EU systems for traceability and security features of tobacco products

- Webinar for solution providers-

Directorate General for Health and Food Safety
European Commission

Brussels, 17 April 2018

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

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

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

Operational system structure

- Requests by MF / IM
- Unit packet level UI
- MF / IM
- Production Line
- Router

OPTIONAL
- Anti-tampering device

Anti-tampering device
- MF / IM
- Requests by distributors & wholesalers
- Production Line
- Router

Primary Repositories
- Secondary Repository
- Copy
- MS user interfaces
Timeframe – ID issuer

Reference point: COM Implementing Regulation

- Entry into force on 20th day following publication in OJ
- Date 6 May 2018

Appointment:
- No later than one year following entry into force → 6 May 2019
Timeframe – Primary repository

Reference point: COM Delegated Regulation

- Entry into force on 20th day following publication in OJ
- Date: **6 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><strong>6/7/18</strong></td>
</tr>
<tr>
<td>2</td>
<td>Approval/rejection of proposed provider by COM</td>
<td><strong>6/8 – 6/10/18</strong></td>
</tr>
<tr>
<td>3</td>
<td>MF/IMP shall propose alternative provider where initial proposal was rejected by COM</td>
<td><strong>6/9 – 6/11/18</strong></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: 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>6/11/18</td>
</tr>
<tr>
<td>2</td>
<td>COM appoints provider of secondary repository</td>
<td>6/1/19</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>6/2/19</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>6/3/19</td>
</tr>
<tr>
<td>2</td>
<td>Establish data dictionary; communicate it to providers of primary repositories</td>
<td>6/3/19</td>
</tr>
</tbody>
</table>

→ Testing of system (and its different components) should start by 20/3/2019
TRACEABILITY AND SECURITY FEATURES:
SOLUTION PROVIDERS

- MAIN ACTIVITIES -
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>Register ordered by Issuing Agency Name</th>
<th>LN</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABOL SOFTWARE INC.</td>
<td>LN</td>
<td>ABOL SOFTWARE INC. 413 Creekstone Ridge Woodstock GA 30188 USA</td>
</tr>
<tr>
<td>Bosch und Siemens Hausgerate GmbH</td>
<td>VBS</td>
<td>Bosch und Siemens Hausgeräte GmbH Carls-Wery-Strasse 34 D-81739 MUNCHEN GERMANY</td>
</tr>
<tr>
<td>Ghana Revenue Authority</td>
<td>GH</td>
<td>Ghana Revenue Authority PMB, TUC Post Office Accra GHANA</td>
</tr>
<tr>
<td>DALO</td>
<td>KDK</td>
<td>DALO Postbox 220 Arsenalvej 55 9800 Hjoring DENMARK</td>
</tr>
<tr>
<td>DHL Express Benelux</td>
<td>VGL</td>
<td>DHL Express Benelux Terminalweg 36 3821 AJ AMERSFOORT THE NETHERLANDS</td>
</tr>
</tbody>
</table>

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

- 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 (Art. 3(2) conj. Art. 8);
- MS define permitted composition(s) of security features;
- Tax stamp may be used to define the permitted security feature.
THANK YOU
FOR YOUR ATTENTION