



Folkhälsomyndigheten
PUBLIC HEALTH AGENCY OF SWEDEN

Systems of traceability and security features for tobacco products

Country visit to Sweden – Stakeholder session

29 November 2018



Agenda

- **13.00 – 13.15** Welcome and introduction
- **13.15 – 14.15** Presentation from European Commission SANTE/B2
- **14.15 – 15.00** Discussion
- **15.00 – 15.30** Update from the Public Health Agency of Sweden
- **15.30 – 16.15** Discussion
- **16.15 – 16.30** Closing remarks

Implementation of Track & Trace in Sweden

- The bill implementing track & trace has not yet been approved by the Parliament.
- Once approved the legislation will:
 - form the legal basis for the implementation of track & trace in Sweden, and
 - clarify the national competent authorities their responsibilities.
- The bill is scheduled to be decided by the Parliament 12th December. We hope any subsequent regulation will be decided shortly after 12th December.
- The Public Health Agency also needs a legal basis to appoint an ID-issuer within the private sector – this work is ongoing within the government.

Public Health Agency of Sweden - role and mandate

- The Public Health Agency of Sweden is tasked by the Swedish Government to prepare for the implementation of the Track & Trace provisions of the Tobacco Products Directive.
 - Ensure that **a proposed** Security Feature can be communicated by 20th September **2018**.
 - Ensure that an ID issuer can be appointed.
- The proposal for regulations on the authentication elements/security feature has been sent out to relevant stakeholders and authorities for consultation.
- Taking all possible preparatory steps while waiting for formal mandate to proceed with decisions and appointments.

Swedish security feature

- No tax Stamp.
- Based on four key factors we have reviewed different authentication elements that could be included in a security feature.
 - Difficulty to imitate
 - Controllability/Verifiability
 - Ability to implement
 - Cost/Cost effectiveness
- While respecting:
 - Timeframe – short time before decision enters into force.
 - Possible to use commercial printing house.
 - One element must be procured from an independent third party supplier.

Proposed Swedish security feature

- Should be composed of the following elements in combination:

- a) guilloche, (overt)

- b) optically variable ink, (overt)

- c) microprint, (semi-covert)

- d) anti-Stokes ink,(covert) and

- e) non-fluorescent paper (semi-covert) along with

- f) fluorescent ink, (semi-covert)

=Solution with satisfactory level of security, allowing the industry to implement within the timeframe and at a reasonable cost.

Standardized security feature?

- No such plans presently.
- Acknowledge the benefits – particularly for control and supervisory purposes.
- Mixed input from industry.
- Flexibility
- Timeframe
- Open for reviewing.
- 2024 "snus" will be included.

Printing or affixing?

According to the proposed regulations currently under review

- The industry may choose whether it should be done with affixing, printing or a combination of these.
- The industry may also choose where the security feature is placed, and what the microprint should consist of.
- We do not intend to regulate the size of the authentication elements at this stage.

Who is affected by the regulations?

- Companies that manufacture or import cigarettes and roll-your-own tobacco - 20th May 2019.
- Companies that manufacture or import other tobacco products - 20th May 2024.
- Retailers and wholesalers.
- Supervisory authorities (not yet regulated).

Public Health Agency - Mandate

Traceability

The government has:

- tasked the Public Health Agency to take necessary measures to ensure the appointment of an ID issuer,
- communicated its intentions to mandate the Public Health Agency to decide on regulations regarding the design of unique identifiers.



ID issuer appointment

Legal basis for an appointment

- Law/decreree with essential prerequisites is still to be decided.
 - The Public Health Agency needs to be authorized to appoint an ID issuer.
 - Regulation/mandate to regulate is required concerning e.g.
 - Swedish use of the derogation in 2018/574 art. 4(1)*,
 - physical delivery, and
 - fees for unique identifiers.
- The Public Health Agency also needs a legal basis to appoint an ID issuer within the private sector – work is ongoing within the government.

**Adoption of the derogation would result in the competent ID issuer being the entity appointed for the Member State on whose market the products are placed rather than the ID issuer appointed for the Member State in which the products are manufactured.*

ID issuer appointment

Preparatory work and time plan

- Based on the bill, preparatory work is in progress to allow an appointment via a potential future procurement.
- Appointment no later than 6 May 2019 according to the Implementing regulation 2018/574
- The time plan relies on the progress in the regulatory process (the bill for a new Tobacco act and legal basis for appointing an ID issuer within the private sector).
- Provided that the legislation and other prerequisites are in place in time, the provisional time plan is to appoint an ID-issuer by the end of March 2019.



ID issuer appointment

Regulations

- The Government has communicated its intentions to mandate the Public Health Agency to decide on implementing regulations on the design of unique identifiers.
- Requirements for unique identifiers are related to a potential procurement and still under consideration/investigation.



Folkhälsomyndigheten
PUBLIC HEALTH AGENCY OF SWEDEN

Questions and discussion



For discussion - traceability

- The EU-Directive states that the traceability requirements include reporting of the transport (which supplies tobacco) registration number.
 - How do we handle the situation including other transportation like boats, helicopters or where transshipments to another carrier happen?
 - How should reporting be done in those cases?
- As a wholesaler, we sometimes deliver single loaf of cigarettes per run, in these cases, must we report the transport's registration number? Is there any minimum requirement / maximum number of loafs per transport?
- If we divide a parti and put loose lumps from different lots into a new carton. Will we then use aggregated lot numbers? Or how will it work?

For discussion - traceability

- What does the connection to GS1 look like? What is the status of this work? Is the solution transparent with the corresponding solution for ex. traceability of fish? Are we building a solution that can be used for all types of traceability?
- When handling large volumes of tobacco, manual reporting is time consuming. Is there a refund to apply if we wish to automate the flow of tobacco traceability?
- To whom should we report?
- When can we apply for EOID: s, FID: s for our customers? What happens if the ID-issuer hasn't been appointed for the Swedish market?

For discussion – Security Feature

- Will we as manufacturers have the possibility to produce our own security feature approved by the Swedish PHA and using the security elements selected by the Swedish authorities?