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."

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

2. Facility identifier code (Arts. 16 & 17).

- 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' (∞).
- Prescribed structure of unit level UIs:

<table>
<thead>
<tr>
<th>prefix</th>
<th>serial number</th>
<th>product code</th>
<th>YYMMDDhh</th>
</tr>
</thead>
</table>
  
ID Issuer – independent 3rd party

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:

- 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):

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

- 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):

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>COM starts appointment procedure for provider of secondary repository</td>
<td>06/11/18</td>
</tr>
<tr>
<td>2</td>
<td>COM appoints provider of secondary repository</td>
<td>06/01/19</td>
</tr>
<tr>
<td>3</td>
<td>Contracts between providers of primary repository and provider of secondary repository must be concluded and submitted to COM</td>
<td>06/02/19</td>
</tr>
</tbody>
</table>
### Timeframe – Secondary repository

**Coordination tasks (Art. 28):**

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>List of specifications required for data exchange with secondary repository and router; communicate it to providers of primary repositories</td>
<td><strong>06/03/19</strong></td>
</tr>
<tr>
<td>2</td>
<td>Establish data dictionary; communicate it to providers of primary repositories</td>
<td><strong>06/03/19</strong></td>
</tr>
</tbody>
</table>

- Information session for approved primary repository providers is planned for 2\textsuperscript{nd} 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 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