EU systems for traceability and security features of tobacco products

Directorate General for Health and Food Safety
European Commission

Meeting with industry stakeholders
Madrid, February 2018
OUTLINE

1. General introduction & timeframe

2. Main responsibilities of economic operators

3. Main activities for solution providers
Operational system structure

Logistic Chain:
- Requests by MF / IM
- 3rd party ID Issuer
- UI generation
- Time Stamp
- Application
- Verification
- Anti-tampering device
- Aggregation level UI
- Aggregation
- Dispatch
- Receipt
- WH / DS
- Dispatch
- T1
- T2
- First retail outlet

Data Capture:
- Primary Repositories
- Secondary Repository
- Copy
- MS user interfaces
- Router

OPTIONAL Ant-tampering device
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):

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
<th>Deadline</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>15/07/18</td>
</tr>
<tr>
<td>2</td>
<td>Approval/rejection of proposed provider by COM</td>
<td>15/08 – 15/10/18</td>
</tr>
<tr>
<td>3</td>
<td>MF/IMP shall propose alternative provider where initial proposal was rejected by COM</td>
<td>15/09 – 15/11/18</td>
</tr>
</tbody>
</table>

→ 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):

<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>15/11/18</td>
</tr>
<tr>
<td>2</td>
<td>COM appoints provider of secondary repository</td>
<td>15/01/19</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>15/02/19</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>15/03/19</td>
</tr>
<tr>
<td>2</td>
<td>Establish data dictionary; communicate it to providers of primary repositories</td>
<td>15/03/19</td>
</tr>
</tbody>
</table>

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

- Main regulatory aspects -
Identifier codes

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

- 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:

<table>
<thead>
<tr>
<th>prefix</th>
<th>serial number</th>
<th>product code</th>
<th>YYMM DDhh</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 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."

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.
TRACEABILITY AND SECURITY FEATURES

- Main activities for solution providers -
ID ISSUER

Selection and appointment by Member States (Art. 3)

- Compliance with ISO 15459-2:2015;
- Application to Registration Authority for registration and assignment of an Issuing Agency Code (IAC);
- Allocation of IAC from character A to Z, and 0 to 9 (GS1) depending on specific criteria;
- List of existing issuing agencies is available online.
Examples of registered Issuing Agencies

<table>
<thead>
<tr>
<th>1. Register ordered by Issuing Agency Name</th>
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<tbody>
<tr>
<td>ABOL SOFTWARE INC.</td>
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<tr>
<td>Bosch und Siemens Hausgerate GmbH</td>
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<tr>
<td>Ghana Revenue Authority</td>
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<td></td>
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<tr>
<td>DALO</td>
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<tr>
<td>Danish Defence Acquisition and Logistics</td>
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<tr>
<td>Organization</td>
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<td></td>
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<tr>
<td></td>
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<tr>
<td>DHL Express Benelux</td>
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Source: http://www.aimglobal.org/?Reg_Authority15459
ID ISSUER

- Subcontracting only permitted if contractor's identity is known to Member State (para. 2);
- Independence requirement (para 3; see Art. 35);
  - Legal and financial independence, absence of conflict of interest.
- Ensure continuity and exit plan in the case an ID issuer is being replaced (para. 8);
- ID issuer may charge fees to the economic operators (for UI generation) (para. 9);
  - Non-discriminatory, proportionate.
Anti-tampering devices

"... device allowing for the recording of the verification process following the application of each unit level unique identifier by means of a video or a log file, which once recorded cannot be further altered by an economic operator."

- Device must be supplied and installed by an independent party
  - Declaration of independence (provider > MF/IMP > Member State/COM);
  - See Art. 35 for independence criteria.
Primary repository

- One repository per manufacturer/importer;
- Technical requirements → see Arts. 25, 26;
- Access (physical/virtual) only by MS, Commission, auditors;
- Must be physically located on EU territory;
- Contractual requirements → see Delegated Regulation
  - Technical expertise;
  - Legal and financial independence (see Art. 35).
- Approval of provider by the Commission → see Part A, Annex I.
Secondary repository

- Central storage, hosts global (up-to-date) copy of all primary repositories data;
- Technical requirements → see Arts. 25, 27, 28, 29;
- 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;
- Graphical/non-graphical user interfaces (database search function for MS/COM/auditor);
- Appointment carried out by COM amongst providers of primary repositories (Part B, Annex I).
Security features

- MS define permitted composition(s) of security features;
  - Tax stamp may be used to define the permitted security feature.
- Security feature composed of (at least) 5 authentication elements:
  - 1 overt (ISO 12931:2012, category 'overt');
  - 1 semi-covert (ISO 12931:2012, category 'covert', off-the-shelf tools);
- Independence criteria for at least one provider of an authentication element used in a security feature.
THANK YOU
FOR YOUR ATTENTION