

## Implementing & Delegated Acts concerning the tracking and tracing of tobacco products (Articles 15 & 16)

of

Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

**Disclaimer:** The European Commission has not yet issued any proposal with regards to the implementation of articles 15 and 16 of the EUTPD (Directive 2014/40/EU) and repeatedly stated that the views presented thus far are only those of the Contractor, Everis. As a consequence, the European Commission is not overstepping its mandate, but questions and criticisms can be made on the approach undertaken by the Contractor.

### Executive Summary

Some recommendations made in the Everis' Interim Report<sup>1</sup>, if followed by the European Commission, would overstep its powers and mandate in establishing technical standards for the EU Tracking and Tracing as laid down in articles 15 and 16 of the European Tobacco Products Directive (2014/40/EU).

- **EU Products intended for Export:** Tobacco products manufactured in the EU, but intended for export in third countries, do not fall within the scope of the European Tobacco Products Directive. Therefore, the obligations to bear an EU Unique Identifier (UID) should not apply to these products;
- **Anti-tampering system:** The introduction of an anti-tampering system on the production lines was not foreseen by the co-legislators when adopting the Directive. Article 15 gives a mandate to the Commission to determine the technical standards for the Track & Trace system, not to establish a disproportional and ineffective surveillance system to oversee the activities of legal and compliant manufacturing;
- **Pre-authorisations system & acknowledgements:** Besides being practically impossible, the pre-authorisations and acknowledgements system would oblige Member States to create additional administrative bodies, adding burden to governments and tax-payers. Such a system is not an essential technical standard for the operation of the tracking and tracing system, since compliant manufacturers and economic operators can ensure the UID allows determining the information referred in Article 15 (2) (a) to (k) without requesting pre-authorisations and receiving acknowledgements;
- **EU Administrative & Surveillance Committee:** European co-legislators already foresaw that the tracking and tracing system would require monitoring the third parties' activities, as explicitly and sufficiently stated in Article 15 (8). Whilst the recommendation in Everis' report suggests this EU Committee "*would be responsible for the operational management of the services and activities of the system*", the Directive clearly states that such obligations fall on Member States.

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<sup>1</sup> Everis, *Implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products*, Interim Report III, May 2017.



## The Legal Basis – Directive 2014/40/EU

Article 15 (11) reads “The Commission shall, by means of implementing acts:

- (a) **determine the technical standards** for the establishment and the operation of the tracking and tracing system as provided for in this Article, including the marking with a unique identifier, the recording, transmitting, processing and storing of data and access to stored data;
- (b) **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.

*Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).”*

Article 15 (12) empowers the Commission to adopt “delegated acts in accordance with Article 27 to **define the key elements of the data storage contracts** referred to in paragraph 8 of this Article, such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts”.

Article 16 (2) reads “The Commission shall, by means of implementing acts, **define the technical standards for the security feature and their possible rotation** and adapt them to scientific, market and technical developments. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).”

## The Interrogations on Everis’ Draft Report and Recommendations

The key question is whether the Commission’s Contractor, Everis, is making recommendations that would mean that the Commission is overstepping its powers if it were to follow these Recommendations. The main determinant is what is meant with establishing technical standards. A technical standard is an established norm or requirement regarding technical systems. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes and practices.

At this stage the Everis Interim Report<sup>2</sup> and recommendations on an EU Tracking and Tracing system goes beyond the establishment of “technical standards” as per the articles in question by suggesting that the system includes:

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<sup>2</sup> Everis, Implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products, Iterim Report III, May 2017.

## A. EU Products intended for Export

In its Interim draft Report, Everis assumes that tobacco products manufactured in the EU, but intended to export to non-EU countries, will have to bear an EU unique Identifier (UID).

1. This constitutes a clear misinterpretation of the Directive, as it applies to products placed on the EU market only. Article 15 of the Directive reads “*Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier*” while Article 2 (30) defines unit packets as follows: “*the smallest individual packaging of a tobacco or related product that is placed on the market*”. Thus, the obligation to bear an UID does not apply to products intended for export;
2. Article 15 also reads: “*In the case of tobacco products that are manufactured outside of the Union, the obligations laid down in this Article apply only to those that are destined for, or placed on, the Union market.*” This means that non-EU products, transiting through the EU but not placed on the EU Market will not bear an UID. The Directive is correctly addressing this practice, and it would follow that the same goes for any product manufactured in the EU but not placed on the EU market;
3. The Everis’ interpretation ignores third countries’ regulations, which may require that only their marking is applied on the unit packets, which would lead to a de facto ban of products “made in EU”, because of the EU UID. In light of the incompatibility with other systems in third countries, manufacturers and Member States would not be able to retrieve data in case of failure of deliveries or return of the goods, which is the opposite of the Directive’s objectives;
4. EU-products intended for export are already monitored by well-established and functioning tools, such as those of the Excise Movement and Control System (EMCS). Besides, The EMCS is currently being revised, modernised and simplified by the European Commission;
5. With this interpretation, the European Commission indicates Track & Trace would also implement the obligations of Article 8 of the FCTC Protocol to eliminate illicit trade in tobacco products. First, implementing powers can only be granted and used for the provision of “further detail” in relation to the content of a legislative act and as described by the provision granting the implementing power, namely Article 15(11) of the Tobacco Products Directive only. It is therefore not open to the Commission to introduce an implementing act with requirements that go beyond the technical standards the EU co-legislator set out in in the Directive. Second, Article 8 of the FCTC Protocol clearly states that such system shall be established for tobacco products other than cigarettes within a period of 10 years after the entry in force of this Protocol.

## B. An Anti-Tampering System

To “*assure the accomplishment of Article 15*”, Everis recommends the establishment of an anti-tampering system, which “*is intended to oversee the scanning and verification process of the data carriers in the production line and the temporary buffer equipment*”. Everis adds “*These measures can either be passive, such as making it difficult to manipulate or obstruct the system; or active, such as tamper-detection techniques, which make a process non-operational if tampered*”. Going further, Everis suggests, “*The manufacturer or importer shall not be able to mark any unit packet of tobacco product unless a previously approved anti-tampering solution is installed in the production line and is fully operational*”.

1. While Article 15(11)(a) empowers the Commission “*to determine the technical standards for the establishment and the operation of the tracking and tracing system (...) including the marking with a unique identifier, the recording, transmitting, processing and storing of data and access to stored data*”, it does not empower the Commission to establish a surveillance

system to oversee the activities of legal manufacturers, which is not mentioned in articles 15 & 16 of the EUTPD;

2. The European Anti-Fraud Office (OLAF) reports in 2016<sup>3</sup> that *“the prevalence of contraband on the EU tobacco market has significantly decreased in the last decade. A Commission Staff Working Paper published in 2016 showed, for example, that contraband in genuine Phillips Morris products on the illicit EU tobacco market dropped by around 85% from 2006 to 2014. This, however, did not lead to an overall reduction of illicit products on the EU market as smugglers turned their attention to traffic with “cheap whites,” which are non-branded cigarettes.”*;
3. This observation is supported by the latest results of the Project SUN<sup>4</sup>, which finds in 2016 that *“illicit cigarettes from outside the EU accounted for 86% of the Counterfeit & Contraband identified in the study”*. Besides *“counterfeit declined by 19%, as 55 factories producing counterfeit product were closed in the EU”*. Conclusion, *“illicit Whites make up the majority of large seizures (accounting for 97% of OLAF supported seizures)”*;
4. Illicit trade of tobacco products is mostly a cigarette issue, whilst almost non-existent in other tobacco products, such as pipe, traditional nasal snuff or chewing tobaccos. The establishment of an anti-tampering system on the production lines of compliant manufacturers is not only overstepping the mandate given by the Article 15, but also a disproportional measure establishing production counter and volume control mechanisms. This clearly ignores the realities of production and the specificities of traditional tobacco products, which involves a more important human component. Failures and damages on tobacco product therefore happen more frequently. If the objective of such tracking and tracing system was to monitor compliant manufacturers, co-legislators would have made this clear in the Directive, as was the case for the involvement of third parties regarding data storage.

### C. Pre-authorisations system & Acknowledgments

The draft system developed by Everis provides that manufacturers, importers, wholesalers and distributors will have to request a pre-authorisation at every stage of the production and trade of tobacco product (including re-aggregation) and to receive acknowledgments in order to generate the UID. These pre-authorisation requests are then supervised, since *“the responsible for the management of the registration and authorisation of economic operators shall monitor and control the process of registration of actors and request for serial numbers”*.

1. This pre-authorisation system requires economic operators to request one authorisation to produce per product unit (approximatively 29 billion a year, 80 million a day), an authorisation per intended shipment route, per production line, per day and per consumer. Besides, the authorisation requests to send all invoices related to the products before the product has been actually sold and before excise tax has been paid, which entirely ignores the reality of trade and is practically impossible to implement;
2. Such unnecessary and burdensome *“pre-authorisations”* will create bottlenecks in the production process, increased complexity of the system and its operation and will oblige the

<sup>3</sup> European Anti-Fraud Office (OLAF), *The OLAF Report 2016*, p. 20, 2017. Available online: [https://ec.europa.eu/anti-fraud/about-us/reports/olaf-report\\_en](https://ec.europa.eu/anti-fraud/about-us/reports/olaf-report_en)

<sup>4</sup> KPMG, *Project SUN: A study of the illicit cigarette market in the European Union, Norway and Switzerland 2016 Results*, p. 11, 2017/ Available online: <https://assets.kpmg.com/content/dam/kpmg/uk/pdf/2017/07/project-sun-2017-report.pdf>

Member States to create a pre-approval administrative body, adding burden to governments and tax-payers;

3. Article 15 requires the European Commission to adopt “*technical standards for the establishment and operation of the tracking and tracing system*” but not to oblige Member States creating additional administrative bodies, when these latter are not essential to the operation of the tracking and tracing system. On the other hand, compliant manufacturers and economic operators can ensure the UID allow determining the information referred in Article 15 (2) (a) to (k) without requesting pre-authorisations;

#### **D. EU Administrative & Surveillance Committee**

When discussing the governance model of the tracking and tracing system, Everis suggests establishing a Steering Committee, whose aim “*would be to ensure the successful performance of the system, which includes maximising the benefits from the projects and ensuring that the competent authorities are appropriately represented in the management of the system. The proposed members of the Steering Committee would be (non-exhaustive): CHAFAEA, DG SANTE, DG TAXUD, OLAF, Customs control representatives from the Member States, Health control representatives from the Member States, Law enforcement representatives and Tax Authorities from the Member States*”.

In addition, this Committee “*would be responsible for the operational management of the services and activities of the system*” and would, amongst other things, monitor the activities of third parties, monitor the system security and ensure the maintenance of the tracking & tracing system.

1. When adopting the Tobacco Products Directive in 2014, European co-legislators already foresaw that the tracking and tracing system would require monitoring the third parties’ activities. For this purpose Article 15 (8) of the Directive clearly states: “*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. The external auditor shall submit an annual report to the competent authorities and to the Commission, assessing in particular any irregularities in relation to access*”. Therefore, the provisions laid down in this article are sufficient and do not require the creation of a EU surveillance body;
2. Everis suggests that this Steering Committee, which would encompass one European Regulatory Agency and three Commission’s Directorate Generals, would be “*responsible for the operational management of the services and activities of the system*”. The European Tobacco Product Directive and co-legislators, on the other hand, repeatedly (8 times in Article 15) and clearly stipulated that such obligations fall on the Member States.