

Mr. Ben Smulders
Cabinet of First Vice President
Frans Timmermans
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European Smoking Tobacco Association
(ESTA)
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CC: Mr. Antoine Colombani

By email and post

Brussels, Monday 02 October 2017,

Subject: Implementation of the Articles 15 and 16 of the European Tobacco Products Directive – 2014/40/EU (Track & Trace)

Attachment: ESTA Detailed Position on the Implementation of Track & Trace

Dear Mr. Ben Smulders,

The European Smoking Tobacco Association (ESTA) would like to raise with you the development of Implementing and Delegated Acts of the 2014 Tobacco Products Directive's Articles 15 and 16 on tracking and tracing of tobacco products¹. Three Draft Acts were published on 4th September².

In our view, the Commission has missed the opportunity to apply the Better Regulation principles when developing these three acts. The consequence is that the proposed acts are either contradicting EU law, and the 2014 Tobacco Products Directive, or side-stepping the principles of better-regulation and most of all are against any business logic and trading practices.

DG SANTE spent the better part of three years requesting two external contractors to come up with requirements satisfying both politically inspired health mantras and contradictory technical standards reflecting commercial and trading practices. This also resulted in governmental customs experts being kept out of the dossier. After two years, the first contractor could not do other than to fail miserably. Then, being pressed for time, the second contractor, and consequently DG SANTE, drafted a system that simply will not work.

¹ Articles 15 & 16 of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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.

² Commission draft implementing regulation on technical standards for the establishment and operation of a traceability system for tobacco products ([here](#)) and Commission draft implementing decision on technical standards for security features applied to tobacco products ([here](#)) and Commission draft delegated regulation on data storage contracts ([here](#)).



After the adoption of the 2014 Tobacco Products Directive, ESTA and its Members have committed themselves to work closely with DG SANTE and the Commission in developing the necessary implementing legislation. This was clear when developing the Act for Ingredients Reporting where industry experts were in continuous – monthly and later weekly – contact with Commission experts developing a working IT platform.

Where it concerns the current three acts an entirely different approach was followed. Over a three-year period in a mere three workshops the emphasis was on presenting politically inspired ideas rather than consulting trade and IT experts and developing technical standards. We understand that DG SANTE, but also, the contractor has never visited a smaller logistical trading company, such as a wholesaler or distributor of consumer goods including tobacco products.

Representing many smaller and mid-sized companies as well as SMEs, ESTA remarks that the Small Business Act and the “*Think Small First approach*” have simply been cast aside. The whole system is developed for large scale cigarette manufacturing and is clearly not tailored for other (niche) tobacco products manufactured by smaller companies in Europe. Including export products and aggregate packaging in its own right to carry Unique Identifiers (UIs) are two examples where the implementing regulation is contradicting the Directive.

In several instances, the draft regulation violates EU competition law by requiring that UIs are supplied by a single commercial third-party, appointed by each Member State, thereby establishing an unnecessary monopoly transforming the tobacco market economy into an unprecedented “state-like-directed” business. A further example of anti-competitive measures is the EU-level repository system, for which the operator will be designated either by the commercial companies operating the sub-systems if they can “*agree amongst themselves*” or by the Commission “*based on an assessment of objective criteria*” without further specifications.

The Commission's draft decision fails to provide the necessary details and specifications for the Security Feature to be placed on tobacco packaging. It establishes stringent and costly requirements, which are incompatible with current packaging materials used for traditional and niche tobacco products. While the 2014 European Tobacco Products Directive aims to further harmonise tobacco regulation in the EU, the optional nature of the draft implementing decision will result in too many different security features in use in the EU Member States and further distorting the internal market.

Considering the above and the complexity of the system, the number of economic operators involved, the amount and sophisticated structure of the data to be recorded and transmitted (for approximatively 80 million products daily), the ambitious missions and obligations falling on the repository systems providers, the lengthy selection procedures to be implemented by the Members States and the stringent obligations of the security feature, it seems nearly impossible that such a Track & Trace system can be implemented



and functional by the required deadline. The draft regulation even shortens the implementation deadline as prescribed in the Directive by requiring all economic operators, including wholesalers and distributors, to establish a “functional” system by 20 March 2019 (only 15 months after the expected adoption of the Acts).

Given that half of the Member States were late in implementing the 2014 Directive, how can the Commission again set unrealistic deadlines? Using a regulation and a decision make this even more problematic.

The implementation of Track & Trace cannot be qualified as better regulation at all. Implementing technical standards served as a pretext for DG SANTE to introduce its own policy agenda that was intentionally kept out of the primary law by European Legislators. The alternative health motive of impacting large multinationals will inevitably not be achieved, but will drive many smaller tobacco manufacturers out of business, leading to further concentration of the sector.

ESTA therefore requests your assistance in clarifying the interpretation of Articles 15 and 16 of the Tobacco Products Directive and the principles of “Better Regulation” with your colleagues in DG SANTE.

For your information, we have attached a full position on the subject and remain at your disposal.

Yours sincerely,



Peter van der Mark,
Secretary-General ESTA

The European Smoking Tobacco Association (ESTA) represents mainly mid-sized companies including SMEs and several generation-old family-owned businesses. These companies manufacture and distribute fine-cut tobacco, pipe tobacco, traditional European nasal snuff and chewing tobacco. Many ESTA members are still rooted in their original locality and have moved from manufacturing and selling only locally, to truly European companies selling across the EU and beyond. These traditional and artisan European tobacco products are part of European cultural heritage.

