

The published EU directive (2014/40/EU of April, 3rd 2014) on tracing the manufacturing and distribution of tobacco products imposes an obligation to monitor the transfer of tobacco products from the manufacturing line of the manufacturer to the last chain of delivery except for the retail outlet. Art. 15 Of the Directive assumes that the monitoring system and its administration should be independent on the manufacturers of tobacco preparations and products. It stipulates product labelling with a unique code (independent of the excise stamp). Data recorded in the tracing system shall allow for unequivocal identification of the product source (including the product, factory, machine, country). Data recorded in the system must be available to other EU member states. The Directive provisions do not indicate unequivocally and do not specify whether the so called 'trusted third party' is supposed to be one organisation for all EU member states or whether product manufacturers are free to conclude agreements with entities independent from the manufacturers, whose task will be to develop and maintain a T&T solution for tracing tobacco products.

Below we present our understanding of the questions from the questionnaire.

C1. In option A2 the third party may be understood equivocally as:

- a) One operator for all EU member states
- b) One operator for a given country
- c) Operating and maintaining the solution for a given region from the territory of another EU member state.

It is difficult to imagine the collection and processing of data in the whole tobacco products distribution chain and the independence of the T&T system in option A1, when the solution is located on the manufacturer's level, but pursuant to the provisions it should be managed by a 'third party'. A similar question concerning the system's effectiveness and time to access the data as well as updating it arises in the case of developing a centralised system run by a single operator.

Our choice is option A3 as in our understanding of the tobacco products tracing system is a connection of the manufacturer's system/s (providing the data, that is data supply) and the system of tracing and registering events, whose operator is the 'third party'.

C2-C4 If we assume the A1 model, then additional control is necessary due to the fact that in this model the whole solution is located with the manufacturer, so independent verification of events is necessary. It is difficult to estimate the costs as of today. Regardless of which option is selected, the data must be updated, processed and reported.

C3 - our answer (Yes) results from the belief that only a 'third party' being a neutral entity, independent from all participants of the tracing and registration process assures the provision of full events reporting.

C7 - C11 Lack of credible and objective specification of the notion of a 'centralised' and 'decentralised' data base. In our understanding: - a national data base is a data base for manufacturers, importers located in a given country; - a regional base covers >1 countries located in

a region. At the same time, we assume that the central data base has fully redundant centres, i.e. a primary and a backup one with full data replication (used in case of a breakdown) and an implemented system of making backup copies and their storage. The solution selection from question C1 does not determine answers to questions C7 - C11. We assume that the author of the questions had in mind a central data base for a country / region and hence result our answers in the questionnaire:

C7 – Option B2,

C8 – Yes,

C9 – Decentralised data storage,

C10 – Geographic decentralisation with all the data on a single product stored in one place,

C11 – In all the regional/national data storages of a given product's presence, incl transit countries. Tobacco products manufactured in a given country / region should be covered by a tracing system regardless of their place of destination and the same concerns imported products. The data should be available to all interested parties, including transit countries (among others for products manufactured outside the EU borders).

C13 – C15. There is no specification of the notion 'single data carrier' - is this a unique code used by manufacturers independent of each other; or is it the use of a homogeneous labelling system for all manufacturers. The Directive assumes that the code shall be unique for a tobacco product and not for all manufacturers. That is why a limited number of encoding versions should be allowed, while maintaining their uniqueness. It should be taken into account that some of the manufacturers already use labelling with unique codes. An attempt to change the system to a homogeneous code will generate additional system implementation costs. Due to the above the selection we made is answer C1. In our understanding a unique code on a unit package of the tobacco product is meant and not on bulk packaging, which should be labelled according to the standard used in transport logistics.

C15 - in our understanding a 'free system' is an open system pursuant to licenses concerning open source code systems. In our assessment a free system does not assure lower system implementation and maintenance costs.

Manufacturers of code scanning devices, together with the change in software platforms, make available up to date proper drivers (verified for their operating with the system) and the party maintaining the T&T system may easily update it. Taking into account the expected problems with adjustment and operation of drivers with an open system, in extreme cases it may even lead to an outage of the event registration and tracing system. In our opinion it would be reasonable for the European Commission to indicate a list of secure and acceptable devices used in case of systems meeting interoperability requirements.

C17 - C22 Tracing the product in real time in the whole delivery chain is a basic feature of the T&T solution. In our understanding, the 'delivery chain' is registering events (entering / leaving the warehouse) in all places of presence (initial / intermediate / final), covering also status changes. Breaking the chain by delays in data updating undermines the idea of tracing. The product status should be up-to-date in real time. It is important from the point of view of control bodies and

financial services. Reports generated for the needs of authorised stakeholders are a separate issue. Such reports are a feature of the system and constitute one of its elements.

A full T&T solution should assume the association of a unique number (together with the required information content in the data base) with the T&T system solely as the source of data (an ERP/MRP system or other systems carrying information on the unitary product may be a similar data source). The configured T&T system manages it all and processes information. The information contents in the central (from the point of view of a country / region) data base shall be used as a source of information among others for importers, exporters, wholesalers and control bodies. They are also data providers for the central system. Products manufacturers are only one of the participants of the whole T&T process. The assumption is that the system tracing the flow of tobacco products should be independent from the tobacco industry manufacturers. In our understanding of the Directive, the legislator assumes the creation of national systems enabling the exchange of information with other operators in EU member states.