



Implementation of Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU

**European Commission's
Directorate General for Health and Food Safety, Unit D4**



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Outline

- Problem statement
- Nature and scale of the problem
- Available solutions to the problem
- Relevant legal provisions
- Work accomplished so far
- Further work
- Timeline

Problem statement

- Illicit tobacco products do not comply with the requirements of tobacco product regulation, in particular with respect to ingredients and labelling rules. Illicit products also create a low priced supply and hence make tobacco products more affordable, in particular to young people.
- As the result, illicit products undermine the free circulation of compliant products on the Internal Market. They put at risk the health policies of Member States aimed at curbing tobacco consumption (as the most significant cause of premature deaths in the EU) as well as considerably reduce the tax revenues (about €10 billion a year).

Nature and scale of the problem

- Illicit trade is broadly defined as any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase, including any practice or conduct intended to facilitate such activity.
- Tobacco products are subject to intra- and extra-EU smuggling, counterfeiting, illegal manufacturing and other fraudulent practices.

Table: Estimated volume of illicit trade in cigarettes (in EU25)

	2009	2010	2011	2012	2013
Actual consumption in million sticks	734,627	705,303	665,839	635,639	596,014
Illicit trade in million sticks	64,397	73,664	65,612	66,883	67,780
% penetration of illicit trade	11.39%	13.88%	12.60%	12.79%	13.21%

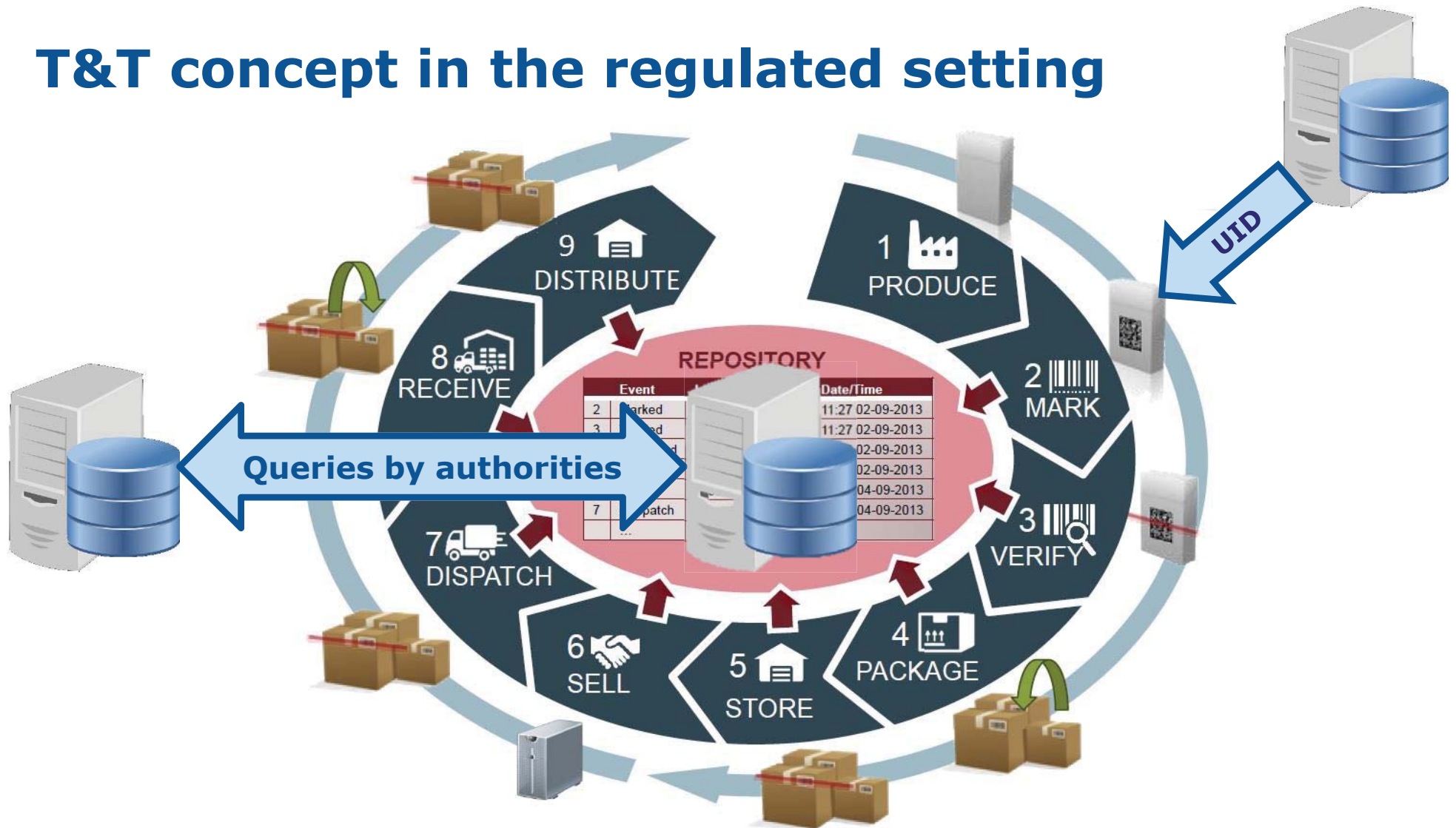
Note: figures exclude Cyprus, Luxembourg and Malta

Source: Euromonitor

Available solutions

- Tracking - marking products with a unique identifier so they can be monitored from the point of production up to the point of sale to the customer, including each step of the process, creating a time and location history for every step.
- Tracing - ability to identify the past or current location of an item.
- Overt security features – features that can be verified by the human eye, such as colour changing inks, holograms, latent images, watermarks and security threads.
- Covert security features - not instantly recognizable or interpretable by the human senses, but requiring authentication tools and/or specialized knowledge to verify their presence and validity.

T&T concept in the regulated setting



Examples of available solutions for security features

- 1) UV
- 2) Microprint
- 3) Hologram
- 4) Fingerprinting
- 5) Colour shifting inks

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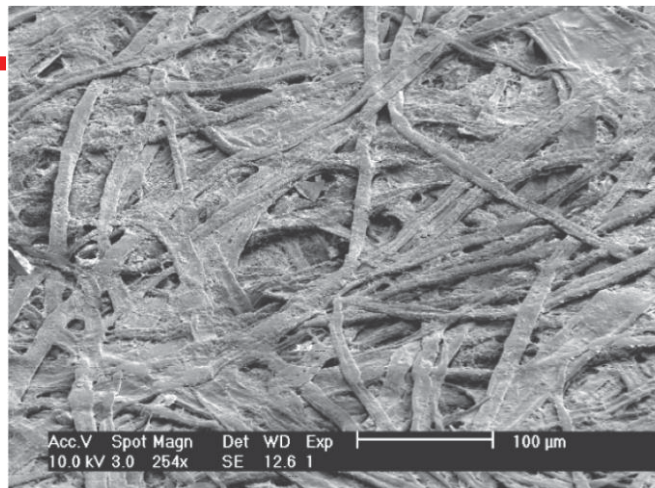
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Relevant legal provisions (1/2)

- Article 15 TPD - requires that all unit packets of tobacco products are marked with a unique identifier and that their movements are recorded throughout EU. The requirement applies to all products manufactured in and destined for the EU market. The envisaged system covers all economic operators involved in the trading of tobacco products, from the manufacturer to the last economic operator before the first retail outlet.
- Article 16 TPD - requires that all unit packets of tobacco products, which are placed on the EU market, carry a tamper proof security feature composed of visible and invisible elements.
- Article 8 FCTC Protocol – the Parties agree to establish a global tracking and tracing regime, comprising national and/or regional tracking and tracing systems (controlled by the Parties) and a global information-sharing focal point (at the FCTC Secretariat).

Relevant legal provisions (2/2)

- By means of implementing and delegated acts, the Commission shall:
 - determine the technical standards for the establishment and the operation of the tracking and tracing system (Art. 15(11(a) TPD);
 - determine the technical standards for ensuring that the systems used for the unique identifier and the related functions are fully compatible with each other across the Union (Art. 15(11(b) TPD);
 - define the key elements of the data storage contracts (Art. 15(12) TPD);
 - define the technical standards for the security feature and their possible rotation and adapt them to scientific, market and technical developments (Art. 16(2) TPD).

Feasibility Study (1/3)

- Carried out by an external contractor;
- Published on 7 May 2015;
- Main conclusions:
 - Full traceability of EU tobacco products is achievable;
 - Many solutions for security features meet the TPD requirements;
 - No matter which traceability and security feature option is selected, the benefits clearly outweigh the costs from both economic and social perspective.
- Feasibility Study presents four potential solutions for traceability and four for security features.

Feasibility Study (2/3)

- Proposed traceability solutions:
 - Option 1: an industry-operated solution, with direct product marking carried out by tobacco manufacturers; manufactures are free to select an independent data storage provider;
 - Option 2: a solution operated by a third party responsible for the product marking process on the production line; the system operates with one central independent data storage provider;
 - Option 3: each Member State selects between Option 1 and 2 regarding the entity responsible for product marking (manufacture or independent solution provider); the system operates with multiple independent data storage providers;
 - Option 4: a unique identifier is integrated with a security feature and affixed in the same process as a security feature; the system operates with (a) independent data storage provider(s).

Feasibility Study (3/3)

- Proposed solutions for security feature:
 - Option 1: a security feature using similar authentication technologies to a tax stamp;
 - Option 2: reduced semi-covert elements as compared to Option 1, where the co-presence of a unique identifier is regarded as equivalent to the semi-covert level of protection;
 - Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection;
 - Option 4: a security feature is integrated with a unique identifier (see Option 4 for traceability).

Targeted stakeholder consultation (1/2)

- Launched following the publication of the Feasibility Study (consultation period: 7 May 2015 to 31 July 2015);
- Targeted stakeholders: (i) manufactures, (ii) wholesalers and distributors, (iii) solution providers and (iv) governmental and non-governmental organisations (tobacco control & anti-illicit trade)
- Opinions sought on:
 - Appropriateness of each of the four options for tracking and tracing system
 - Appropriateness of each of the four options for the security features
 - Level of agreement with the cost/benefit analysis
 - Appropriateness of different possible building blocks and modalities

Targeted stakeholder consultation (2/2)

- Stakeholder consultation attracted over 100 respondents representing a variety of interests. Results will feed into the next stage of the Commission's implementation work.

Type of respondent	
Manufacturer of tobacco products destined for consumers (finished tobacco products)	25
Operator involved in the supply chain of finished tobacco products (excluding retail)	19
Provider of solutions	20
Governmental organisation	12
NGO	21
Other	12
Total	109

Further work – Implementation study (1/2)

- Pending open call for tender (till 9 October 2015) to provide the Commission with the necessary input for development of the implementing legislation, based on Articles 15 and 16 of the TPD.
- Specific objectives as regards the tracking and tracing system:
 - a reassessment of the options proposed in the Feasibility Study;
 - a proposal for optimal design including system architecture with system interfaces, including the minimum technical standards and describing how adequate levels of security and interoperability will be achieved;
 - a proposal for optimal design and minimum technical standards with respect to operating the independent data storage, including the key elements of the data storage contracts.

Further work – Implementation study (2/2)

- Specific objectives as regards the security feature:
 - a reassessment of the options proposed in the Feasibility Study;
 - a proposal for optimal design of the system for the security feature, including the technical standards for the security feature and their possible rotation.

Further work - consultations

- Independent expert seminars;
- Stakeholder seminars;
- Regular meetings of the Subgroup of experts (experts are designated by Member States);
- Public consultation (as a part of the Impact Assessment under the Better Regulation Initiative)

Further work - timeline

- Last quarter 2015 – start of a new contract for external expertise (Implementation Study) ;
- 1st half 2016 – public consultation under the Better Regulation Initiative;
- 2nd half 2016 – Impact Assessment;
- Mid 2017 – adoption of implementing and delegated acts;
- The industry will have to deploy a new system (for cigarettes and RYO tobacco) by 20 May 2019.

Thank you!

Any questions?

Further Information

http://ec.europa.eu/health/tobacco/policy/index_en.htm