

Targeted stakeholder consultation on the implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU

Fields marked with * are mandatory.

This is a targeted stakeholder consultation. The purpose of this consultation is to seek comments from stakeholders:

- directly affected by the upcoming implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the new Tobacco Products Directive (Directive 2014/40/EU), or
- considering to have special expertise in the relevant areas.

In the Commission's assessment, the following stakeholders, including their respective associations, are expected to be directly affected:

1. manufacturers of finished tobacco products,
2. wholesalers and distributors of finished tobacco products,
3. providers of solutions for operating traceability and security features systems,
4. governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade.

Not directly affected are retailers and upstream suppliers of tobacco manufacturers (except the solution providers mentioned in point 3 above).

The basis for the consultation is the Final Report to the European Commission's Consumers, Health and Food Executive Agency (CHAFAEA) in response to tender n° EAHC/2013/Health/11 concerning the provision of an analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereafter the Feasibility Study). The Feasibility Study was published on 7 May 2015 and is available at http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf. The interested stakeholders are advised to review the Feasibility Study before responding to this consultation.

The comments received in the course of this consultation will be an input to the further implementation work on a future EU system for traceability and security features. In particular, the comments will be taken into account in a follow-up study.

Stakeholders are invited to submit their comments on this consultation at the following web-address <https://ec.europa.eu/eusurvey/runner/trace> until 31 July 2015. The web-based survey consists of closed and open questions. For open questions stakeholders will be asked to provide comments up to the limit of characters indicated in the question or to upload (a) separate document(s) in PDF format up to the limit of total number of standard A4 pages (an average of 400 words per page) indicated in the question. Submissions should be - where possible - in English. For a corporate group one single reply should be prepared. For responses from governmental organisations, which are not representing a national position, it should be explained why the responding body is directly affected by the envisaged measures.

The information received will be treated in accordance with Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Community (please consult the [privacy statement](#)). Participants in the consultation are asked not to upload personal data of individuals.

The replies to the consultation will be published on the Commission's website. In this light no confidential information should be provided. If there is a need to provide certain information on a confidential basis, contact should be made with the Commission at the following email address: SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu with a reference in the email title: "Confidential information concerning targeted stakeholder consultation on the implementation of an EU system for traceability and security features". A meaningful non-confidential version of the confidential information should be submitted at the web-address.

Answers that do not comply with the specifications cannot be considered.

A. Respondent details

*A.1. Stakeholder's main activity:

- a) Manufacturer of tobacco products destined for consumers (finished tobacco products)
- b) Operator involved in the supply chain of finished tobacco products (excluding retail)
- c) Provider of solutions
- d) Governmental organisation
- e) NGO
- f) Other

***A.1.f. If other, please specify**

Text of 1 to 800 characters will be accepted

The DCTA is an association which promotes technical standards and digital solutions designed to secure supply chains for excisable fast moving consumer goods, such as tobacco and alcohol.

The DCTA also provides an anti-illicit trade portal (AIT Portal) which is a tool enabling product queries to (i) retrieve track and trace data from respective data sources, and (ii) validate product authenticity.

The DCTA also provides a software module known as the "Dispatcher". It is used to redirect data from separate repositories to a single database which can be managed by an independent 3rd party such as national governments or other entities.

***A.2. Contact details (organisation's name, address, email, telephone number, if applicable name of the ultimate parent company or organisation) - if possible, please do not include personal data**

Text of 1 to 800 characters will be accepted

Digital Coding & Tracking Association (DCTA)
Address: c/o Transcontag, Dufourstrasse 117, 8008 Zurich, Switzerland
Email: info@dcta-global.com
Tel: 00 41 43 443 00 60
Fax: 00 41 43 443 00 69

***A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):**

Yes No

***A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.**

• [e18f1f00-4420-4f80-a2be-e6f78b8c1be1/DCTA - registry extract.pdf](#)

B. Options proposed in the Feasibility Study

B.1. Please rate the appropriateness of each option for tracking and tracing system set out in the Feasibility Study in terms of the criteria listed in the tables below

B.1.1. Option 1: an industry-operated solution, with direct marking on the production lines carried out by tobacco manufacturers (for further details on this option, please consult section 8.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

B.1.2. Option 2: a third party operated solution, with direct marking on the production lines carried out by a solution or service provider (for further details on this option, please consult section 8.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.1.3. Option 3: each Member State decides between Option 1 and 2 as to an entity responsible for direct marking (manufacture or third party) (for further details on this option, please consult section 8.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.1.4. Option 4: a unique identifier is integrated into the security feature and affixed in the same production process (for further details on this option, please consult section 8.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)

- **6cd71d0a-f62a-470e-bdf6-a68003495c14/DCTA - ANNEX B - Tracking and tracing.pdf**

B.2. Please rate the appropriateness of each option for security features set out in the Feasibility Study in terms of the criteria listed in the tables below

B.2.1. Option 1: a security feature using authentication technologies similar to a modern tax stamp
 (for further details on this option, please consult section 9.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

B.2.2. Option 2: reduced semi-covert elements as compared to Option 1 (for further details on this option, please consult section 9.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

B.2.3. Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection (for further details on this option, please consult section 9.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

B.2.4. Option 4: security feature is integrated with unique identifier (see Option 4 for traceability)
 (for further details on this option, please consult section 9.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

- [a12214f7-e365-4ec6-b715-e8e9bd68b07e/DCTA - ANNEX B - Security Feature.pdf](#)

C. Cost-benefit analysis

C.1. Do you agree with?

	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	No opinion
*The benefit analysis presented in section 11.3.1 of the Feasibility Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*The cost analysis presented in section 11.3.2 of the Feasibility Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

*C.1.1. If you selected option "Disagree" or "Somewhat disagree" in the previous question, please upload your main reasons for disagreement (max. 5 pages)

• 21d353cc-556c-4ddc-9812-f776d25caf8a/DCTA - ANNEX C - Cost-benefit analysis.pdf

D. Additional questions

The questions in this section relate to different possible building blocks and modalities of the envisaged system (questions D.1, D.3, D.4, D.6, D.8, D.10, D.12, D.14 and D.16). When replying please take into account the overall appropriateness of individual solutions in terms of the criteria of technical feasibility, interoperability, ease of operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities.

*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier, see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single standard provided by a relevant standardization body
- b) A public accreditation or similar system based on the minimum technical and interoperability requirements that allow for the parallel use of several standards;
- c) Another solution
- d) No opinion

*D.1.a. Please indicate your preferred standardization body

Text of 1 to 400 characters will be accepted

GS1 using GTIN+ serial number as the unique code for the lower packaging levels such as pack. Upper levels should use either SGTIN or SSCC.

*D.1.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

To ensure the uniqueness of the code, we believe that Codentify offers a secure option when placed under the control of either the member states or their designated third party(ies). This could also be an EU wide body which would then potentially avoid conflicts with unique identifiers on packs generated by tracking systems outside the EU, should these packs be found in the EU.

D.2. Please upload any additional comments relating to the rules for generation of a serialized unique identifier referred to in question D.1. above (max. 2 pages)

• **50b9c1b3-e572-4c43-bb33-047dfb2cd3b1/ANNEX D.2. - Rules for generation of a serialized unique identifier.pdf**

*D.3. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) Solution based on a single data carrier (e.g. 1D or 2D data carriers)
- b) Solution based on the minimum technical requirements that allow for the use of multiple data carriers;
- c) Another solution;
- d) No opinion

*D.3.a. Please indicate your preferred data carrier and explain why

Text of 1 to 400 characters will be accepted

Different packaging types will need different data carriers:
- Pack: AIM Dot code is the only available data carrier which will allow machine readable and human readable codes at high speed
- Bundles/Cartons etc.: GS1 DataMatrix
- Other Tobacco Products (OTP): large packaging GS1 DataMatrix
- Master case: GS1 128
- Pallets: GS1 (SSCC) 128
The most widely used carriers are preferred.

*D.4. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) System only operating with machine readable codes;
- b) System operating both with machine and human readable codes;
- c) No opinion

D.5. Please upload any additional comments relating to the options for (a) data carrier(s) for a serialized unique identifier referred to in questions D.3 and D.4 above (max. 2 pages)

• **3b2d6223-2fdf-4153-b551-8c81753815f9/ANNEX D.5. - Data carriers and serialized unique identifier.pdf**

*D.6. Regarding the physical placement of a serialized unique identifier, when should it happen (multiple answers possible)?











- a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
- b) After a pack/tin/pouch/item is folded/assembled and filled with products;
- c) No opinion

D.7. Please upload any additional comments relating to the placement of a serialized unique identifier referred to in question D.6. above (max. 2 pages)

- **98ea8453-585e-4a4f-9a62-5ac97efdc07c/ANNEX D.6 - Physical placement.pdf**

D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Marking products with serialized unique identifiers on the production line	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Verifying if products are properly marked on the production line	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Scanning products upon dispatch from manufacturer's/importer's warehouse	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Scanning products upon receipt at distributor's/wholesaler's premises	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*Scanning products upon dispatch from distributor's/wholesaler's premises					
*Aggregation of products					

D.9. In relation to question D.8. above, please specify any other measures that your organisation considers relevant

Text of 1 to 1200 characters will be accepted

The independent party responsible for generating serialized unique identifiers should be approved by the EU or MS. The following activities should be added to ensure proper operation of the system:

- Monitoring of the information captured by the Independent third party to ensure that all information required by the system has been transmitted correctly and enabling detection of potential breaches in the system or in the information returned by economic operators involved in the tobacco trade.

- Auditing of the information to ensure that the information is correct.

*D.10. Regarding the method of putting the security feature on the pack/tin/pouch/item, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A security feature is affixed;
- b) A security feature is affixed and integrated with the tax stamps or national identification marks;
- c) A security feature is printed;
- d) A security feature is put on the pack/tin/pouch/item through a different method;
- e) No opinion

*D.10.d. Please explain your other method

Text of 1 to 800 characters will be accepted

The security feature should be an intrinsic part of the packaging itself. There are many security features available on the market which are suitable such as taggants and finger printing which do not need a label, but are intrinsic parts of the packaging.

Random secure serialisation is also a feature which has been used over many years with success to authenticate products.

D.11. Please upload any additional comments relating to the method of putting the security feature on the pack referred to in question D.10 above (max. 2 pages)

*D.12. Regarding the independent data storage as envisaged in Article 15(8) of the TPD, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single centralised storage for all operators;
- b) An accreditation or similar system for multiple interoperable storages (e.g. organised per manufacturer or territory);
- c) Another solution
- d) No opinion

D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages)

*D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)?

- a) Provider of solutions to collect the data from the manufacturing and distribution chain;
- b) Provider of data storage services;
- c) Another entity
- d) No opinion

*D.14.c. Please explain

Text of 1 to 800 characters will be accepted

Only those with deep understanding of the manufacturing processes of tobacco products and database structure - which is very granular - can develop such tools.

D.15. Please upload any additional comments relating to the development of reporting and query tools referred to in question D.14. above (max. 2 pages)

*D.16. Do you consider that the overall integrity of a system for tracking and tracing would be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones)?

- a) Yes
- b) No
- c) No opinion

D.16.a. If yes, please explain your considerations

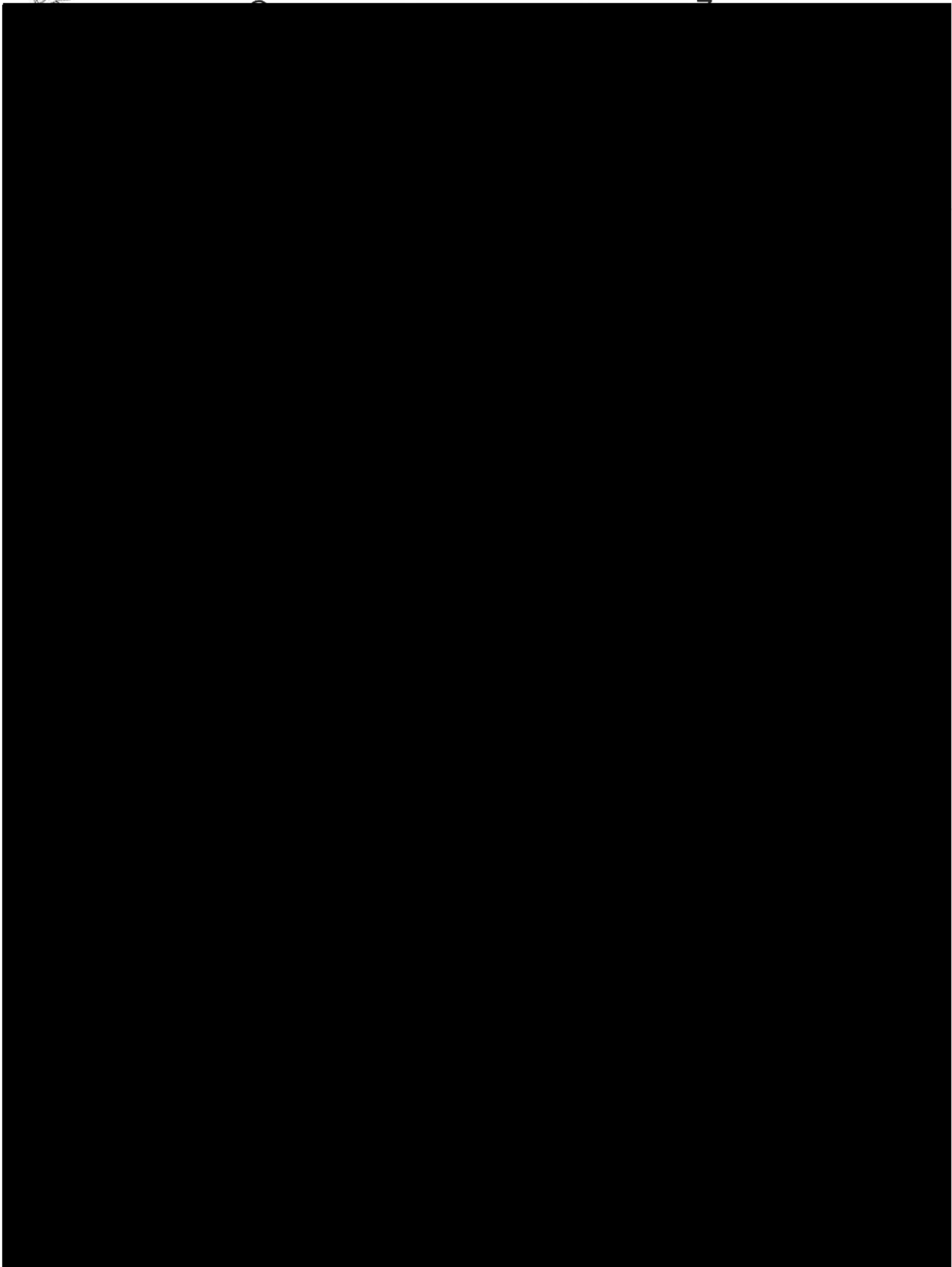
Text of 1 to 800 characters will be accepted

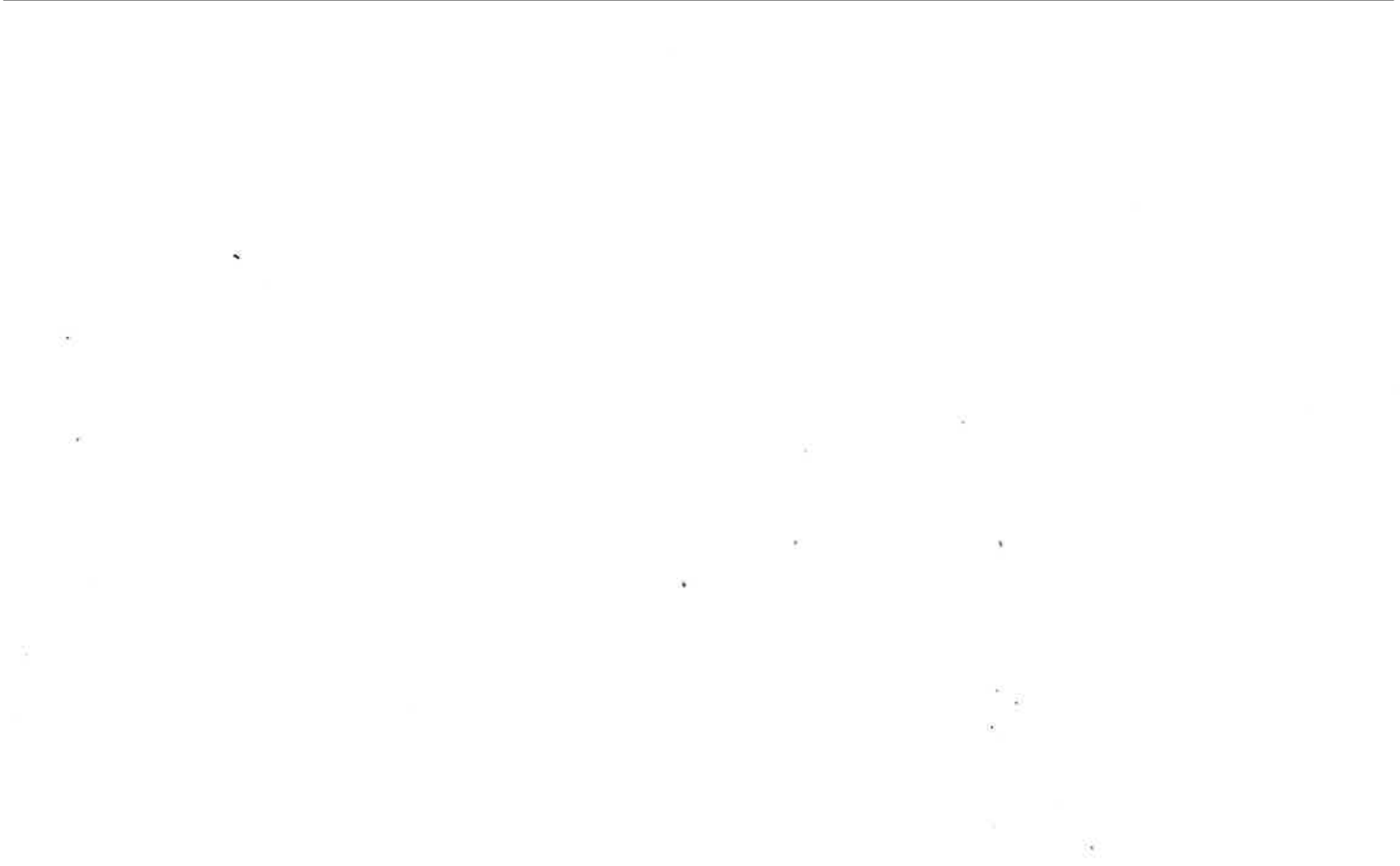
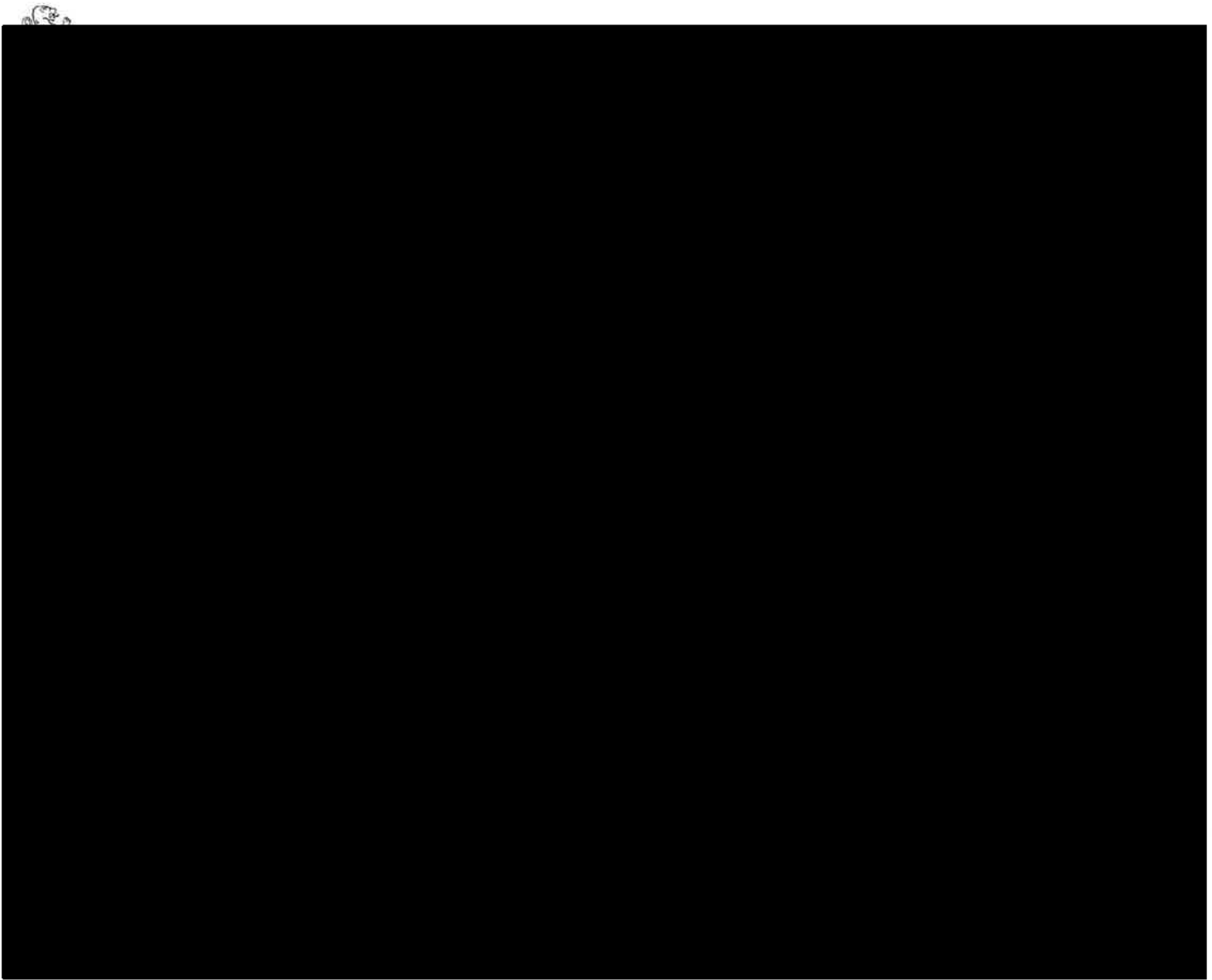
The more persons validating the authenticity of products the more likely that the system will have a positive effect for authentication purposes and consumers.

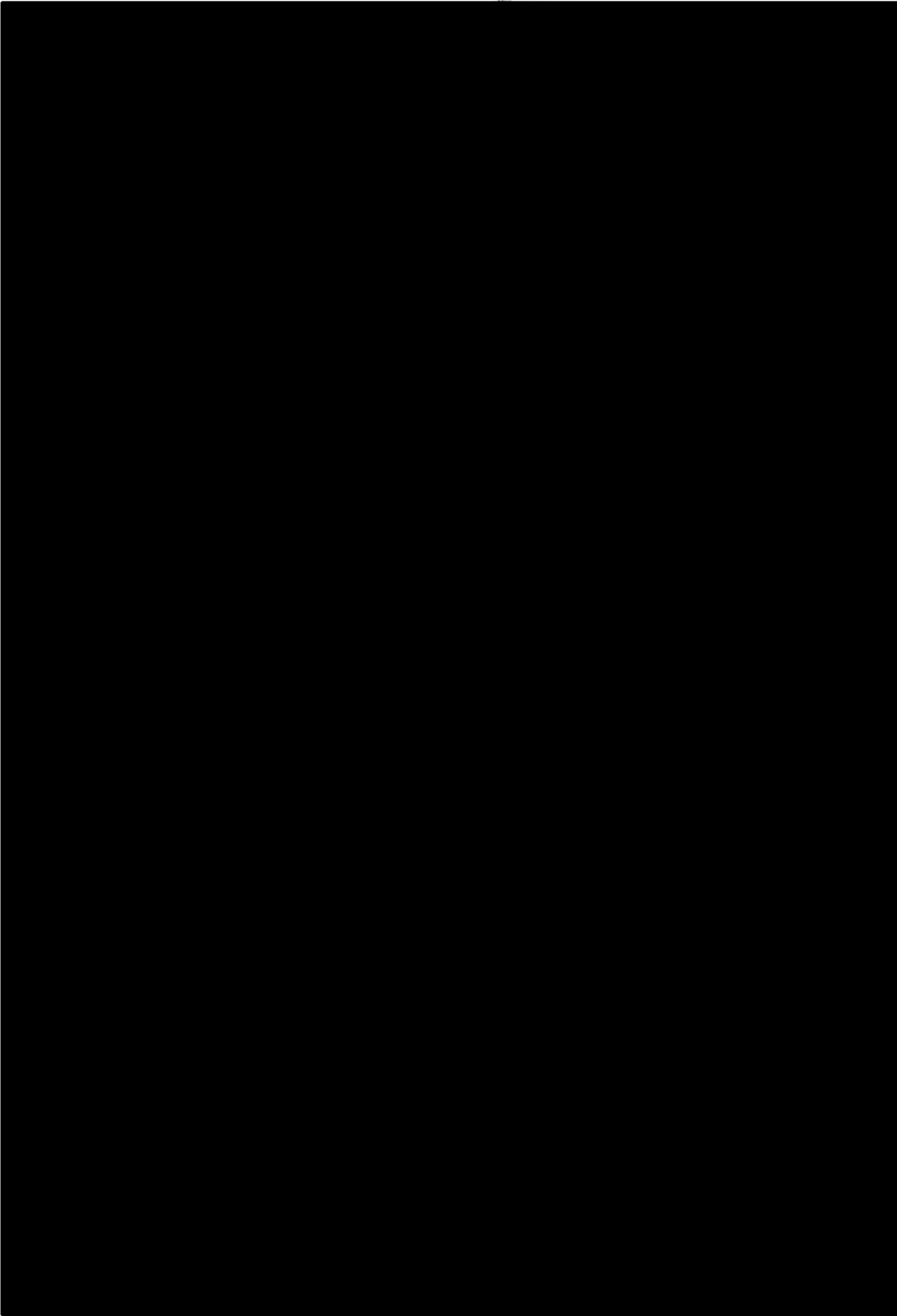
D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)

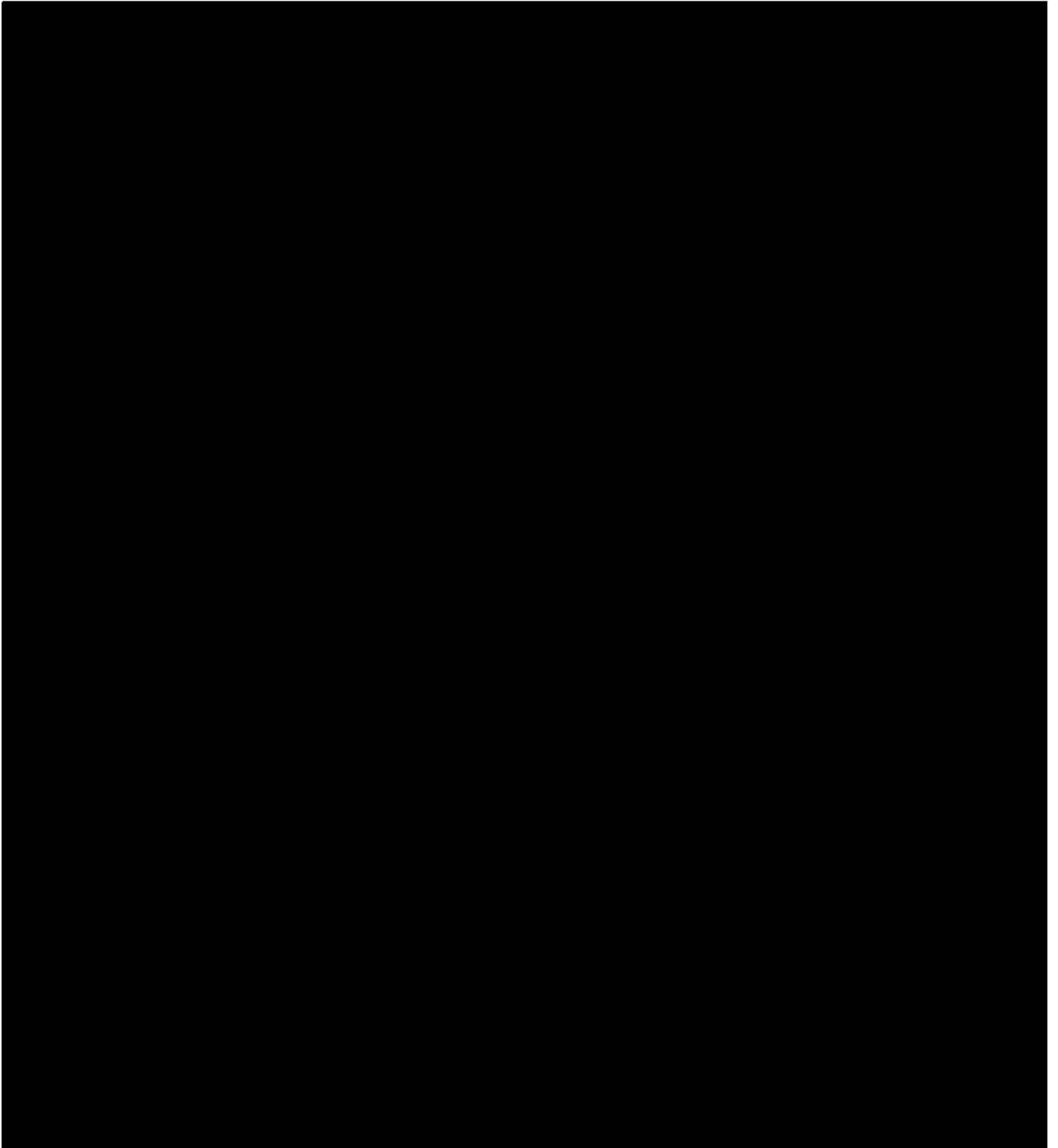
Contact

✉ SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu









ANNEX B.1.1.-4. – TRACKING AND TRACING

A track and trace (T&T) system similar to „Option 1” has been operating for over 10 years across the EU and several countries outside, by tobacco manufacturers which combined have more than 90% market share in the EU. The industry T&T system is the most robust solution in place and it is fully interoperable with systems operating outside the EU. It is also endorsed by law enforcement authorities, including OLAF.

Unique identifiers are already placed on the overwhelming majority of packs in the EU. Any legitimate tobacco manufacturer which sells products destined for the EU market (as well outside the EU) is able to get a license for the use of the serialisation technology (for creating the unique identifiers) on which these tracking systems are based royalty-free. The implementation and running costs are low.

Comments on B.1.1. - Option 1: an industry-operated solution, with direct marking on the production lines carried out by tobacco manufacturers

- This solution is endorsed by authorities across the European Union, including the European Anti-Fraud Office (OLAF).
- Proven effective over 10 years of operation under legally-binding agreements between member companies of the DCTA, the Member States of the European Union (MS) and the European Commission.
- Based on internationally-recognised technical standards (i.e. GS1), and used by companies which have more than 90% share of the EU tobacco market.
- Ensures low administrative burden for the European Commission and the MS.
- Generating unique identifiers can be controlled by the governments themselves.
- T&T database can be hosted and managed by independent third parties.
- The only tracking and tracing solution interoperable with systems already deployed by major manufacturers in countries outside the EU (including in many countries deemed to be the source of illicit product).

Comments on B.1.2. - Option 2: a third party operated solution, with direct marking on the production lines carried out by a solution or service provider

- Solution not in existence, heavy development will be needed on production lines, interfaces with each manufacturer and logistics operator.
- Unnecessary financial and operational burden to MS from the implementation of a new, untested system. Currently when customs seize tobacco products the four major tobacco manufacturers inspect the product and collect all T&T codes, which are then fed into their T&T databases. Manufacturers provide reports to customs as to their validity and where the product was last shipped.
- There is no requirement in Directive 2014/40/EU (TPD) that suppliers must be independent from the tobacco industry.
- No flexibility of solution providers.
- Potential for manufacturing process down-time.
- Reduced flexibility for tobacco manufacturers.

- Probability that proprietary equipment will be needed to retrieve tracking and tracing data, thus limiting usefulness and increasing compliance costs.
- Supplier(s) would need to be on site 24 hours per day, 365 days per year, to provide support which might raise confidentiality and compliance concerns with manufacturers' internal practices and national compliance requirements.
- Manufacturers have no access to recorded data. Data liability is an important point to raise as manufacturers cannot be held liable for data integrity.
- Limits competition and technical developments among solution providers.
- Due to development and implementation requirements, it is unlikely that this option could be implemented in time for the May 2019 deadline.
- Database will not contain data from outside the EU – where the vast majority of illicit tobacco products are sourced, thus limiting its effectiveness

Comments on B.1.3. - Option 3: each Member State decides between Option 1 and 2 as to an entity responsible for direct marking (manufacture or third party)

- Unnecessarily increases costs of data storage.
- Creates a complex manufacturing environment, with the potential for many solutions installed on a single production line, each operated by a different provider.
- Will require several supplier representatives in the same manufacturing facility to maintain their tracking and tracing systems.
- Significant difficulty in creating interfaces between systems.
- Lack of clarity for responsibility of data integrity at manufacturing level.
- Could make manufacturing for export uneconomical and therefore unviable.
- Substantial cost impact through managing multiple systems.
- Lack of data ownership. Accountability for data should be ensured.

Comments on B.1.4. - Option 4: a unique identifier is integrated into the security feature and affixed in the same production process

- Authenticity of the stamp may be assured but not the product to which it is affixed. As a stamp is not a packaging good, this tracking and tracing solution would fail.
- A full tracking and tracing solution based on paper labels does not exist and as such has not been tested in the tobacco industry.
- Large development effort required to make it compatible with highly automated production lines.
- Does not meet TPD requirements as some data cannot be added later on in the unique identifier itself, only linked. This is a weak link and could be subject to manipulation, with the manufacturer place, date and time included in the unique identifier, posing a security threat to the supply chain.
- In case of products destined for export, an additional label could be required to be applied, although TPD does not cover products for export.

- There could be a scenario where a product has a security label of the country of manufacture, and a tax stamp of the destination country. Laws of the destination country may limit such a possibility.
- All stamps applicators on production lines will need to be modified to allow the unique identifier to be read, requiring significant manufacturing changes, adaptations and downtime.
- Unnecessarily increases the costs of data storage.
- Creates a complex manufacturing environment with potentially several solutions installed on a single production line.
- Potentially not feasible on all production lines. Unique identifier will not be visible during the production process to allow vision systems to link to the outer/carton for aggregation purposes.
- The cost analysis does not consider the cost of developing a system for generating the unique identifier.
- Vision system and product aggregation managed by different entities.
- Lack of clarity over responsibility for data integrity.
- Reduces security by having all elements on the paper label, presenting the opportunity for loss, theft or tampering as the stamp has a supply chain of its own. Counterfeiters might use original stamps and when data is not linked it might further increase the vulnerability of the system.

ANNEX B.2.1.-4. – SECURITY FEATURE

The DCTA believes that all four options presented for the Security Feature will prove ineffective at addressing the counterfeiting of tobacco products.

We believe that the Report cements an outdated technology and erects barriers to innovation, as it favors only one solution: security features that are based on a paper stamp glued onto a pack. This limitation is justified neither by the TPD nor by the FCTC Protocol.

We believe the TPD implementing regulation should allow the use of innovative technologies to comply with the security feature requirements, including use of:

- A secure and human-readable serialisation code printed directly on the pack (visible, tamperproof and irremovable element).
- A hidden feature based on forensic-level technology which exploits the integral ‘fingerprint’ properties of the pack itself (invisible, tamperproof and irremovable element).
- Use of taggant-based technologies embedded in the cellophane tear-tape (tamperproof).
- Tried-and tested forensic methods based on laboratory testing of the product, as is already carried out today not just for tobacco, but for a wide range of consumer products (and is the only way to provide court-admissible evidence).

The key concerns with Options for glue-on Security Feature are the following:

- Technical feasibility highly depends on the stamp’s base material and specifications and its method of application.
- Frangible Paper on high speed production lines is not currently used and has not been tested.
- Interoperability is dependent on the stamp sizing, ensuring all stamps are compatible with existing machinery.
- Security integration. It is well known that even the modern stamps can be easily mimicked and give a false sense of security to consumers who do not have the specialised tools to differentiate between genuine and counterfeit products.
- A number of different tools and readers will be needed to authenticate the different stamps used across the EU.
- Burden on authorities to trace stolen or counterfeit stamps.
- Can be easily removed and reused.
- May require additional, paper based security feature, on top of tax stamps, disrupting the manufacturing process and create unnecessary costs
- Glue-on security features only authenticate themselves therefore not admissible as court evidence to authenticate the product. A glue-on Security feature will not be admissible to assist in authenticating the product in court, which would require brand owner’s forensic analysis. In contrast, fingerprint security feature would assist authentication in court
- Disregard technical innovation.
- The Report indicates that one EU-wide solution provider for the Security Feature should be considered to benefit from the economies of scale. In fact, it would create a monopoly with an incentive to charge higher prices and a limited incentive for innovation.

Specific comments on the various options

Comments on B.2.2. - Option 2: reduced semi-covert elements as compared to Option 1

- Far too complex.
- If required, volume reporting from the T&T system would be sufficient to effect Tax declaration validation. There are other ways than banderoles to provide the possibility of volume verification to the release to consumption declaration (i.e. digital tax verification).

Comments on B.2.4. - Option 4: security feature is integrated with unique identifier

- Unproven technology, the serialisation method could be different across the EU from market to market with no inherent product information within the unique identifier.
- Application during manufacturing will be highly complicated as codes will have to be placed in a very accurate location on unit packets in order to be optically read during aggregation. This may in practice turn out to be impossible in the manufacturing environment.
- Does not remove the need for additional printing on unit packets for some markets, e.g., price.
- All member states will have to have to comply with the same security specifications, making counterfeiting easier.

ANNEX C – COST-BENEFIT ANALYSIS

The benefit analysis is based on the total illicit trade most of which comes from outside the EU (85%) which will not be impacted by the TPD measures. This therefore makes the assumptions incorrect and highly misleading.

The costs analysis misrepresented the figures provided by the members of the DCTA, by applying them to options 2, 3, and 4. This assumption does not take into consideration the initial development cost which any supplier would need to recover. Crucially, the calculations also do not take into consideration that each DCTA member has invested significantly on developing and implementing a tracking and tracing system, and all manufacturers use their own engineering staff to support the implementation and the maintenance of the system. Combined, this means the cost of using industry systems has been substantially and erroneously inflated.

Specifically with regards to track and trace:

- **Option 2** – the cost has been highly underestimated. Manufacturers would need the supplier's representatives to be on site 24 hours a day to address technical issues and maintain high production efficiency. There is no supplier in the market who has enough staff or technical expertise to implement and maintain their system in 230+ tobacco enterprises, on 745+ production lines in 2,450+ wholesalers. There would be little or no capital expenditure costs as the manufacturers would not own the equipment, but operating expenses will be very high.
- **Option 3** - with so many interfacing suppliers used, it is impossible to calculate solution costs without specific information. The costs-analysis is therefore extremely speculative.
- **Option 4** - underestimated the cost of manufacturing equipment's capital expenditure which would need to be adjusted to host labels with unique identifiers that are capable of being aggregated (stamps are currently not in an optimal position for aggregation purposes). Industry T&T systems will need to be re-developed as they are based on online serialisation.

The same error was replicated on the logistics side by taking figures from DCTA and applied to all the hardware required across the supply chain. Again no development costs, no interfacing costs, no technical support costs and no independent supplier's profit were considered.

ANNEX D.2. – RULES FOR GENERATION OF A SERIALIZED UNIQUE IDENTIFIER

The unique identifier is following the sGTIN GS1 standards and is composed of two distinct elements:

- GTIN that uniquely identify the product;
- Serial number that uniquely identify an item within a class of product.

The GTIN is generally unique per product and per market of retail sale.

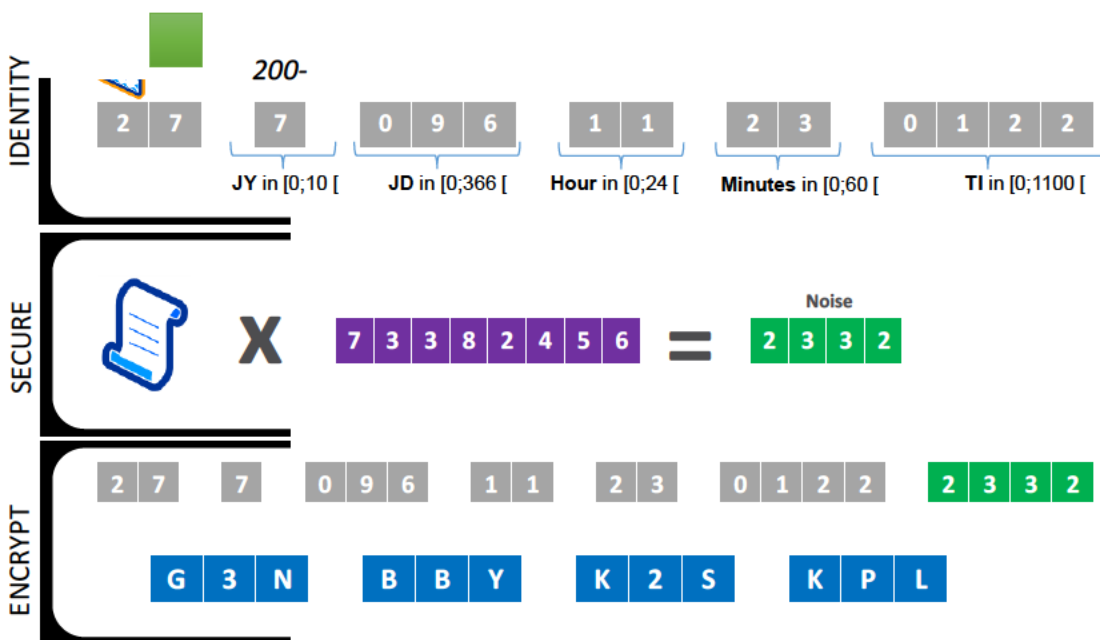
In the case of Codentify, the serial number uniquely identifies the item regardless of the product reference and this information can be used as an additional verification to ensure that information has not been tampered with.

The serial number is composed of two elements:

- Identity part;
- Security part.

In addition the information is encrypted in order to guarantee confidentiality of information in the identifier.

The following figure shows the different elements of the serial number and the actions applied on the Identity part



- 1) The identity part is created using Date/Time and counter within the minute. Codentify guarantees that the Date/Time is an integral part of the Unique Identifier as required in the TPD Article 15.

- 2) The code generator ID (number 27) is a unique number that is associated with a production line in a factory. Maintaining this association as a reference also complies with TPD Article 15 that requires that the unique identifier contains the place of manufacturing, the manufacturing facility, and the machine used to manufacture tobacco products.

Any information known at the time of manufacturing required by TPD Article 15 can be either embedded in the unique identifier if endorsed by GS1 standard and technically feasible or accessible by means of a link. In addition, any information returned by means of link can be used during generation of the security part as additional information to ensure non-repudiation and that the information is not tampered when returned without being detected.

ANNEX – D.5. – DATA CARRIERS AND SERIALIZED UNIQUE IDENTIFIER

We propose to use GS1 approved (or in process of being approved) data carriers for the unique identifier:

- AIM ISS Dot Code or GS1 DataMatrix (when technically and economically feasible) for the unit packets



- GS1 Datamatrix for Bundles
- For all the packaging level above the bundles, any GS1 compliant format required by the supply Chain in order to provide and guarantee integration with their system such as GS1 128 bar, GS1 Datamatrix or GS1 SSCC 128 code.

The flexibility in the choice of the data carrier, will ensure smooth implementation of the serialization technology:

- The selection of the serialization technology should be flexible and not bound to a limited list of providers. Most of the machines producing for EU markets are today already equipped with coding equipment that can be used for this serialization.
- The installation of serialisation technology on a machine producing tobacco products can be done following existing guidelines and existing interfaces so the roll-out and cost associated with it will not be impacted.

Using approved GS1 standards for the data carrier, will ensure coherency and homogeneity with other tobacco supply chain economic operators and industries in the deployment of a Tracking and Tracing system and minimize the impact on the supply chain.

Attachment D.7

ANNEX D.6. – PHYSICAL PLACEMENT OF A SERIALIZED UNIQUE IDENTIFIER

This depends on the type of product, but generally the placement of the unique identifier should take place during production and timed close to the finalisation of the saleable pack so that the unique identifier can give an accurate date, time and place of manufacturer within the unique identifier itself.

The placement of the serialized unique identifier on the unit pack itself should be flexible as it should be placed on the unit packets in such a way that it guarantees proper aggregation of the unit packets.

The physical position should not interfere with any other elements required by the legislation.