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.e. Please specify:

- (●) i) NGO active in the area of fight against illicit trade of tobacco products
- ii) Other

*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

Lithuanian Tobacco and Alcohol Control Coalition, Stikliu st. 8, Vilnius, info@ntakk.lt, www.ntakk.lt

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

(•) Yes ( ) No

*A.3.1. Please enter your registration number in the Transparency Register

733250713893-78

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

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

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

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

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

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

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

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

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

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

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

- **99359530-524d-40ff-90d0-9e70096ca375/NTAKK response to stakeholder consultation on the implementation of an EU system for traceability and security features.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	○	○	○	○	○	◉
*The cost analysis presented in section 11.3.2 of the Feasibility Study	○	○	○	○	○	◉

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)?

- [x] 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

NTAKK does not have definite view on which standardization body should be used for this
purpose. The most important is that the standardization body should also be independent of the tobacco industry.

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)

- **0d80891e-baa9-41ba-8d68-17c34d7eaac9/D2.docx**
- **925a7d18-adb1-4842-a74e-6bea29d52aa8/NTAKK response to stakeholder consultation on the implementation of an EU system for traceability and security features.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;
- [x] d) No opinion

*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;
- [x] 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)

- **363f390f-10e7-4019-a643-c8cf868703b9/D5.docx**

*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;
- [x] 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	○	○	◉	○	○
*Marking products with serialized unique identifiers on the production line	○	○	◉	○	○
*Verifying if products are properly marked on the production line	○	○	◉	○	○
*Scanning products upon dispatch from manufacturer's/importer's warehouse	○	○	◉	○	○
*Scanning products upon receipt at distributor's/wholesaler's premises	○	○	◉	○	○

*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 chosen system should not leave open the possibility for the tobacco industry to repeat the use of valid unique identifiers or use of some valid unique identifiers for products known to be intended for diversion into illicit channels, for example through deliberate over supply to stated destination markets. We therefore consider that an independent party should generate the unique identifiers.

*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;
- [x] 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
- [x] 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;
- [x] 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)

*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

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

Attachment A4

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

Lithuanian Tobacco and Alcohol Control Coalition (NTAKK) response

A4.

Please note that this response has been prepared by Smoke Free Partnership on behalf of the SFP Coalition, taking into account the responses of the Association of the European Cancer Leagues and Action on Smoking and Health (UK). NTAKK is member of SFP Coalition.

Lithuanian Tobacco and Alcohol Control Coalition (NTAKK) is legal association of NGO's and individuals, which was established in 2008. NTAKK members are those bodies or individuals, who work and/or are interested in alcohol and tobacco control field. At the moment NTAKK has 29 member organizations. NTAKK's mission - to advocate for implementation of science-based alcohol and tobacco control measures and prevention of psychoactive substances. NTAKK is actively participating in tobacco control field on a national and international level. NTAKK is a member organization of the European Network for Smoking Prevention (ENSP), the Framework Convention on Tobacco Control Alliance (FCA), the European Alcohol Policy Alliance (Eurocare), North Alcohol and Drug Policy Network (NORDAN). NTAKK is also Smoke Free Partnership Coalition partner.

NTAKK serves as a platform of best practices, for policy analysis, advocacy, research and capacity building. NTAKK has representative in the national working group on EU Tobacco Products Directive. NTAKK in 2011 together with Smoke Free Partnership ant partner organizations organized and hosted international training on tax and illicit trade. NTAKK as umbrella organization consists of many various NGO's and members of NTAKK are connected with topic of the project my many different ways- as tobacco policy experts, researchers, tobacco prevention organizers, psychologists who help to quit smoking etc.

General comments: SFP welcomes the Commission's initiative to seek comments from stakeholders regarding 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. We trust that our comments will be useful for the implementation work on a future EU system for traceability and security features and that they will be taken into account in the follow-up study. The SFP Coalition would also like to stress the importance of the Protocol to Eliminate Illicit Trade in Tobacco Products (ITP) which was developed by the Parties to the WHO FCTC. The ITP provides tools for preventing and counteracting illicit trade through international cooperation and national measures to better control the tobacco product supply chain. One of the core elements of the ITP is the tracking and tracing regime. According to Article 8 of the ITP, each Party shall require that unique, secure and non-removable identification markings, such as codes or stamps, are affixed to or form part of all unit packets, packages and any outside packaging of cigarettes within a period of five years and other tobacco products within a period of ten years of entry into force of the Protocol. The ITP, adopted in November 2012, will come into force on the 90th day following the date of the 40 ratification of the protocol. Only parties which ratify the protocol will be bound by its obligations. Despite the fact that the EU has been the driving force behind the adoption of the ITP and despite the Commission's announcement on

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Bank code: 73000, SWIFT code: HABALT22

4 May 2015 calling for the EU to ratify the ITP soon, urging the Council to adopt this decision with the consent of the European Parliament, we are concerned that the EU and its Member States are slow in preparing for ITP ratification. The SFP Coalition believes that it is essential that the introduction of a tracking and tracing system should meet the requirements of Article 8 of the Illicit Trade Protocol. It should be noted that the Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry. In particular, Article 8.2 states that the tracking and tracing system is "controlled by the Party". Also, Article 8.12 states that obligations assigned to a Party shall not be performed by or delegated to the tobacco industry and
Article 8.13 states that each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.

Our understanding of the tracking and tracing system: Tracking and tracing covers a wide variety of systems to determine the current and past locations of goods. When a company packs a box with a specific item, a Unique Identifying Number (UID) can be assigned. Companies that ship packages internationally usually scan the UID of the packages at every stage of transport. That information is sent to a data server that allows the company and client to learn a package's precise location at any time during its shipping. In the case of tobacco products, tracking and tracing refers to the determination of the past and recording future location of all tobacco packaging such as packs, cartons, master cases and pallets through the supply chain, from the manufacturer, importer, exporter, trader to distributor and retailer.
In particular:

- Tracing means the re-creation by competent authorities or any other person acting on their behalf of the route or movement taken by tobacco products through their respective supply chains of manufacture, sale, distribution, storage, shipment, import or export, or any part thereof.
- Tracking means systematic monitoring by competent authorities or any other person acting on their behalf of the route or movement taken by tobacco products through their respective supply chains of manufacture, sale, distribution, storage, shipment, import or export, or any part thereof.

Thus tracing can be seen as a retrospective system reviewing past movements, and tracking as a prospective one monitoring current movements.

B1.

NTAKK firs of all would like to stress the importance of the Protocol to Eliminate Illicit Trade in Tobacco Products (ITP) which was developed by the Parties to the WHO FCTC. The SFP Coalition believes that it is essential that the introduction of a tracking and tracing system should meet the requirements of Article 8 of the Illicit Trade Protocol. It should be noted that the Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry. In particular, Article 8.2 states that the tracking and tracing system is "controlled by the Party".
Also, Article 8.12 states that obligations assigned to a Party shall not be performed by or delegated to the tobacco industry and Article 8.13 states that each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.

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Only Option 2 and Option 4 are in line with Article 8 of the Illicit Trade Protocol and are thus are our preferred options.

Our analysis of the feasibility study shows that Option 1 and Option 3 (as both options would permit an industry-operated system) are not in line with Article 8 of the Illicit Trade Protocol and should be rejected on this basis alone.

This is how we see all suggested options:

Option 1 should be excluded, because it is in contradiction with Art. 8 the Illicit Trade Protocol: The first option is the Codentify system and should be excluded because it is controlled by the industry and in conflict with the FCTC Protocol. The Codentify system is not a transparent or open source system and has been developed by PMI. In fact, Codentify is not a tracking and tracing system, but is a code generator system installed at the production line that generates unique codes on packs. Codentify uses elements of production related information (such as production line and time of production) to generate with a secret "key" an unpredictable and unique encrypted 12character combination of letters and numbers to identify and authenticate a pack of cigarettes. The number, linked with a digital signature, can be read by a human or by a computer. Since its creation in 2010, Codentify has been licensed for use by the three other multinational companies, BAT, JTI and Imperial Tobacco. These four companies have now formed the "Digital Coding and Tracking Association", based in Zurich, to promote the system to governments and independent agencies. Codentify serves tobacco industry interest, is managed and controlled by the tobacco industry and is protected by a tobacco industry patent.[1] We cannot favour a system which is controlled by the industry because the tobacco industry has a long record of complicity in illicit trade. According to the World Health Organization, "The tobacco industry covertly and overtly supports the illegal trade, from providing products to the market, to working to block tobacco control by trying to convince governments that measures like health warnings or tax increases will lead to more illicit trade." [2] Furthermore, there is evidence that tobacco industry complicity in illicit trade has continued in recent years.[3] The tobacco industry has also used the threat of illicit trade to try to deter governments in the European Union and around the world from pursuing public health policies to reduce tobacco use, including tax rises. The tobacco industry has also tried to use the issue of illicit trade to build relationships with governments, local authorities and enforcement agencies, often in breach of Article 5.3 of the FCTC and its accompanying guidelines. For example, in 2011 INTERPOL accepted a $23.5 million donation from Philip Morris International, and has announced that it will be working with the industry's Digital Coding and Tracking Association to use the industry's "Codentify" system through the INTERPOL Global Register. The tobacco industry's secretive behaviour means that there has been no full independent assessment of the security of the Codentify system. Without such an assessment, governments could be opting for a "black box" system, with features and possible weaknesses that only the tobacco industry is aware of.[4]

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[1] Joossens L, Gilmore AB. The transnational tobacco companies' strategy to promote Codentify, their inadequate tracking and tracing standard. *Tob Control* 2013;:tobaccocontrol – 2012–050796. doi:10.1136/tobaccocontrol-2012050796

[2] http://www.who.int/mediacentre/factsheets/fs339/en/

[3] Crackdown seizes more than 2.5 million illegal cigarettes: Chartered Trading Standards Institute 28/1/2015

[4] http://www.fctc.org/media-and-publications/fact-sheets/1319-illicit-trade-in-tobacco-beware-industry-solutions

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According to the FCTC Secretariat, the Codentify system would be in conflict with the FCTC Protocol and does not meet the requirement of ITP Article 8.2 that the tracking and tracing system has to be "controlled by the Party".[5]

Furthermore, it may require Member States who ratify the protocol to implement a second tobacco tracking and tracing process in parallel with an industry-operated one in order to meet their WHO FCTC obligations.

Options 2 is, under certain conditions, our preferred option, because an EU system would simplify the operations and facilitate the exchange of information within the EU: The second option is an EU system operated by an external provider(s). The system could be a good option, if it meets certain criteria. The advantage of this option is that there will be only one system in the 28 EU countries and as such operational between EU countries. In addition, it complies with both the EU Directive and the FCTC Protocol. The risk is that the EU would be too dependent on one or more external providers. For this reason, a system in option 2 should be chosen that could be supplied by several providers and not lead to a monopoly.

Option 3 operated by the tobacco industry should be excluded and option 3 operated by external providers is more complicated than option 2 - The third option is a set of national systems operated by external providers or the tobacco industry. This option might complicate the exchange of data within the EU and is not an option, if it is operated by the tobacco industry (see comments option 1) .

Option 4 could be a possibility, but is less preferable than Option 2, because it remains a combination of national systems: Option 4 combines the traceability solution with security features. In most countries, Option 4 would mean that tax stamps would incorporate unique digital identifiers and security features. Additional requirements for markings are needed for exported products and bigger, secondary packaging (cartons, master cases etc.) that carry no tax stamps. As in Option 1, markings operated by the tobacco industry are not an option for those additional requirements.

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NTAKK has no preferences regarding the security features, but believes that a combination of overt, covert and forensic features should be recommended.

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The main objective of a tracking and tracing regime for tobacco products is to facilitate investigations into tobacco smuggling by providing analysis of smuggling trends and export practices and identification of the point of diversion to the illicit market, whenever an audit or a seizure is made. We would like to reiterate that the introduction of a tracking and tracing system should meet the requirements of Article 8 of the Illicit Trade Protocol. As a reminder, the Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry.

The unique identifier suitable for use in tracking and tracing of tobacco products should encompass the following elements:

- A marking for each package of tobacco products that should be unique and non-predictable. For instance, in your passport you have a combination of letters and figures that is unique for each person. The attribution of this combination identifies each person and is not predictable, unlike figures in a row 12345 for example. Digital Mass Encryption is a prevalent method to make codes less predictable. Valid codes can only be generated if mathematic formula (algorithms) and secret keys are known that are used for their creation.

- A data carrier that contains the unique identifier and other information available at the time of manufacturing such as place and time of production. This data carrier should be suitable for high speed production and storing and reading of data, and ideally, should follow a prevalent international standard in order to be readable by commercially available equipment tools. Two dimensional bar codes, for instance, are machine readable and widely used on many consumer products in an international environment.

- A link and parent-child relationships (called aggregation) between different packaging units that allow, for instance, traceability of pallets without scanning all master cases, cartons and packs that are inside the pallet.

Recording of any shipping and receiving events along the supply chain, for instance the recording of the departure of the pallet at the manufacturing site and the arrival of the consignment at trader x in country y.

Internationally accepted standards to describe the main characteristics of the products (such as country of manufacture, product description, date of manufacture), to encode the data in thedata carrier, and to record events along the supply chain among the supply chain partners. The storage of the data and events along the supply chain in an independent database, by preference a single database across the EU, controlled by competent government authorities.

At global level, we expect a multitude of national and/or regional databases that should be interconnected to facilitate international inquiries by competent authorities. Similarly, the access to and retrieval of this data should also be independent of the parties being controlled.

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For the data carrier we have a clear preference for the two-dimensional bar codes:

2D bar codes have already been used on many consumer products, such as food, alcohol, pharmaceuticals and tobacco products.
2D bar codes are machine readable and can be implemented at high speed production lines
2D bar codes can be read by inexpensive readers (including smart phones) along the supply and distribution chain
2D bar codes can be supplied by multiple suppliers
2D bar codes are a cost effective solution

Other solutions should not be excluded in the near future, but under the conditions, 2D bar codes are our preferred option for the data carrier.

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General comments: SFP welcomes the Commission's initiative to seek comments from stakeholders regarding 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. We trust that our comments will be useful for the implementation work on a future EU system for traceability and security features and that they will be taken into account in the follow-up study. The SFP Coalition would also like to stress the importance of the Protocol to Eliminate Illicit Trade in Tobacco Products (ITP) which was developed by the Parties to the WHO FCTC. The ITP provides tools for preventing and counteracting illicit trade through international cooperation and national measures to better control the tobacco product supply chain. One of the core elements of the ITP is the tracking and tracing regime. According to Article 8 of the ITP, each Party shall require that unique, secure and non-removable identification markings, such as codes or stamps, are affixed to or form part of all unit packets, packages and any outside packaging of cigarettes within a period of five years and other tobacco products within a period of ten years of entry into force of the Protocol. The ITP, adopted in November 2012, will come into force on the 90th day following the date of the 40 ratification of the protocol. Only parties which ratify the protocol will be bound by its obligations. Despite the fact that the EU has been the driving force behind the adoption of the ITP and despite the Commission's announcement on

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4 May 2015 calling for the EU to ratify the ITP soon, urging the Council to adopt this decision with the consent of the European Parliament, we are concerned that the EU and its Member States are slow in preparing for ITP ratification. The SFP Coalition believes that it is essential that the introduction of a tracking and tracing system should meet the requirements of Article 8 of the Illicit Trade Protocol. It should be noted that the Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry. In particular, Article 8.2 states that the tracking and tracing system is "controlled by the Party". Also, Article 8.12 states that obligations assigned to a Party shall not be performed by or delegated to the tobacco industry and
Article 8.13 states that each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.

Our understanding of the tracking and tracing system: Tracking and tracing covers a wide variety of systems to determine the current and past locations of goods. When a company packs a box with a specific item, a Unique Identifying Number (UID) can be assigned. Companies that ship packages internationally usually scan the UID of the packages at every stage of transport. That information is sent to a data server that allows the company and client to learn a package's precise location at any time during its shipping. In the case of tobacco products, tracking and tracing refers to the determination of the past and recording future location of all tobacco packaging such as packs, cartons, master cases and pallets through the supply chain, from the manufacturer, importer, exporter, trader to distributor and retailer.
In particular:

- Tracing means the re-creation by competent authorities or any other person acting on their behalf of the route or movement taken by tobacco products through their respective supply chains of manufacture, sale, distribution, storage, shipment, import or export, or any part thereof.
- Tracking means systematic monitoring by competent authorities or any other person acting on their behalf of the route or movement taken by tobacco products through their respective supply chains of manufacture, sale, distribution, storage, shipment, import or export, or any part thereof.

Thus tracing can be seen as a retrospective system reviewing past movements, and tracking as a prospective one monitoring current movements.

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Only Option 2 and Option 4 are in line with Article 8 of the Illicit Trade Protocol and are thus are our preferred options.

Our analysis of the feasibility study shows that Option 1 and Option 3 (as both options would permit an industry-operated system) are not in line with Article 8 of the Illicit Trade Protocol and should be rejected on this basis alone.

This is how we see all suggested options:

Option 1 should be excluded, because it is in contradiction with Art. 8 the Illicit Trade Protocol: The first option is the Codentify system and should be excluded because it is controlled by the industry and in conflict with the FCTC Protocol. The Codentify system is not a transparent or open source system and has been developed by PMI. In fact, Codentify is not a tracking and tracing system, but is a code generator system installed at the production line that generates unique codes on packs. Codentify uses elements of production related information (such as production line and time of production) to generate with a secret "key" an unpredictable and unique encrypted 12character combination of letters and numbers to identify and authenticate a pack of cigarettes. The number, linked with a digital signature, can be read by a human or by a computer. Since its creation in 2010, Codentify has been licensed for use by the three other multinational companies, BAT, JTI and Imperial Tobacco. These four companies have now formed the "Digital Coding and Tracking Association", based in Zurich, to promote the system to governments and independent agencies. Codentify serves tobacco industry interest, is managed and controlled by the tobacco industry and is protected by a tobacco industry patent.[1] We cannot favour a system which is controlled by the industry because the tobacco industry has a long record of complicity in illicit trade. According to the World Health Organization, "The tobacco industry covertly and overtly supports the illegal trade, from providing products to the market, to working to block tobacco control by trying to convince governments that measures like health warnings or tax increases will lead to more illicit trade." [2] Furthermore, there is evidence that tobacco industry complicity in illicit trade has continued in recent years.[3] The tobacco industry has also used the threat of illicit trade to try to deter governments in the European Union and around the world from pursuing public health policies to reduce tobacco use, including tax rises. The tobacco industry has also tried to use the issue of illicit trade to build relationships with governments, local authorities and enforcement agencies, often in breach of Article 5.3 of the FCTC and its accompanying guidelines. For example, in 2011 INTERPOL accepted a $23.5 million donation from Philip Morris International, and has announced that it will be working with the industry's Digital Coding and Tracking Association to use the industry's "Codentify" system through the INTERPOL Global Register. The tobacco industry's secretive behaviour means that there has been no full independent assessment of the security of the Codentify system. Without such an assessment, governments could be opting for a "black box" system, with features and possible weaknesses that only the tobacco industry is aware of.[4]

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[2] http://www.who.int/mediacentre/factsheets/fs339/en/

[3] Crackdown seizes more than 2.5 million illegal cigarettes: Chartered Trading Standards Institute 28/1/2015

[4] http://www.fctc.org/media-and-publications/fact-sheets/1319-illicit-trade-in-tobacco-beware-industry-solutions

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[1] Joossens L, Gilmore AB. The transnational tobacco companies' strategy to promote Codentify, their inadequate tracking and tracing standard. *Tob Control* 2013;:tobaccocontrol – 2012–050796. doi:10.1136/tobaccocontrol-2012050796

[2] http://www.who.int/mediacentre/factsheets/fs339/en/

[3] Crackdown seizes more than 2.5 million illegal cigarettes: Chartered Trading Standards Institute 28/1/2015

[4] http://www.fctc.org/media-and-publications/fact-sheets/1319-illicit-trade-in-tobacco-beware-industry-solutions

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According to the FCTC Secretariat, the Codentify system would be in conflict with the FCTC Protocol and does not meet the requirement of ITP Article 8.2 that the tracking and tracing system has to be "controlled by the Party".[5]

Furthermore, it may require Member States who ratify the protocol to implement a second tobacco tracking and tracing process in parallel with an industry-operated one in order to meet their WHO FCTC obligations.

Options 2 is, under certain conditions, our preferred option, because an EU system would simplify the operations and facilitate the exchange of information within the EU: The second option is an EU system operated by an external provider(s). The system could be a good option, if it meets certain criteria. The advantage of this option is that there will be only one system in the 28 EU countries and as such operational between EU countries. In addition, it complies with both the EU Directive and the FCTC Protocol. The risk is that the EU would be too dependent on one or more external providers. For this reason, a system in option 2 should be chosen that could be supplied by several providers and not lead to a monopoly.

Option 3 operated by the tobacco industry should be excluded and option 3 operated by external providers is more complicated than option 2 - The third option is a set of national systems operated by external providers or the tobacco industry. This option might complicate the exchange of data within the EU and is not an option, if it is operated by the tobacco industry (see comments option 1) .

Option 4 could be a possibility, but is less preferable than Option 2, because it remains a combination of national systems: Option 4 combines the traceability solution with security features. In most countries, Option 4 would mean that tax stamps would incorporate unique digital identifiers and security features. Additional requirements for markings are needed for exported products and bigger, secondary packaging (cartons, master cases etc.) that carry no tax stamps. As in Option 1, markings operated by the tobacco industry are not an option for those additional requirements.

B2.

NTAKK has no preferences regarding the security features, but believes that a combination of overt, covert and forensic features should be recommended.

[5] FCTC. 6th Conference of the Parties to the WHO Framework Convention. Secretariat study of the basic requirements of the tracking and tracing regime to be established in accordance with Article 8 of the Protocol to Eliminate Illicit Trade in Tobacco Products. Executive Summary, White Paper. Moscow: 2014.

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D2.

The main objective of a tracking and tracing regime for tobacco products is to facilitate investigations into tobacco smuggling by providing analysis of smuggling trends and export practices and identification of the point of diversion to the illicit market, whenever an audit or a seizure is made. We would like to reiterate that the introduction of a tracking and tracing system should meet the requirements of Article 8 of the Illicit Trade Protocol. As a reminder, the Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry.

The unique identifier suitable for use in tracking and tracing of tobacco products should encompass the following elements:

- A marking for each package of tobacco products that should be unique and non-predictable. For instance, in your passport you have a combination of letters and figures that is unique for each person. The attribution of this combination identifies each person and is not predictable, unlike figures in a row 12345 for example. Digital Mass Encryption is a prevalent method to make codes less predictable. Valid codes can only be generated if mathematic formula (algorithms) and secret keys are known that are used for their creation.

- A data carrier that contains the unique identifier and other information available at the time of manufacturing such as place and time of production. This data carrier should be suitable for high speed production and storing and reading of data, and ideally, should follow a prevalent international standard in order to be readable by commercially available equipment tools. Two dimensional bar codes, for instance, are machine readable and widely used on many consumer products in an international environment.

- A link and parent-child relationships (called aggregation) between different packaging units that allow, for instance, traceability of pallets without scanning all master cases, cartons and packs that are inside the pallet.

Recording of any shipping and receiving events along the supply chain, for instance the recording of the departure of the pallet at the manufacturing site and the arrival of the consignment at trader x in country y.

Internationally accepted standards to describe the main characteristics of the products (such as country of manufacture, product description, date of manufacture), to encode the data in thedata carrier, and to record events along the supply chain among the supply chain partners. The storage of the data and events along the supply chain in an independent database, by preference a single database across the EU, controlled by competent government authorities.

At global level, we expect a multitude of national and/or regional databases that should be interconnected to facilitate international inquiries by competent authorities. Similarly, the access to and retrieval of this data should also be independent of the parties being controlled.

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D5.

For the data carrier we have a clear preference for the two-dimensional bar codes:

2D bar codes have already been used on many consumer products, such as food, alcohol, pharmaceuticals and tobacco products.
2D bar codes are machine readable and can be implemented at high speed production lines
2D bar codes can be read by inexpensive readers (including smart phones) along the supply and distribution chain
2D bar codes can be supplied by multiple suppliers
2D bar codes are a cost effective solution

Other solutions should not be excluded in the near future, but under the conditions, 2D bar codes are our preferred option for the data carrier.

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Attachment D.2

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Internationally accepted standards to describe the main characteristics of the products (such as country of manufacture, product description, date of manufacture), to encode the data in thedata carrier, and to record events along the supply chain among the supply chain partners. The storage of the data and events along the supply chain in an independent database, by preference a single database across the EU, controlled by competent government authorities.

At global level, we expect a multitude of national and/or regional databases that should be interconnected to facilitate international inquiries by competent authorities. Similarly, the access to and retrieval of this data should also be independent of the parties being controlled.

Attachment D.5

For the data carrier we have a clear preference for the two-dimensional bar codes:

2D bar codes have already been used on many consumer products, such as food, alcohol, pharmaceuticals and tobacco products.
2D bar codes are machine readable and can be implemented at high speed production lines
2D bar codes can be read by inexpensive readers (including smart phones) along the supply and distribution chain
2D bar codes can be supplied by multiple suppliers
2D bar codes are a cost effective solution

Other solutions should not be excluded in the near future, but under the conditions, 2D bar codes are our preferred option for the data carrier.