

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.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

Action on Smoking and Health
Suites 59-63, 6th Floor
New House
67-68 Hatton Garden
London EC1N 8JY
United Kingdom
+44(0)20 7404 0242
enquiries@ash.org.uk

- *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.

• **7940879e-218d-42e3-b10e-e4ab0f45c1b4/About ASH.docx**

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 type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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.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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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.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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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 checked="" type="radio"/>	<input 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.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)

- **1f0a8ea9-60b3-45a9-8a30-ee2dec374108/Response to Question B1.5.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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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.2.3. 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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.2.4. 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input 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.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

- [eec1ff7d-96f8-4a01-a84d-34d3c8f6cee1/Response to Question B2.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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*The cost analysis presented in section 11.3.2 of the Feasibility Study	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

We have no firm view on which standardisation body should be used for this purpose, but our research suggests that GS1 would be fit for purpose, inter alia because of its links with other recognised standards bodies such as ISO, although it would need to demonstrate and retain its independence from the tobacco industry, both in policy and practical operations.

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)

• [8de9e252-8a33-49b1-b0ab-6d9e0352603b/Response to Question D2.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

While we consider this a technical issue rather than one of policy principle, it appears to us that a 2D data carrier is the option that offers the most flexibility, and would allow for further ready expansion of the system.

***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)

***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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Marking products with serialized unique identifiers on the production line	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Verifying if products are properly marked on the production line	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Scanning products upon dispatch from manufacturer's/importer's warehouse	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Scanning products upon receipt at distributor's/wholesaler's premises	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*Scanning products upon dispatch from distributor's/wholesaler's premises	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Aggregation of products	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

We consider that the system should be as robust as possible in relation to possible misuse at the production facility. Such misuse could include repeat 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 third party should generate the unique identifiers, and that marking should be supervised by the relevant state authority.

*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.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)

*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

Since we consider demand reduction for illicit tobacco to be important as well as the interdiction of supply, we consider that tamper-free visible security features should be included in pack design, and in higher level tobacco packaging, so that consumers wishing to avoid the possible purchase of illicit products can have confidence that the products they are purchasing are genuine. If this is not achieved through the unique identifier, some other form of visible security feature that is common across the EU should be adopted.

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

About ASH

Action on Smoking and Health (ASH) is a campaigning health charity founded in 1971 by the Royal College of Physicians to work towards eliminating the harm caused by tobacco. (Charity number: 262067; Limited Company number: 998971)

Based in London, UK, ASH works with many tobacco control organisations and advocates around the world and is an active member of the Framework Convention Alliance, an NGO working to support full implementation of the WHO's Framework Convention on Tobacco Control. Periodically ASH commissions research on various aspects of tobacco control which underpins the organisation's campaigning work. This includes public opinion surveys, economic research and other reports.

Response by ASH to Question B1.5 of the EU Stakeholder Consultation

1. Action on Smoking and Health strongly supports the introduction as soon as reasonably practicable of a tracking and tracing system for tobacco products across all countries of the European Union. Our strong preference is for a single system, which is demonstrably free from tobacco industry interference and subject to close supervision by an independent agency. Since we wish to see the European Union and Member States cooperate with countries outside the EU to tackle illicit trade at a global level, we strongly support early ratification of the Illicit Trade Protocol, a subsidiary treaty under the WHO Framework Convention on Tobacco Control. Therefore, we urge the European Union to adopt a tracking and tracing system for tobacco products that is compliant both with Article 15 of the revised EU Tobacco Products Directive and with Article 8 of the Protocol, which has some different elements, identified in a separate accompanying document to this consultation response.
2. The illicit tobacco trade remains a serious threat to both public health and Government revenues. According to tax gap estimates from HM Revenue & Customs, in the United Kingdom in 2013/14 an estimated 10% of cigarettes and 39% of hand rolled tobacco consumed in the UK were illicit. The estimated lost tax revenue was £2.1 billion. This represents a small rise on the estimates for 2012/13, after a long period where more effective enforcement action had reduced the level of illicit trade from its peak in 2000/01, when HMRC estimated the proportion of illicit cigarettes in the UK market at 21% and hand rolled tobacco at 63%.
3. The tobacco industry has a long record of complicity in illicit trade, as in effect conceded by the big four tobacco manufacturers when they made compensation payments for lost tax revenue to the European Union and the Member States under the legal agreements concluded between 2004 and 2010. According to the World Health Organisation, *“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.”*¹
4. There is evidence that tobacco industry complicity in illicit trade has continued in recent years. In November 2013, the UK Parliament’s Public Accounts Committee accused tobacco multinationals of deliberately oversupplying European markets, with the tobacco smuggled back into the UK. Committee Chair Margaret Hodge said: *“The supply of some brands of hand-rolling tobacco to some countries in 2011 exceeded legitimate demand by 240 per cent. HMRC must be more assertive with these manufactures. So far it has not fined a single one of them.”* In November 2014, British American Tobacco was fined £650,000 by HMRC for deliberate over-supply of cigarettes to Belgium. Between May and November 2014, trading standards officers across nine English regions recently took part in “Operation Henry”, a programme of search and seizures of illicit tobacco. MORE than 2.5 million cigarettes were seized together with other tobacco products including

¹ <http://www.who.int/mediacentre/factsheets/fs339/en/>

hand-rolled tobacco, raw tobacco, and shisha tobacco. More than 70% of the cigarettes seized were genuine products diverted into illicit channels. ²

5. The tobacco industry has 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 and in the United Kingdom the introduction of legislation requiring the standardised packaging of cigarettes and other tobacco products. To this end, in the UK, as in other countries, the tobacco industry routinely both exaggerates the extent of illicit trade and misrepresents the nature of the illicit market. For example, KPMG produces “Project Star” reports on illicit trade in the EU for Philip Morris International. The KPMG estimate of the illicit trade in cigarettes in the UK in 2012 was 16.4% of the total market: HMRC figures for 2012/13 show a level of 9%. Industry material on illicit trade focusses on counterfeit products and cheap whites and routinely underplays the issue of legitimate products being smuggled back into the UK market.
6. 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 Framework Convention on Tobacco Control 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.
7. For these reasons our preference is for Option B.1.2. We note that the Feasibility Study identifies as potential disadvantages of such a system that it could “*reduce flexibility for manufacturers*” and would require “*risk mitigation*” to reduce the chances of production down-time. While these matters would properly be considered as significant concerns in regard to most products manufactured in the EU, the unique character of tobacco products (their very serious consequences for public health) and the clear evidence of previous complicity in illicit trade by the tobacco industry means that they should be largely discounted when considering a tobacco tracking and tracing regime.
8. We would advocate that if Option B.1.2 it should be further refined so that multiple providers of the solution would be possible. We consider that the system would benefit from this important element of competition.

Codentify

9. We have particular concerns about the possible adoption of the tobacco industry preferred solution to the unique identifier – Codentify (therefore we do not support Option B.1.1 or Option B.1.3a (in so far as that appears consistent with the possible use of Codentify)).
10. Codentify is a code generator system installed at the production line that generates unique codes on packs. It uses elements of the production (such as production line and time of production) to generate with a secret “key” an unpredictable and unique

² [Crackdown seizes more than 2.5 million illegal cigarettes](#): Chartered Trading Standards Institute 28/1/2015

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. Codentify was developed by PMI, and since 2010 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.³

11. We consider the Codentify system to have at least the following major disadvantages:

- a. 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 of which only the tobacco industry is aware. The Codentify system as it currently exists links serial numbers with manufacturing information held in a form that only the tobacco industry understands.
- b. The system uses relatively unsecured commercially available equipment on sites where operators may have a vested interest in misusing it.
- c. The system does not appear to prevent valid codes from being used twice. Therefore, counterfeiters and other illicit manufacturers could simply copy codes ("this is sometimes called "code cloning"). Since Codentify codes are visible, it could be easy to collect a large number of such codes. If the same code is scanned twice on different packs it appears to be impossible to tell which is licit and which is not.
- d. The system may also be vulnerable to "code recycling", to print valid codes on illicit products, for example by using codes originally printed on tobacco products that have been rejected and destroyed. Particularly if these codes are placed on tobacco products sold in the same market as the licit products whose codes have been copied, it may be impossible for enforcement authorities to identify them as illicit.
- e. The key system may be usable to generate apparently licit tobacco products in factories "after hours". For example, factories could "under-use" individual keys, so that unused codes remain from a production run and can be used to produce additional products that are intended for illicit trade but may appear valid if the code is traced. In addition, manufacturers could use invalid codes on their products for the illegal market in other countries and subsequently claim that they are not responsible because the products have invalid codes and should be classified as counterfeit.
- f. The system may allow for "code migration"; where codes printed in one country can be reprinted in another, creating apparently legal products that enforcement agencies could not effectively trace.⁴

³ <http://www.dcta-global.com/>

⁴ These problems are in effect admitted by the industry in the Codentify patent documentation, which states that: "[0008] [...] the production codes can easily be imitated or cloned." (patent EP1719070 (B1) Page 2)

g. Use of Codentify codes by enforcement agencies could be transparent to the industry, allowing it to manipulate replies and hide key data.

12. Given the existence of alternative systems that are independent of the tobacco industry, some of which (e.g. 2d barcode systems) appear better placed to meet the detailed requirements of the Directive and Protocol, we believe that Option B.1.1. should be rejected.

Response by ASH to Question B2

1. Action on Smoking and Health has no issue of principle in relation to the integration of security features with the traceability solution. From discussions with enforcement officers in the UK, we would suggest that there should be a combination of visible and invisible features, and that the visible features should be readily usable by potential consumers of tobacco products, so that those who wish to make sure that they are not purchasing illicit products can easily do so.

Response by ASH to Question D2

1. Action on Smoking and Health considers the following to be essential requirements for a unique identifier suitable for use in the tracking and tracing of tobacco products:
 - a. A marking for each package of tobacco products that should be unique and non-predictable.
 - b. 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 international exchange, storing and reading of data. Two dimensional bar codes, for instance, are machine readable and widely used in an international environment on many consumer products, such as food, alcohol, pharmaceuticals and tobacco products.
 - c. 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. We consider that this could be best achieved by a *single* system that operates across each level of packaging, rather than adding a separate pack based system to the systems already used by the tobacco industry for higher level units.
 - d. 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.
 - e. 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 the data carrier, to record events along the supply chain among the supply chain partners.
 - f. The storage of the data and events along the supply chain in an *independent* database controlled by competent government authorities. At global level, we would expect in the first instance that there would a number of databases that could be used to share data and could be accessed by relevant authorities from any jurisdiction. In the longer term, we would support moving to a single international database, and we consider that the use of a single database across the EU would be likely to speed this process up.

2. We wish to see the introduction of a tracking and tracing system that meets the requirements of Article 8 of the Illicit Trade Protocol, as well as Article 15 of the revised Tobacco Products Directive. The Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry. Article 8.2 states that the tracking and tracing system is "*controlled by the Party*". 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.