



EU systems for traceability and security features of tobacco products

- Webinar for solution providers -

Directorate General for Health and Food Safety
European Commission

Brussels, 17 April 2018

Please note that any views expressed in this presentation may in no way be regarded as stating an official position of the Commission.

- What will be the structure/format of the selection process of the provider of the secondary repository? What are the qualification and selection criteria to participate?
- What does the supply chain of authentication elements look like in countries which do not have an excise duty stamp system in place?
- Referring to semi-covert and covert authentication elements, who is in charge of the quality control of these elements in tobacco production in case no excise duty elements are applied to the tobacco package?

- With regard to the anti-tampering device, what will it control exactly? What are its technical requirements, what does it record, what alerts does it react to, what marking failures does it account for, and what happens in case of anomaly detection?
- What will the primary repositories have as a control role? what mechanism of automatic alert for law enforcement and what supply chain event failures will they report?
- What appointment procedure for the ID issuer should be applied by each Member State?
- What is the usefulness of the "flat file"? Shouldn't enforcement authorities always access information via the repository system?

- Anti-tampering systems to be installed on critical "stations" on the production lines:
 - Should they be installed on UI printing stations only or also for UI code printing on aggregation stations?
- Does the definition of unit packet include overwrap and tear-tape? This would form an acceptable carrier medium for security features but only up to the point of sale of the product (at which point the the overwrap would be discarded).
- How should Member States specify the authentication elements to be adopted? Will this be a nominated provider of an authentication element, or through a set of technical specifications that may be satisfied by more than one authentication element provider?

- GS1 provides identification of products, logistic units, economic operators, facilities, and machines. Can you clarify whether we would be identifying natural or legal persons, or rather, companies as economic operators?
- Using a GTIN product code and product brand name would uniquely identify the product. Can you confirm that 'GTIN' together with 'brand name' would be a sufficient response for "the product description" in the flat file master data exchanged? If not, can you clarify what other data would be required?
- It is our interpretation that officials with offline devices in the field will receive an upUI algorithm and a flat file, "master data" updates for their device from the secondary repository's EU-wide registry in a centralized way, rather than from 28 separate ID Issuer Registries. Can you confirm our interpretation?

- Since the Commission has a short timeframe in which it must review the data repository contracts, it would be helpful if the Commission could publish a template contract that meets its expectations.
- What should be the content and structure of the acknowledgment messages to be issued by the repositories system?
- Will it be possible to store data virtually (in the cloud) if storing takes place (partially) outside of the Union? What about storage maintenance being performed from outside the EU?
- The FCTC Protocol (art 4.2 and art 8) applies to “Parties”, so to the States which have ratified it. Based on the precautionary principle, will it be possible to extend the requirements to entities which are not covered by Art. 35 and the WHO Protocol definitions?



**THANK YOU
FOR YOUR ATTENTION**