EU systems for traceability and security features of tobacco products

– Stakeholder session –

Directorate-General for Health and Food Safety, European Commission

4th Regional Workshop
Rome, 19 April 2018
AGENDA

1. General introduction & timeframe
2. Session for manufacturers & importers
3. Session for wholesalers & distributors
4. Session for solution providers
5. Concluding remarks
TRACEABILITY SYSTEM

- INTRODUCTION -
Operational system structure
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>6/7/18</td>
</tr>
<tr>
<td>2</td>
<td>Approval/rejection of proposed provider by COM</td>
<td>6/8 – 6/10/18</td>
</tr>
<tr>
<td>3</td>
<td>MF/IMP shall propose alternative provider where initial proposal was rejected by COM</td>
<td>6/9 – 6/11/18</td>
</tr>
</tbody>
</table>
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>
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 SYSTEM:
MANUFACTURERS & IMPORTERS

- MAIN RESPONSIBILITIES -
Identifier codes


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


- Required for all manufacturers and importers;
- Request must be sent to the relevant ID issuer(s);
  - Transmits code within 2 working days following the request.
- In duly justified cases, MS may request a code to be deactivated;
- No fee for generation of identifier codes.
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.
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.

- Bear costs for repositories system
  (proportionate to the number of unit level UIs).
Recording/transmission of product movements

Recording of information on product movements (Art. 32)

- Required for: application of UI, dispatch, arrival, trans-loading;
- Disaggregation of aggregated level UI intended for reuse (i.e. those generated by economic operators).

Transmission of information on product movements (Art. 32)

- Transmission of information to primary repository;
- 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 the respective event occurred / event can be linked to unit level UIs concerned.
- Responsibility to transmit information lies with the vendor.
- Transmission of information to primary repository;
- 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;
  - 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:
MANUFACTURERS & IMPORTERS

- MAIN ACTIVITIES -
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:
MANUFACTURERS & IMPORTERS

- FINANCIAL ASPECTS -
Cost implications by preferred policy options:

<table>
<thead>
<tr>
<th>Preferred policy options</th>
<th>Annualised cost (EUR)</th>
<th>Cost per unit pack (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a/3: Mixed solution (industry and third party)</td>
<td>8 digit figure</td>
<td>8 digit figure</td>
</tr>
<tr>
<td>1b/1: Near real time reports</td>
<td>8 digit figure</td>
<td>8 digit figure</td>
</tr>
<tr>
<td>1c/3: Combined model</td>
<td>Low 8 digit figure</td>
<td>Low 9 digit figure</td>
</tr>
<tr>
<td>2/4: Limited data carriers per level (and optional)</td>
<td>8 digit figure</td>
<td>Low 9 digit figure</td>
</tr>
<tr>
<td><strong>Total (Article 15 TPD)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/2: Printing or affixing or a combination of printing and affixing</td>
<td>8 digit figure</td>
<td></td>
</tr>
<tr>
<td><strong>Total (Articles 15 &amp; 16 TPD)</strong></td>
<td></td>
<td>Low 9 digit figure</td>
</tr>
</tbody>
</table>

Distribution of costs and benefits per stakeholder group:

<table>
<thead>
<tr>
<th>Affected stakeholders</th>
<th>Social benefits</th>
<th>Economic benefits</th>
<th>Economic costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent authorities</td>
<td>9 digit figure</td>
<td>10 digit figure</td>
<td>7 digit figure</td>
</tr>
<tr>
<td>Economic operators, incl.:</td>
<td>n/a</td>
<td>8 digit figure</td>
<td>9 digit figure</td>
</tr>
<tr>
<td>- manufacturers/importers</td>
<td></td>
<td>8 digit figure</td>
<td>8 digit figure</td>
</tr>
<tr>
<td>- distributors/wholesalers</td>
<td></td>
<td>7 digit figure</td>
<td>8 digit figure</td>
</tr>
<tr>
<td>- retailers</td>
<td></td>
<td>7 digit figure</td>
<td>n/a</td>
</tr>
<tr>
<td>General public</td>
<td>10 digit figure</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Total (EUR)</strong></td>
<td>10 digit figure</td>
<td>10 digit figure</td>
<td>9 digit figure</td>
</tr>
</tbody>
</table>

→ very favourable benefit-cost ratio
TRACEABILITY SYSTEM:
DISTRIBUTORS & WHOLESALERS

- MAIN RESPONSIBILITIES -
Identifier codes

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

- Applies to all other economic operators (EO) involved in tobacco trade (distributors, wholesalers, transporting companies, including operators of first retail outlets);
- Retail outlets: request for identifier code may also be discharged by another EO;
- Request must be sent to relevant ID issuer(s);
  - Transmits code within 2 working days following the request.
- In duly justified cases, MS may request an existing code to be deactivated;
- No fees for generation of identifier codes.
Unique identifier (aggregated level)

- Marking of aggregated packaging: unique identifiers may be requested from the relevant ID issuer or generated directly by the economic operator (Art. 10).

- Request to relevant ID issuer:
  - Electronic delivery only;
  - Prescribed structure (same as for unit level UIs).

- Self-generation:

- Link between aggregated level and unit level UIs.
Permitted data carriers

- Electronic UI delivery → EO 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.
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 (i.e. those generated by economic operators).

**Transmission of information on product movements (Art. 32)**

- Transmission of information via router to secondary repository;
- 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 the respective event occurred / event can be linked to unit level UIs concerned.
- Responsibility to transmit information lies with the vendor.

- Transmission of information via router to secondary repository;
- 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.
BREAK
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

## 1. Register ordered by Issuing Agency Name

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

Source: [http://www.aimglobal.org/?Reg_Authority15459](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