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.a. Please specify:

- [x] i) Cigarettes
- [x] ii) RYO
- [x] iii) Cigarillos
- [x] iv) Cigars
- [x] v) Pipe tobacco
- [ ] vi) Water pipe tobacco
- [ ] vii) Smokeless tobacco including chewing, oral and nasal tobacco
- [x] viii) Other

*A.1.a.viii. If other, please specify

Text of 1 to 800 characters will be accepted

Producer and distributor of e-cigarettes and snus.

*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

British American Tobacco Plc
Globe House, 4 Temple Place,
WC2R 2PG London
United Kingdom
(+0044) 207 845 1000

*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

ID: 2427500988-58
Registration date: 21/01/2009

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

• **56511379-c323-4195-a917-73c1dd2cc302/BAT answer to section A.4 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

B. Options proposed in the Feasibility Study

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

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	◉	○	○	○	○	○
*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)

- **7f0c35ee-9bbb-4f87-ba8e-62b1b934a9ca/BAT answer to section B.1.5 in the Targeted Consultation by DG SANTE on the SBS Study.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	○	○	○	○	◉	○
*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)

- **db0d8687-9bdd-49a9-90be-c65363760225/BAT answer to section B.2.5 in the Targeted Consultation by DG SANTE on the SBS Study.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	○	○	○	◉	○	○

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

• **ea9315ab-acb8-45a7-b4b1-1ebeb47280f1/BAT answer to section C.1.1 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

D. Additional questions

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

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

- [x] a) A single standard provided by a relevant standardization body
- [x] 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

A GS1 defined standard for creation and management of all supply chain data, including the serialized unique identifier, is very strongly preferred. GS1 Standards are well established and widely recognized across the supply chain, including by both manufacturers and retails, and provide a robust and widely-known basis on which to exchange, store, process and access data.

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)

• **952768b9-d0fd-4d01-a9c7-b7b08c0d92e1/BAT answer to section D.2 in the Targeted Consultation by DG SANTE on the SBS Study.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)
- [x] b) Solution based on the minimum technical requirements that allow for the use of multiple data carriers;
- [x] c) Another solution;
- [ ] d) No opinion

*D.3.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

For pack tracking, a Dotcode is most appropriate. It can be printed on packs at high speed (+ 1,000 packs/minute) using standard printers (i.e. ink/laser jets); can carry a large volume of information; is machine-readable; can be printed in the limited space available; and be interrogated using non-proprietary inspection equipment (i.e. mobile phone). For carton and master-case tracking, GS1 data carriers (such as EAN-128 and 2D DataMatrix) should be used.

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

- [ ] a) System only operating with machine readable codes;
- [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)

- **2c49b4a6-9414-4c92-8e89-c5abb280c3c1/BAT answer to section D.5 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

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

- [ ] a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
- [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)

- **479cb494-5a24-4bf8-8e16-1daa0d14e9b2/BAT answer to section D.7 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	○	○	◉	○	○
*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 most legitimate and workable strategy is for the economic operators directly involved in generating/marking/verifying the unique identifier and scanning, aggregating, receiving and dispatching products to be directly responsible for these actions, as long as they meet pre-defined EU-wide technical standards, set by the Commission. This is in line with the requirements of Article 15.11(a) and 15.11(b).
The Directive only empowers the Commission to approve the 'suitability' of the third party database provider, and it is only this provider that is subject to audit. The Directive does not empower the EU or Member States to impose a third party auditor or other supervisory authority over the activities outlined in Question D8. The presence and application of pre-defined, internationally-recognised (or 'open') technical standards - and their rigorous enforcement through existing mechanisms - will support the 'policing' of an effective EU-wide traceability regime.
Where such standards are non-proprietary and easy-to-adopt, such a regime should rapidly support self-compliance, as is the case with traceability in the pharma, automotive and explosives-for-civil-use sectors.

*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;
- [x] c) A security feature is printed;
- [x] d) A security feature is put on the pack/tin/puch/item through a different method;
- [ ] e) No opinion

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

Text of 1 to 800 characters will be accepted

Our preferred security feature consists of : 1) the encrypted and human-readable Unique Identifier used to track and trace products as a visible security feature, printed directly onto the pack at the point of manufacture; 2) 'event' data drawn from this Unique Identifier, which displays a picture of each pack's journey through the supply chain 3) capturing a digital 'fingerprint' of the arrangement of cardboard fibres in the cigarette packaging (invisible element); 4) (should authorities require it) a taggant imbedded into the tear-tape of the cellophane (providing a tamper-proof element); and other technologies and techniques as they evolve. Elements 1-3 can be easily verified using a smartphone. Element 4 (typically used by law enforcement only) requires a low cost reader.

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)

• **1c83e461-0030-4046-a579-195651b50f38/BAT answer to section D.11 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

*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)

• **9935e759-da92-457e-b62a-2c1f6ad29fd2/BAT answer to section D.13 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

*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)

• **809c6ab0-f880-48dd-aac2-80bbf849d489/BAT answer to section D.15 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

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

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

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

Text of 1 to 800 characters will be accepted

> 'Democratising' the process of verifying packs – whereby consumers are able to quickly access basic traceability data using ubiquitous devices such as a mobile phone – will dramatically increase the number of people able to 'enforce' the law. It would help consumers understand the origin/authenticity of their product and enable them to make better informed choices when combined with education on illicit trade. Limiting a system only to enforcement authorities and economic operators limits coverage and 'detection opportunities'. However we continue to believe that the biggest beneficiary of a traceability regime will be law enforcement authorities and economic operators.

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

• **18ecee4d-5474-4ce1-8647-9717bafc4cb8/BAT answer to section D.17 in the Targeted Consultation by DG SANTE on the SBS Study.pdf**

Contact

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

Attachment A4

- British American Tobacco (BAT)

Identification number:
2427500988-58
Registration date:
21/01/2009
Section:
II - In-house lobbyists and trade/business/professional associations
988 British American Tobacco 2427500988-58 BAT British American Tobacco is the world's second largest**...**business sustainability. British American Tobacco is a member of various associations

Attachment B.1.5

Common issues with the 4 options

Firstly, the directive (2014/40/EU) only authorises the Commission to determine "*technical standards*" and "*key elements of data storage contracts*". It does not include any authorisation of the Commission or Member States to prescribe or appoint any specific traceability system, solution provider, or database management provider.

Secondly, the Report fails to take into consideration the fact that British American Tobacco (together with the other major tobacco manufacturers) has already developed and implemented a track and trace system across the EU and several non-EU countries (which are deemed to be a source of illicit product into the EU) as part of a legally binding Cooperation Agreement with the Commission and Member States.

Pursuant to this agreement, a significant amount of resources, time and effort has been expended to develop a comprehensive track and trace solution which can fulfil the requirements of the Directive. British American Tobacco had a reasonable expectation under the Cooperation Agreement that the solution it has developed would not be legally excluded or prevented from future use, especially considering that the solution already fulfils much of what is required by the Directive and needs only an extension of capabilities further down the supply chain in order to achieve full compliance. Failing to allow its continued use would be a failure to capitalise on the resources and efforts spent, expertise gained and will set back progress by many years, meaning the 2019 compliance deadline is unachievable. Options 2, 3 and 4 would render this agreement obsolete and be open to legal challenge.

Thirdly, Article 15.8 clearly states that "*manufacturers and importers of tobacco products conclude data storage contracts with an independent third party"* and monitored by an independent auditor (selected by the manufacturer and approved by the Commission). As such, the Report's attempt to stipulate who can and cannot provide this service is, in our view, not in line with the letter or spirit of the Directive.

Comments to the 4 options

Option 1: We consider Option 1 as the only technically feasible and legally compliant solution which can be implemented in the given timeframe.

Technical considerations:

- Allows the continued use of proven track and trace solutions already implemented by major international tobacco manufacturers and over 850 distribution outlets across the EU as part of legally binding agreements with the European Commission and Member States (EUCAs);
- Ensures maximum interoperability across economic operators , systems and borders, both within the EU and with countries outside the EU (which are the primary source of illicit trade in the EU), as industry solutions are based on internationally-recognised technical standards (i.e. GS1) for unique identifiers, pack marking and recording, exchanging, storing and reporting data;
- Is based on the same technology used by major manufacturers to track and trace tobacco master cases, cartons and packs outside the EU in more than 130 countries;
- Enables smaller manufacturers who have not yet implemented track and trace systems to select the most appropriate technology 'off-the-shelf' according to their product category, production speeds, degree of automation, IT infrastructure and financial capacity using local suppliers providing a local service in a local language;

- Permits direct marking of packs with a unique identifier – the most secure form of applying a unique identifier;
- Enables use of industry-proven aggregation methods. It should be noted that to date no third party solution provider has yet been able to aggregate tobacco packaging (establishing a parent-child relationship between packaging units) in such a way as to enable effective tracking and tracing);
- Ensures manufacturers can conclude data storage contracts with independent third party providers, as required by Article 15.8;
- Promotes competition among solution providers, thereby reducing compliance costs (especially for small- and medium-sized economic operators) and supporting innovation and adoption of the latest technologies;
- Leverages over 10 years of investments, technology experience and expertise gained by manufacturers, independent suppliers and consultant companies (most of which are based in the EU) in implementing tobacco tracking systems;
- Will allow law enforcement to use a single, non-proprietary device to query a product during inspections, regardless of brand owner, country of consumption, or underlying track and trace technology used;
- Is the only Option which could be fully implemented by 2019.

Legal considerations:

- The only Option fully compliant with the Directive and general principles of EU law (see Legal considerations under Options 2, 3 and 4 below);
- The Report incorrectly interprets Article 15(8) and recital 31 in applying an "amber" rating (p 158-160) on their "critical success factor" pertaining to storing data independently. It speculates that there is a concern with tobacco companies having access to their own copy of the traceability data. However, Article 15(8) is concerned with ensuring full transparency and access to data at all times for Member States, not with denying tobacco companies a copy of the data needed to monitor their performance and compliance with the Directive and manage their own supply chain, including taking remedial action. The Report also incorrectly interprets Article 15(1) in applying an "amber" rating (p 159-160) on their "critical success factor" that pertains to resistance to manipulation. This is incorrect, as the track and trace systems currently used by the tobacco industry ensures the integrity of the data to the highest standards.

Option 2

Technical considerations:

- In our view, Option 2 will not be possible to implement in the given timeframe due to the need for the solution provider and economic operators to 'start from scratch' (indeed, it will take the longest implementation period) and would create a *de facto* monopoly in the EU for traceability for tobacco products.
- It will substantially increase the costs and operational burden for all economic operators given the need to use completely new and proprietary equipment, duplicating what is already in place.
- The appointment by the Commission of an independent data storage provider and establishing a single EU-wide database would be both unlawful under the Directive and, given its size and complexity, extremely costly and problematic to operate.

Legal considerations:

- The plain language of the Directive and its legislative history make clear that the notion of a single EU track and trace system chosen and operated by the Commission was rejected by the Council and European Parliament. The Commission does not have the power to reintroduce such a system using secondary legislation.
- Option 2 is not compliant with Article 15 and clearly exceeds the powers conferred upon the Commission by the EU legislature. As such, if applied it would infringe Article 290 TFEU and the principle of conferred powers, for two key reasons:
    - Article 15.11 empowers the Commission to adopt implementing acts to determine technical standards in relation to the track and trace system, to ensure that they *'are fully compatible with each other across the Union'*. This means that the adoption by the Commission of a single, harmonized system (as foreseen in Option 2) would not only violate the principle of conferred powers as laid down in Article 5 TEU and Article 291 TFEU, but also be contrary to the plain language of the Directive and to basic competition law principles. The Directive stipulates that the Commission should *'define technical standards'* that enable economic operators to choose a solution, as long as they comply with the technical standards.
    - Article 15.12, the European Parliament and the Council have decided that the Commission may adopt delegated acts on key elements of data storage contracts (such as their independence from manufacturers, contract duration, renewability, monitoring and evaluation). Under Article 290 TFEU (delegated acts) a directive may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act. Therefore, the Commission may not go further than that and adopt any measures which would be considered "essential elements" relating to track and trace. Option 2, as set out in the Report, clearly goes beyond the powers conferred upon the Commission by the EU legislature, and would therefore infringe Article 290 TFEU and the principle of conferred powers (Article 5 TEU).
- Option 2 would lead to a distortion of the market which would result in an increased barrier to trade for SMEs.

Option 3a and 3b

Technical considerations:

- The potential for up to 28 different national track and trace systems (plus any system applicable for products exported from the EU) would create an extremely complex manufacturing environment, with potentially multiple solutions installed on any one production line and each solution operated by a different provider. One simple example of the challenges this Option presents is the typically limited physical space available in factories to accommodate this, making it extremely difficult if not impossible to practicably implement;
- These Options would require the appointment by Member States of a single national data storage provider, necessitating contracts with up to 28 providers and, where exports and imports are concerned, creating significant confusion for manufacturers, wholesalers and distributors about what data should be stored/allocated in each national database;
- When combined, this Option would impose a significant and unjustified economic burden and additional level of complexity for all economic operators and member states which, in our view, the Report authors severely underestimate.

Legal considerations:

- Article 15.11 empowers the Commission to adopt implementing acts to *'determine technical standards'* in relation to the track and trace system to ensure that they *'are fully compatible with each other across the Union'*. As a consequence, the Commission has no authority to give Member States the power to appoint a solution provider to implement the traceability system and or select a database provider. Indeed, Article 15.8 prescribes tobacco manufacturers should conclude data storage contracts;
- There is no requirement in the Directive for the track and trace technology or solution provider to be independent from tobacco industry – indeed, this provision when tabled during the drafting of the TPD, was expressly rejected by the European Parliament and Member States;
- The requirements of Option 2 would amount to technical regulations pursuant to the Technical Barriers to Trade (TBT) Agreement. The potential for having 28 different technical regulations throughout the EU, and the ensuing restrictions to trade arising from the diverging regulatory requirements, may give rise to significant concerns under Article 2.2 of the TBT Agreement, as the ensuing regulatory framework would likely be more trade-restrictive than necessary to achieve the objective pursued by the track and trace regime. Concerns may also arise pursuant to Article 2.1, as the failure to implement an EU-wide standard and instead opting for fragmented solutions at the Member State level could confer treatment that is more favourable to national products vis-a-vis those originating in other countries.
- This Option would present a barrier to entry under WTO Technical Barriers to Trade rules and EU and Member States' procurement and competition regulations. Favouring a single EU-wide or national-level provider or technology solution (potentially proprietary and not based on internationally-recognised standards) will prevent the creation of a level playing field for competitors and hinder the free movement of goods and services between Member States and with countries outside the EU
- Option 3B would also contradict the Directive's objectives of reinforcing the internal market by obliging economic operators to comply with potentially 28 different track and trace systems. In short, the Directive permits the Commission to define technical standards that then enable economic operators to choose a system and provider, as long as they comply with the technical standards.

Option 4

Technical considerations:

- A pre-printed Unique Identifier on a sticker applied onto a pack is not compliant with Art 15.3, which requires that the date and place of manufacturing; manufacturing facility; the machine used to manufacture the tobacco products; production shift or time of manufacture; product description; intended shipment route; and where applicable the importer into the Union *'shall form part of the unique identifier'*. As such, the above information can only be captured at the exact time and place of manufacture, which can only be done via the direct application of a Unique Identifier.
- Furthermore, the physical location of a sticker-based track and trace system (which, as envisaged under this Option, is placed on the top/side of a pack so as to also double as a tamperproof security feature which breaks on opening) would make impossible the scanning of the Unique Identifier on packs during the production process and their consequent aggregation with cartons (a 'must' for effective tracking and tracing).
- Finally, pre-printed Unique Identifiers require production, storage, delivery and management at a separate site and then the secure movement to hundreds of tobacco production facilities

across the world, presenting a risk of loss, theft, damage and tampering. Modelled on a typical paper tax stamp, these types of product marking have also been easily counterfeited by criminal gangs, including even supposedly 'secure' security elements, such as holograms, serialisation numbers, colour-shifting inks and marks.

Legal considerations:

- Any proposal that delegates to the Commission the power to appoint a data management provider is not compliant with the plain language of the Directive;
- Much of the most important data required under Article 15.2 of the Directive will not form part of the pre-printed Unique Identifier (as explained above), as it would be pre-printed, shipped to a manufacturing facility and then applied to a pack once it has been produced;
- Option 4 would make the export of tobacco products from Member States either impossible or extremely cumbersome as EU-based manufacturers/exporters would have to add an export sticker. Such a marking would contravene the packaging regulations of the destination market and, if pursued, would need to be approved by governments in that country, presenting a significant legal and administrative burden. This challenge will be multiplied where the destination country also requires a tax stamp or other similar label;

This Option would also contradict the Directive's objectives to reinforce the internal market by obliging manufacturers to comply with potentially 28 different track and trace systems, plus any extra systems needed for exports.

Attachment B.2.5

All four Options for security features within the Report are based on paper solutions which are intended to be attached/glued onto packaging. We consider this to be the Report's most astonishing shortcoming – nowhere does it present any option for an on-pack forensic or digital solution which would be infinitely more secure. The Report fails to consider the significant body of evidence which proves that paper-based solutions can and have been easily counterfeited, while failing to properly consider more advanced and robust digital solutions directly on the pack.

Technical concerns with Options 1-4

- All Options are 'material-based' and premised on a paper stamp/marker/label being glued onto a pack. Stamps are out-dated and evidence shows that they can and have been easily copied by criminal networks in as little as a few weeks from their introduction onto the market, including even supposedly 'sophisticated' features such as holograms, colour-shifting inks and complex patterns such as those mentioned in the Report;
- Paper stamps do not form an integral, irremovable part of a pack. As such, they can only ever verify the authenticity of the stamp itself, rather than the pack, thus providing a false sense of security;
- Anything affixed onto packaging can, by its very nature, be removed and potentially re-used on a different product;
- Proprietary (and often expensive) reading devices are needed to verify the authenticity of paper stamps. These devices are not always in the possession of law enforcement officials and are never owned by consumers, limiting their usefulness and impact as mass a authentication tool (this point does not strike me as credible – can you please consider further whether it really stands up to scrutiny);
- Many of the security features listed are proprietary and can only be provided by one or a limited number of suppliers, most of which are based outside the EU. This would seriously restrict competition in the market for security feature solutions, leading to higher costs and preventing adoption of the latest technologies;
- *Option 2 only:* This Option misleadingly states that using a track and trace unique identifier printed directly onto a pack as an authentication device is a 'weak' option because it is 'separate' from the security feature (which the Report authors for some unknown and unjustifiable reason state must be on a paper stamp although no decision about its application should have been made at this point). Other security features, such as Codentify, which exploit the tracking and tracing Unique Identifier printed directly onto product packaging are discounted or not considered altogether (see below for the advantages of this approach).
- *Option 3 only:* This Option does not consider the success of digital 'fingerprint' technology that exploits the inherent physical properties *of the tobacco pack itself* and which has been successfully implemented by major tobacco manufacturers. Option 3 only considers its application *on a paper stamp*, which as a result would only verify the authenticity of the stamp, rather than the pack (see below for the advantages of this approach)
- *Option 4 only:* Using a pre-printed unique identifier on a stamp (and its associated production information) as an authentication tool would not be compliant with the wording of Article 15.3 of the Directive. The Directive requires that the unique identifier contain specific manufacturing information which can only be captured at the exact time

of manufacture. It should also be noted that this Option contradicts the results regarding the location of the tax stamps / labels presented by another DG SANTE report (Chafea/2014/Health/22).

- In short, stamp based anti-counterfeiting devices provide a false sense of security for law enforcement, economic operators and consumers. It is therefore a fundamental flaw in the report that it only presents stamp based options while omitting any option at all for digital and/or forensic solutions directly on the pack.

The advantages of an on-pack digital/forensic security feature

- We believe the most robust form of security feature combines: 1) the unique identifier used for tracking and tracing which is digitally printed directly onto a pack, such as Codentify (visible, tamperproof and irremovable); with: 2) forensic-level technology which exploits the inherent and completely unique properties of the cardboard structure of the pack itself (invisible, tamperproof and irremovable).

1. On-pack digital track and trace unique identifier

- Each encrypted code (i.e. Codentify) used for tracking and tracing purposes is unique, printed indelibly directly onto each pack and is visible to the human eye. Duplicate codes can be immediately identified as counterfeit as no two codes are the same. When combined with the 'event' data associated with each pack's journey through the supply chain which is captured through this unique identifier and held in the track and trace system, this creates a unique, tamper-proof picture of the authenticity and provenance of a pack which is almost impossible to replicate. The code can be easily queried by law enforcement, economic operators and consumers using a smartphone, SMS or website, producing results in seconds.
- This technology is already being used by the major international tobacco manufacturers across the EU and their global supply chains, as well as to support anti-counterfeiting efforts by a host of national governments, including in the UK.

2. On-pack forensic-level technology

- Each cigarette pack has a unique internal arrangement of cardboard fibres, analogous to a human fingerprint or DNA. Because each pack's fibre structure is unique, it is impossible to replicate. A copy of this 'fingerprint' is captured during production, encrypted and stored on a data-base (which can be accessed both on- and off-line). Supply chain stakeholders can verify this 'fingerprint' during inspections using a smart phone. Because this digital 'fingerprint' is integral to the pack, nothing needs to be added or glued onto it, making it exceptionally secure.
- This technology is forward-looking approach to tackling counterfeit. It can be used on production lines producing in excess of 1,000 products per minute and, contrary to statements in the Report, has been industrialised for tobacco products and has proven robust and cost-effective.

General brand enforcement concerns with Options 1-4

- All Options challenge and indeed contradict long-established and widely trusted forensic brand enforcement and protection methods used for consumer products, including tobacco products. Relying on the forensic properties of a pack is the most robust security feature available, while brand owners are ultimately the only entity that can verify with absolute certainty that their products are genuine, or an imitation. Such an approach is widely accepted as the only trusted method for providing court-admissible evidence for distinguishing between genuine and counterfeit goods. Tobacco brand owners should be able to continue using these impossible-to-copy methods and the latest technologies which support this (see above). Moving away from these tried and tested techniques – for example by relying on material-based security features such as labels and stamps applied to products – is a step backwards and will severely impede brand protection efforts and, where applicable, law enforcement investigations.
- Mandating the use of a 'one-size-fits-all' EU-wide or national-level security feature would eliminate brand owners' flexibility to change the security feature in the face of a counterfeit threat, rendering it useless. Brand owners must be able to stay one step ahead of counterfeiters when it comes to the security features used to protect tobacco products and have the flexibility to adapt, change and adopt new security feature technologies in the face of this threat and as technology evolves. Without flexibility, a security feature risks being easily compromised, leaving consumers, economic operators and law enforcement without a mechanism to validate a tobacco pack's authenticity.
- Publishing detailed specifications about the composition of a tobacco product security feature is contradictory and will completely undermine its purpose. The very nature of a 'security feature' is that its technical elements and method of construction should not be known by those wishing to copy it. Publishing such details only serves to provide a blueprint for criminal activity. As with currencies, valuable documents and other consumer products, the details about tobacco product security features should remain highly confidential and, ideally, only be known by the brand-owners themselves.
- The success of measures aimed at tackling tobacco product counterfeiting relies heavily on close cooperation and dialogue between regulators and tobacco brand owners. Government should focus on setting standards or guidelines, while allowing the brand owners to choose the specific technologies in response. This principle has been adopted across a range of other areas, notably in the choice of anti-counterfeiting technologies used on pharmaceuticals as part of the EU Falsified Medicines Directive.

Comments on the use of existing tax stamps already in place as a security feature

- All the points made above with reference to the inferiority of stamp based security solutions versus solutions which are an intrinsic part of the pack apply equally to tax stamps.

Attachment C.1.1

The Benefit analysis

The benefit analysis assumes illicit trade constitutes 8.25% of consumption, not far from the 10.4% illicit trade found in the KPMG SUN report. However, the authors then split the 8,25% illicit trade into 50% counterfeit, 30% contraband and finally 20% illicit whites (also contraband). The same numbers in KPMG SUN report are split into: 56% contraband, 6.6% counterfeit, 37.4% illicit whites.

In the EU we have not recorded counterfeit cigarette products counting for such a large proportion of illicit trade. Counterfeiters and their networks run a completely illegal operation from start to finish, from sourcing, through production to distribution. The authors estimate that counterfeits can be reduced by 10%, which we find too high. We believe that a traceability system as envisaged under Options 2, 3, and 4 will have very limited to no impact on counterfeit.

More importantly the benefit analysis does not address the origin of the illicit products found in the EU. The KPMG SUN report estimates that 85% of all contraband and counterfeit cigarettes found in EU originate from markets outside the EU. These illegal products will not be affected by any intra-EU traceability system and will continue to enter the European Union. The authors assume that contraband can be reduced by 30% - however if more than four out every five cigarettes originate from outside EU, then the benefit would only be a reduction of 30% of the 15% of contraband and counterfeit cigarettes originating from within EU. While this is not insignificant, the authors' conclusions do not address this bigger, more important picture, leading to conclusions that can be questioned.

The Cost analysis

One can always discuss what costs shall or shall not be included in a Cost-Benefit analysis. But the authors' cost analysis does not take into account any of the costs already incurred by tobacco manufacturers, importers and more than 850 wholesalers and distributors in implementing a track and trace system under the legally-binding Cooperation Agreements signed with the EU Commission and Member States and which are still in force. British American tobacco alone has invested more than Euro 100 million as part of its Agreement since 2008, details of which were provided to the Report's authors.

Also the Report does not take into consideration the costs of the different security feature technologies which the tobacco industry as a whole has already introduced in many Member States, such as the UK, where industry's system is already being used by law enforcement agencies and trading standards to support anti-counterfeiting efforts.

In general, we believe that both the historic investments made to date and the annual operating costs incurred by British American Tobacco and other leading tobacco manufacturers, as well as our wholesale and distribution partners, have been ignored and/or misinterpreted, resulting in an inaccurate analysis and representation of where things stand today and the most cost-effective and practicable course of compliance. As an example, what the author's suggest as being the total investments made by all tobacco manufacturers (€122.1million) represents roughly only the hardware investment of the single biggest manufacturer. We estimate that the actual investment already made by economic operators throughout the supply chain to date is approximately EUR 500million.

The investments under Options 2, 3 and 4 have not been calculated. We presume they are based on those significantly underestimated investments in Option 1. For Option 4, the Study assumed a saving of €322,500 per line for a laser printer. In fact, we buy such laser printers for around €30,000. In reality, Option 4 creates substantial additional costs.

We question the statements regarding the current implementation among the manufacturers that already have agreements with the EU Commission. Regarding Option 1 the Study states in the Executive summary (page 33) that only around 5% of manufacturing lines have been equipped so far. But on page 278 the report tells us that one of the largest manufacturers will have a fully operational T&T system by end of 2014. As such the coverage will be much more than the 5% manufacturing lines quoted in the Executive summary.

Attachment D.2

The generation of a serialized unique identifier must:

- Conform to GS1 rules on serial numbers;
- Be unique, both within the EU/TPD scope and with identifiers generated in other non-EU countries under their local legislation or common supply chain standards
  (a feature of a GS1 compliant system);
- Have sufficient alphanumeric characters in order to ensure they are unique for the required data retention period;
- Be as short as possible so that they can fit onto the bottom of a cigarette pack;
- Be non-sequential so that counterfeiters cannot predict valid unique identifiers;
- Not be stored so as to prevent counterfeiters from hacking into a database containing valid identifiers.

Attachment D.5

For high-speed, large-volume manufacturers, a machine-readable code is essential for any aggregation process – establishing a parent-child relationship between packs, cartons and master-cases as they move along production lines at high speed. Aggregation is a key element of tracking and tracing.

Furthermore, a machine readable code can also enable law enforcement, economic operators and consumers to easily verify a tobacco product during investigations, inspections or queries using a smartphone app (and scanning the machine-readable code), eliminating the opportunity for misreading of the unique code by the human eye or mistyping (for instance, a GS1 compliant unique identifier may be up to 37 characters long to ensure uniqueness).

Human-readable codes (such as a serialisation number) cannot be printed or read reliably at high production speeds, thereby preventing aggregation if they are absent or mis-read. However, the presence of a human-readable code does provide a secondary method of investigating, inspecting or querying a Unique Identifier, which can be particularly useful for consumers (especially if not in the possession of a device that can scan the machine-readable code). Indeed, we believe the provision of a human-readable code would enable consumers to play a much more active role in verifying the products they purchase and so playing a bigger part in the fight against illicit trade.

Attachment D.7

1. Article 15.3 requires that the date and place of manufacturing; manufacturing facility; the machine used to manufacture the tobacco products; production shift or time of manufacture; product description; intended shipment route; and where applicable the importer into the Union *'shall form part of the unique identifier'*. This information can only be captured and associated with the product at the exact time and place of manufacture via directly printing the Unique Identifier onto a pack *in situ* on the production line. A pre-printed Unique Identifier based on a stamp/label applied onto a pack after folding/assembly is not legally compliant with the Directive.
2. A Unique Identifier printed directly on a pack at the point of manufacturer is also the most practical and accurate method of capturing the key data elements required by the Directive (15.3 a, b, c, d, e, f, g and, where applicable, h). Unique Identifiers which are allocated in advance would need to have the specific characters for every value or each parameter known at the time of pre-printing (i.e. exact production date, time, shift, production line) and could only be applied in the valid period of that parameter, which is not only extremely inflexible from a manufacturing perspective, but also extremely cumbersome and inflexible from a data generation and management perspective. In short, it would create many individual number ranges with massive inbuilt inflexibility. The drawbacks of this include:
    a. Major handling and control of this many separate and discrete number ranges, from both the issuing authorities and the tobacco manufacturer;
    b. Quantities of numbers would need to be pre-calculated and pre-ordered in advance. Any changes in actual performance or manufacturing plans would result in many unusable numbers – manufacturers could not swap the authorized unique identifiers to another machine, shift, etc. that was indicated by a different value. Therefore a massive returns and reconciliation process for the unused serial numbers would be required;
    c. Manufacturers would need to be allocated tolerance and "spare" codes to cope with all normal and abnormal eventualities or factories would be prevented from producing. Variations that are a normal part of factory operation include machine breakdown, variations in production speeds and changes to plans.
    d. The Unique identifiers would have to be very long to accommodate these needs, and so become unwieldy to print, read, re-enter etc.

An example of how many stamp number ranges would be required if pre-printed unique identifiers were used:

TPD Requirement	Volume	Ranges	
(a) the date and place of manufacturing	365	365	Possible production days in year
	5	1,825	To confirm data retention period in years
	230	419,750	This is the minimum, and increases if they have more than one facility
(c) the machine used to manufacture the tobacco products	1345	564,563,750	Cigarette and cigar lines, to confirm how many further machines for HRT etc.

(d) the production shift or time of manufacture	3	1,693,691,250	Shifts
(e) the product description;	V. large	V. large	Numbers of Products in EU is massive number in 10s of thousands
(f) the intended market of retail sale;	28	V. large	Would be more if applied to export markets as well
(g) the intended shipment route;	V. large	V. large	
(h) where applicable, the importer into the Union;	V. large	V. large	

3. Pre-printed Unique Identifiers based on a stamp/label require a supply chain of their own, including production, storage and management from a separate site and then their secure delivery/movement to hundreds of tobacco production facilities across the world that produce products destined for consumption in the EU. This is not only a costly and time-consuming process, but also opens up the possibility of loss, theft, damage and tampering.
4. A significant quantity of materials is wasted in the production process, either due to manufacturing quality assurance processes or because (and where appropriate) a tax stamp (which is akin to a pre-printed, stamp-based unique identifier used for traceability) is not applied to the pack correctly or cannot be validated. The identifier, therefore, should be marked on a pack as late as possible in the production process and ideally only when a pack is fully formed and containing the tobacco product itself (cigarette, lose tobacco etc.). This has the advantage of minimising the number of codes placed on wasted packs (which are never released for consumption) and the reconciliation of such codes. Reconciliation of wasted pre-printed unique identifiers will be an extremely time-consuming administrative process, involving the manual removal of the label/stamp (requiring additional time, resources and effort by manufacturers) and their reconciliation, which typically involves physically sending the stamp/label back to authorities to verify that it has not been used (requiring additional time, resources and effort by authorities as well).
5. The physical location of a pre-printed, sticker-based Unique Identifier also needs to be considered. The Options proposed in this Report contradict the results presented by another DG SANTE report (Chafea/2014/Health/22) regarding the location of paper labels / tax stamps. In short, as a result of the new position requirements, aggregation (a ‘must’ for traceability and which requires the unique identifier/data carrier to be positioned on the top or bottom of a pack to allow scanning while on the production line) would be considerably more complex and less reliable.
6. For products manufactured outside the European Union it may be beneficial to allow marking upon receipt into the European Union, especially if sourced from smaller foreign plants that cannot be economically equipped to meet the requirements of the Directive. Of course, this exception can be avoided in Option 1, since the manufacturer would be more easily able to mark all products using a global system no matter where they are made and where they are sold.

We believe the most robust form of security feature is where it forms an intrinsic, integral part of the pack/packaging itself, rather than being material-based (e.g. a paper stamp, label) and applied/glued onto the pack.

Our approach consists of four elements:

First, the visible element of the security feature is based on the track and trace unique identifier, in our case a secure, encrypted Codentify code. Each encrypted code is unique, printed indelibly directly onto each pack and is visible to the human eye. Duplicate codes created by criminals can be immediately identified as counterfeit as no two codes are the same.

Second, 'event' data associated with each pack's journey through the supply chain captured by the track and trace system through this Unique Identifier adds another layer of verification regarding the provenance of a pack which is extremely difficult for counterfeiters to replicate.

Third, for the invisible element we exploit the forensic internal arrangement of cardboard fibres in the cigarette packaging itself to generate digital 'fingerprint' or signature of the pack which is completely unique and impossible to copy, as all packaging structures are different. This 'fingerprint' is stored in a secure database and is linked with the Unique Identifier serialisation code, which combined creates a 'double lock' security feature.

Fourth, a tear-tape with embedded taggant ink technology provides a tamperproof security element; tear-tapes cannot be re-used and it is immediately evident if a pack is missing its tear-tape.

Elements 1-3 can be verified using low-cost non-proprietary inspection equipment, such as a smart phone. The taggant in Element 4 (typically only used during law enforcement inspections) requires a low cost reader.

In addition, we continue to believe that forensic testing in accredited laboratories of the unique and inherent qualities of the product itself or packaging remains a highly robust and reliable method for detection of counterfeit tobacco products. These forensic details (such as material structure, print marks and glue patterns) are known only by the brand owner, identifiable only via detailed forensic examination and are widely accepted as the only method for providing court-admissible evidence for distinguishing between genuine and counterfeit goods. Moving away from these tried and tested techniques and towards material-based security features (e.g. paper stamps, labels) is a step backwards and will severely impede brand protection efforts and law enforcement investigations.

As mentioned, we believe that material-based security features have several fundamental flaws:

- They can and have been easily counterfeited, including even supposedly ‘sophisticated’ security elements like those mentioned in the Report;
- They can and have been removed and re-used (genuine stamps/labels have been found affixed to counterfeit product, meaning the information they provide relates to the security feature itself, rather than the product);
- They have a supply chain of their own and can be lost, stolen, damaged and tampered with in the period between production and delivery to manufacturers;
- They require a huge amount of unnecessary paper, chemical inks, metals, metal traces and other substances to produce.
- In short, they can only ever verify the authenticity of the security feature itself, rather than the pack, thus creating a false sense of security.

Attachment D.13

A system of different storage interoperable among different operators in the supply chain should be used. The data should be created by different operators working in the supply chain. The manufacturers should provide the initial repository and data while the products are their property. At certain steps data should be reversed (duplicated) into a single efficient data base managed by the data storing company for each Member State. The independent data storing company should be responsible for the data included in the official repository. Authorities should be able to access the repository at any time through special IT tools to control all the relevant information for product authentication and tracking and tracing.

In order to develop such tools, key requirements include an understanding of the types of queries that will be required and of the underlying data and track and trace processes in the tobacco industry, in order to allow: a) database structures, indexes and data to be optimised to give an acceptable response time and b) ensure that the most appropriate data is provided and that the risk of false understandings from misinterpreting data is avoided.

Internationally recognised technical standards

Managing and exchanging data consistently across economic operators, systems and borders is an integral requirement for tracking and tracing. Systems must be able to 'talk' to each other, both within and between EU member states, and between the EU and non-member countries (for imports and exports). To support this, internationally recognised (or 'open') technical standards should be used for: 1) establishing and operating the unique identifier; 2) recording, transmitting, processing and storing of data; and 3) accessing stored data. Standards are beneficial because they:

- Ensure maximum interoperability between systems and countries within the EU;
- Support maximum interoperability between an EU tracking and tracing regime and systems deployed in countries outside the EU, which are predominantly the source of illicit trade found in the Union;
- Enable the use of existing equipment already in place in warehouses, distributions centres and factories, or if not in place, the purchase of non-proprietary equipment off-the-shelf at low-cost;
- Limit the disruption and impact to existing supply chain operations;
- Reduce compliance costs for all stakeholders, including governments and small- and medium-sized economic operators;
- Reduce barriers to entry for solution providers and promote competition, allowing economic operators to select the most appropriate and effective solutions to fit their needs;
- Allow law enforcement to use a single device to query a product during inspections or seizures, regardless of brand owner, country of consumption, or underlying track and trace technology used.

Economic operators should be able to select the most appropriate track and trace system based on their size, complexity and local technology constraints, as long as they meet pre-defined technical standards

Tracking and tracing is not only about scanning packaging to obtain data. It also requires identification of purchasers, invoicing, payment and shipment information and, therefore, interfaces with economic operators' internal administration and IT systems.

There are around one hundred manufacturers of tobacco products within the EU (many of which are small-and medium-sized operators) producing a range of products (including cigarettes, cigars, cigarillos, snus, fine-cut, pipe, chewing, snuffing and water-pipe tobacco). The degree of sophistication of IT infrastructure differs widely among these economic operators, and all use significantly different systems for administering invoicing and payments. Meanwhile, distributors,

wholesalers and importers typically supply a range of tobacco and non-tobacco products to multiple customers and already have IT systems and processes in place to do this.

Mandating additional, proprietary systems specifically to track tobacco products would significantly increase the complexity, cost, effort and time required to establish an EU-wide track and tracing regime. Manufacturers should therefore be able to select different track and trace technologies according to their specific circumstances and be able to use systems or parts of systems already in place, provided they comply with a minimum set of technical standards as set out by the Commission. Wholesalers, distributors and importers should also be able to select their own equipment, provided that they can record and transmit the relevant information to the data storage facilities, as required by the Directive.

This approach ensures a competitive marketplace for solution providers, supporting adoption of the latest technologies and reasonable compliance costs. Limiting choice or excluding certain suppliers would be inconsistent with the principles of the Internal Market, breach EU competition law and run counter to several WTO international trade agreements. It should be noted that this approach is also considered best-practice by experts, including in a WHO Expert Review[1] and by KPMG and GS1 in a report on tracking and tracing tobacco products[2]. It is also common among other industries in the EU which have to track products, such as pharmaceuticals and food.

Data exchange, transmission and access

GS1 Electronic Product Code Information Services (EPCIS) interface standards and GS1 Application Identifiers (AI's) should be used to facilitate the exchange, transmitting and accessing of data across economic operators, systems and borders.

EPCIS standards specify only the interfaces between systems that capture data and those that need access to it; they do not specify how the systems or databases themselves should be implemented. The interfaces enable interoperability while enabling economic operators to determine the most appropriate technology according to their needs and allows for competition. GS1 EPCIS standards and AI's are already being used by economic operators involved in the distribution and sale of tobacco products in the EU and can be easily adopted.

Analysis of the system in operation in Brazil

The system deployed in Brazil – called 'Scorpios' – is not a track and trace system. While this is acknowledged at one point in the Report (p 103), the overall – and misleading – conclusion drawn by the Report's authors, together with its implications, is that this system could meet the requirements of the Directive.

[2] *Track and Trace: Approaches in Tobacco, KPGM and GS1, 2014*

To clarify, the system in Brazil is a volume verification tool. It monitors and reports the volume of tobacco products (i.e. packs) produced at the time of production in order to verify the amount of taxes to be paid by manufacturers to government. Beyond this point in the factory, there is no marking, scanning, aggregation or monitoring of tobacco products as they move forwards through the supply chain up to the last economic operator before the first retail outlet (which is what is required by the Directive). Our business in Brazil (where we have over 65% market share) is simply not equipped with any tracking and tracing equipment.

The Report also fails to take into consideration that a review of track and trace systems commissioned by the World Health Organisation in 2010 and which specifically assessed the system in operation in Brazil concluded that it is not a track and trace solution. It states that:

"…in order to meet the requirements of an international track-and-trace regime for tobacco products, the following issues characterizing the current system would need to be dealt with:

- *international serialization standards are not used;*
- *international data exchange standards are not used;*
- *events are not tracked along the supply chain; and*
- *aggregation does not take place (only cigarette packs are marked)."*[3]

We would welcome the opportunity to bring representatives from DG SANTE to our facilities in Brazil where they would be able to inspect first-hand how the system works and its limitations.

No silver bullet

There is no "silver bullet" solution to tackling the illicit trade in tobacco products. The answer lies with collaboration between the affected industries, including responsible tobacco manufacturers, third parties, government (including law enforcement), other supply chain economic operators and consumers. Proper enforcement of existing laws governing the sale and distribution of tobacco would arguably have the biggest impact. Nevertheless, by sharing knowledge, promoting open technical standards and adopting a practicable, workable and cost-effective approach to traceability and security features, there is a good opportunity to help improve efforts in the fight against this growing problem.

[3] *Analysis of the available technology for unique marking in view of the global track and trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products*, World Health Organisation, FCTC/COP/INB-IT/4/INF.DOC./1, February 2010, pp21-22