EUROPEAN SMOKING TOBACCO ASSOCIATION

ESTA

FINE CUT - PIPE - NASAL - CHEWING

POSITION

ON

THE DRAFT IMPLEMENTING REGULATION ON TECHNICAL STANDARDS FOR THE ESTABLISHMENT AND OPERATION OF A TRACEABILITY SYSTEM FOR TOBACCO PRODUCTS

AND ON

THE DRAFT IMPLEMENTING DECISION ON TECHNICAL STANDARDS FOR SECURITY FEATURES APPLIED TO TOBACCO PRODUCTS

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

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. The traditional and artisanal European tobacco products are part of European cultural heritage.

Executive Summary

The Commission's draft Regulation on the one hand sets technical standards where no competency exists and on the other fails to set standards where these are mandated and badly needed. Where it correctly sets standards, many are too complex making the standards unlikely to be internationally shared. The Commission's draft Decision on the security feature completely ignores the Directive's harmonisation purpose, and lacks setting uniform standards.

The proposed system of tracking and tracing and the security feature therefore will be prohibitively costly and unworkable for mid-sized and smaller firms. The proposed system obliges all companies in the tobacco supply chain to re-organise and modify their business and trading processes beyond what is necessary to establish a well-functioning tracking and tracing system as specified in Article 15 of the Tobacco Products Directive (2014/40/EU).

The Commission's draft Implementing Regulation raises many legal and practical questions. The following must be either clarified or amended appropriately:

1. The Commission cannot base any measure or requirement on anything else than the delegation of powers as laid down in Articles 15 and 16 of the 2014 Tobacco products Directive;

2. This draft implementing Regulation cannot be based solely on the requirements of the Framework Convention on Tobacco Control (FCTC) Protocol Against Illicit Trade in Tobacco Products (AIT Protocol);

3. The draft Regulation, being directly applicable in Member States, must be concise and complete at the same time, proposing all necessary technical arrangements. Unfortunately, the current draft is far from complete;

4. A too complex system will not be adopted by third countries. Cheap illicit whites are originating from some of these countries necessitating an interoperable system to effectively tackle the main source of illicit trade;

5. Tobacco products manufactured in the EU but not placed on the market, including those for export, are not within the scope of the implementing Regulation, as they are not covered by the 2014 Tobacco Products Directive;

6. The Unique Identifier must include the date and time stamp which can only be applied in real time on the packaging line. The regulation cannot derogate form Article 15.2.d of the Directive;

7. The draft Regulation provides for an anti-tampering device to be installed by a third party, without any base for this in Article 15 of the 2014 Directive, and fails to provide the necessary details and specifications for it;

8. The specification of information to be delivered to the third-party ID issuer includes information not mentioned in Article 15 of the 2014 Directive;

9. The 2014 Directive does not prescribe the involvement of an independent third party in applying elements of security features, and so the draft Decision should neither. The draft Commission Decision also does not prescribe any provision for liability questions arising from this provision;

10. The draft implementing Decision assumes manufacturers can themselves complete tax stamps with additional types of authentication elements if so lacking whilst the 2014 Directive explicitly prohibits this;

11. The draft Regulation introduces the establishment of a secondary repository to be set up together by companies providing the services for the first repository. This is against commercial practice and competition law;

12. The draft Regulation introduces a system based on production authorisation, which requires manufacturers to provide information and transmit financial information that is not known at the time of packaging;

13. The draft Regulation states that ID issuers will choose whether UIs will be delivered electronically or physically, thereby ignoring manufacturers' needs and specificities and the required interoperability with tax stamps;

14. The draft Regulation fails to set out the required specifications ensuring the proper interoperability amongst primary repository systems and with the secondary repository system;

15. The draft Regulation requires the data carrier to be composed of 50 alphanumeric characters, which is therefore too long and incompatible with current printing technologies, machinery and GS1 standards currently in use;

16. The requirements for the security features are to complex and are incompatible with current packaging materials used for traditional and niche tobacco products, which are mainly manufactured by smaller and mid-sized companies;

17. The draft Implementing Decision fails to set requirements for a uniform security feature;

18. The security feature's requirements must be simplified to allow Member States to use current tax stamps and their technologies as the security features;

19. Considering the complexity of the system, the lack of legal clarity and the number of economic operators involved, the ambitious implementation timetable is impossible to keep.

Solution: The only practical and legal solution is therefore to remove this needless requirement for Member States to appoint a third-party ID issuer. Generating and applying the UI at the time of packaging is the only way to comply with the Directive and to overcome unnecessary complexity. The integrity of the generation and application of the UI can be established through control mechanisms of the Member States, such as is the case for the Electronic Movement and Control System (EMCS) and tax stamp application and alternatively by integrating an anti-tampering device.

I - Legal issues and liability concerns

Article 15.11(a) of the European Tobacco Product Directive (2014/40/EU) empowers the European 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*". The Commission can therefore not change or amend or add to requirements clearly specified in the Directive by the Legislator, examples of which are given below:

EU Unique Identifier does not apply to tobacco products intended for export

The draft Regulation is to apply to all tobacco products manufactured in the Union, including tobacco products intended for export. This constitutes a clear misinterpretation of the scope of the 2014 Directive.

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*", i.e. made available to the customer located in the EU (Article 2(40)). The Directive and therefore the obligation to bear an UI only applies to products placed onto the EU Market, which is not the case with product destined for export.

Fine-cut tobacco and other tobacco products, including pipe tobacco, are mainly manufactured in the EU and exported to the rest of the world. It is therefore crucial for manufacturers, including many mid-sized and smaller companies, that the system does not establish new trade barriers hampering the export of EU manufactured products.

This draft Regulation also ignores third countries' regulations, which may require that only their marking is applied on the unit packets. This would lead to a *de facto* ban of products "made in EU" or encourage EU manufacturers to move their production outside the Union, something which may be possible for large multinational companies, but impossible for smaller and mid-sized companies.

The Commission, in Consideration 4 of the draft Regulation, attributes "*false declaration of exports*" to illicit trade and as such justifies the application of the UI to EU-manufactured products destined for export. It needs to be noted that illicit trade is mainly made up of illicit "cheap whites and counterfeit" cigarettes smuggled into the EU as well as illicit products manufactured by illegal factories within the EU[1]. Both have nothing to do with legally manufactured products destined for export or in fact with fine-cut tobacco and other niche products. The draft Regulation therefore overplays "*false declaration of exports*", which is sufficiently covered by EMCS and the Union Customs Code.

[1] Progress Report on the Implementation of the Commission Communication "Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products – COM(2017)235 – May 2017, p. 8

Structure of the Unique Identifier (Article 8) including the time stamp (article 21.4)

Article 21.4 of the draft Regulation reads: "*by way of derogation from paragraph 1, manufacturers and importers may encode the time stamp separately from unit level UIs*". This is not in line with Article 15.2(d) of Directive 2014/40/EU, which clearly states in that the time stamp must be part of the Unique Identifier[2].

The Commission correctly understands that the timestamp can only be applied on the packaging line at the time of making individual unit packages. Unless the UI is created at the same time, the timestamp can never form part of the UI as specified in the Directive. The Commission is circumventing this by proposing to add the timestamp separately to the UI. Manufacturers doing so would be further in breach of Article 15.9 of the Directive as they would have to modify the recorded data.

Whilst Article 15 of the European Tobacco Products Directive repeatedly states that Member States are responsible for the establishment and the operation of a Track & Trace system, this draft Regulation overrides the Directive and obliges Member States to appoint a commercial third-party ID issuer. This raises multiple questions regarding the public tender procedures, the selection procedures, the liability issues in case a Member States fails to ensure the issuing of UIs and, more generally, this raises major concerns regarding the freedom of competition.

In addition, Article 11 of the draft Implementing Regulation, laying down the requirements for the UI at aggregated packaging level also oversteps the 2014 Directive. Article 15.5 of the Tobacco Products Directive only requires marking unit packs with unique identifiers and further provides that this "***may be*** *complied with by the marking and recording of aggregated packaging*". The draft Implementing Regulation, however, obliges operators to mark aggregated packaging with a separate UI and requires economic operators to request this UI to the ID issuer, thereby introducing further and unnecessary complexity, which was not foreseen by the Legislator.

Solution: The only practical solution is therefore to remove this needless requirement for Member States to appoint a third-party ID issuer, thereby simplifying the system and increasing its interoperability, efficiency and adaptability to actual trade practices. The integrity of the generation and application of the UI can be established through control mechanisms of the Member States, such as is the case for the Electronic Movement and Control System (EMCS) and tax stamp application.

Introduction of an "anti-tampering device" (see Article 7)

The introduction of an anti-tampering device (see Article 7.2) on the production lines, supplied by an independent commercial third-party, is not foreseen by the legislator in the 2014 Directive. Unlike the involvement of third parties for data storage as foreseen in the Directive, the anti-tampering device is fully absent from the Directive as it was not deemed necessary by the Legislator.

[2] The FCTC Protocol to Eliminate Illicit Trade in Tobacco Products (AIT) also require time stamp to be part of the Unique Identifier as per Article 8 (4.1).

The introduction of an anti-tampering device, besides increasing the complexity of the system, cannot be simultaneously integrated into the packaging line and be independent from the manufacturers. Obligations as laid down in articles 7.4 & 7.5 of the draft Regulation cannot be met as manufacturers cannot ensure the availability of recorded data whilst this device is to be supplied and controlled by an independent third-party.

Article 7 also raises several legal and liability concerns, and does not provide the necessary details, specifications and qualifications for the selection of such independent third-party supplier. The draft Regulation does not foresee any liability provisions in case of malfunction of the device. Article 7 also fails to ensure compliance with European competition laws.

On the security feature and independence

The same rationale applies regarding the one Security Feature's authentication element to be provided by a third-party provider (Article 3.2 & Article 8 of the draft Implementing Decision). This is also absent from Directive 2014/40/EU as it was not deemed necessary by the Legislator. The integrity of a security feature comes from the applied technology and the subsequent ability of law enforcement authorities to determine whether a product is authentic or not (already covered in Article 7), and therefore is not coming from its provider. Neither article 3.2 nor Article 8 of this draft Decision provide the necessary specifications for the selection procedures and obligations of this so-called 'third-party solution provider".

On the use of tax stamps as security feature

Article 4 of the draft Implementing Decision wrongly assumes that manufacturers can themselves complete tax stamps with additional types of authentication elements if so lacking. In most national jurisdictions, tax stamps can only be applied without further changes or tampering. The Legislator does not allow any tax stamp as the security feature if it is not complying with all the standards set by the draft Implementing Decision. Directive 2014/40/EU Article 16.1 clearly reads: "*Member States requiring tax stamps or national identification marks used for fiscal purposes may allow that they are used for the security feature provided that the tax stamps or national identification marks fulfil **all** of the technical standards and functions required under this Article*". Tax Stamps can therefore not be complemented with authentication elements by the manufacturer as Article 4 of the draft Decision assumes.

Selection procedure for the independent third-party operating the secondary repository system (see Article 27 and Annex I, Part B)

Article 27 of the draft Implementing Regulation introduces an EU-level secondary repository system. It fails to provide the necessary technical specifications and does not sufficiently protect commercial and sensitive data.

Describing the selection procedure for the third-party operating this secondary repository system, Annex I - Part B, states that the commercial companies responsible for the operation of the primary repository will agree amongst themselves to appoint the company that will operate the secondary

repository. In case those companies cannot agree, the Commission appoints the operator of the secondary repository "*based on an assessment of objective criteria*". This procedure obviously violates competition law.

Manufacturers of cigarettes and fine-cut tobacco will have to comply with this Regulation 5 years before manufacturers of other tobacco products. Those manufacturers will therefore not have the opportunity to have their appointed repository operators participating in the selection process, thereby distorting competition even more.

Liability Issues

Where the draft Regulation in many of the examples described above exceeds the Commission's mandate, in the case of liability the absence of technical standards and legal clarity is the problem, leaving many questions unanswered. For example:

- What will happen if a tender is legally challenged and cancelled or if a Member State fails to appoint the ID Issuer within six months after the entry into force of this draft Regulation?

- What will happen if a public tender in a Member States receive no applicant or only applicants that do not meet all the requirements?

- What will happen if the independent third-party ID issuer fails to issue the UIs in time, or at all?

- What will happen if the third-party operating the secondary repository fails to carry out its obligations in due time or due costs?

II - Complexity and non-interoperability issues

The Commission has proposed the following overly complex and unnecessary requirements, making it very costly for smaller companies producing fine-cut and niche tobacco products to continue operating.

"Production authorisation" creates bottlenecks in the production

The draft Regulation requires UIs to be supplied by a so-called independent third party following requests by the manufacturer. Production can therefore not commence until these UIs have been delivered. Flexible production practices build up over many years aimed at economic optimisation will no longer be possible to the detriment of smaller companies that commercialise this manufacturing flexibility.

- Articles 8.1, 8.2, 9.2 as well as point 1.2 of Section II of Chapter II of Annex II require manufacturers request UIs separately for each product, intended market, manufacturing site and to provide information which is often not known at the time of production. For example, the intended shipment route, the transport mode and the first country of transport prior to manufacturing.

- Article 33 of the draft Regulation requires manufacturers to transmit financial information (invoice, order number and payment). Most manufacturers produce to stock, hence purchase orders do not trigger production. Reporting of financial events therefore cannot always be linked to logistic events via the UI since payment receipts come in too many formats and different timings to be properly integrated into the UI. In addition, Annex 4.1 of the draft regulation also requires operators to include references to UIs when reporting on transactional events. Such obligation leads to make-to-order manufacturing and requires making new payment arrangements with trade partners, thereby ignoring well-established business practices and creates additional barriers to trade.

- Article 9.3 states that the ID issuers will choose whether UIs will be delivered electronically or physically. Both methods of delivery must be possible and based on the manufacturers' needs, including their production and trading specificities. Choice should not be allowed when UIs can be delivered electronically, especially because the draft Regulation fails to provide further specification and obligations regarding the size, the material or the quality for physical UIs.

- Articles 9.4 to 9.6 require ID issuers to deliver the UIs (either electronically or physically) within respectively 2 and 10 working days. This delay obstructs mid-sized and smaller firms that compete by being able to swiftly produce and deliver small batches.

- Article 9 also raises concerns in terms of interoperability with tax stamps and national identification marks in use in 22 Member States. UIs cannot be delivered physically if additional tax stamps are required. UIs imbedded in tax stamps would also be impractical, both for manufacturers and Member States as each will have to be specific for each product, machine, facility, intended market, shipment route etc.

The system fails to ensure interoperability amongst "sub-systems" and with other existing regulations

Whilst Member States and the European Commission are currently revising the Electronic Movement Control System (EMCS) and committed to fully implement a modern Union Customs Code, the draft Regulation fails to ensure the interoperability of the Track & Trace system with existing and well-functioning regulations.

- Much of the information to be provided when requesting UIs (listed in point 1.2 of Section II of Chapter II of Annex II) is already available through the EMCS (e.g. CN Code, EU-CEG Code, shipment etc). Duplication will not only increase the burden for all actors, including Member States and customs authorities, but will also disproportionally hit the smaller and mid-sized companies, which also provide this information manually.

- Articles 14 to 19 of the draft Regulation require excessive and impractical registrations and identifier codes for all economic operators, facilities and machines and require these codes to be unique "*within the pool of the ID Issuer*". The registration of more than a million retail outlets in the EU by a commercial third-party, as well as the registration of thousands of distribution and transport operators and vending machines is not only simply impossible by the deadline, it also exceeds the mandate of the Commission. The objective and function of the database as laid down in the 2014 Directive does not require such registration and is unnecessary as operators are already identified by their fiscal authorities or registered in the EMCS.

- Article 24.2 of the draft Regulation states that "*sub-systems shall be fully interoperable with one another*" without providing any further specification, requirements or guidance. Since the third-party operating the second repository will not be selected and functional before late 2018 at the earliest, it seems impossible to ensure the interoperability of the hundreds of primary repositories.

The system ignores the realities of trading practices

Because of the many unnecessary, cumbersome and inoperable requirements described above (e.g. third-party ID issuer, pre-authorisations, information to be provided prior to production, excessive registrations), the data carrier composed of 50 alphanumeric characters is too long and incompatible with current printing technologies and machinery. Although consensus exists to employ open-standards, the current length of the code prevents to comply with the GS1 standards in use. The data carrier is also incompatible with niche products, their manufacturing process and packaging surface materials, including traditional nasal snuff tobacco, packaged in small unit packs.

Security features: too complex and diverse

The Commission's draft Decision fails to provide the necessary details and specifications for the Security Features to be placed on tobacco packaging. While the European Tobacco Products Directive (2014/40/EU) 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.

Whilst it is recognised that a combination of overt and covert authentication elements is more effective in the fight against counterfeit goods and Intellectual Property Rights infringements, the combination of five of them is disproportional and unrealistic, especially for products which are often packaged in very small size (e.g. nasal snuff tobacco, chewing tobaccos).

In addition, the draft implementing Decision identifies three categories of authentication elements (overt, semi-covert and covert) whilst only two categories are recognised and classified by international standards[3] and by the European Commission's in-house science hub, the Joint Research Centre[4]. All elements described as "semi-covert" in the Annex to the Implementing Decision, are considered as "covert". The European Legislator decided in Article 16.1 the use of a security feature "*composed of visible* [i.e. overt] *and invisible* [i.e. covert] *elements*".

The structure of the security feature and authentication elements listed in annex must be compatible with current packaging materials used for traditional and niche tobacco products, which are mainly manufactured by smaller and mid-sized companies.

Finally, Article 6.1 of the draft Implementing Decision states that "*Member States may decide, at any moment, to implement or withdraw schemes for the rotation of security features*". Any rotation schemes or any changes to the security feature must notified well in advance to the manufacturers, and is only feasible if manufacturers can use a year of transitional period to clear the market.

On the use of tax stamps as security feature

22 Member States in the European Union (and not only some as the draft Regulation refers to) use tax stamps. The security feature's requirements must be simplified to allow Member States to use current tax stamps and their security technologies. The requirements of Articles 3.1 & 3.2 will oblige a large majority of Member States to implement substantial and costly changes to their national identification technologies.

On the other hand, in the non-tax stamp Member States, the economic operator will be disadvantaged as they will have to bear the full costs of the security feature and not the State as is the case with tax stamps.

[3] ISO 12931 : 2012
[4] Joint Research Centre, Survey of techniques for the fight against counterfeit goods and Intellectual Property Rights (IPR) infringement, JRC98181, 2015, page 8, available online here.

Solution: The only practical solution for the security feature is therefore to remove the reference to the non-existent "semi-covert" category and subsequently limit the number of required authentication elements to three. Rather than listing compliant technologies, the draft regulation must make specific reference to international standards and performance criteria described in ISO 12931:2012. In simplifying the requirements for the security feature, the regulation would also allow Member States to use their current technologies for tax stamps as the security feature without triggering costly and burdensome compliance upgrades.

The system cannot be fully implemented and functional in due time

Considering the complexity of the system, the number of economic operators involved, the amount and complexity of the data to be recorded and transmitted, 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 very unlikely that such a Track & Trace system can be implemented and functional in due time.

- According to Annex II - Part A, manufacturers will have to finalise the selection of their primary repository provider within two months after adoption of the Regulation, expected in late 2017. This means that manufacturers will contract third-party providers without knowing the format for the transmission of the information, the content of information to be provided, the identity of the third-party operating the secondary repository, the data-dictionary, and therefore, the cost.

- Article 28 of the draft Regulation requires that the commercial third-party operating the secondary repository publishes the data dictionary and specifications for the exchange of data and the router within two months after its appointment (provided that all ID issuers have been successfully appointed and that all economic operators have been registered). This is unrealistic.

- Article 31 of the draft Regulation further shortens the implementation deadline as prescribed in the Directive by requiring all economic operators, including wholesalers and distributors, to establish the system by 20 March 2019. This is also unrealistic and the testing period must be longer if one considers the system requirements and the number of actors involved.

Concluding, the implementation timetable set out in this draft Regulation is impossible to keep and raises crucial liability issues. The implementation timetable is for example, shorter than for the implementation of the EMCS, which was much simpler compared to this draft Tack & Trace system.

III – Conclusions & solutions

A well-functioning track and trace system can be established strictly following Article 15 of the 2014 Directive. Such a system needs to be fully integrated into the production process whilst being independently verified and controlled by Member States authorities.

The feasibility and efficiency of Track & Trace therefore depends on the ability of the Commission to adopt a uniform, feasible and clear protocol ensuring a harmonised application throughout the Union and allowing third countries to easily adopt it as well. This can only be possible by removing the unnecessary third-party requirements for the issuing of the UIs, providing the anti-tampering device as well as providing one authentication element for the security feature. As with the EMCS regime, controls and verification create independence and functionality of a system.

Export products must be excluded avoiding self-imposed trade barriers whilst export is already covered by the EMCS system.

To be successfully and timely implemented, the draft Implementing Decision on the security feature must better define the standards that will ensure a uniform application throughout the EU.