EU system of tobacco traceability

DG SANTE, European Commission
Cross-border health care and tobacco control

Taipei
September 2019

Please note that any views expressed in this presentation may in no way be regarded as stating an official position of the Commission.
Introduction – EU context
Legislative response to the problem of illicit trade
Legal basis of the EU system of tobacco traceability
General architecture and the key entities
Product marking and structure of unique identifiers
Recording rules
Public control over the system
Cost-benefit of the system
Final remarks

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Nature of illicit trade in the EU

- Volume: 10-11% of the overall market; tax losses: €10bn+;
- Important public health implications;
- Composition of illicit market changes: contraband from major international products, cheap whites and counterfeits, domestic illicit manufacture;
- Main countries of provenance for smuggled tobacco in the EU: China, UAE, Vietnam, Malaysia, Russia, Singapore, Belarus, Ukraine;
- Points of entry: EU Eastern border, Eastern Mediterranean, Western Balkans;
- Fuels the shadow economy;
- Often domain of organised criminal groups;
- Worldwide, complex problem -> needs to be addressed in a comprehensive way, both geographically and in terms of rules, resources and products.

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Factors contributing to illicit trade

- High incentives and substantial loopholes
- Insufficient supply chain control measures
- Enforcement challenges
- Low disincentives

(COM Communication: stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products)
EU response

- Articles 15 and 16 of Tobacco Products Directive 2014/40/EU establish:
  - EU-wide system for tracking and tracing (from the manufacturer to the last point before the retail outlet)
  - Security features

International response

- FCTC Protocol (Article 8, on traceability)
Articles 15 of the Tobacco Products Directive 2014/40/EU (TPD) provides for an EU-wide system of traceability for tobacco products to address the issue of illicit trade. It introduces the tracking and tracing system with a unique identifier (UI) at the level of a unit packet of tobacco products;

International Treaties: Article 15 of Framework Convention on Tobacco Control (FCTC) and Article 8 of the FCTC Protocol requiring the Parties to establish a tracking and tracing system.


Implementation deadline under the TPD: 20/05/2019 (for cigarettes and RYO) and 20/05/2024 (for other tobacco products).
Timeline

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Art. 15(5) TPD: Member States shall ensure 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. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

Art. 15(1) TPD → Art. 6 CIR:
1. Manufacturers and importers shall mark each unit packet manufactured or imported in the Union with a unique identifier (‘unit level UI’) compliant with Article 8.
2. In the case of tobacco products that are manufactured outside the Union, the unit level UI shall be applied on the unit packet before the tobacco product is imported in the Union.
EU-wide system for traceability of tobacco products requires that all unit packets of tobacco products produced in, destined for or placed on the EU market:

- Have to be marked with a unique identifier;
- Their movements need to be recorded throughout the entire supply chain;
- Related information needs to be made available to authorities for enforcement purposes.
Time Stamp
Application
3rd party ID
Issuer
Requests by MF / IM
Independent UI generation
Aggregation level UI
Requests by distributors & wholesalers
Aggregation
Dispatch
Receipt
WH / DS
Aggregation
T1
T2
First retail outlet
Production Line
MF / IM
MF / IM
3rd party ID
Issuer
Aggregation
Anti-tampering device
Optional
Request by MF / IM
Unit packet level UI
Optional
Independent Data Capture
Primary Repositories
Copy
Secondary Repository
Router
MS user interfaces

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Key entities

- **ID issuers**
  - **key responsibility**: generation and issuing UIs and registration of economic operators, facilities and machines
  - appointed by Member States on a national basis;
  - maximum number: as many as Member States.

- **Primary repositories**
  - **key responsibilities**: storage of traceability data on products of a given manufacturer/importer;
  - contracted by individual manufacturers/importers and approved by the Commission;
  - maximum number: as many as manufacturers/importers;

- **Secondary repository**
  - **key responsibilities**: central router, central copy of traceability data, access interfaces for authorities, common data dictionary and connectivity specifications;
  - selected among the primary repositories by the Commission;
  - maximum number: one.

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Pursuant to Art. 35 CIR, ID issuers, providers of repository services and anti-tampering devices as well as, where applicable, their subcontractors shall be independent and exercise their functions impartially.

The following criteria are used to assess independence:

- independence from the tobacco industry in terms of legal form, organisation and decision making;
- independence from the tobacco industry in financial terms;
- absence of conflicts of interests with the tobacco industry of the persons in the management positions.

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Art. 8(1) CIR provides that a unit level UI shall not exceed 50 characters and be composed of the following data elements:

- the **ID issuer identification** (in line with ISO 15459);
- **Serial number**;
- **Product code** allowing for determining:
  - the place of manufacturing;
  - the manufacturing facility;
  - the machine used to manufacture the tobacco products;
  - the product description;
  - the intended market of retail sale;
  - the intended shipment route;
  - where applicable, the importer into the Union;
- **Time stamp**.

Art. 8(4) CIR requires that unit level UIs shall not include any other data elements.

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Marking with UIs

+ a human-readable code that enables electronic access to the information related to the unique identifiers stored in the repositories system.

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UIs – main steps for the industry

- Pre-registration in the system to obtain codes for economic operator, facility & machine;
- Request for UIs from competent ID issuer;
  - Delivery methods: electronically (default), physically (at discretion of Member States);
  - 6 months validity of UIs (from date of receipt to application);
- Marking of unit packets with UIs at the production line;
- Verification as to correct application/readability of UIs;
  - Anti-tampering devices;
- Further reporting on all logistic and financial operations concerning the marked products on the basis of UIs.

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## Request for UIs (1/3)

### 2.1. Request for unit level UIs

<table>
<thead>
<tr>
<th>Item #</th>
<th>Field</th>
<th>Comments</th>
<th>Data Type</th>
<th>Cardinality</th>
<th>Priority</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Message_Type</td>
<td>Identification of message type</td>
<td>Text</td>
<td>S</td>
<td>M</td>
<td>2-1</td>
</tr>
<tr>
<td></td>
<td>EO_ID</td>
<td>Economic operator identifier code of the submitting entity (either EU manufacturer or EU importer)</td>
<td>EOID</td>
<td>S</td>
<td>M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F_ID</td>
<td>Facility identifier code</td>
<td>FID</td>
<td>S</td>
<td>M</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Process_Type</td>
<td>Indication if the production process involves machinery</td>
<td>Boolean</td>
<td>S</td>
<td>M</td>
<td>0 – No (only for fully hand made products) 1 – Yes</td>
</tr>
<tr>
<td></td>
<td>M_ID</td>
<td>Machine identifier code</td>
<td>MID</td>
<td>S</td>
<td>M</td>
<td>M, if Process_Type = 1</td>
</tr>
<tr>
<td></td>
<td>P_Type</td>
<td>Type of tobacco product</td>
<td>Integer</td>
<td>S</td>
<td>M</td>
<td>1 — Cigarette 2 — Cigar 3 — Cigarillo 4 — Roll your own tobacco 5 — Pipe tobacco 6 — Waterpipe tobacco 7 — Oral tobacco 8 — Nasal tobacco 9 — Chewing tobacco 10 — Novel tobacco product 11 — Other (product placed on the market before 19 May 2014, not covered by categories 1-9)</td>
</tr>
</tbody>
</table>

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## Request for UIs (2/3)

<table>
<thead>
<tr>
<th>Item  #</th>
<th>Field</th>
<th>Comments</th>
<th>Data Type</th>
<th>Cardinality</th>
<th>Priority</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>P_OtherType</td>
<td>Description of other type of tobacco product</td>
<td>Text</td>
<td>S</td>
<td>M, if P_Type = 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P_CN</td>
<td>Combined Nomenclature (CN) code</td>
<td>Text</td>
<td>S</td>
<td>O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P_Brand</td>
<td>Brand of tobacco product</td>
<td>Text</td>
<td>S</td>
<td>M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P_weight</td>
<td>Average gross weight of unit packet, including packaging, in grams with 0.1 gram accuracy</td>
<td>Decimal</td>
<td>S</td>
<td>M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TP_ID</td>
<td>Tobacco product identifier used in the EU-CEG system</td>
<td>TPID</td>
<td>S</td>
<td>M, if Intended_Market is an EU country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TP_PN</td>
<td>Tobacco product number used in the EU-CEG system</td>
<td>PN</td>
<td>S</td>
<td>M, if Intended_Market is an EU country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended_Market</td>
<td>Intended country of retail sale</td>
<td>Country</td>
<td>S</td>
<td>M</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Intended_Route1</th>
<th>Indication if the product is intended to be moved across country boarders with terrestrial/water/air transport</th>
<th>Boolean</th>
<th>S</th>
<th>M</th>
<th>0 – No 1 – Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended_Route2</td>
<td>The first country of terrestrial/water/air transport after the product leaves the Member State of manufacturing or the Member State of importation established on the basis of a check point on the land border, next seaport or next airport respectively</td>
<td>Country</td>
<td>S</td>
<td>M, if Intended_Route1 = 1</td>
<td></td>
</tr>
<tr>
<td>Import</td>
<td>Indication if the product is imported into the EU</td>
<td>Boolean</td>
<td>S</td>
<td>M</td>
<td>0 – No 1 – Yes</td>
</tr>
<tr>
<td>Req_Quantity</td>
<td>Requested quantity of unit packet level UIs</td>
<td>Integer</td>
<td>S</td>
<td>M</td>
<td></td>
</tr>
</tbody>
</table>
Recording rules (1/3)

Recording of information on product movements (Art. 32 CIR)

- 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 CIR)

- 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

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Recording rules (2/3)

Recording of information on transactions (Art. 33 CIR)

- Required for: issuing of order number/invoice, payment receipt
  - Once the relevant event occurred and can be 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

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**Recording rules (3/3)**

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

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Public control provided by the combination of several measures:

- Independent issuers of unique identifiers;
- Independent storage of traceability data;
- Strict set of rules detailing the independence criteria;
- Presence of a central dataset;
- Message and data dictionaries;
- Specific and strict timeframe for reporting, including prior notification of products in move, combined with live monitoring by authorities;
- Pre-registration and coding of all economic operators, facilities (including retail outlets) and production machines;
- Regular audits.
# Cost-benefit calculations

## Cost implications per preferred policy options:

<table>
<thead>
<tr>
<th>Preferred policy options</th>
<th>Annualised cost (EUR million)</th>
<th>Cost per unit pack (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a/3: Mixed solution (industry and third party)</td>
<td>43.0</td>
<td>0.001451</td>
</tr>
<tr>
<td>1b/1: Near real time reports</td>
<td>48.7</td>
<td>0.001642</td>
</tr>
<tr>
<td>1c/3: Combined model</td>
<td>10.5</td>
<td>0.000353</td>
</tr>
<tr>
<td>2/4: Limited data carriers per level (and optional)</td>
<td>37.6</td>
<td>0.001268</td>
</tr>
<tr>
<td><strong>Total (Article 15 TPD)</strong></td>
<td><strong>139.7</strong></td>
<td><strong>0.004714</strong></td>
</tr>
</tbody>
</table>

| 3/2: Printing or affixing or a combination of printing and affixing | 14.9 | 0.000502 |
| **Total (Articles 15 & 16 TPD)** | **154.6** | |

## 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>219</td>
<td>2029</td>
<td>4.1</td>
</tr>
<tr>
<td>Economic operators, incl.:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- manufacturers/importers</td>
<td>n/a</td>
<td>59.1</td>
<td>150.6</td>
</tr>
<tr>
<td>- distributors/wholesalers</td>
<td></td>
<td>45.4</td>
<td>78.9</td>
</tr>
<tr>
<td>- retailers</td>
<td></td>
<td>5.8</td>
<td>71.6</td>
</tr>
<tr>
<td>General public</td>
<td>1497</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Total (EUR)</strong></td>
<td><strong>1716</strong></td>
<td><strong>2088</strong></td>
<td><strong>155</strong></td>
</tr>
</tbody>
</table>

*Annual costs and benefits per stakeholder group (in EUR million)*

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The EU system:

- is in full compliance with the FCTC Protocol;
- is a good fit for the needs of any other FCTC Party with well-developed IT infrastructure;
- has all the core rules designed by the public authorities (not a private operator with vested interests);
- involves multiple public authorities looking at the same data in real time (peer pressure); use of AI;
- is a system in which verification of independence is a continuous exercise;
- is designed to accommodate multiple providers and hence provides for a higher level of independence; any potential collusion with TI is much less likely to occur.
For more information, please consult:

https://ec.europa.eu/health/tobacco/tracking_tracing_system_en

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