



Implementation of Articles 15 and 16 of the Tobacco Products Directive

**Brussels
12 October 2017**

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



- Art. 15 TPD: introduces the tracking and tracing system with a unique identifier at the level of a unit packet of tobacco products;
- Art. 16 TPD: requires that all unit packets carry a tamper proof security feature, composed of visible and invisible elements;
- 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.

- *Implementing and delegated acts (containing technical specifications) are tentatively foreseen by the end of 2017, the Commission's draft proposals were published on 4/09/2017:*
 - https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4305467_en
 - https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4305537_en
 - https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4305574_en
- *Implementation deadline under the TPD: 20/05/2019 (for cigarettes and RYO) and 20/05/2024 (for other tobacco products).*

15.2. The unique identifier shall allow the following to be determined:

- (a) the date and place of manufacturing;
- (b) the manufacturing facility;
- (c) the machine used to manufacture the tobacco products;
- (d) the production shift or time of manufacture;
- (e) the product description;
- (f) the intended market of retail sale;
- (g) the intended shipment route;
- (h) where applicable, the importer into the Union;

15.3. [...] shall form part of the unique identifier

- (i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;
- (j) the identity of all purchasers from manufacturing to the first retail outlet; and
- (k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

15.4. [...] is electronically accessible by means of a link to the unique identifier



15.5. 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.



15.8. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party [...] The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract, shall be approved by the Commission.

The third party's activities shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. [...]

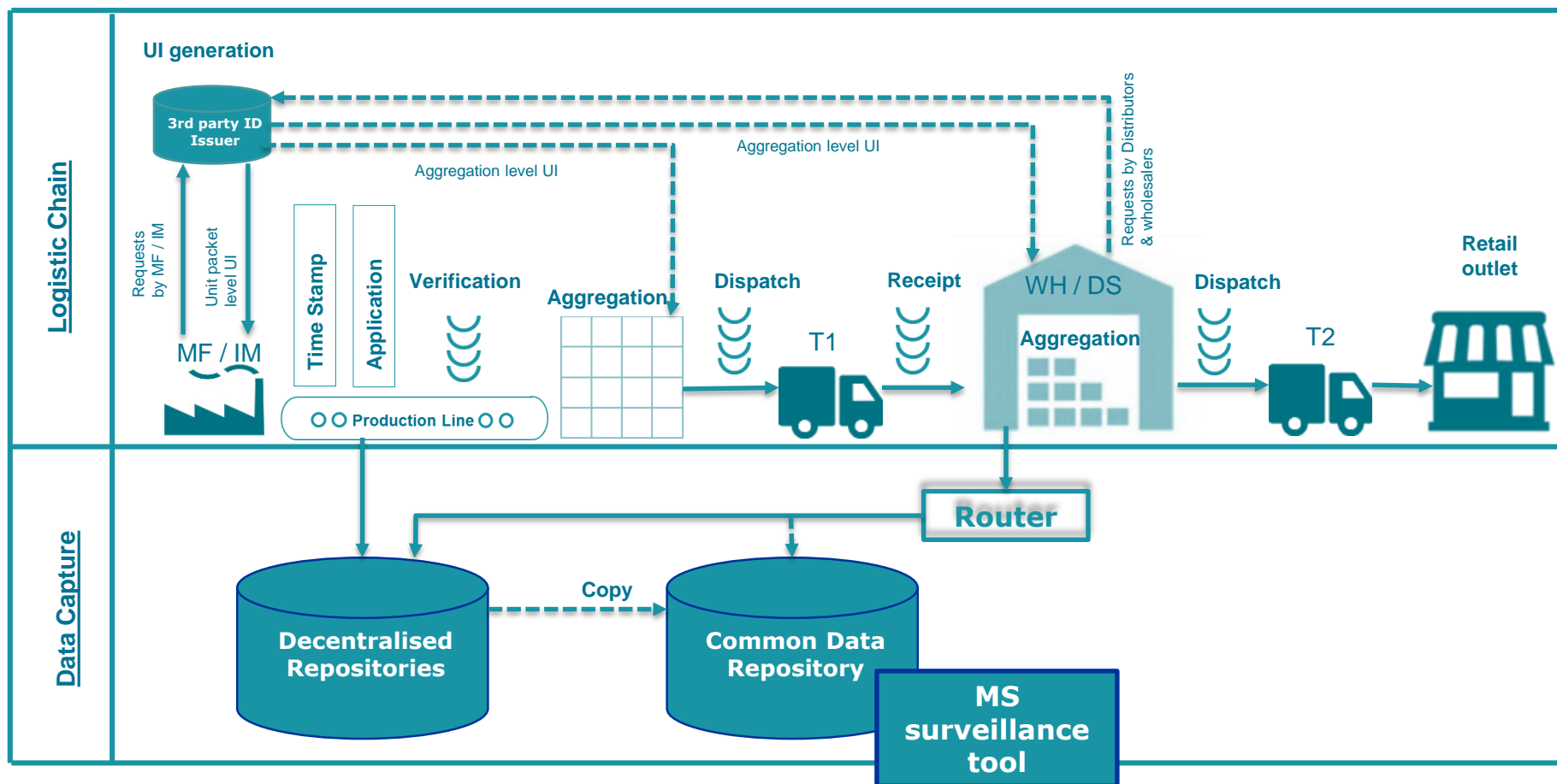
Member States shall ensure that the Commission, the competent authorities of the Member States, and the external auditor have full access to the data storage facilities. In duly justified cases the Commission or the Member States may grant manufacturers or importers access to the stored data [...]



Recital (31) TPD: In order to ensure **independence and transparency of the tracking and tracing system**, manufacturers of tobacco products should conclude data storage contracts with independent third parties. [...] The **data** related to the tracking and tracing system should be kept separate from other company related data and **should be under the control of, and accessible at all times by, the competent authorities from Member States and the Commission.**

Art. 8.2 FCTC Protocol: Each Party shall establish, in accordance with this Article, a tracking and tracing system, **controlled by the Party** for all tobacco products that are manufactured in or imported onto its territory taking into account their own national or regional specific needs and available best practice.

General architecture

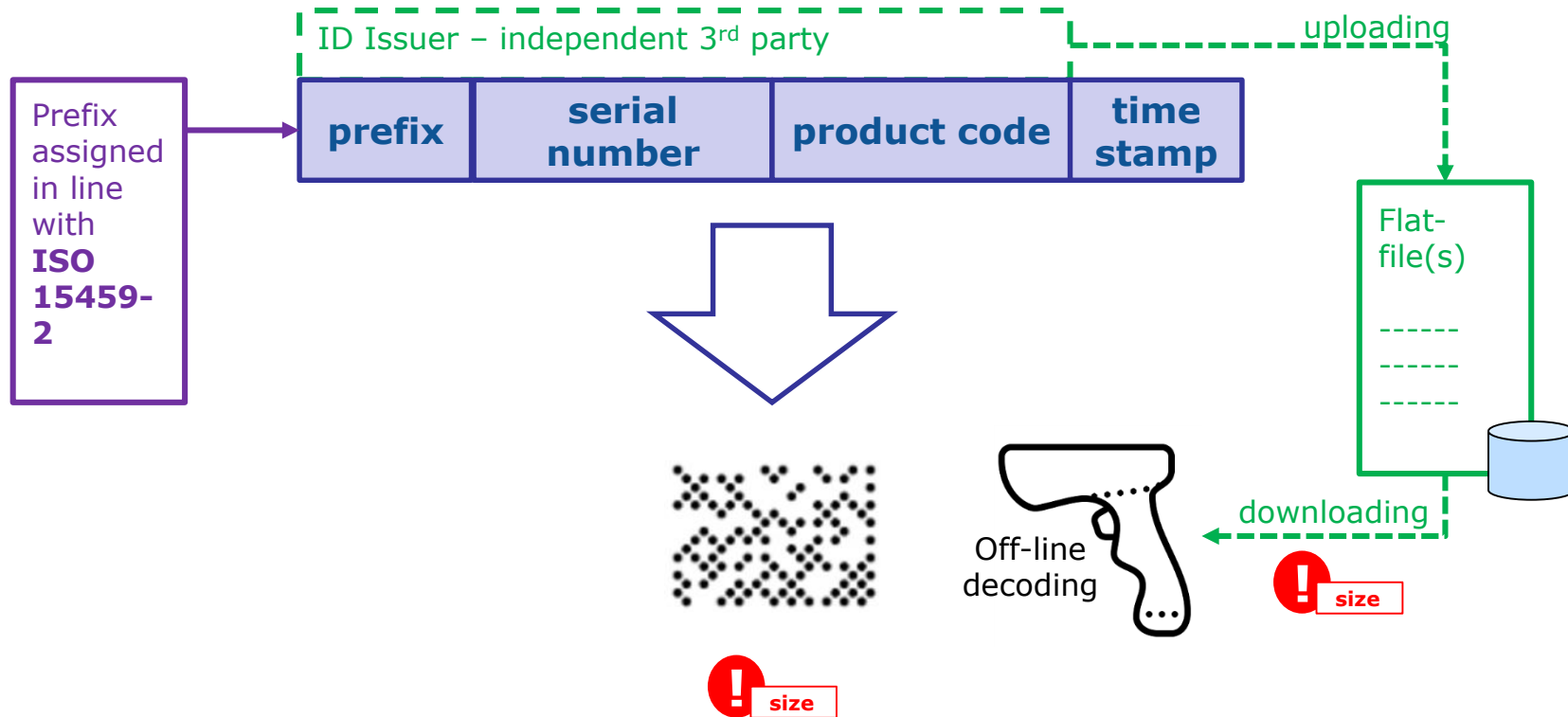


Unit pack level UIs



Art. 15(1) → uniqueness

Art. 15(2) (a) to (h) → data items to be determined



Main responsibilities of public authorities



Member States	<p><u>ID issuer</u></p> <ul style="list-style-type: none">– Selection and appointment of an ID issuer (Art. 3)– Ensure the independence of ID issuers, providers of repository services and anti-tampering devices (Art. 35) <p><u>Repositories system</u></p> <ul style="list-style-type: none">– Selection of national administrator managing access rights to surveillance tool (Art. 25.I.I.)
European Commission	<p><u>Repositories system</u></p> <ul style="list-style-type: none">– Approval of repository providers (Annex 1, A.3 and 4)– Publication of a list of notified and approved providers (Annex 1, A.8)– Selection and appointment of secondary repository provider in the absence of any agreement by primary repository providers on this matter (Annex 1, B.3)

Main responsibilities of independent providers



ID issuers:

- Control over serial numbers and product codes (Art. 8 of Draft IR);
- Issuing of unit level UIs (Art. 9 of DIR);
- Issuing of aggregated packaging level UIs (Art. 13 of DIR);
- Issuing of economic operator, facility and machine identifier codes (Art. 15, 17 & 19 of DIR);
- Establishing of offline flat-files (Art. 20 of DIR);
- Security protocols and connectivity rules for communications between ID issuers and economic operators (Art. 36 of DIR).

Main responsibilities of independent providers



Providers of secondary repositories:

- provide for graphical and non-graphical user interfaces that enable Member States and the Commission to access and query the data stored in the repositories system (Art. 27 of Draft IR);
- communicate to providers operating primary repositories, ID issuers and economic operators, the list of specifications required for the data exchange with the secondary repository and the router (Art. 28 of Draft IR);
- establish a common data dictionary (Art. 28 of Draft IR);
- set up and manage a router (Art. 29 of Draft IR).



Several ISO standards in the area of information technology will find their application in establishing, operating and maintaining the system, DIR explicitly refers to:

- ISO/IEC 15459-2:2015;
- ISO/IEC 6346:1995 → ISO/IEC 15459-1:2014;
- ISO/IEC 16022:2006;
- ISO/IEC 18004:2015;
- ISO/IEC 15417:2007;
- ISO/IEC 15415:2011;
- ISO/IEC 15416:2016;
- ISO/IEC 646:1991;
- ISO/IEC 3166-1:2013;
- ISO/IEC 4217:2015;
- ISO/IEC 8859-15:1999.

Thank you for attention!