Case Id: d05dfbe6-7b04-42c7-a892-9c56142bdc43

Date: 31/07/2015 11:51:15

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 (CHAFEA) 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.c. Please specify:
 - i) Provider of solutions for tracking and tracing systems (or parts thereof)
 - ii) Provider of solutions for security features (or parts thereof)
 - iii) Data Management Providers (or parts thereof)

*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

FractureCode Corporation ApS is a company organised and validly existing under the laws of Denmark with registered address at Amager Strandvej 390 - 2 etage, DK-2770 Kastrup, Denmark and company registration no. DK 26 72 20 55. E-mail: info@fracturecode.com and telephone +45 88 96 01 50. Website: www.fracturecode.com.

- *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.
 - 964ca70a-2a90-4ef2-b0ec-f53cec3f590b/FractureCode Registration.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	•	0	0	0	0	0
*Interoperability	•	0	0	0	0	0
*Ease of operation for users	•	•	0	0	0	0
*System integrity (e.g. low risk of manipulation)	•	•	0	0	0	0
*Potential of reducing illicit trade	•	•	0	0	0	0
* Administrative/financial burden for economic operators	•	•	0	0	0	0
* Administrative/financial burden for public authorities	•	•	0	0	0	0

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	0	0	0	•	0	0
*Interoperability	0	0	0	0	•	0
*Ease of operation for users	0	•	0	•	•	0
*System integrity (e.g. low risk of manipulation)	•	•	0	•	•	©
*Potential of reducing illicit trade	0	•	•	•	©	0
* Administrative/financial burden for economic operators	0	•	0	•	•	0
* Administrative/financial burden for public authorities	0	©	0	©	•	0

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	0	0	•	0	0	0
*Interoperability	0	0	0	•	0	0
*Ease of operation for users	0	0	0	•	0	0
*System integrity (e.g. low risk of manipulation)	0	©			•	0
*Potential of reducing illicit trade	0	•	0	•	0	0
* Administrative/financial burden for economic operators	0	©	0	•	•	0
* Administrative/financial burden for public authorities	0	©	0	•	•	0

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	0	©		0	•	0
*Interoperability	0	•	0	•	0	0
*Ease of operation for users	0	•	0	•	•	•
*System integrity (e.g. low risk of manipulation)	•	•	•	•	•	•
*Potential of reducing illicit trade	0	•	0	•	•	•
* Administrative/financial burden for economic operators	0	•	•	•	•	0
* Administrative/financial burden for public authorities	0	©	0	©	•	0

- B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)
 - 0df9bd52-9aea-4ad7-829a-bd565e97fb6a/FractureCode Response to EU TPD B15.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	0	0	0	©	0	•
*Interoperability	0	0	0	0	0	•
*Ease of operation for users	0	©	0	©	0	•
*System integrity (e.g. low risk of manipulation)	0	©	0	0	0	•
*Potential of reducing illicit trade	0	©	0	0	0	•
* Administrative/financial burden for economic operators	0	©	0	0	0	•
* Administrative/financial burden for public authorities	0	•	0	©	•	•

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	0	0	0	0	0	•
*Interoperability	0	0	0	0	0	•
*Ease of operation for users	0	©	0	0	0	•
*System integrity (e.g. low risk of manipulation)	0	©	0	0	•	•
*Potential of reducing illicit trade	0	•	0	0	0	•
* Administrative/financial burden for economic operators	0	•	0	0	0	•
* Administrative/financial burden for public authorities	0	©	0	•	•	•

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	0	0	0	0	0	•
*Interoperability	0	•	0	0	0	•
*Ease of operation for users	0	•	0	•	•	•
*System integrity (e.g. low risk of manipulation)	•	•	•	•	•	•
*Potential of reducing illicit trade	0	©	0	0	0	•
* Administrative/financial burden for economic operators	0	©	•	•	•	•
* Administrative/financial burden for public authorities	0	©	0	•	•	•

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	0	0	0	©	0	•
*Interoperability	0	0	0	0	0	•
*Ease of operation for users	0	©	0	©	0	•
*System integrity (e.g. low risk of manipulation)	0	©	0	0	0	•
*Potential of reducing illicit trade	0	©	0	0	0	•
* Administrative/financial burden for economic operators	0	©	0	0	0	•
* Administrative/financial burden for public authorities	0	•	0	©	•	•

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

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	•	©	©	•	•	•
*The cost analysis presented in section 11.3.2 of the Feasibility Study	©	©	©	•	•	©

- *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)
 - 81f36250-32a2-4880-b306-89f336e4af56/FractureCode Response to EU TPD C11.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.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)
 - 892a5088-b9e0-4fa6-b8b3-c3048daa23dc/FractureCode Response to EU TPD D1A.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.c. Please explain your other solution
Text of 1 to 800 characters will be accepted
GS1 Coding standard should be used
*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) • b62ddf00-f95a-4cc7-9e70-82e6204af0ed/FractureCode Response to EU TPD D5.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)

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	0	0	•	0	©
*Marking products with serialized unique identifiers on the production line	•	•	•	•	0
*Verifying if products are properly marked on the production line	0	•	•	•	©
*Scanning products upon dispatch from manufacturer's/importer's warehouse	0	•	0	•	0
*Scanning products upon receipt at distributor's/wholesaler's premises	0	•	0	•	0

*Scanning products upon dispatch from distributor's/wholesaler's premises	©	•	©	©	•
*Aggregation of products	0	•	0	0	0

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 most cost-effective and legitimate strategy is an industry implementation to a prescribed specification with a third-party and validation. The Tobacco Products Directive (2014/40/EU) refers to a "data storage provider" and not a "third-party" auditor.

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/puch/item through a different method; e) No opinion
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.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)
 - 9028c576-818a-4806-9e84-219c60811ee7/FractureCode Response to EU TPD B15.pdf
- *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

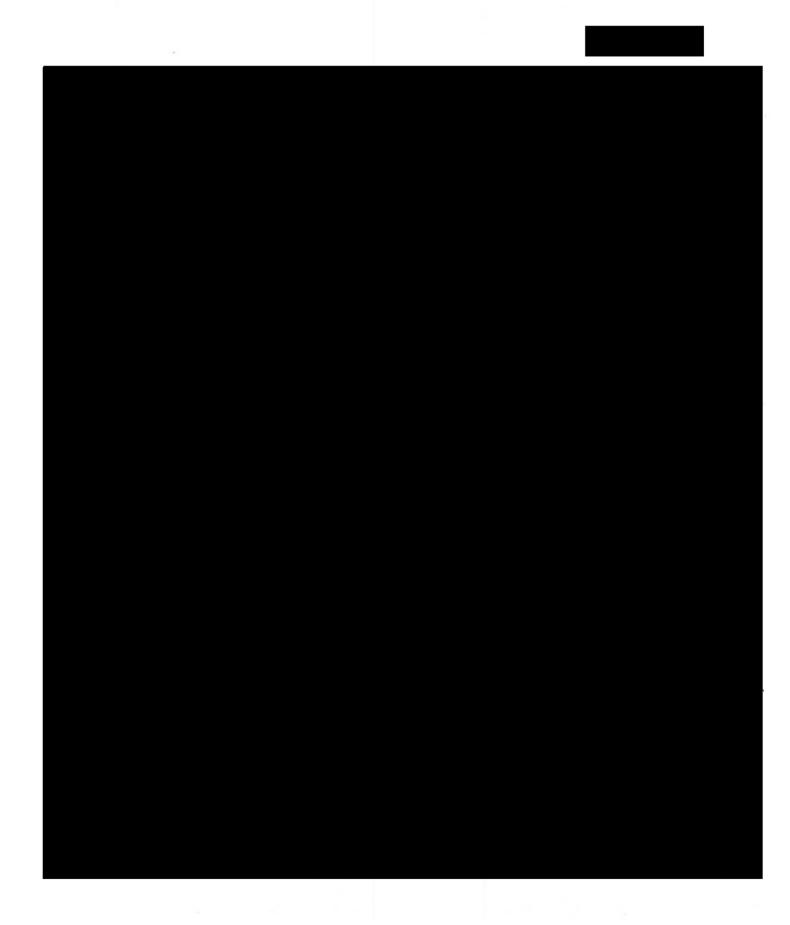
of 1 to 800 characters will be accepted			

- D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)
 - 3654a61e-e201-4ecd-9138-104722f3db4e/FractureCode Response to EU TPD D17.pdf

Contact

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





LOGO THE DANISH BUSINESS AUTHORITY





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

FractureCode Corporation written and supporting comments on the options referred to in question B.1.5



Written comments to B.1.5.

Option 1 is based on existing industry standards, which are, already fully operational for major cigarette brands in the EU. This is the only viable option for swift and effective implementation of T&T for tobacco considering that already almost a decade has been spent by the industry to cover the current production lines with T&T equipment, which is required by the existing agreements. Option 1 ensure low administrative burden for the EU as well as it is the most cost effective for both the EU and the industry. Option 1 will stimulate fair competition and competitive solutions to the benefit of EU and their taxpayers. Many machine builders are building the new generation machines with T&T capabilities allowing manufacturers T&T capabilities "out-of-the-box". Such great innovative initiatives will only be possible under option 1.

Option 2 will require proprietary T&T equipment on the production lines. Proprietary equipment will lead to rebuilding of production lines to meet the specification of the T&T equipment instead of implementation of T&T equipment that fits the production line. It is very likely that this approach could lead to closure of smaller specialised manufacturers that cannot afford to rebuild their production lines. Further option 2 will increase the costs of data storage unnecessarily since the report does not take into consideration that all stakeholders will have to build IT system to hold the T&T data regardless of the fact that T&T data would be requested uploaded to a central EU database.

Option 3 will require a mix of different T&T equipment from different suppliers on the production line and this will ultimately lead to conflicts, inconsistency and ineffectiveness in the T&T programme.

Further option 3 will increase the costs of data storage unnecessarily since the report does not take into consideration that all stakeholders will have to build a system to hold the T&T data regardless of the fact that T&T data would be requested uploaded to each member state.

Option 4 will also increase the costs of data storage unnecessarily for the same reasons explained option 3.

Further option 4 will require proprietary T&T equipment on the production lines. Proprietary equipment will lead to rebuilding of production lines to meet the specification of the T&T equipment instead of implementation of T&T equipment that fits the production line. It is very likely that this approach could lead to closure of smaller specialised manufacturers that cannot afford to rebuild their production lines.



Attachment C.1.1

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

FractureCode Corporation written and supporting comments on the options referred to in question C.1.1



Written comments to C.1.1.

We are concerned that the conclusions in the report are incorrect primarily because it seems like the conclusions are based on wrong pricing mechanisms, since several of the price references used in the report are incorrect. In particular it seems like some of the pricing used under option 1 is wrong by factor 5-8 and that option 1 does not include all the investments made to date under the existing EC agreements.

We agree with the fact the implementing track and trace will help authorities' combat illicit trade.



Attechment D.2

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

FractureCode Corporation written and supporting comments on the options referred to in question D.1.a



Written comments to D.1.a.

The standard for TPD should be based on GS1 coding standard and EPCIS data structure, since this standard is global and already adapted by pharma industry in the EU. Also future traceability programmes for food, spareparts etc will be based on GS1 and EPCIS.



Attechment D.5

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

FractureCode Corporation written and supporting comments on the options referred to in question D.5



Written comments to D.5.

Human readable codes are key for verification of the product ID without the use of a handheld scanner. Human readable codes can also be used by operators to check of the coding is running correctly during production and if the aggregation is being performed correctly.

Further human readable codes has the advantage that consumers can use these codes to check the authenticity of the product.

Machine readable codes can contain more information using less space on the pack and therefore important to include more information in the coding. Machine readable code are critical for making the aggregation process. Machine readable codes can also be read by smart phone making the authenticity check more efficient.



Attachment D.15

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

FractureCode Corporation written and supporting comments on the options referred to in question B.1.5



Written comments to B.1.5.

Option 1 is based on existing industry standards, which are, already fully operational for major cigarette brands in the EU. This is the only viable option for swift and effective implementation of T&T for tobacco considering that already almost a decade has been spent by the industry to cover the current production lines with T&T equipment, which is required by the existing agreements. Option 1 ensure low administrative burden for the EU as well as it is the most cost effective for both the EU and the industry. Option 1 will stimulate fair competition and competitive solutions to the benefit of EU and their taxpayers. Many machine builders are building the new generation machines with T&T capabilities allowing manufacturers T&T capabilities "out-of-the-box". Such great innovative initiatives will only be possible under option 1.

Option 2 will require proprietary T&T equipment on the production lines. Proprietary equipment will lead to rebuilding of production lines to meet the specification of the T&T equipment instead of implementation of T&T equipment that fits the production line. It is very likely that this approach could lead to closure of smaller specialised manufacturers that cannot afford to rebuild their production lines. Further option 2 will increase the costs of data storage unnecessarily since the report does not take into consideration that all stakeholders will have to build IT system to hold the T&T data regardless of the fact that T&T data would be requested uploaded to a central EU database.

Option 3 will require a mix of different T&T equipment from different suppliers on the production line and this will ultimately lead to conflicts, inconsistency and ineffectiveness in the T&T programme.

Further option 3 will increase the costs of data storage unnecessarily since the report does not take into consideration that all stakeholders will have to build a system to hold the T&T data regardless of the fact that T&T data would be requested uploaded to each member state.

Option 4 will also increase the costs of data storage unnecessarily for the same reasons explained option 3.

Further option 4 will require proprietary T&T equipment on the production lines. Proprietary equipment will lead to rebuilding of production lines to meet the specification of the T&T equipment instead of implementation of T&T equipment that fits the production line. It is very likely that this approach could lead to closure of smaller specialised manufacturers that cannot afford to rebuild their production lines.



Attachment D.17

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

FractureCode Corporation written and supporting comments on the options referred to in question D.17



Written comments to D.17.

Any proposed tracking and tracing solution for the Tobacco Products Directive (2014/40/EU) must have at its heart the ability to uniquely identify products. Unique identification is essential not only for authentication purposes, but also enables the aggregation process, as it is building a relationship between different levels of packaging in a manufacturing process.

Interoperability is another key feature. There is a wide choice of suppliers of coding systems extensively supporting manufacturers, across the EU and globally. So the question of interoperability is not just about the tracking and tracing system as a whole (or at a governmental or factory level) but also about the equipment used at line level. Therefore any adopted tracking and tracing solution for use with the Tobacco Products Directive (2014/40/EU) must allow businesses as much choice as possible with regard to sourcing the 'at line' equipment required for tracking and tracing solutions. Allowing as many suppliers as possible to support businesses and governments is the only practical approach to gain a successful outcome and a fair open competitive environment among current and future providers. The positive effect of this is already experienced in relation to the pharmaceutical industry and the European Falsified Medicines Directive (2011/62/EU).

There is no "silver bullet" solution to tackle the counterfeiting of tobacco. The answer lies with collaboration between different industries and organisations and agreed open standards. By sharing knowledge, promoting open standards and technical developments, we have the opportunity to tackle the growing problem of falsification and illicit trade.