.

“Tobaksindustrien” (TI) -EU transparency register ID: 27567784437-46- is a trade association for companies with Danish headquarters and production of tobacco products in Denmark. The members produce pipe tobacco, cigars/cigarillos, fine cut and smokeless tobacco - but not factory made cigarettes.

The European tobacco industry consist of around 230 tobacco manufacturers of which 4 manufacturers represent more than 85 % of the tobacco market. The Danish companies belongs to the group of the residual 226 others which in total share less than 15 pct. of the EU tobacco market.

No Danish company holds a market share of above 2%. of the total EU tobacco market and the smallest has less than 25 employees and a turnover of less than 5 million Euro.

We thank the Commission for the opportunity to submit observations to the drafts:

**Main points:**

* Where the drafts deviate from a strict reading of art 15 and 16 of the Tobacco Products Directive (2014/40/EU),it should be changed and if not Exposed manufacturers (companies with an individual share of the total EU tobacco market of less than 1.5%) should be granted adequate exemptions. See below for details.
* The drafts fail to secure interoperability between all systems, equipment, economical operators and authorities. Instead, this paramount task is handed over to be dealt with by a yet unknown third party after the formal adoption procedure in the EU and the final issuing of the implementing acts.
* The draft art 16 fails to accommodate the well-functioning of the internal market for tobacco products as it allows huge national variations and thereby hampering the free flow of goods across the borders.
* TI notices with great concern that the drafts seem to introduce novelties and interpretations that go beyond a strict reading of art 15 and 16 of the directive. That includes even a partial implementation of the FCTC Illicit Trade Protocol – regardless of the fact that the Protocol has not even entered into force yet and may very well not do so for a long time.
* Despite the absence of an economic impact assessment for the various OTP sectors (cigars/cigarillos, pipe tobacco and smokeless tobacco), we foresee not only overwhelming costs on an annual basis but also huge one-off start-up costs. The latter not least being due to our high number of production lines where new equipment must be set up. This includes e.g. printers and scanners/readers and not to forget the latest novelty: anti- tampering devises.
* The fact that the Danish companies only produce niche products in smaller volumes illustrates the disproportional impact of the cost .The costs to be borne by the Danish companies can consequently only be spread out on an insignificant number of consumer units. Moreover, indeed an insignificant cost spreading possibility compared to the total “astronomic” number of consumer unites present on the EU market mainly produced by four manufacturers holding a total market share of 85% plus.

**Call for changes or an art 15/16 compliant exemption for Exposed Manufactures**

The drafts deviate in a variety of fields from a strict reading of art 15 and 16.We urge the Commission to introduce changes, which bring the drafts into line with a strict reading of art 15 and 16. However if the present drafts shall not lead to a significant distortion of the competition between the manufacturers, we strongly encourage the Commission at least to suggest proper and adequate exemptions in the drafts. These exemptions should be for companies, which by their sheer volume will not have any influence on the grand, total illicit marked in the EU and where requirements going beyond a strict reading of art 15 and 16 results in additional costs and burdens. This is true for manufacturers with a yearly ordering of less than 400 million UIDs and a market share of less than 1.5% of the total EU tobacco market - in the following referred to as **Exposed Manufacturers**.

Exposed Manufacturers should be:

1: Exempted from any payments/costs related to the formation and running of the secondary repository and router.

2: Allowed itself to add all requested information to the UID (The UID shall still be provided by a third party but should only contain what really makes it unique e.g. a code – all with the aim of avoiding the highly inflexible and partly impossible preauthorized UID’s.). (Art 8/9)

3: Exempted from the requirement to use anti-tampering device on production lines. (art 7.2)

4: Exempted from the use of UID and Track and Trace rules on products manufactured in the EU but designated for export. (art 6)

5: Exempted from the use of UID on an aggregated level.( art 10 ff.)

6: Required to have Security features with no less than three types of authentication elements (instead of five) (art 3, Technical Standards for Security Feature)

7: Granted a two-year transitional period. (art 37)

------------------------------------------------------------------------------------------------------

*Detailed comments on art 16 draft*

The aim and legal background of the Tobacco Products Directive is to improve the internal market for tobacco products, and the task of the implementing acts is to set standards to follow. Given that, we are highly concerned as to what extent the drafts fulfil this role. This is especially true when it comes to the rules for Security Features (SF). The SF will be unnecessarily complicated and expensive with its (too) many elements but more importantly, it may very well differ from country to country in all member states thereby putting new trade and technical trade barriers to the well-functioning internal market. Additionally, art 6.1 on possible rotation and 6.3 on security of production and distribution procedures open up for a rich variety of national rules and guidelines which in themselves may create severe obstacles for manufacturers like the Danish ones with mainly central production but export to all 27 members states.

As OTP products are packed in a huge variety of different packaging sizes and materials (wood, plastic, metal, paper etc.) it is important for us that the structure of the security feature and authentication elements listed in annex 1 must be compatible with our current packaging materials.

Art 3 divides authentication elements into three categories by adding a “semi-covert” category to the existing two categories classified by international standards (overt and covert). Art 3 further lays down that security features are to be composed of no less than five of these elements (at least one from each category). From a proportionality point of view, we urge the Commission 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.

Finally, Art 6.1 of the draft Implementing Decision states, “*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 be notified well in advance to the manufacturers, and should only cover products manufactured after the notification.

*Detailed comments on Art 15 draft:*

Instead of one simple central system used by all stakeholders, the draft suggests a repository system containing both a primary and a secondary repository – the latter with a router. This more complicated set-up, which accommodates that some market players call for individual repositories, adds unnecessary to the costs for Exposed Manufacturers. Therefore, we suggest that they should be exempted from any direct or indirect payment for the formation and running of the secondary repository and router. (art 30.2)

The members of Tobaksindustrien do not object to the concept of an independent third party UID provider. However, as niche product producers flexibility in production is very important. Therefore we are urging for a system that complies with art 15 in the directive but at the same time grants us the necessary flexibility. A system where we have to provide specific information prior to the issuing of the UID contradicts our needs for flexibility e.g. change of machine in case of a break down etc. Moreover, some information may simply not be available at the time of the UID ordering. That is the case for the very widespread production to stock only . Or e.g. in case of sudden change of country of destination due to fulfilment of an urgent and unforeseen sale request/opportunity.

For Exposed Manufacturers we therefore suggest an exemption so that the third party only delivers a unique identifier with the code that makes it unique. But that all the other product movement information etc. requested in art 15 are sourced by the manufacturer to the UID before the product leaves the production plant at the latest. This would ensure that when the product leaves the plant, information and reporting wise the Exposed Manufacturers’ UID will be equal to UIDs issued as suggested in the draft.

The Commission has chosen to introduce an anti-tampering device request despite the absence of any mentioning hereof in art 15 in the Directive. We find that it is in the good interest of the producer himself to make sure that the UID is readable and we see the anti-tampering device as not only being redundant but also pursuing a volume control path neither foreseen nor mandated in art 15 etc.

Exposed Manufacturers typically have many production lines despite total low output. The installation and running of anti-tampering devices on the production lines will therefore be yet another unproportioned burden – thus to be avoided. We shall therefore call upon the Commission to reconsider their proposal or at least grant an exemption to Exposed Manufacturers.

Even though art 15 in the directive does not specifically state that UID should also be used on aggregation level, it is nevertheless requested in the draft in art 10 ff. Not only will it be more expensive in terms of buying additional UIDs but it generally complicates the whole system as it puts sever constrains on economical operators including manufacturers who e.g. creates new consignments. Aggregation is a well-known discipline where e.g. GS1 has developed standards used throughout industry and trade. The main purpose of aggregation is to make it easy to handle a number of individual units. The aggregation tells you what a consignment contains, e.g. 100 consumer packs of one cigar SKU with the UID no. X toY. But the aggregation itself does not have to be unique in the sense of UID as to support the track and trace. Consequently, aggregation should remain a mere practical and uncomplicated tool which can be solved through GS1 compliant standard tools. We therefore call upon the Commission to abstain from the requirement to use UID on aggregation level or at least grant an exemption to Exposed Manufacturers.

Export is not part of art. 15 in the directive and should not be covered by the draft.

Members of Tobaksindustrien are exporting a lot to countries outside the EU .They are world leading in cigars as well as pipe tobacco. E.g. more than half of the pipe tobacco consumed worldwide is produced on two plants in Denmark. We are therefore very concerned about an UID/track and trace requirement on our export goods. At least as long as the same rules do not apply to our local competitors around the world. That may indeed not be case before 5 to 10 years counted from 2018 at the earliest. Until then, a solitary EU requirement will only make export more expensive and difficult. The very existence of an internal EU system should be enough for those like OLAF wanting to promote its virtues to non-EU countries. Avoid an export UID/track and trace, which in itself does not work on foreign soil. It is redundant and damaging to export. At least Exposed Manufacturers with their small scale volumes and inability to move production to countries outside the EU should be granted an exemption.

It is an established fact that OTP products like cigars and pipe tobacco have a much slower walk from production to the final sale to consumers than e.g. FMC. Both at the wholesaler but also due to a long shelf life at the retailer. Two years plus from the production to the final sale to a consumer is common for many less-known smaller brands which the pipe tobacco and cigars categories are so rich in.

With only one year for a clean market as suggested in art. 37, we will not only face problems with existing products but moreover we will be forced to start producing with UID well ahead of the 10-year period granted in the directive. In order to honour the 10-year commitment of the directive we suggest that 20 May 2026 is set as a new clear market date in art 37 2 – at least for Exposed Manufacturers.

Additional comments:

Deliverance of UID: according to the draft art 9.3, it is for the UID issuer to determine whether to deliver the UID electronically or physically. As in all other trade, it should be up to the customer to decide on how he wants the product. The wording of art 9.3 should only apply in case the manufacturer has not been vocal on the issue.

We are puzzled why retailers who explicitly do not form a part of art 15 in the directive is now included in the draft. We wonder if the inclusion of tobacco retailers – e.g. in Denmark alone being up to 6,000 - may lead to further complication of an already complicated system desperately short of time.

Finally yet importantly, we would like to voice our concern regarding the apparent lack of specific rules on interoperability in the drafts.

It is a prerequisite for the workability of the system that total interoperability is obtained and maintained on all levels between all economical operators as well as to/from and between the authorities. We see it as one of the main objectives for the Commission to ensure this timely in the drafts. We were therefore very disappointed when we learned that the Commission has handed this paramount important task over to a yet unknown third party - and with a timeline to March 2019 - and then only for testing purposes. The responsibility to set out standards which ensure interoperability between open standards must rest with the Commission.

We shall be happy to answer any questions the Commission may have.

Best regards

**Tobaksindustrien**

Jens Hennild

CEO