Name of ID issuer	INCERT (most possible option)	
Name of subcontracted	No	
party		
(if applicable)		
Method of appointment	Ministerial decree	
Date of appointment	April	
(definite or best		
estimate)		
Unique identification	QCLUXX	
code		
Date of operation	20 May	
(definite or best		
estimate)		

BULGARIA		
Name of ID issuer	Printing Works of the Bulgarian National Bank	
Name of subcontracted	Yes	
party		
(if applicable)		
Method of appointment	Resolution of the National Assembly	
Date of appointment	November 2018 / State Gazette of 27.11.2018	
(definite or best		
estimate)		
Unique identification	LEBGR	
code		
Date of operation	April 2019	
(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	Ordinance		
appointment			
Date of appointment	Date of appointment-Ordinance entered into force on		
(definite or best	19.07.2018_State Gazette,No. 61/2018 from 11.07.2018		
estimate)	National application of Article 4(1)-derogation- Ordinance on		
	Amendements of Ordinance- entered into force on		
	15.12.2018, State Gazette, No. 110/2018, from 7.12.2018.		
Unique identification	LEAKD		
code	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	23 April 2019		
(definite or best			
estimate)			

CYPRUS		
Name of ID issuer General Secretariat of Information Systems, Ministry Finance, Hellenic Republic		
Name of subcontracted	Authentix INC	
party		
(if applicable)		
Method of appointment	Decision of Ministry of Finance	
Date of appointment	25/10/2018	
(definite or best		
estimate)		
Unique identification	LE GR 1	
code		
Date of operation	10 th of May (registration)	
(definite or best	20 th of May (full operation)	
estimate)		

CZECH REPUBLIC		
Name of ID issuer	State printing works of securities	
Name of subcontracted	Atos IT Solutions	
party		
(if applicable)		
Method of appointment	Resolution of the Government of the Czech Republic	
Date of appointment	17.10.2018	
(definite or best		
estimate)		
Unique identification	LESTC	
code		
Date of operation	Start of registration on 15 th April	
(definite or best		
estimate)		

DENMARK		
Name of ID issuer	Wordline SA	
Name of subcontracted		
party		
(if applicable)		
Method of appointment	Public procurement	
Date of appointment	05.03.2019	
(definite or best		
estimate)		
Unique identification	LEWL2	
code		
Date of operation	Testing started in March	
(definite or best		
estimate)		

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

FINLAND		
Name of ID issuer	Allexis s.r.o.	
Name of subcontracted	QBSW a.s.	
party		
(if applicable)		
Method of appointment	Tender for a concession (procurement process)	
Date of appointment	27.03.2019	
(definite or best		
estimate)		
Unique identification	QCALL	
code		
Date of operation	May 2019	
(definite or best		
estimate)		

FRANCE		
Name of ID issuer	Imprimerie Nationale (in groupe)	
Name of subcontracted	-	
party		
(if applicable)		
Method of appointment	Decree State Council – Decree Ministry Order	
Date of appointment	Decree n. 2019 – 177 8 th March 2019	
(definite or best	Decree n. 2019 – 187 13 th March 2019	
estimate)		
Unique identification	Ongoing procedure	
code		
Date of operation	20.03.2019	
(definite or best		
estimate)		

GERMANY		
Name of ID issuer	Bundesdruckerei GmbH	
Name of subcontracted	-	
party		
(if applicable)		
Method of appointment	decree	
Date of appointment	4 May 2019	
(definite or best		
estimate)		
Unique identification	QCBDR	
code		
Date of operation	Best estimate: The ID issuer will be fully operational on 10 th	
(definite or best	May 2019.	
estimate)		

GREECE	
Name of ID issuer	General secretariat of information systems
Name of subcontracted	Authentix, Inc.
party	
(if applicable)	
Method of appointment	Ministerial Decision
	(Government Gazette 2434/B'/26.06.2018)
Date of appointment	26.06.2018
(definite or best	
estimate)	
Unique identification	LEGR1
code	
Date of operation	10 th of May Registration
(definite or best	20 th of May Full Operation
estimate)	

HUNGARY	
Name of ID issuer	ND Nemzeti Dohanykereskedelmi Nonprofit Zrt.
Name of subcontracted	Suaviter Zrt and 4iG Nyrt
party	
(if applicable)	
Method of appointment	Decree 72/2018, Government decree
Date of appointment	06.05.2018
(definite or best	
estimate)	
Unique identification	LEHU1
code	
Date of operation	May 2019
(definite or best	
estimate)	

IRELAND	
Name of ID issuer	Allexis s.r.o.
Name of subcontracted	N/A
party	
(if applicable)	
Method of appointment	Public procurement
Date of appointment	28 th February 2019
(definite or best	
estimate)	
Unique identification	QCALL
code	
Date of operation	1 May 2019
(definite or best	
estimate)	

ITALY	
Name of ID issuer	Custom Monopolies agency
Name of subcontracted	Custom Monopoly Agency will be assisted by its technical
party	partner SOGEI SPA
(if applicable)	
Method of appointment	National decree
Date of appointment	April 2019
(definite or best	Decree is on the table with all 4 Ministries for the signing
estimate)	
Unique identification	Not yet
code	
Date of operation	April 2019
(definite or best	
estimate)	

LATVIA	
Name of ID issuer	VAS "Latvijas Radio un televīzijas centrs
Name of subcontracted	SIA "ZZ Dats"
party	
(if applicable)	
Method of appointment	Law
Date of appointment	29.12.2018
(definite or best	
estimate)	
Unique identification	Issued by Edifice -LERTC
code	
Date of operation	Operational from 15.04.2019
(definite or best	
estimate)	

LITHUANIA	
Name of ID issuer	State tax inspectorate
Name of subcontracted	Worldline and Insoft
party	
(if applicable)	
Method of appointment	Public procurement for subcontractor
Date of appointment	January 2019, finished
(definite or best	
estimate)	
Unique identification	'KLT'
code	
Date of operation	Issuing system now is testing
(definite or best	
estimate)	

LUXEMBOURG	
Name of ID issuer	Incert G.I.E.
Name of subcontracted	-
party	
(if applicable)	
Method of appointment	Ministerial Decree
Date of appointment	23.11.2018
(definite or best	
estimate)	
Unique identification	QCLUXX
code	
Date of operation	10/05/2019
(definite or best	
estimate)	

MALTA	
Name of ID issuer	Opsec
Name of subcontracted	N/A
party	
(if applicable)	
Method of appointment	Public negotiation procedure
Date of appointment	13.11.2018
(definite or best	
estimate)	
Unique identification	Now issued through ITSA: WAAØ
code	
Date of operation	After May 10 th
(definite or best	Before May 20 th
estimate)	

NETHERLANDS	
Name of ID issuer	ATOS
Name of subcontracted	Worldline
party	
(if applicable)	
Method of appointment	Concession
Date of appointment	31.01.2019
(definite or best	
estimate)	
Unique identification	LEWL1
code	
Date of operation	01.03.19 – pilot
(definite or best	20.03.19 – testing in test environment for EO's
estimate)	23.04.19 - Production environment available for registration
	of EO's and processing of the bulk registration forms
	10.05.19 - Dentsu live in production
	14.05.19 - Start of ID issuing - Service fully operational
	20.05.19 – Start date of TPD

POLAND	
Name of ID issuer	Polish Security Printing Works (PWPWS.A.)
Name of subcontracted	N/A
party	
(if applicable)	
Method of appointment	Regulation of the Minister of Finance
Date of appointment	10 April 2019
(definite or best	
estimate)	
Unique identification	KPL1
code	
Date of operation	8 May 2019
(definite or best	
estimate)	

PORTUGAL	
Name of ID issuer	Imprensa Nacional Casa de Moeda - INCM
Name of subcontracted	N/A
party	
(if applicable)	
Method of appointment	Decree
Date of appointment	Concluded 15/02/2019
(definite or best	
estimate)	
Unique identification	3P
code	
Date of operation	02.05.2019 / Start testing in March
(definite or best	
estimate)	

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

SLOVAKIA	
Name of ID issuer	Datacentrum (Public Authority under the Ministry of
	Finance)
Name of subcontracted	N/A
party	
(if applicable)	
Method of appointment	Legal act
Date of appointment	20/04/2019
(definite or best	
estimate)	
Unique identification	LEDTC
code	
Date of operation	10/05/2019
(definite or best	
estimate)	

SLOVENIA	
Name of ID issuer	SMART NET d.o.o.
Name of subcontracted	AGENCIJA ZA KOMERCIJALNU DJELATNOST d.o.o.
party	
(if applicable)	
Method of appointment	Public tender waspublished online. The legal base for tender
	was adopted on 7.03.2019. It was published in OJ on 8.3 (OJ,
	No 14 14.2019). The Minister of Health appointed ID issuer
	by decision. The contract between MOH and SMART NET
	d.o.o. was signed on 26 th of April 2019.
Date of appointment	The contract was signed on 26 th of April 2019
(definite or best	
estimate)	
Unique identification	
code	QCSGSE
Date of operation	20.05.2019
(definite or best	
estimate)	

SPAIN	
Name of ID issuer	Fabrica Nacional de Moneda y timbre (www.fnmt.es)
Name of subcontracted	N A
party	
(if applicable)	
Method of appointment	Ministerial order HAC 1365/2018 (BOE OJ nr. 308-
	22/DEC/18)
Date of appointment	Definite: 23.12.2018 (BOE (OJ) nr. 308 of 22.12.2018)
(definite or best	
estimate)	
Unique identification	1E
code	
Date of operation	20 of March (testing)
(definite or best	20 of May (production)
estimate)	

SWEDEN		
Name of ID issuer	Public Health Agency Sweden appointed by 1 March, but	
	actual ID issuer will be procured: contract awarded 1st	
	April	
Name of subcontracted	Contract signed 15 th April (app)	
party		
(if applicable)		
Method of appointment	Public procurement	
Date of appointment	15 th April	
(definite or best		
estimate)		
Unique identification	Pending signing of contract	
code		
Date of operation	May 2019	
(definite or best		
estimate)		

UNITED KINGDOM	
Name of ID issuer	De la Rue
Name of subcontracted	Atos
party	
(if applicable)	
Method of appointment	Concession contract
Date of appointment	February 25 th 2019
(definite or best	
estimate)	
Unique identification	QCGDLR
code	
Date of operation	23 rd April
(definite or best	
estimate)	

Annex III

Update from Member States on other implementing measures (competent authority, Art. 4(1), Art. 35(2), security feature)

AUSTRIA	
Name of competent authorities	Ministry of Finance and Ministry of Health
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Yes
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes, via website and law
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

	BELGIUM
	Ministry of Finance and Ministry of Public
Name of competent authorities	Health
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Not yet decided
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	In ministerial decree
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

BULGARIA	
Name of competent authorities	National Customs Agency
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes. National legislation
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

	CROATIA
Name of competent authorities	Ministry of Finance, Customs Administration
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	N/A
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Wyes. Tax stamp is our security feature – info
security feature(s) to economic	available at the website of the Customs
operators? How was it notified	Administration. We sent letter to economic
(link to website, law, etc.)?	operators

	CYPRUS
Name of competent authorities	Department of Customs and Excise
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Letters, website
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

CZECH REPUBLIC	
	Czech Agricultural And Food Inspection
Name of competent authorities	Authority
	Ministry of Agriculture
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Yes
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Letter to EOS (14.9.2018)
security feature(s) to economic	Website
operators? How was it notified	
(link to website, law, etc.)?	

DENMARK	
Name of competent authorities	The Danish Safety Technology Authority
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Public decree
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

ESTONIA	
Name of competent authorities	
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Yes
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes, via the website of the Ministry of Social
security feature(s) to economic	Affairs and our customs authority (Tax and
operators? How was it notified	Customs Board)
(link to website, law, etc.)?	

FINLAND	
Name of competent authorities	 Supervisory Authority for welfare and Health (Valvira) The Customs The Muncipalities
Do you apply the second	Yes
sentence of Art. 4(1) of	
Implementing Regulation	
2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	In Finland we don't have anything in our national
Implementing Regulation	legislation concerning this issue. Therefore the
2018/574? (on use of postal	answer (for the time being) is No
operator's own traceability system	
for exports under 10kg)	
Have you notified your	Yes. They were notified by letter and the security
permitted security feature(s) to	feature can also be found at the website of the
economic operators? How was it	Ministry of Social Affairs and Health Decision
notified (link to website, law,	made by Ministry of Health
etc.)?	Decree 290/2019

FRANCE	
Name of competent authorities	French Customs and Ministry of Health
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Not allowed
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Inform by letter, website, Ministry Order
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

GERMANY	
Name of competent authorities	State authorities
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Tax stamp
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

GREECE	
Name of competent authorities	 Ministry of Finance Independent Authority for Public Revenue
Do you apply the second	Yes
sentence of Art. 4(1) of	
Implementing Regulation	
2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Not yet discussed
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your	Ministerial Decision
permitted security feature(s) to	(Government Gazette 735/B'/04.03.2019)
economic operators? How was it	
notified (link to website, law,	
etc.)?	

	HUNGARY
	Minister without portfolio responsible for national
Name of competent authorities	property management and National Tax and
	Customs Administration
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes, we have in two legal sources
security feature(s) to economic	-7Government decree No. 72/2018
operators? How was it notified	-decree of the Minister of National Economy No
(link to website, law, etc.)?	45/2016

	IRELAND
Name of competent authorities	Revenue Commission
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Under discussion
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes E-mail (20.09.2018 and 12.03.2019).
security feature(s) to economic	Revenue Webpage
operators? How was it notified	
(link to website, law, etc.)?	

	ITALY
	Health Ministry – Economy and Financial
Name of competent authorities	Ministry
Do you apply the second sentence	Not
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Not
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	National Decree of 28th August 2018
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

LATVIA	
Name of competent authorities	State Revenue Service (Tax administration)
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Will be notified by ruling of cabinet of Ministers
security feature(s) to economic	- law in the making. Currently in the cabinet of
operators? How was it notified	ministers
(link to website, law, etc.)?	

LITHUANIA	
Name of competent authorities	State Tax Inspectorate
Do you apply the second sentence	No
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Law and website
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

LUXEMBOURG	
Name of competent authorities	Ministry of Health
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Still under discussion
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	The customs and Excise administration and our
security feature(s) to economic	ID issuer regularly meet with economic operators
operators? How was it notified	for TT purpose> Permitted security features were
(link to website, law, etc.)?	communicated orally to EO

	MALTA
Name of competent authorities	Ministry of Finance, Customs Department
Do you apply the second sentence	Yes, Malta applies this derogation
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	There are no Maltese exporters of RYO.
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Notified by e-mail and meetings
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

NETHERLANDS	
Name of competent authorities	To be Confirmed
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes – link to website & letters
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

POLAND	
Name of competent authorities	Ministry of Finance
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes, via law
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

PORTUGAL	
	Customs and tax authority
Name of competent authorities	Authority for Food and Economic security
	Health Directorate General
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	N/A
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Tax Stamp
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

	ROMANIA
	National Agency for Fiscal Administration –
Name of competent authorities	General Directorate of Customs
	Minister of Public Finance
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes by e-mail
security feature(s) to economic	
operators? How was it notified	
(link to website, law, etc.)?	

SLOVAKIA	
	Ministry of Health
Name of competent authorities	Ministry of Finance
	Financial Directorate
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	Not discussed yet
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Tax Stamp is our security feature – communicated
security feature(s) to economic	through legislation
operators? How was it notified	
(link to website, law, etc.)?	

	SLOVENIA
	Ministry of Health and Ministry of Finance –
Name of competent authorities	Financial Administration
Do you apply the second sentence	Yes
of Art. 4(1) of Implementing	
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	With rules on the security features of tobacco
security feature(s) to economic	products (Official Journal no. 10/19)
operators? How was it notified	
(link to website, law, etc.)?	

SPAIN	
Name of competent authorities	Comisionado para el Mercado de Tabacos – Ministry of Finance
Traine of competent authorities	Named y of I marice
Do you apply the second	Yes
sentence of Art. 4(1) of	
Implementing Regulation	
2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your	Yes
permitted security feature(s) to	www.hacienda.gob.es
economic operators? How was it	Ministerial Decree HAC/1365/2018
notified (link to website, law,	
etc.)?	

	SWEDEN
Name of competent authorities	Public Health Agency of Sweden
Do you apply the second sentence	Yes, the Swedish ID-issuer is competent for the
of Art. 4(1) of Implementing	Swedish Market
Regulation 2018/574? (on ID issuer	
competence)	
Do you apply Art. 32(5) of	No
Implementing Regulation	
2018/574? (on use of postal	
operator's own traceability system	
for exports under 10kg)	
Have you notified your permitted	Yes, via our website and also stated in
security feature(s) to economic	regulations
operators? How was it notified	
(link to website, law, etc.)?	

UNITED KINGDOM		
Name of competent authorities	HM Revenue and Customs	
Do you apply the second sentence	Yes	
of Art. 4(1) of Implementing		
Regulation 2018/574? (on ID issuer		
competence)		
Do you apply Art. 32(5) of	Yes	
Implementing Regulation		
2018/574? (on use of postal		
operator's own traceability system		
for exports under 10kg)		
Have you notified your permitted	Yes. Link to website, e-mail	
security feature(s) to economic		
operators? How was it notified		
(link to website, law, etc.)?		