



EU systems for traceability and security features of tobacco products

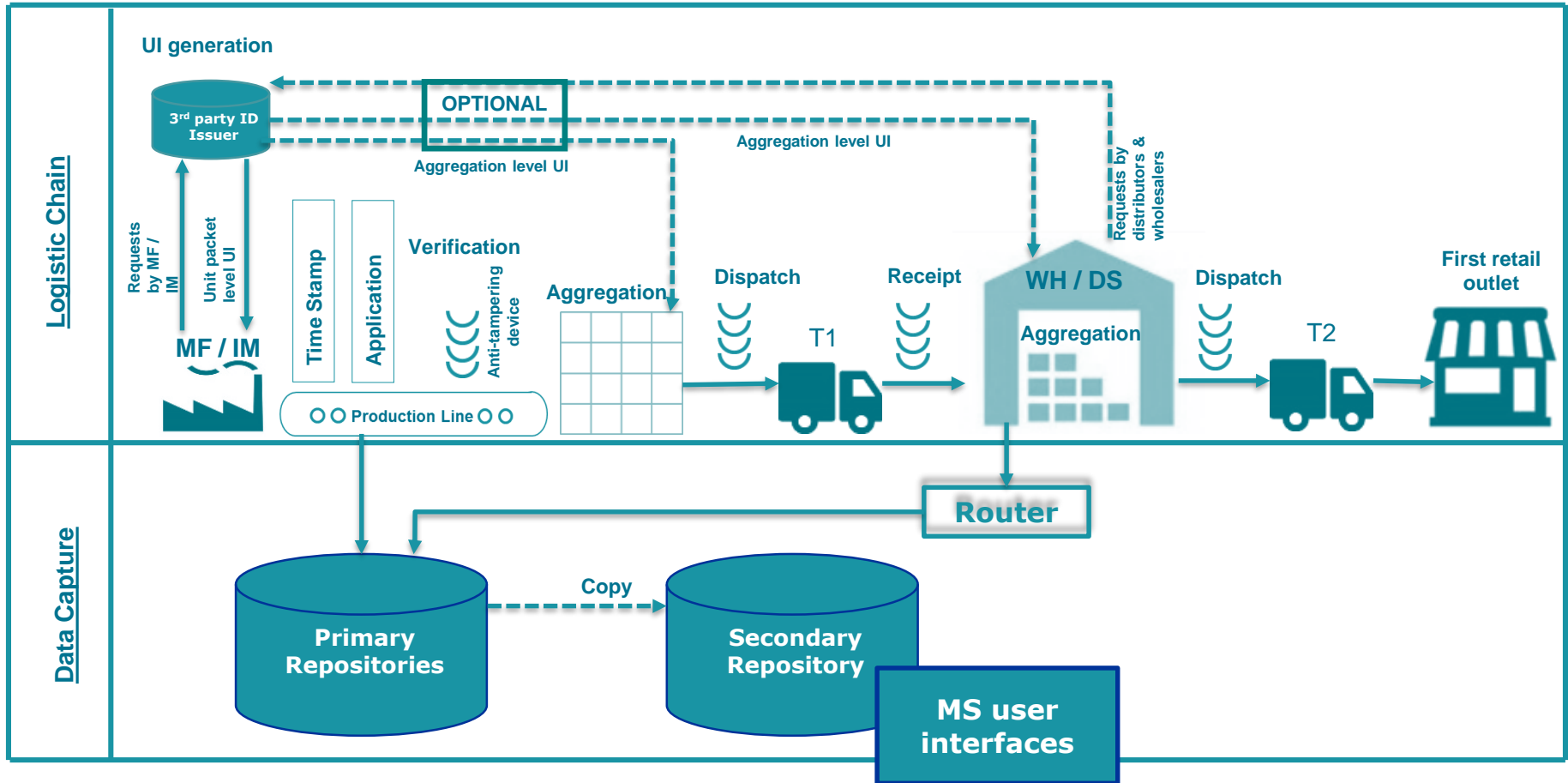
- Webinar for economic operators -

Directorate General for Health and Food Safety
European Commission

Brussels, 23rd April 2018

Please note that any views expressed in this presentation may in no way be regarded as stating an official position of the Commission.

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/Implementing 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	06/07/18
2	Approval/rejection of proposed provider by COM	06/08 – 06/10/18
3	MF/IMP shall propose alternative provider where initial proposal was rejected by COM	06/09 – 06/11/18

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

Timeframe – Secondary repository

Reference point: COM Delegated/Implementing 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	06/11/18
2	COM appoints provider of secondary repository	06/01/19
3	Contracts between providers of primary repository and provider of secondary repository must be concluded and submitted to COM	06/02/19

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	06/03/19
2	Establish data dictionary; communicate it to providers of primary repositories	06/03/19

→ Testing of system (and its different components) should start by **20/03/2019**

TRACEABILITY SYSTEM

- Main regulatory aspects -

Identifier codes

1. Economic identifier code (Arts. 14 & 15).
 2. Facility identifier code (Arts. 16 & 17).
 3. Machine identifier code (Arts. 18 & 19).
- Required for all economic operators from the manufacturer to the first retail outlet (wholesalers, distributors, transport companies, ...); also importers;
 - Retail outlets: request for identifier code may be discharged by another EO;
 - Request must be sent to the relevant ID issuer(s);
 - In duly justified cases, MS may request a code to be deactivated (territorial restriction);
 - No fees for generation by ID issuer.

Unique identifier (unit level)

- Request UI from competent ID issuer; delivery method: electronically (default), physically (at discretion of MS);
 - 6 months validity of UIs (from date of receipt to application);
- Marking of unit packets with a unique identifier (Art. 6);
- Verification as to correct application/readability of UI (Art. 7);
 - Anti-tampering devices (declaration of independence);
 - Applicable **derogations**: '< 120mil UIs per year' (1y), 'SMEs' (2y), 'fully manual production processes' (∞).
- Prescribed structure of unit level UIs:

ID Issuer – independent 3rd party

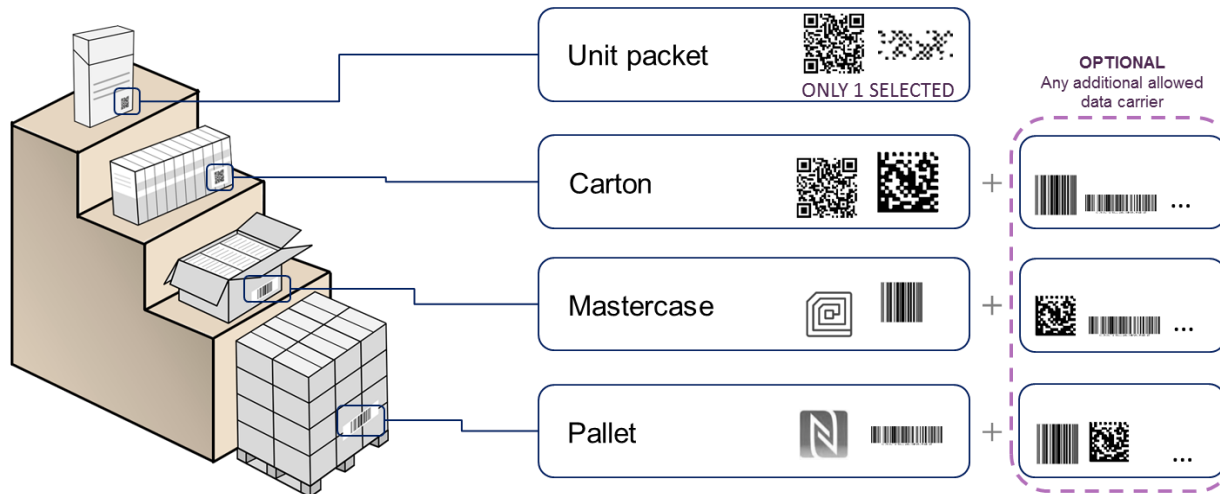
prefix	serial number	product code	YYMM DDhh
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Note: position of 'prefix' and 'time stamp' are fixed.

Unique identifier (aggregated level)

- Generation of unique identifiers for aggregated levels by ID issuers **or** by economic operators (Art. 10).
- Request to competent ID issuer:
 - Electronic delivery only;
 - Prescribed structure (similar to unit level UIs).
- Self-generation by economic operator:
 - Generation of code in accordance with ISO/IEC 15459-1:2014 or 15459-4:2014.
- Link between aggregated level and unit level UIs.

Permitted data carriers



- Electronic UI delivery → EO responsible for encoding;
- Physical UI delivery → ID issuer responsible for encoding;
- Time stamp may be added separately as human readable code;
- Marking "TTT" may be added next to data carrier.

Primary repository system

- One primary repository per manufacturer/importer (Art. 26);
- Obligation to notify proposed provider to the COM; approval of provider carried out by COM (see Annex I, Part A).
- Required documentation:
 - Draft contract + table of correspondence (see Delegated Regulation);
 - Written declaration of technical expertise (see Art. 25);
 - Written declaration of legal/financial independence.
- Repository must be located on Union territory.

Secondary repository system

- Central storage, hosts global (up-to-date) copy of all primary repositories data;
- 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;
- Appointment carried out by COM amongst providers of primary repositories (Part B, Annex I).

Recording/transmission of product movements

"[...] that all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the **entry** of all unit packets into their possession, as well as all **intermediate movements** and the final **exit** of the unit packets from their possession."

See: Article 15(5) Directive 2014/40/EU

Recording/transmission of product movements

Recording of information on product movements (Art. 32)

- Required for: application of UI, dispatch, arrival, trans-loading;
- Special cases: vending machines, vending vans;
- Disaggregation of aggregated level UI intended for reuse (self-generated UIs).

Transmission of information on product movements (Art. 32)

- Transmission of information to primary repository (for MF/IMP) or via router to secondary repository (for all other EOs);
- Stolen/ destroyed products require deactivation request;
- Correct transmission = positive acknowledgment from repository.

→ See section 3, Annex II

Recording/transmission of transactional information

- Required for: issuing of order number/invoice, payment receipt (Art. 33);
 - Once invoice can be associated with the relevant event / linked to respective UIs.
- Responsibility to transmit information lies with the vendor;
- Transmission of information to primary repository (for MF/IMP) or via router to secondary repository (for all other EOs);
- Correct transmission = positive acknowledgment from repository.

→ **See section 4, Annex II**

Time frame for transmission of information

Within **3 hours from the** occurrence of the event

- Required for the following events:
 - Application of unit level and aggregated level UIs;
 - Arrival of tobacco products at a facility;
 - Disaggregation (where UI is intended for reuse);
 - Delivery to multiple retail outlets via a vending van;
 - Transactional events.
- Applicable only from 20 May 2028; until then **24h rule** applies.
- General **derogation** (i.e. 24h rule applies permanently) for
 - Undertakings/group of undertakings which handle <120mil UI per year;
 - Undertakings/group of undertakings that meet the definition of SME.

Within **24 hours prior to** the occurrence of the event

- Required for the following events:
 - Dispatch of tobacco products from a facility;
 - Trans-loading.

SECURITY FEATURES

- Main regulatory aspects -

Security feature

- MS communicate to MF/IMP the permitted combination(s) of authentication elements that are to be used to form a security feature (Art. 3(3));
 - Communication deadline: **20/09/2018.**
- Independence criteria for at least one provider of an authentication element used in a security feature (Art. 3(2) conj. Art. 8);
- MS may introduce rotation schemes; compromised security features must be replaced and EO informed (5 days) (Art. 6).

Tax stamp as the security feature

- MS must ensure that tax stamps are used as '*the security feature*' only if they are compliant with all requirements (Art. 4(1));
- For non-compliant tax stamps, MS will communicate to MF/IMP additional information necessary for them to develop a compliant security feature based on the tax stamp (Art. 4(2));
 - Communication deadline: **20/09/2018** (Art. 4(3)).
- Note: MS may decide to make available the authorised security feature(s) to MF/IMP directly via a trusted third party .



**THANK YOU
FOR YOUR ATTENTION**