

SFP - ECL Position Paper

**on the proposed Implementing Regulation on a Traceability
System for Tobacco Products,
Delegated Regulation on Data Storage Contracts and
Implementing Decision on Security Features**

TOP PRIORITIES

- 1** Independent third party companies (under Article 35 of the Implementing Regulation and Article 8 of the Implementing Decision) should generate less than 5% turnover from the tobacco sector before and less than 15% after signing the contract.
- 2** No further role should be given to the tobacco industry beyond printing/affixing Unique Identifiers. According to article 8.12 of the WHO FCTC Protocol, the generation of unique identifiers cannot be an obligation performed by or delegated to the tobacco industry.
- 3** There should be no delays in the adoption of implementing and delegated acts.

General comments regarding adoption of the implementing and delegated acts

We welcome the fact that the Commission and its consultants have conducted a thorough and detailed process to inform the drafting of the Implementing Regulation, Implementing Decision and Delegated Regulation, and that this process is founded on a commitment to ensure that an EU wide traceability system for tobacco products is effective in tackling illicit trade and cannot be co-opted or subverted by the tobacco industry.

We applaud the Commission for keeping to the implementation calendar despite the complexity of the matter and the pressures of vested interests. We would like to emphasise that the adoption of the acts should not be delayed. This is because the date of implementation of the Delegated Regulation on Data Storage Contracts and Implementing Decision on Security Features (20th May 2019) cannot be changed, regardless of when the acts are adopted.

We also welcome Recitals 5 and 24 of IR Art 15(11), which demonstrate the Commission's efforts to respect and implement the Illicit Trade Protocol (ITP). The ITP has been ratified by the EU and 8 Member States (MS)¹ to date. We recall that the ITP was developed as a response to the fact that the majority of illicit tobacco products are genuine and diverted from the legal supply chain. We must also stress that there is a strong economic incentive for operators to allow legal products to be diverted into illicit channels. The main goal of the traceability system, therefore, must be to control the legal supply chain.

We consider the traceability system to be a crucial part of the revised Tobacco Products Directive and essential in the fight against the illicit tobacco trade. This document therefore sets out, in more detail than our response to the online Commission consultation, our remaining concerns about the draft proposals.

Independence from the tobacco industry

Independence from the tobacco industry (defined in a broad sense as including all commercial elements in the tobacco supply chain) is absolutely necessary if the traceability system is to work as intended. It is also necessary to comply with the EU and Member States' current and likely future commitments under Article 5.3 of the Framework Convention on Tobacco Control (FCTC) and under Article 8 of the Illicit Trade Protocol (ITP).

We consider that the principle of independence must apply to the entirety of the traceability system, as explained in Recital 24, in particular:

- ID issuers (Recitals 5, Articles 3.2, 3.7(a) of the Implementing Regulation).
- anti-tampering devices (Recital 14 and Article 7. 2 of the Implementing Regulation).
- data repositories (Recital 19 and Article 26.1 of the Implementing Regulation).
- contracts with repository providers (Recitals 1, 4, Articles 7.2(a), 8, 17.3(b) of the Delegated Regulation).
- Providers of the authentication element of the security feature (Recital 6 and articles 3.2 and 8 of the Implementing Decision Art 16.2).

¹ Parties from the EU who have ratified the ITP: Austria, Spain, Portugal France, Latvia, Slovakia, Cyprus and Lithuania; https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4-a&chapter=9&lang=en

We therefore recommend the following revisions to Article 35 of the Implementing Regulation:

- The term “entity” needs to be broadly defined – it currently is not defined at all. We are aware of two possible definitions in existing EU law (there may of course be more). The first is “public interest entity”, defined by Article 2 of Directive 2013/34/EU (on accountancy issues) as “governed by the law of a Member State and whose transferable securities are admitted to trading on a regulated market of any Member State”. The second, which we prefer in this context, is in Chapter 1 of Article 1 of Council Directive 2001/23/EC (dealing with the transfer of undertakings), which defines “entity” more widely as “an organised grouping of resources which has the objective of pursuing an economic activity...”, in other words this definition does not require an “entity” to be a free-standing public company².
- in 2(d) the entity should have to provide evidence and a signed legal declaration that it is fully independent of the tobacco industry and this documentation should be made public.
- In 2(e) companies should only be considered if their turnover from the tobacco industry is less than 5% before the application date for a contract under the Regulations and of less than 15% thereafter.
- No provider shall subcontract any of the authentication elements or other tasks to any party that does not meet the above mentioned definitions of Independence.
- The conflict of interest criteria should also cover technical and operational staff in addition to management, and be retrospective for at least two (preferably five) years.
- Member States should establish and review, at least annually, a list of providers of data storage, anti-tampering devices and authentication elements which comply with the independence criteria.
- We propose that should an UI issuer, anti-tampering device provider, data repository or authentication element provider cease to comply with the independence criteria, this would immediately void their contracts.

Security of Unique Identifiers

We welcome the provisions requiring unique identifiers to be generated by an independent third party at the request of the Member States. Unique identification markings are an obligation under article 8.3 of the WHO FCTC Illicit Trade Protocol (ITP) and shall not be performed by or delegated to the tobacco industry (article 8.12 of the ITP).

We are concerned that the proposed requirements of the unique identifiers (UI) do not appear to guarantee their security, which is of course an obligation of the Illicit Trade Protocol. Specifically, data carriers are not adequately protected against cloning or copying. We do not believe that the EU repository system will always alert the Member States when codes are copied.

The current draft Regulation requires producers to print a UI onto tobacco product packaging, using an electronic file received from an independent issuer. Producers are also required to verify the UI

² The tobacco industry has developed a proprietary system for tobacco products, Codentify, which was transferred to the company Inexto in June 2016. Inexto is in turn part of the French group Impala. If Inexto is an “entity” for the purpose of Article 35, it would not be considered as “independent” since it would certainly generate more than 20% of its turnover from the tobacco industry (Article 35.2(e)). If the Article 35 “entity” is Impala, this would not be the case. The Impala Group also has a subsidiary called Arjo Solutions, which provides security features for commercial products; similar considerations could apply in relation to its independence from the tobacco industry.

themselves. The verification system would be fitted with an anti-tampering device to prevent alteration of recorded entries. But it could not detect if a single UI has been printed multiple times, since a producer engaging in such an activity would only enter the UI into the system once.

When products are exported outside the EU they will not contain a security feature and will not be registered in the EU system as illegal, only as exported. Copied codes could be applied on packs and transported illegally in the EU without registration. If these products were seized, authenticity could not be checked (since there would be no security feature) and verification in the EU repository system would suggest that they were legal (showing that they have been exported, with no further information).

The anti-tampering device would appear only to verify that the data carrier is correctly applied but not that it is applied to the right product (brand description mentioned in the unique identifier). We understand that in Brazil, for instance, a camera on the production line verifies that unique identifiers are applied on the right products.

We therefore suggest an amendment to Article 7.1 as follows:

“Manufacturers and importers shall ensure that the application of unit level UIs is directly followed by the verification of those unit level UIs in terms of application *to the correct products* and readability.”

We believe that the current proposals have some dangerous weaknesses which might make the system less effective than it should be in addressing the diversion of legitimately manufactured tobacco products into illicit channels.

Interoperability

The UI provisions appear to require all Member States to use the same encryption method. We consider it a highly desirable feature of the traceability legislation at EU level that it should as far as possible set *standards* for Member States to follow rather than (by implication or explicitly) specify a *proprietary* system. It could be worrying that UI providers encrypt information which is not defined by the Directive and without informing the Member States and the Commission.

We strongly recommend that there should be an additional requirement in Article 8.5 as follows:

“The unique identifier shall not encrypt any data except those listed in article 8 1.c. Encryption shall only be used for compression or security reasons. Competent UI providers shall provide all relevant information on the encryption process to the Member States and the Commission”

The current proposals do not appear to give full consideration to the Electronic Identity Authentication and eSignature (eIDAS), which comes into effect in January of next year.³ As far as possible, we think that the eIDAS standards should be applied throughout the traceability system, so that it covers UIs,

³ <https://ec.europa.eu/digital-single-market/en/trust-services-and-eid>

data aggregation, code inspection, etc. We understand, however, that at present eIDAS would not provide for all the elements of the traceability system mandated by the Tobacco Products Directive, and would therefore require further refinement to be suitable.

Data Storage Providers

Article 26 of the Implementing Regulation requires manufacturers and importers to contract with a third party to establish a primary repository. The third party should be independent as defined by Article 8 of the Delegated Regulation (and Article 35 of the Implementing Regulation). The criteria for their independence should be those we recommend above. We would prefer that providers of primary repositories should be selected by Member State government, not the tobacco industry.

We urge the Commission to ensure that the approval of data storage contracts is carried out in collaboration with Member States.

Also, indirect influence by the tobacco industry of the secondary repository is of concern, because:

- The tobacco industry has no obvious incentive to select a common data provider who would do a thorough job and report all irregularities
- The data service and auditors will have a financial relationship with those they should monitor. This may create a conflict of interest between the watchdog and the customer.
- The common data repository will not be managed by the Commission or the Member States. Neither will closely supervise the data provider; they can only request, in case of unsatisfactory performance, the end of the contract. But contract termination could be highly disruptive to the system.

As a minimum, the operator of the secondary repository should not be selected by the operators of primary repositories (Article 27.1), and the operator of the secondary repository should not have to be selected from this group alone.

Costs

Article 3.8 of the Implementing Regulation states that: “The ID issuer *may* charge fees to economic operators for generating and issuing unique identifiers”. “May” should be replaced with “shall”.

Article 3 of the Implementing Decision on security features does not allocate the costs to the tobacco industry, and the issue is also not addressed in Article 16.2 of the Implementing Regulation on traceability. This should be rectified.

Audits

Article 15 of the Delegated Regulation on data storage contracts provides for “external auditors approved by the Commission”. Requirements for independence from the tobacco industry should be included in the Article, defined as excluding companies that act as auditors for the major tobacco manufacturers or their subsidiaries.