EU systems for traceability and security features of tobacco products
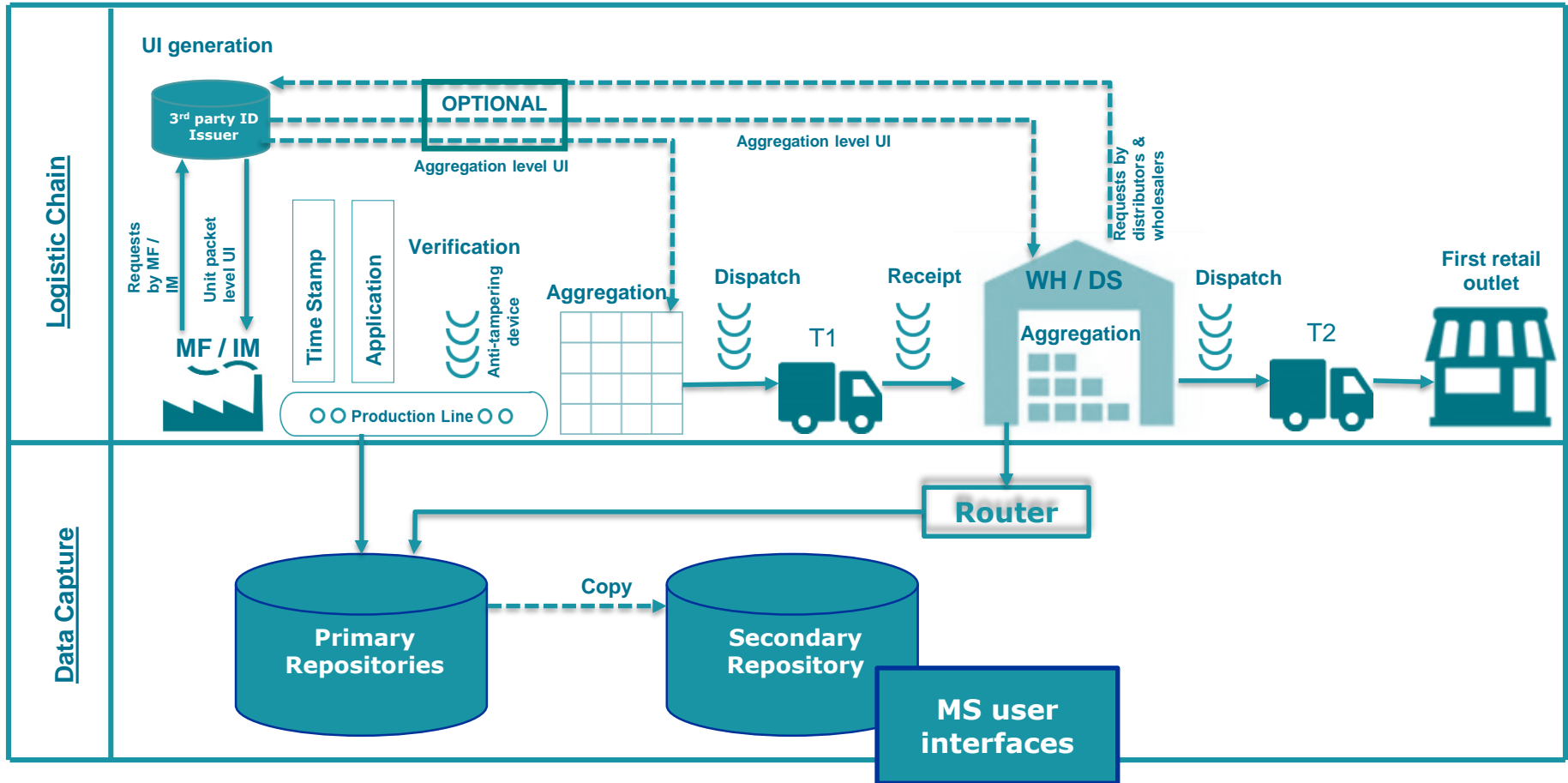
- Webinar for solution providers-

Directorate General for Health and Food Safety

European Commission

Brussels, 17 April 2018

Operational system structure

TRACEABILITY SYSTEM

- TIMEFRAME -

Timeframe – ID issuer

Reference point: COM Implementing Regulation
  ➢ Entry into force on 20th day following publication in OJ
  ➢ Date **6 May 2018**

Appointment:
  ➢ No later than one year following entry into force → **6 May 2019**

Timeframe – Primary repository

Reference point: COM Delegated Regulation

  ➢ Entry into force on 20th day following publication in OJ

  ➢ Date: **6 May 2018**

Selection/contracting procedure (see Annex I, Part A):

Step	Task	Deadline
1	MF/IMP shall notify to COM the proposed provider, incl. draft contract, declarations, correspondence table	**6/7/18**
2	Approval/rejection of proposed provider by COM	6/8 – **6/10/18**
3	MF/IMP shall propose alternative provider where initial proposal was rejected by COM	6/9 – **6/11/18**

→ Different deadline for MF/IMP of products other than cigarettes/RYO

Timeframe – Secondary repository

Reference point: COM Delegated Regulation
- ➢ Entry into force on 20th day following publication in OJ
- ➢ Date: **6 May 2018**

Selection/contracting procedure (see Annex I, Part B):

Step	Task	Deadline
1	COM starts appointment procedure for provider of secondary repository	**6/11/18**
2	COM appoints provider of secondary repository	**6/1/19**
3	Contracts between providers of primary repository and provider of secondary repository must be concluded and submitted to COM	**6/2/19**

Timeframe – Secondary repository

Coordination tasks (Art. 28):

Step	Task	Deadline
1	List of specifications required for data exchange with secondary repository and router; communicate it to providers of primary repositories	**6/3/19**
2	Establish data dictionary; communicate it to providers of primary repositories	**6/3/19**

→ Testing of system (and its different components) should start by **20/3/2019**

TRACEABILITY AND SECURITY FEATURES:

SOLUTION PROVIDERS

- MAIN ACTIVITIES -

ID ISSUER

Selection and appointment by Member States (Art. 3)

➢ Compliance with ISO 15459-2:2015;

➢ Application to Registration Authority for registration and assignment of an Issuing Agency Code (IAC);

➢ Allocation of IAC from character A to Z, and 0 to 9 (GS1) depending on specific criteria;

➢ List of existing issuing agencies is available online.

Examples of registered Issuing Agencies

1. Register ordered by Issuing Agency Name

ABOL SOFTWARE INC.	LN	ABOL SOFTWARE INC. 413 Creekstone Ridge Woodstock GA 30188 USA
Bosch und Siemens Hausgerate GmbH	VBS	Bosch und Siemens Hausgeräte GmbH Carls-Wery-Strasse 34 D-81739 MUNCHEN GERMANY
Ghana Revenue Authority	GH	Ghana Revenue Authority PMB, TUC Post Office Accra GHANA
DALO Danish Defence Acquisition and Logistics Organization	KDK	DALO Postbox 220 Arsenalvej 55 9800 Hjorring DENMARK
DHL Express Benelux	VGL	DHL Express Benelux Terminalweg 36 3821 AJ AMERSFOORT THE NETHERLANDS

Source: http://www.aimglobal.org/?Reg_Authority15459

ID ISSUER

➢ Subcontracting only permitted if contractor's identity is known to Member State (para. 2);

➢ Independence requirement (para 3; see Art. 35);

    ➢ Legal and financial independence, absence of conflict of interest.

➢ Ensure continuity and exit plan in the case an ID issuer is being replaced (para. 8);

➢ ID issuer may charge fees to the economic operators (for UI generation) (para. 9);

    ➢ Non-discriminatory, proportionate.

Anti-tampering devices

"… device allowing for the recording of the verification process following the application of each unit level unique identifier by means of a video or a log file, which once recorded cannot be further altered by an economic operator."

➢ Device must be supplied and installed by an independent party
  ➢ Declaration of independence (provider > MF/IMP > Member State/COM);
  ➢ See Art. 35 for independence criteria.

Primary repository

➢ One repository per manufacturer/importer;

➢ Technical requirements → see Arts. 25, 26;

➢ Access (physical/virtual) only by MS, Commission, auditors;

➢ Must be physically located on EU territory;

➢ Contractual requirements → see Delegated Regulation

  ➢ Technical expertise;

  ➢ Legal and financial independence (see Art. 35).

➢ Approval of provider by the Commission → see Part A, Annex I.

Secondary repository

➢ Central storage, hosts global (up-to-date) copy of all primary repositories data;

➢ Technical requirements → see Arts. 25, 27, 28, 29;

➢ Contains routing service (= reporting entry point for WS/DB);

➢ Establishes data dictionary /data exchange formalities to be used by providers of primary repositories and ID issuers;

➢ Graphical/non-graphical user interfaces (database search function for MS/COM/auditor);

➢ Appointment carried out by COM amongst providers of primary repositories (Part B, Annex I).

Security features

- ➤ Security feature composed of (at least) 5 authentication elements:

    - ➤ 1 overt (ISO 12931:2012, category 'overt');

    - ➤ 1 semi-covert (ISO 12931:2012, category 'covert', off-the-shelf tools);

    - ➤ 1 covert (ISO 12931:2012, category 'covert', purpose built tools).

- ➤ Independence criteria for at least one provider of an authentication element used in a security feature(Art. 3(2) conj. Art. 8);

- ➤ MS define permitted composition(s) of security features;

- ➤ Tax stamp may be used to define the permitted security feature.

THANK YOU
FOR YOUR ATTENTION