

Action on Smoking and Health (UK) submission

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

ASH also endorses the submissions of SFP and ECL.

Process

The short timescale of this consultation is of concern, given that the adoption process consists of a straight yes or no decision, without the possibility of amendments.

Independence

The traceability system, application of security features, and at least the secondary repository of data generated by the traceability system, should be operated independently of the tobacco industry. The tobacco industry should be treated by the Commission as *sui generis*: the World Health Assembly (resolution WHA69.1) states: *"WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry"*.

Essential definitions are lacking. Article 2 does not define the term "entity". There are at least two possible definitions in existing EU law. The first is "public interest entity", defined by Article 2 of Directive 2013/34/EU (on accountancy) 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 is in Chapter 1 of Article 1 of Council Directive 2001/23/EC (on transfer of undertakings), which defines "entity" more widely as *"an organised grouping of resources which has the objective of pursuing an economic activity..."*. We believe the second definition is most appropriate.

Article 8 of the Implementing Decision on security features refers to *"a provider of authentication elements"*, without defining "provider". The Explanatory Note states that *"Member States will have to ensure that no conflict of interest exists among the persons responsible for the management of the provider"*, but provides no definition of conflict of interest.

A stricter turnover requirement in Article 35(2)(e) is needed, of 0% of turnover before a contract under the Regulations, and 15% after. The conflict of interest criteria in Article 35(2)(f) should cover senior technical and operational staff as well as management, and to be retrospective for at least five years.

Security of Unique Identifiers

The requirements of the unique identifiers do not appear to guarantee their security, which is an obligation of the WHO FCTC Illicit Trade Protocol. Specifically, data carriers are not protected against cloning or copying. We do not believe that the EU repository system will always alert the Member States when codes are copied. For instance, 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 are seized, authenticity can't be checked (no security feature) and verification in the EU repository system will reveal that they are legal (exported, but no further info).

The proposed anti-tampering device only seems to verify that the data carrier is readable, but not that it is applied to the right product (brand description mentioned in the unique identifier).

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 above.

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

- The tobacco industry has no 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.

The current proposal does not meet the terms of recital 31 of the Tobacco Products Directive, which states that: *“the data related to the tracking and tracing system should be under the control of ... the competent authorities from Member States and the Commission.*

Costs

Article 3 of the Implementing Decision on security features does not allocate the costs to the tobacco industry, and this is also not addressed in Article 16(20) of the Implementing Regulations on traceability.

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.