



# **EU systems for traceability and security features of tobacco products**

Directorate General for Health and Food Safety  
European Commission

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

# TRACEABILITY SYSTEM

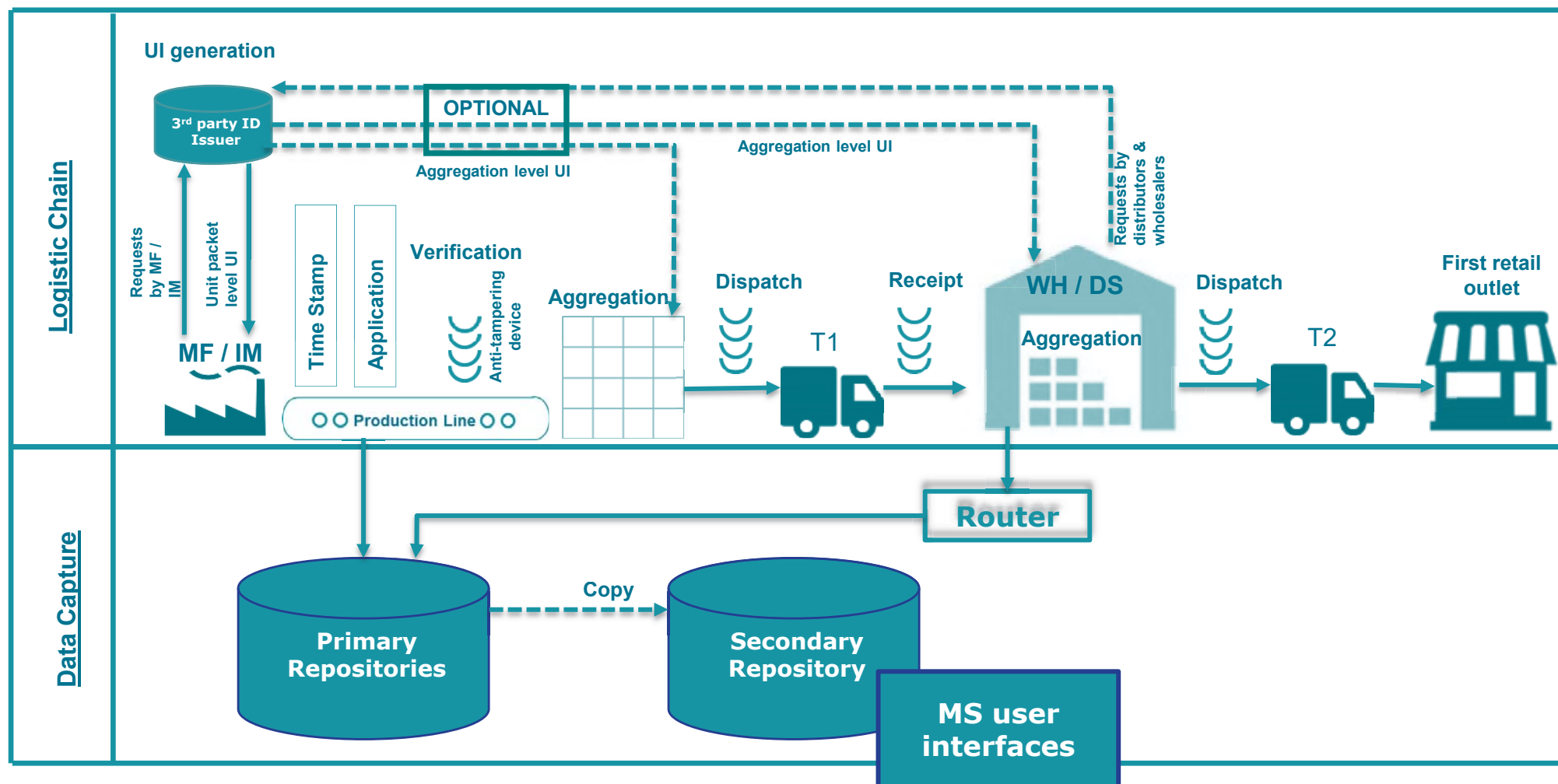
**- Main regulatory aspects -**

## Scope of the traceability system

"[...] 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

## Operational system structure



## ID issuer

- Operated by an independent third party
- Responsible for generation and issuing of:
  - identifier codes
  - unique identifiers

### Appointment by individual Member States:

- No later than one year following the entry into force of the Implementing Regulation → **6 May 2019**

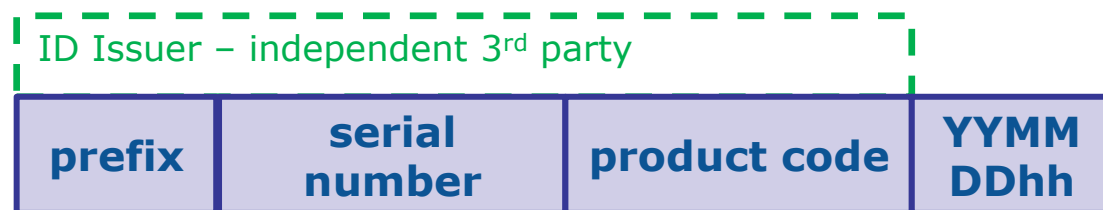


## Identifier codes

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;
  - Request must be sent to the relevant ID issuer(s);
  - Retail outlets: request for identifier code may be discharged by another EO;
  - In duly justified cases, MS may request a code to be deactivated (territorial restriction);
  - No fees for generation and issuing to be charged 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' ( $\infty$ ).
- Prescribed structure of unit level UIs:



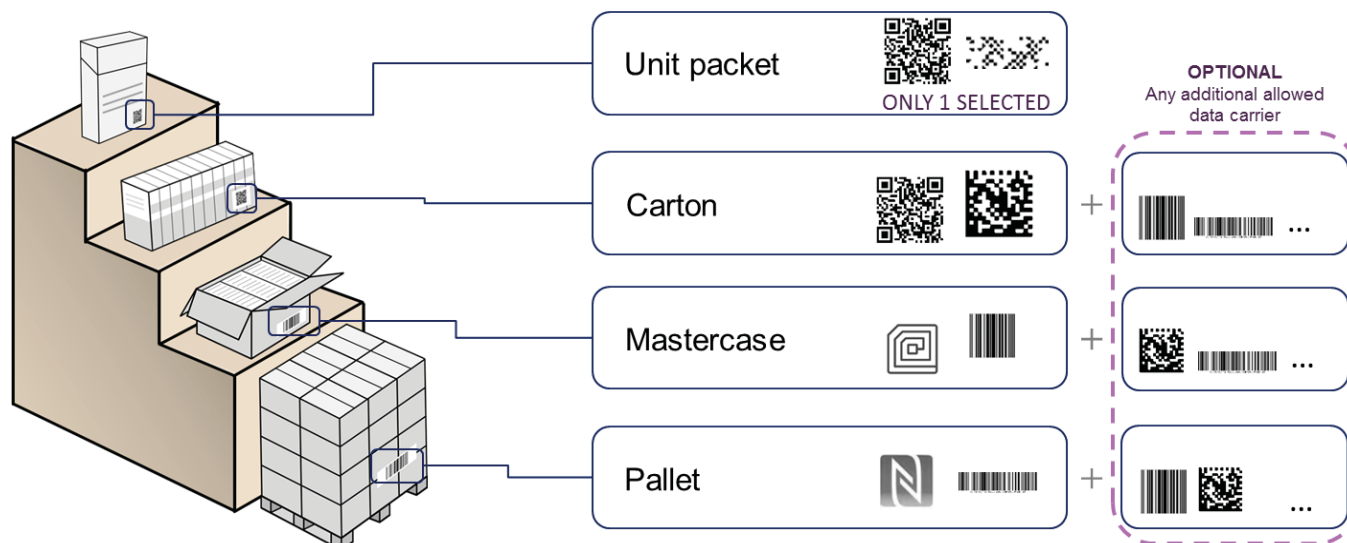
Note: position of 'prefix' and 'time stamp' are fixed.

## 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 → MF/IMP 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 repositories system

- One primary repository per manufacturer/importer (Art. 26);
- Repository must be located on Union territory and accessible to national authorities, the Commission and auditors;
- 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.

## Timeframe – Primary repository

Reference point: COM Delegated Regulation

➤ Entry into force: **6 May 2018**

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

Step	Task	Initial deadlines
1	MF/IMP shall notify to COM the proposed provider, incl. draft contract, declarations, correspondence table	<b>06/07/18</b>
2	Approval/rejection of proposed provider by COM (within 3 months from the receipt of notification)	06/08 – <b>06/10/18</b>
3	MF/IMP shall propose alternative provider where initial proposal was rejected by COM	06/09 – <b>06/11/18</b>

- List of the first eight notified and approved providers published on 10/10/2018;
- Process to be continued:
  - different deadline for MF/IMP of products other than cigarettes/RYO;
  - potential new entrants, etc.

## Secondary repository system

- Central storage, hosts global (up-to-date) copy of all primary repositories data;
- Contains routing service (single reporting entry point);
- Establishes data dictionary /data exchange formalities to be used by providers of primary repositories and ID issuers;
  - Electronic communication using secure means; security protocols and connectivity rules based on non-proprietary open standards.
- Appointment carried out by COM amongst providers of primary repositories (Part B, Annex I).

## Timeframe – Secondary repository

Reference point: COM Delegated Regulation

➤ Entry into force: **6 May 2018**

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

Step	Task	Deadline
1	COM starts appointment procedure for provider of secondary repository	<b>06/11/18</b>
2	COM appoints provider of secondary repository	<b>06/01/19</b>
3	Contracts between providers of primary repository and provider of secondary repository must be concluded and submitted to COM	<b>06/02/19</b>

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

- Information session for approved primary repository providers is planned for 2<sup>nd</sup> half of October;
- Information on selection/appointment procedure to be published on SANTE website;
- Testing of repositories system (and its different components) should start by 20/03/2019.

## **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);
- Additional optional elements subject to national direction (rotation schemes, guidelines on production/distribution procedures etc.)

## 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)).

**THANK YOU  
FOR YOUR ATTENTION**

