

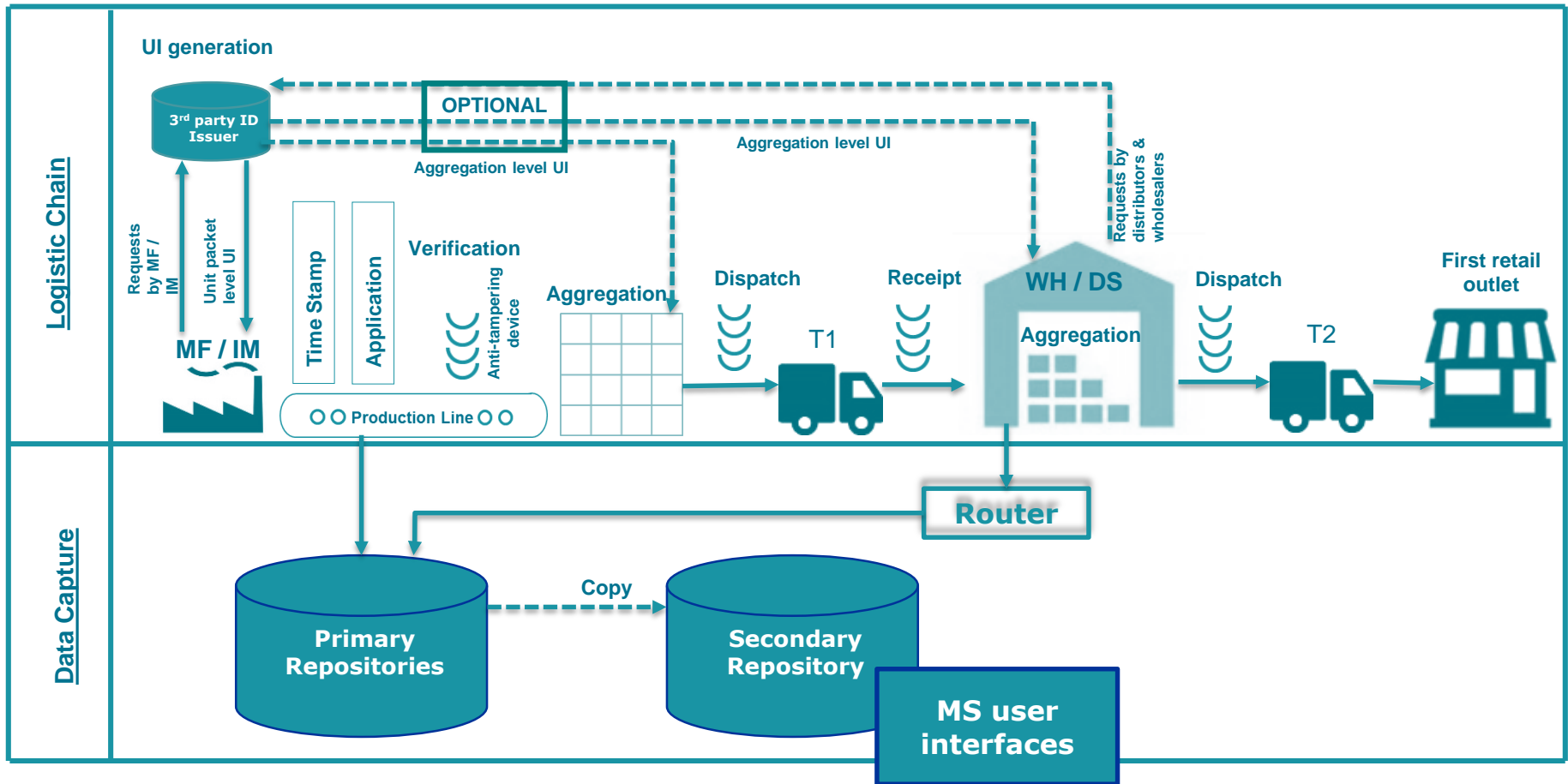


EU systems for traceability and security features of tobacco products

Directorate General for Health and Food Safety
European Commission

Berlin, 27 February 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 (estimate): **15 May 2018**

Appointment:

- No later than one year following entry into force → **15 May 2019**

Timeframe – Primary repository

Reference point: COM Delegated Regulation

- Entry into force on 20th day following publication in OJ
- Date (estimate): **15 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	15/07/18
2	Approval/rejection of proposed provider by COM	15/08 – 15/10/18
3	MF/IMP shall propose alternative provider where initial proposal was rejected by COM	15/09 – 15/11/18

→ 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 (estimate): **15 May 2018**

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

Step	Task	Deadline
1	COM starts appointment procedure for provider of secondary repository	15/11/18
2	COM appoints provider of secondary repository	15/01/19
3	Contracts between providers of primary repository and provider of secondary repository must be concluded and submitted to COM	15/02/19

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	15/03/19
2	Establish data dictionary; communicate it to providers of primary repositories	15/03/19

→ 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, transporting 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

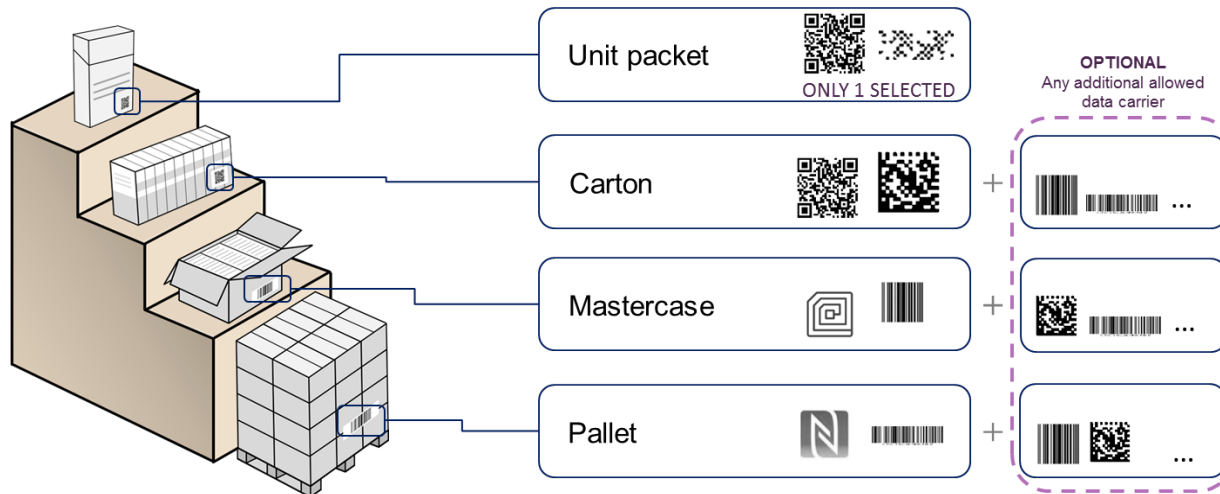
prefix	serial number	product code	YYMM DDhh
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Note: position of 'prefix' and 'time stamp' are fixed.

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 → 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 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.

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.

**THANK YOU
FOR YOUR ATTENTION**

