



EU systems for traceability and security features of tobacco products

Directorate General for Health and Food Safety, EU Commission

**Country Visit, Sweden
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TRACEABILITY SYSTEM

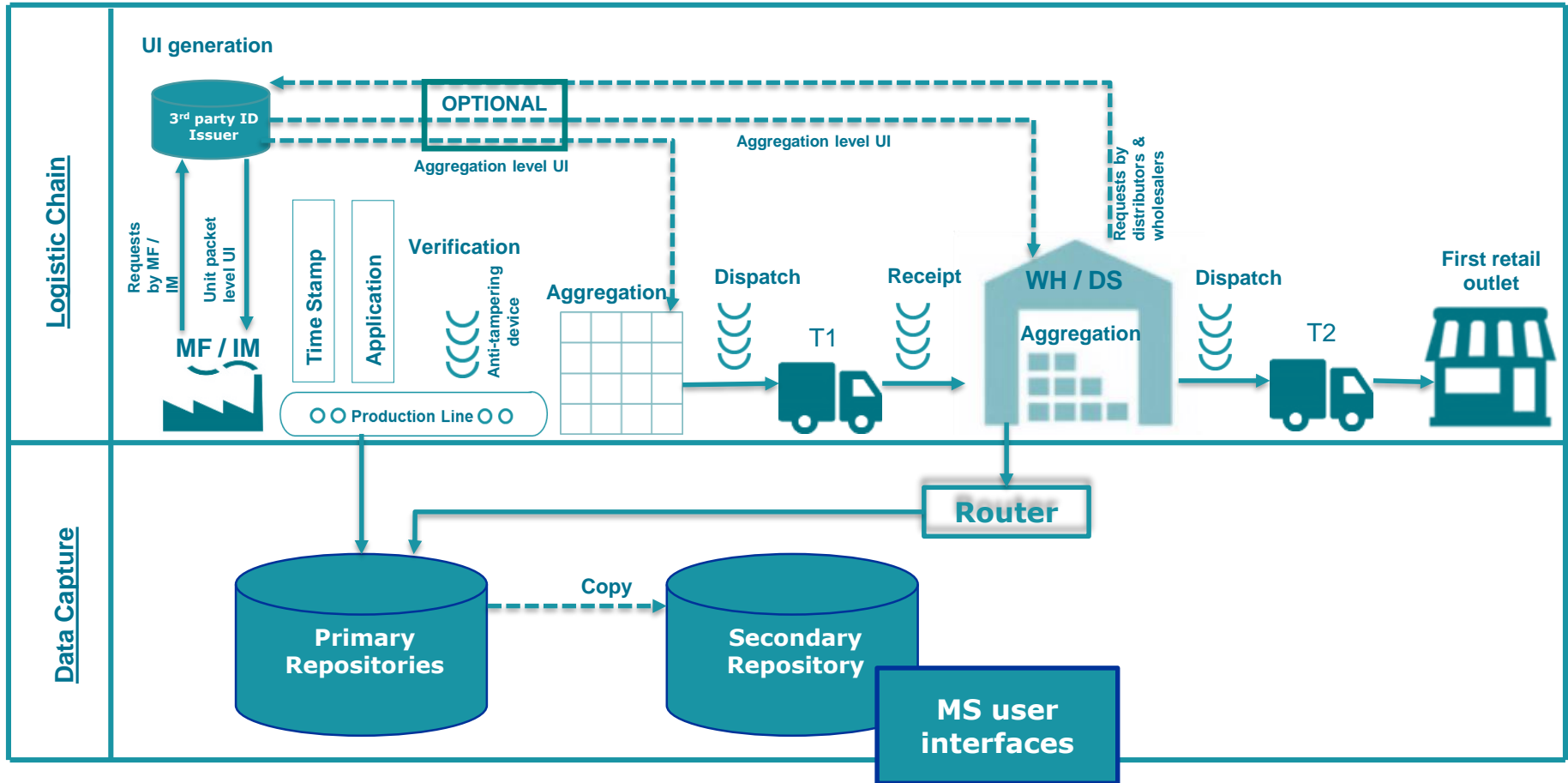
- Main regulatory aspects -

Scope of the traceability system

- Under the traceability system all unit packets of tobacco products **produced** in, **destined for** or **placed on** the EU market are required:
 - A) to be marked with a **unique identifier**;
 - B) their **movement recorded** throughout the supply chain;
 - C) and related info made **available to authorities** (i.e. to determine at which point the product was diverted into illicit trade).

Directive 2014/40/EU (Art. 15 TPD)

Operational system structure



ID issuer

- Operated by an independent third party (para 3; see Art. 35);
- 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**
- Notify to the COM the identity of the ID issuer and its identification code within 1 month of appointment (para. 6);
- Information on the ID issuer must be published (para. 7);

ID Issuer

- Subcontracting only permitted, if the contractor' identity is known to Member State (para. 2);
- Ensure continuity and exit plan (para. 8);
- Appointment has no implications in terms of public spending;
 - Fees charged by the ID issuer to economic operators for UI generation (para. 9): **non-discriminatory** and **proportionate**.

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;
 - 6 months validity of UIs (from date of receipt to application);
- Marking of unit packets with a unique identifier (Art. 6);
- **Prescribed structure of unit level UIs (ISO646:1991):**

ID Issuer – independent 3rd party

prefix

serial
number

product code

YYMM
DDhh

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

- Verification as to correct application/readability of UI (Art. 7);
 - **Anti-tampering devices**:

“the device allowing for the recording of the verification process (..) by means of a **video** or **log file**, which once recorded cannot be further altered”(Art. 2 IR)

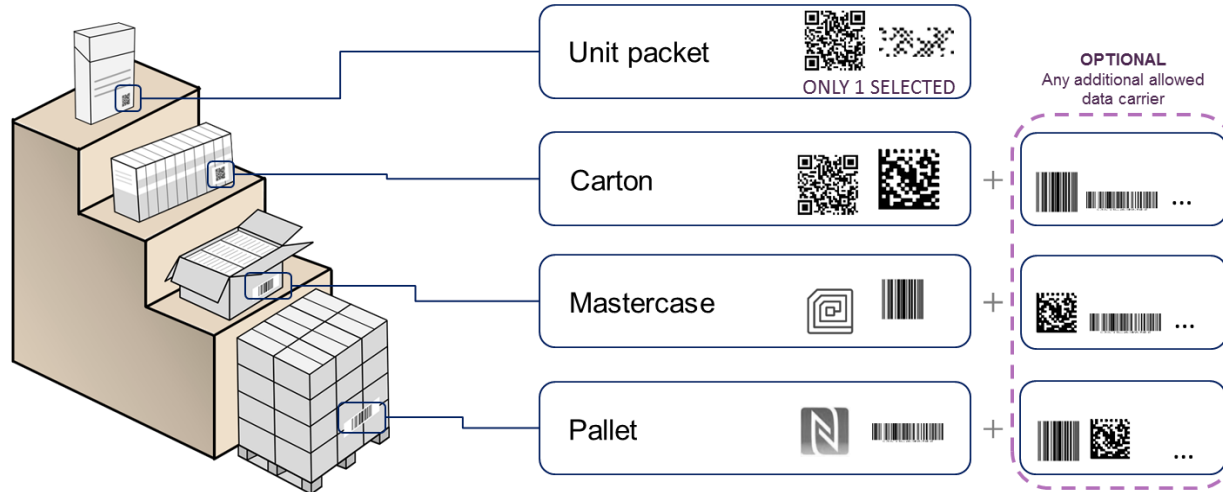
Which is:

 - Installed by an independent third party
 - Declaration to relevant MS and COMM (declaration of independence)
 - Information recorded need to be available for 9 months
 - Record of info must be available to MS and COMM (if requested)
 - Applicable **derogations**: '< 120mil UIs per year' (1y:20 May 2020), 'SMEs' (2y: 20 May 2021), 'fully manual production processes' (∞).

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;
 - Fees: art. 3(9): Fees: are to be non-discriminatory and proportionate.
- 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: established by sending info on application (aggregated/unit) to repository.

Permitted data carriers



- Permitted: Data Matrix, QR, **Dot Code** (unit), **Code 128** (aggregated) based on non-proprietary, open standards
- 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	06/07/18
2	Approval/rejection of proposed provider by COM (within 3 months from the receipt of notification)	06/08 – 06/10/18
3	MF/IMP shall propose alternative provider where initial proposal was rejected by COM	06/09 – 06/11/18

➤ Process to be continued:

- different deadline for MF/IMP of products other than cigarettes/RYO (31/12/2022);
- potential new entrants

Primary repository – Update on approval process

- Official COMM decisions adopted & forwarded (approval/rejection)
- List of the first eight notified and approved providers published on 10/10/2018
- Assessment based on written declarations and draft contract
- New notifications: will be assessed

- NOTE: Ensure that data stored in the repositories system is only used for the purposes of Directive 2014/40/EU (Art. 15(8) TPD);
 - 'duly justified cases' clause.

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

- Testing of repositories system (and its different components) should start by 20/03/2019.
- Updates:
 - Adopted Public Procurement Procedure
 - Intention to finalise as soon as possible

Recording Information

"[...] 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 movements

Recording of information on product movements (Art. 32)

- Required for:
 - Application of UI (unit/aggregated)
 - Dispatch (important info on Destination type: EU/ non EU/ VM/VV)
 - Arrival (return info can be included)
 - Transloading
 - Deactivation: reasons to indicate (i.e. stolen/destroyed products)

Recording of information on transactional information (Art. 32)

- 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;

Recording/transmission of information

- In both cases transmission of information to primary repository (for MF/IMP) or via router to secondary repository (for all other EOs);
- → **See Annex II, Chapter II, Sections 3 and 4.**
- Correct transmission = positive acknowledgment from repository.

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 shall require that **all unit packets** of tobacco products, which are **placed on the market** (made available to consumers located in the EU), carry a tamper proof **security feature**” (Art. 16 TPD)
- Security features must be:
 - Composed of visible and invisible elements
 - Irremovably printed or affixed
 - Indelible
 - Not hidden or interrupted in any form
 - 5 or more authentication elements (i.e. 1 overt, 1 semi-covert, 1 covert (Art. 3 Decision))

- Independence criteria for at least one provider of an authentication element used in a security feature (Art. 3(2) conj. Art. 8);
- 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.**
- Additional optional elements subject to national direction (rotation schemes, guidelines on production/distribution procedures etc.)
- BUT, obligation to rotate where there is reason to believe (or actual knowledge) that a security feature in use on the market is compromised (Art. 6(2));

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**