

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.a. Please specify:

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

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

Text of 1 to 800 characters will be accepted

Solaris - electronic cigarettes, and IQOS heat not burn tobacco product.

*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

Philip Morris International Inc.
Address for correspondence:
Avenue de Rhodanie 50
1007 Lausanne
Switzerland

e-mail: media@pmi.com
phone: 0041 (0) 58 242 00 00

*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

51925911965-76

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

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B. Options proposed in the Feasibility Study

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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C. Cost-benefit analysis

C.1. Do you agree with?

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

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

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D. Additional questions

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

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

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

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

Text of 1 to 400 characters will be accepted

GS1 using SGTIN standard.

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

Text of 1 to 800 characters will be accepted

Philip Morris International has widely implemented and uses a unique secured serialized identifiers marked on every product. This solution, provided in compliance with GS1 format, and accessible through GS1-compliant data carriers, is also widely implemented by the other tobacco manufacturers present in the European Union. The generation of the unique identifiers can be controlled by governments or other independent third parties by using customized signature algorithm. This technology is available royalty-free to any tobacco manufacturer, and ensures (i) data integrity, and (ii) compatibility with FMCG industry standards. Please see our response to sec. D.2. for more information.

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)

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*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.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)

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*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)

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D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Marking products with serialized unique identifiers on the production line	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input 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

*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)

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*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)

• **733a0c9b-feb9-40ed-bb7c-16f20f8a4bc3/D.13. PHILIP MORRIS INTERNATIONAL INC..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.14.c. Please explain**

Text of 1 to 800 characters will be accepted

Reporting and query tools will have a significant impact on the usability of the traceability system. To develop practical IT architecture, only companies that have a deep understanding of (i) the traceability system used; (ii) tobacco manufacturing processes; and (iii) database structure, should be considered by the Commission to complete this task.

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

Empowering consumers to decode and verify serialized unique identifiers with mobile devices, such as smartphones, increases the likelihood of detecting non-compliant products, both counterfeit and diverted. Consumer-level verification with the use of modern-day tools also increases the awareness of the issue of illicit trade and is already used in other industries. In addition, data generated as a result of code verification could be used by the authorities to determine areas where illicit products are sold, including the possibility of tracing non-compliant supply chain operators.

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

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Contact

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



EXHIBIT A

EXTRACT FROM PHILIP MORRIS INTERNATIONAL INC. 2014 ANNUAL REPORT¹

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



EXHIBIT B

COPY OF THE CERTIFICATE OF GOOD STANDING

Commonwealth of Virginia



State Corporation Commission

CERTIFICATE OF GOOD STANDING

[REDACTED]



*Signed and Sealed at Richmond on this Date:
June 19, 2013*

[REDACTED]

[REDACTED]



Of the Analysis and Feasibility Assessment's ("Assessment")¹ traceability options, only Option 1 offers technical compliance by 20 May 2019 with an acceptable degree of certainty. Option 1 may be implemented based on widely-accepted unique coding identifier in compliance with open standards (GS1) supported by high speed printing data carrier on pack (DotCode) and data transfer (EPCIS) standards, admitting multiple system architectures. Below, to make Option 1 more concrete, we discuss PMI's traceability system, one system consistent with Option 1.

We then discuss the other traceability options' technical and operational shortcomings. Options 2, 3, and 4 are untested in a factory environment; no accumulated experience would guide their implementation. As such, our discussion of those options represents our views on what is feasible to implement and operate in factory environment, and what is not, given what can be surmised about these options. We focus more on Option 4 because it is, in our view, the most technically misguided, but Options 2 and 3 also have serious operational shortcomings that the Assessment does not fully recognize.² Five pages is few to comment on the Assessment's discussion of traceability options, so we have been selective in our comments. However, PMI is ready to provide detailed analysis of all the traceability options at the European Commission's request.

Option 1: Example of Traceability at PMI

PMI's traceability system was designed to be easy to operate, reliable and cost effective in a very demanding high-speed production environment. It has been improved over 11 years to meet ever-increasing performance goals and requirements under PMI's agreement with the European Union and Member States ("EC Agreement").

PMI manufactures cigarettes and finecut tobacco for the EU market in 16 locations on 176 production lines. Most of these locations are equipped for traceability at the master case level, consistent with the EC Agreement. Furthermore, PMI has implemented master case tracking to its first customers in 121 markets worldwide, integrating 70 fully interoperable tracking systems in more than 440 warehouses.

PMI has equipped the overwhelming majority of its manufacturing locations to permit carton-level traceability. As of March 2015, approximately 80% of our cigarettes manufactured for the EU market are traceable at the carton level. As we roll out traceability capabilities globally, we analyze the potential to track products beyond our first customer. Our business partners often agree to introduce such a system, although they are not legally obliged to do so. As a result, we have successfully implemented product tracking beyond PMI's first customer in 8 markets. PMI alone has already invested more than EUR 130 million in the development and global implementation of the traceability solution. The major cost advantage of Option 1 is that it could leverage the investment already made by PMI and other tobacco manufacturers.

¹ *Feasibility Assessment Regarding EU systems for Tracking and Tracing of Tobacco Products and for Security Features*, Eurogroup Consulting and Sovereign Border Solutions, March 2015.

² Options 2-4 also face substantial legal and practical challenges that we discuss in the final section of this Consultation.



PMI's traceability system relies on global GS1 standards, which are followed by virtually all industries moving goods. Multiple solution providers compete to develop and sell the cutting-edge printers, scanners, readers and other equipment that PMI and other players across the supply chain (distributors, wholesalers, and logistic companies) use. We currently work with more than 20 vendors.

PMI currently plans to reach worldwide cigarette pack tracking capability for products destined for the EU within 2 to 3 years, meaning that, by that time, all unit cigarette packs bearing PMI trademarks, manufactured by PMI and third-party manufacturers, will be traceable. PMI produced approximately 50 billion cigarette packs last year. Tracking product at such large volumes, and with such granularity (pack level), requires traceability solutions of much greater scale than in any other industry.³

PMI grants the Commission and Member States access to all this traceability data. With one database per manufacturer, as in Option 1, global PMI traceability data will be available to the authorities, as it is today, from a single source with an immediate replication of all records hosted by a third party without PMI access right to modify data recorded.

The Assessment alleges, but does not support, vulnerabilities that may compromise integrity in tobacco manufacturers' current traceability systems. (pg. 26) Given that the Assessment does not disclose its authors' identities or credentials, such unsupported allegations are difficult to credit. The Assessment authors did not request further information from PMI regarding the points it raises. In any case, these allegations are not grounds to abandon the accumulated experience and investments of the industry; if due diligence were to find an issue, surely a modest fix could be found.

Option 4 – Traceability Solution on Security Feature Label Approach⁴

Option 4 prescribes a solution according to which labels with pre-printed codes would be distributed to tobacco manufacturers. Member States requiring tax stamps may, however, decide to code their current tax stamps, allowing such codes to become unique identifiers at a later stage, but the Assessment is silent about the mechanism for the code application process. Manufacturers would then apply those pre-printed labels, but a third party would scan them and send the scanning events to the database. Once scanned, product information would be linked with them. Only then would those codes become the unique identifiers.

Option 4 would impose exorbitant costs on manufacturers because the location of the stamps would have to change to make aggregation technically possible. Currently most tax stamps are placed on the back or side of cigarette packs, so the stamp is broken when the pack is opened. If the unique identifiers are to be read, processed and aggregated on the line, the tax

³ The Assessment recognizes that "[t]he primary single factor that differentiates the implementation of a track and trace system in the Tobacco industry is cardinality, which is probably second to any other track and trace system after the postal domain." (pg. 92)

⁴ Vulnerabilities of paper-based solutions are addressed in more detail in our response to sec. B.2.5.



stamp location would have to change to the top and side of the flip-top pack, making it partially visible to cameras as the packs travel across the production line. The visible part would have to carry unique identifiers. The label applicator on each production line would require re-arranging, a process that can only be done by the production equipment's manufacturer. In PMI's experience, adjusting a label applicator on one production line takes approximately 4 weeks, and testing and calibrating the line can take an additional week. Downtime for each production line would be at least one month.

PMI currently uses machines manufactured by three companies. To the best of our knowledge, these equipment manufacturers have up to 3 teams of experts capable of adjusting the label applicator. For the 176 production lines on which PMI now manufactures cigarettes and RYO for the EU market, it would take approximately 48 months at current equipment manufacturer capacity to adjust those lines to comply with Option 4. The Assessment estimates that there are 745 cigarette production lines in the EU, all of which would require adjusting. Option 4 would thus impose total production down-time of more than 745 months, or 62 years. Assuming that 5 main manufacturers of cigarette production equipment⁵ could expand capacity to have 5⁶ teams of expert technicians each, adjusting label applicators would not take less than 3 years.

The Assessment's authors ignore the costs of adjusting manufacturing equipment under Option 4. According to a price quotation from a leading cigarette packaging equipment manufacturer, PMI would have to pay EUR 500,000 to adjust one production line to meet Option 4 requirements. In total, using this estimate, PMI would spend approximately EUR 50 million to adjust label applicators to comply with Option 4. Applying this estimate to the Assessment's estimate of 745⁷ cigarette production lines in the EU, the total cost to the industry of adjusting label applicators to comply with Option 4 would amount to approximately EUR 372.5 million.

Option 4 is technically infeasible if intended to accommodate different Member State fiscal stamps. Option 4 appears to be designed to give Member States the ability to utilize their currently used tax stamps as security features, if "enhanced to include a secure serialized number, making each label uniquely identifiable". (pg. 199) This is not technically feasible except in the most hypothetical way, even after the costly adjustment of label applicators described above. Currently, on average, PMI manufactures products for as many as 15 markets on a single production line during one week. Existing Member State fiscal stamps have a variety of sizes, shapes, and placements; a few examples are pictured below.

⁵ There are now three cigarette packaging equipment manufacturers and two companies that produced such equipment, but only service it now.

⁶ Current practice is that there are two to three teams of technicians able to adjust label applicators.

⁷ The number of production lines required to comply with T&T and SF requirements under TPD is far greater, as several tobacco manufacturers make cigarettes and RYO for the EU market outside the EU.



If differently configured tax stamps also contain unique identifiers that must be read with finely-placed cameras (pg. 199), manufacturers would have to adjust and test the set-up and location of the vision system whenever a line produces product for a different market. Production flexibility would be so substantially impaired as to make the process practically infeasible.

The Assessment fails to explain how aggregation is possible where a government-mandated third party reads the unique identifiers. Under Option 4, tobacco manufacturers apply labels, but a third party reads the unique identifiers. Without the ability to read the unique identifiers, tobacco manufacturers cannot aggregate packaging units.

The Assessment neither offers solutions to these shortcomings nor reflects them in the critical success factors or cost analysis. The Assessment recognizes that Option 4 suffers from “potential system performance disadvantage”, and “higher implementation and change management effort” (pg. 29), and suggests that tobacco manufacturers “will be required to source and operate a mechanism of the combined security feature and unique identifier on their production line” (pg. 202), so its authors may recognize that Option 4 would require substantial adjustment to production lines. The Assessment also acknowledges that Option 4 “potentially creates aggregation complexity” (pg. 29), because tobacco manufacturers would not be operating the vision system that scans unit packets.

The Assessment does not reflect these severe shortcomings in its critical success factor ratings or cost analysis for Option 4. Option 4, the Assessment finds, fully “support[s] the concept of aggregation” (Critical Success Factor 3) and is “compatible with current tobacco production, packaging and the trade environment to minimize the impact on tobacco production.” (Critical Success Factor 8). The Assessment finds that Option 4 “offers a reduced capital investment requirement” (pg. 199) relative to Option 1, but does not include costs of adjusting the label applicator (appr. EUR 372,5 million plus enormous downtime costs, including for some products manufactured for export (pg. 209)).

Important Operational Shortcomings Shared by Options 2, 3 and 4

Options 2, 3 and 4 present additional significant technical and operational shortcomings that the Assessment does not recognize in its critical success factor or cost analyses.⁸

⁸ PMI disagrees with the Assessment’s choice and rating of critical success factors. Because of space constraints we focus only on operational shortcomings related to two factors. Shortcomings in the cost/benefit analysis are addressed in more detail in our response to sec. C.1.1.



Compatibility with Current Tobacco Production (Critical Success Factor 7). Compatibility with current production and packaging processes ensures that production lines can accommodate coding equipment and minimizes the impact on the entire tobacco supply chain. As the Assessment recognizes, this factor is interwoven with internal market proportionality obligations.⁹

Option 2 relies on a single solution that has never been used in practice, operated by an inexperienced third party or parties that, to meet the requirements of multiple tobacco manufacturers, will quickly have to acquire the knowledge that the entire tobacco industry has accumulated over more than a decade. The Commission-selected service providers may have little incentive to remain up-to-date with technological developments in production equipment. The single data management host managing the EU-wide database under Option 2 would be prone to digital attacks or failures that could temporarily shut down all tobacco manufacturers. The Assessment recognizes that “[m]anaging these huge numbers is a significant burden on data management and selecting the proper architecture and technology is, as expected, a matter of compromises and priorities” (pg. 97) and Option 2 would require “additional mitigation . . . to not cause production down-time by 3rd party.” (pg. 27) But it fails to consider that a single solution provider’s failure in operation would affect all tobacco manufacturers, in contrast to Option 1’s risk-mitigating solution of dividing the database per manufacturer.

Option 3 would in practice require multiple solutions on a single production line. (pg. 217) There is no industry experience, and the Assessment suggests no reason to believe that multiple traceability solutions on a single production line is technically feasible.

Avoid Unnecessary Burden to the Supply Chain (Critical Success Factor 11). Option 1, already in use by many supply chain operators, is the least burdensome in reaching the objective of Article 15 TPD. Option 2 is very burdensome, “requiring [supply chain operators] to upgrade their warehouse management systems, packaging label printers and handheld reading devices where they choose not to use the Solution Provider(s) provided standalone solution.” (pg. 173) Option 3 is as burdensome as Option 2, unless Option 3A is applied throughout the EU. Option 4 would have the highest impact on supply chain operators dealing with products imported from the EU. Such products would carry labels, which may prevent them from applying labels required under local law, such as tax stamps.

⁹ Option 1 is able to ensure that this success factor is met because it is based on systems currently in use in demanding high-speed production environments and has been tested and refined over years.



This section summarizes PMI’s comments to the Analysis and Feasibility Assessment’s (“Assessment”) findings on security features. PMI disagrees with the Assessment’s conclusion that paper-based solutions are best fit to meet the Article 16 security feature requirements. Since the time frame for Article 16 compliance is extremely tight, the best path forward is to maintain flexibility.

Under Article 16, and to ensure timely implementation, implementing acts should give Member States the right to retain currently used tax stamps as security features, as long as the stamps fulfil all of the technical standards and functions required under this Article. But Member States that do not use tax stamps should be able to permit the unique identifier as a visible element of security feature, and taggant tear tape or other intrinsic solutions, such as digital fingerprint, as the invisible element. Wherever possible, tobacco manufacturers, who are experienced in securing their products to deter counterfeiting, should be accountable for securing their products.

Paper-Based Security Features Suffer Serious Shortcomings

All four options for security features suffer from the same shortcomings. They (i) secure only themselves, but not the product they are applied to; (ii) can be stolen and applied to any product; (iii) can be removed and re-applied; (iv) discourage technological progress; and (v) offer no flexibility to Member States that do not have tax stamps or are planning to discontinue them.

Paper-based security features are not the most effective to fight illicit trade. They are easy to copy, and once copied, create a false sense of security that the product they are applied to is genuine. Genuine paper-based security features can be lost or stolen and then applied to illegal products. Given how long paper-based solutions have been used, one would expect they would have been significantly enhanced. They have not, perhaps because their material base inhibits further innovation or because of generally low incentive to innovate solutions that are mandated through long-term contracts with public authorities.

Below are photos of modern-day “advanced” tax stamps similar to those presented in Options 1 - 4. They are usually mimicked by counterfeiters in one month of introduction,¹ and the quality of copies makes them difficult to distinguish from the original with a naked eye.

	Turkey	Ukraine	California (United States)
Genuine			
Counterfeit			

¹ See: *Changing the tax stamp: feasibility report*. Indiana Department of Revenue, November 2009, pg. 5.



Despite tax stamps' shortcomings, Article 16 allows them to be used as security features, provided that they meet Article 16's requirements, as some currently used ones do. The Assessment ignores this; instead it bases all options on novel labels that would be required across the EU.

Users Of Security Features

Law enforcement agencies require a robust solution, allowing field officers to determine whether or not a product is authentic. Depending on the outcome of such analysis, further investigative or enforcement actions may be taken, therefore accuracy is paramount. The possibility to authenticate products without additional devices or off-line is secondary, and all law enforcement officers in the EU are expected to have communication devices by May 2019.

Consumers require an easy-to-use solution. Consumers want to authenticate the product itself, not a stamp. If this requires using a device, according to our experience, consumers accept it. We currently enable consumers to verify product authenticity using unique identifiers in Portugal (website) and Germany (hotline). Consumer feedback is very positive.

Tobacco manufacturers must authenticate their own products using security features. Testifying on product authenticity is every brand owner's responsibility. In 2014, PMI issued 611 product examination reports, related to 317 million PMI-branded products (both genuine and counterfeit). We were always certain whether a product was genuine or counterfeit.

We would not be able to determine a product's authenticity based on a label attached to it. Such analysis could also not be the basis for, e.g., a trademark infringement claim. It would expose the person giving the testimony to liability for false testimony if a genuine label had been applied to a counterfeit product.

The images below illustrate how labels applied to a cigarette pack fail to assist in authenticating the product. Both labels look the same and include the same "advanced" security features, but one product is genuine and the other, counterfeit. We assume that the labels are also genuine and counterfeit, but they may as well both be genuine.





Tobacco Manufacturers Are Best Placed To Choose Security Features

As tobacco manufacturers already know, securing a product requires multiple approaches to security features, depending on product type. We link various application methods and techniques to the product type and its material and packaging. Cigarette packs are made of paper, roll-your-own pouches of plastic, and tins of aluminum. Those materials on the one hand call for different application methods, but on the other hand offer different possibilities for securing the product.

We share our authentication practices with law enforcement officers on a regular basis through counterfeit recognition trainings. In 2014 PMI provided trainings to 761 officers. After completing the trainings, they are able to recognize which PMI-branded products are genuine.

We also adjust security features to current counterfeiting trends, often on the basis of samples we receive for authentication. Counterfeiting is a global problem, and quite often counterfeit PMI products destined for the EU market are seized outside the EU. We use those learnings to protect our products, and if a given security feature is copied, we design and implement a new one. Because of our experience and ability to adapt relatively quickly to current threats from counterfeiters, we believe tobacco manufacturers are best placed to choose security features.

Implementing Acts Should Allow Flexibility

If the Member States are responsible for developing security features, the implementing acts should allow them flexibility. Only then will security features adapt to current threats from illicit trade.

Implementing acts should not be a guide to counterfeiters; they should neither explicitly mention specifications of the security features, nor cement an outdated technology.

The Commission or Member States should not rely on a single, or limited number, of solution providers, as monopolists have little incentive to innovate. They also are prone to threats from illicit manufacturers. For example, if manufacturing secrets of a monopolistic service provider are compromised, so would be all the EU tobacco products carrying the security features it manufactures or designs.

Exchange of industry best practices should be encouraged, to ensure that Member States do not design security features from scratch. This would also prevent the design and implementation of security features that are either impossible, or overly expensive.



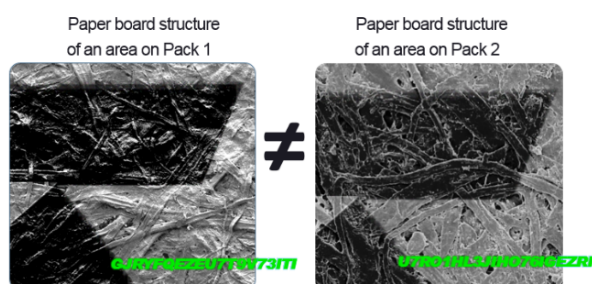
Tear tape used today on cigarette packs should be allowed as a security feature under Article 16 TPD. It is an integrated part of a pack - if removed, one would instantly see this. It is also not possible to re-apply it, which makes tear tape tamper proof.

The implementing acts should foster modern technologies. Digital fingerprinting (recognized in Option 3, but regrettably linked with a paper-based solution) is one example, but in our opinion, the array of available security solutions is so broad that the Commission should not limit itself to one specific technology. Other novel solutions include digital taggants, and traditional taggants printed or sprayed over products. The implementing acts should allow the flexibility to utilize the most effective solution for a given type of products at a particular time.

PMI Complies With Art. 16 TPD Requirements

The security features we currently apply to our products meet and exceed Article 16 TPD requirements. The unique identifiers we apply to enable tracking and tracing can be regarded as the visible element. The tear tape that PMI uses today meets the requirements of the invisible element. The Assessment's authors, instead of contacting any tobacco manufacturer using tear tape to better understand this security feature, state that "[u]sing clear wrap or tear tape packaging elements did not readily meet the requirements for an irremovable security feature". (pg. 24) Tear tapes, as any element of packaging, can be removed. Not all elements are, however, tamper-proof. The removal of tear tape would be visible, and mean that the pack had been tampered with.

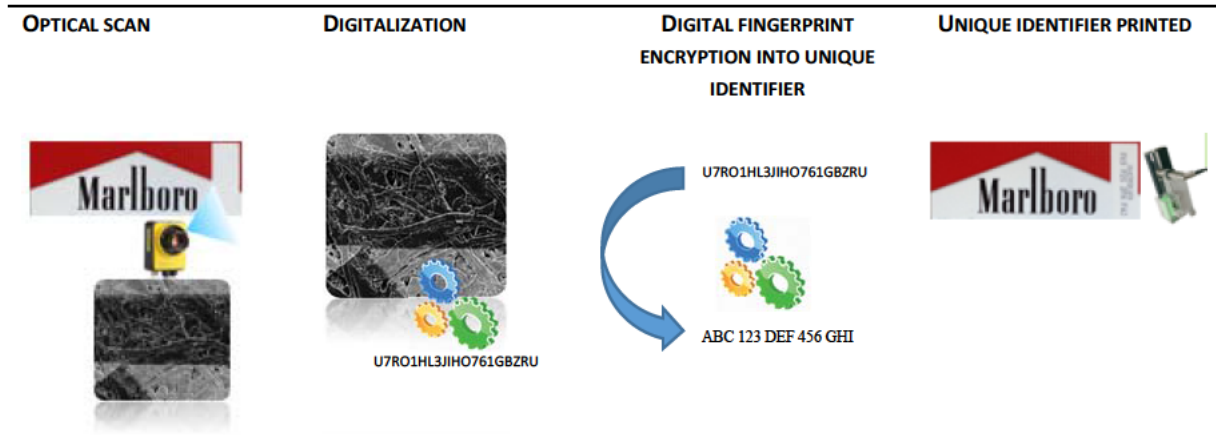
Moreover, as part of our on-going efforts to secure our products, we are cooperating with solution providers who developed a system in which an optical scan generates a unique digital fingerprint, enabling the analysis of unique product characteristics. The Assessment recognizes digital fingerprinting in Option 3, describing it as "an opportunity to authenticate a product with great certainty". (pg. 77) It can be visualized as follows.



In 2011, the Royal Canadian Mint began using digital fingerprint technology to secure its coins. PMI has also started implementing this solution on its production lines, and some products currently manufactured by PMI bear unique identifiers created using digital fingerprint as one of their elements.



The fingerprint security feature is created in four steps, as follows.



Despite recognizing digital fingerprinting, the Assessment’s authors mistakenly believe that an additional label must be applied to meet the requirement of the visible element of the security feature, instead of utilizing the unique identifier printed on a unit packet. (pg. 29, 30, 253) The Assessment does not even analyze this possibility, stating only that “[t]hese claims [that a human readable unique identifier can be the visible security feature] fall short, as the proposed serialisation technique by itself fails to meet requirements of an overt security feature”. (pg. 22)

We do not argue that the unique identifier is an overt security feature. This is not what Article 16 TPD requires.² It requires that the security feature has a visible element that can be irremovably printed. This is what the unique identifiers applied by PMI are—visible and irremovably printed. For more information on how the unique identifier is generated, please refer to our response to sec. D.2. of this consultation.

The Assessment also states that “[h]owever, at this stage, cost and speed (in particular the fingerprinting process) are the main barriers to the adoption of this technology.” (pg. 77) PMI believes that the costs of digital fingerprint solution are clearly outweighed by its benefits. In order to be cost-efficient, it should, however, neither be applied to labels (as the Assessment suggests at pg. 253), nor rely on additional labels to be the visible elements of the security feature. Instead, the visible element of security feature should be the unique identifier.

We would welcome the possibility to discuss the security features we are using with the Commission and the EU Member States. Direct correspondence or, preferably, meetings would ensure that this information remains confidential and not undermine our efforts to secure PMI products. Our learnings could then also be shared with other legitimate tobacco manufacturers.

² Please refer to our response to sec. D.17. for more information on the difference between overt/covert, and visible/invisible elements of security features.



In this section we summarize PMI's comments to the cost-benefit estimates of the Analysis and Feasibility Assessment ("Assessment"). The Assessment concludes that for all the traceability options, the benefits are approximately the same (pg. 273), and benefits exceed costs (pg. 277). The Assessment states that traceability Option 1 is more cost-effective than the other options¹ (pg. 303), and presents combined traceability and security feature Option 4 as roughly equivalent of the most cost effective combination of traceability Option 1 plus security feature Option 2. At the same time, the Assessment acknowledges that the estimates are not fine-tuned enough to rank options. (pg. 352) Even for the limited claims the Assessment authors make based on their cost-benefit estimates, the estimates are too flawed and speculative to be plausible.

The Assessment fails to incorporate in its cost and benefits estimates that only traceability Option 1 is based on technology that has already been developed, and is successfully used by tobacco manufacturers representing more than 90% of the EU tobacco market. The Assessment also fails to come to grips with the fact that illicit tobacco products consumed in the EU originate primarily from outside the EU.

The Assessment's failure to account for the actual experience with the existing tracking and tracing system and the facts of illicit trade flows has at least four important implications for its analysis. First, the costs of Option 1 are substantially overestimated relative to the other options, because the Assessment gives no credit for existing investments, or the favorable basis on which the existing technology may be extended to other tobacco manufacturers. Second, because traceability Options 2-4 are not based on existing traceability systems or cost estimates from service providers, the cost estimates for options 2-4 are purely hypothetical constructs. Third, because benefits are highly dependent on the usability of traceability systems outside the EU, which are only proven under an Option 1-type system, the benefits of Option 1 are undervalued relative to the other Options. Fourth, the Assessment fails to consider that the likelihood of realizing benefits by reducing illicit trade is only proven for Option 1 because that is the only system that has already delivered actual, strong results across the EU.

With respect to security features, the Assessment's cost estimates are much too incomplete to be plausible. They include only expensive, paper-based solutions and omit, without sound basis, other existing, more effective and less costly methods of securing products.²

The Assessment substantially overestimates the costs of Option 1.

The Assessment's cost estimates for Options 2-4 use Option 1 as a basis, and hypothesize cost increases or decreases from that base. (pg. 290) But the Option 1 cost estimate disregards the investments already made in development and implementation. By way of illustration, for PMI alone those investments have amounted globally to more than EUR 130 million. The major cost

¹ The Assessment recognizes, however, that the costs of traceability Option 4 must be considered together with the costs of security feature Option 4. When this is done, Option 4 costs are presented as marginally higher (by approximately 0.7%) than the allegedly least expensive combination of traceability Option 1 and security feature Option 2. (pg. 281)

² Please refer to our response to sec. B.2.5. and D.17. for additional comments to security features solutions presented in the Assessment.



advantage of Option 1 is that it could leverage the investment already made by PMI and other manufacturers.³

The traceability Option 1 cost estimate does not acknowledge or credit the significant investments made by all four largest tobacco manufacturers. Despite recognizing that “[o]ne of the largest companies is expected to have Codentify fully operational . . . by December 2014”, the Assessment confirms that “the degree of implementation of each participant of the survey [tobacco company] was not considered.” (pgs. 278-279) In turn, this led to wrong assumptions on investments that have already been made and those that would still need to be made.

Further, any other legitimate tobacco manufacturer can obtain a royalty-free license to use the already existing technology used by the four largest manufacturers.⁴ The Assessment does not take this cost advantage into account.

The Assessment replicates hardware costs related to Option 1 across all traceability options (except Option 4). Those costs would, however, be different for traceability options 2-4, as third party operators would have little or no incentive to minimize costs to the industry. To the contrary, they would have an incentive to maximize their own profits.⁵

The Assessment makes wrong assumptions about installation costs. Installation costs are one-off expenditures that last throughout the lifespan of production equipment. They are significantly higher than mere hardware costs, amounting to approximately EUR 300,000 per one high-speed production line. But those installation costs have already been borne by PMI and, contrary to what the Assessment assumes, will not have to be repeated every six years. The Assessment thus fails to take into account the investment in installation which would be obsolete if an option other than Option 1 were chosen. To illustrate the magnitude of wasted installation costs, even assuming that there are only 46 high speed production lines manufacturing for the EU market, the total wasted installation costs amount to EUR 13.8 million. (pg. 295)

The cost estimates for Options 2-4 are purely hypothetical constructs.

The Assessment does not justify its estimates of the costs of Options 2-4 relative to Option 1 with any solid analysis or support. These estimates are apparently hypothetical, not based on any concrete solution, and not supported by any hard research into actual costs.

Option 2. To estimate the costs of traceability Option 2, the Assessment adds a 10% margin to the cost of Option 1, stating that “there are no other significant differences between traceability Option 1 and traceability Option 2 costs.” (pg. 301) The 10% margin, the Assessment assumes, includes expected “additional overhead cost associated with a service provider

³ When analyzing costs, the Assessment disregards investments made to develop traceability Option 1. (pgs. 278-279) It does, however, consider existing investments made into tax stamp applicators that could be used with traceability Option 4 and security features Options 1-4. (pgs. 198, 329)

⁴ Please refer to our response to sec. B.1.5. and D.17. for additional comments to traceability solutions presented in the Assessment. The cost advantages of traceability Option 1 were recognized in the TPD Impact Assessment, which commented that “there are possibilities to benefit from existing experience [of tobacco industry]” and that “PMI declared its readiness to grant royalty free licenses to third parties that want to use PMI’s tracking and tracing software.” (TPD Impact Assessment, pg. 108).

⁵ Even if the Assessment authors had obtained cost estimates from equipment manufacturers, those would be very rough estimates as it is impossible to provide exact quotations for machinery to support a system that does not yet exist.



providing independent oversight and a profit component” (pg. 301), but reflects presumed benefits from economies of scale.

The Option 2 cost estimate is not based on any concrete technology or solution provider and there is no evidence that the authors validated this assumption with any potential solution provider.⁶ The 10% assumption apparently is not more than a guess. Common sense suggests that a 10% margin would not suffice, in particular since this 10% increase in cost includes development and additional overhead cost, in addition to the profit margin.

The Assessment claims that the costs associated with a solution provider’s staff are included in the 10% margin, but its authors do not attempt to measure the number of employees, including additional machine operators required to implement and maintain traceability Option 2 on each of the 745 production lines. These costs must be speculative, as we do not know of a single solution provider that could provide system maintenance on more than 745 production lines, operated by more than 230 tobacco manufacturers and at more than 2,450 wholesalers.

To calculate the cost of developing Option 2, the Assessment’s authors assume that Option 2 could be specified and developed in 50% of time that required to develop Option 1. (pg. 317) But again they provide no basis for this assumption, which artificially drives down the cost for Option 2 relative to Option 1.

Option 3. The cost estimate for traceability Option 3 envisages “sub-optimal implementation and allocation of equipment.” (pg. 302) The Assessment estimates that Option 3 will cost 25% more than Option 1. This 25% excess cost, however, includes only estimated increased operational expense due to a need to support different systems across the EU, including different databases. (pg. 303) As for Option 2, the Assessment’s estimate of the cost of Option 3 is not based on any existing solutions, or concrete proposals. The Assessment does not estimate how costs may vary depending on different Member State choices of solution providers.

The Assessment does not estimate or include any development costs, or the cost of equipping production lines with hardware supporting multiple traceability solutions across the EU.

Option 4. The Assessment presents Option 4 as the most cost-efficient traceability option. Without a security feature element, the Assessment authors calculate it as approximately 40% less expensive in hardware costs. This is because they ignore the need for direct printing on unit packets. They assume additional cost savings of approximately 85% are from unspecified reductions in operational costs. The authors do not provide any explanation that would support this calculation, other than that packaging and labelling costs would decrease. In practice, Option 4 may well be the most expensive, due to the following important but omitted factors:

- Cost of marking products for export⁷ (pg. 209);
- Label applicator adjustment costs, which we estimate at EUR 372.5 million for the tobacco industry manufacturing for the EU market, without which packs-to-bundles product aggregation would not be possible;⁸

⁶ Please refer to our response to sec. B.1.5. for additional comments.

⁷ According to the Assessment, “. . . it cannot be excluded that the most efficient solution could be to apply security features to all production, including exports.” (pg. 209)

⁸ Please refer to our response to sec. B.1.5. for additional comments.



- Printing equipment costs, as some markets will require additional information to be printed directly on unit packets, e.g., price or expiration date (pg. 304); and
- Cost of adjusting the vision system to read unique identifiers each time a label is in a different location. (pg. 304)

Because it incorrectly assumes that illicit trade in the EU can be fought with intra-EU systems, the Assessment undervalues the benefits from Option 1 relative to the other Options.

The Assessment suggests that traceability systems and security features will curb the illicit trade in the EU. It concludes that, for all options, benefits exceed costs. But the estimates are based on the incorrect assumption that the illicit trade in the EU can be fought with *intra*-EU traceability and security feature systems.

Yet, illicit tobacco products consumed in the EU originate primarily from *outside* the EU. According to the latest KPMG Project SUN report, 85% of all counterfeit and contraband products consumed in the EU come from outside the EU.⁹ This means that only 15% of illicit trade in the EU could potentially be targeted by TPD art. 15 and 16 measures, unless a traceability option is selected that is proven to be globally interoperable. Option 1 is a globally interoperable solution that has been implemented in 121 markets worldwide.

In contrast, whether any of Options 2-4 would be capable of tracing the relevant product flows coming in from outside the EU to the same degree as Option 1 is largely unknown and not something that has been tested anywhere.

The Assessment fails to consider the likelihood that benefits will be realized.

The likelihood of realizing benefits must be expressed for each option. In doing so, the Assessment would have had to take into account the extent to which the different options have already been shown to reduce illicit trade. Using a system similar to Option 1, PMI has already been successful in implementing product tracking in and outside the EU. As a result, illicit inflows of genuine PMI product to the EU fell by over 45% in the past five years.¹⁰ The Commission recognized this efficacy of the existing traceability system and stated that “[t]he measures implemented by the four big manufacturers under the Cooperation Agreements, such as tracking and tracing of tobacco products, due diligence in relation to customers and prevention of money laundering, have clearly led to a significant reduction in the presence of these companies’ products on the illicit market.”¹¹

The Assessment entirely ignores this hard evidence which is central to any benefit analysis. Instead, it tries to shed doubt on the credibility of Option 1 by assigning an amber rating to it with respect to critical success factors 4 (independent data storage) and 9 (resistance to manipulation). We believe these ratings are wrong; all options should be rated at the same level for these two factors because they would all utilize independent data storage providers, and similar methods of generating codes. But, in any event, the decisive point is that, unlike Option

⁹ KPMG Project SUN 2014 report, pg. 10.

¹⁰ According to the latest KPMG Project SUN report, inflows into the EU from the Designated States under the Agreement between the European Union and the Member States declined by 45.5% between 2009 and 2014.

¹¹ Communication from the Commission, *Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - A comprehensive EU Strategy*, COM(2013) 324 final, pg. 8.



1, which builds on existing technology, none of the other options have already shown to deliver actual results in reducing illicit trade across multiple countries.

Thus, at a minimum, it is fair to say that Option 1 is very likely to achieve the intended benefits from reducing illicit trade, while for Options 2-4, the likelihood is simply unknown. This makes Option 1 superior not just in terms of costs but also in terms of benefits.

The Assessment disregards effective, cost-efficient security features.

The Assessment fails to analyze the effective, cost-efficient security features that are already applied to tobacco products. Instead, it proposes only paper labels as security features. Paper labels, however, are largely ineffective because they secure only the label itself, and they are very expensive.

As discussed in our response to sec. B.2.5, we believe that a system mandating paper-based labels as security features will not reduce illicit trade. To the contrary, paper-based security features confuse consumers and law enforcement authorities, creating a false sense of security, as the consumers and law enforcement authorities would only be able to authenticate such labels – not the product.

In terms of cost, security labels similar to the ones that the Assessment analyzes have recently been quoted to PMI by one solution provider at EUR 0.054 per packaging unit. This price exceeds the total cost of more than 30 authentication elements used by PMI on a cigarette pack more than 150 times. Despite their high price, in markets where they are used, they have been readily copied, depriving governments and tobacco manufacturers of their revenues.

In contrast, if the unique identifier is used as the visible element of the security feature, and a taggant tear tape as the invisible element, the cost is between EUR 0.0002 and EUR 0.0003 per packaging unit, compared to EUR 0.0019 for the least expensive option analyzed in the Assessment (Option 2). The unique identifier and taggant tear tape are existing solutions, which guarantee compatibility with the traceability system, and current manufacturing and tobacco supply chain requirements.

The Commission's objective should be to allow effective and cost-efficient solutions, not only the most expensive solutions. But without sound basis, the Assessment disregards effective, cost-efficient solutions in favor of outmoded, expensive paper labels.



The Commission should require in the implementing acts that unique identifiers are generated in a way that ensures (i) integrity of the data they store, and (ii) compatibility with various data carriers.

To ensure integrity, unique identifiers must securely store the information they contain. PMI applies a security element to the information recorded, and encrypts the final code. This allows the unique identifier to serve as an element of the security feature.

To ensure compatibility with various data carriers, unique identifiers should follow internationally recognized standards. PMI uploads data in a GS1 format, using GS1-compliant data carriers.

More specifically, unique identifiers generated by PMI follow sGTIN GS1 standards, and comprise two elements:

1. A Global Trade Item Number (GTIN) that uniquely identifies the product; and
2. A serial number that uniquely identifies an item within a class of product.

The unique identifier applied to PMI products is composed of 2 parts: (i) Identity, and (ii) Security; and generated in three steps.

The first step generates the product identity part of the identifier. The identity information by default contains core information on the manufactured product, the production line it is manufactured on, and production date (year, month, day, time, including a counter that specifies time to within a minute).

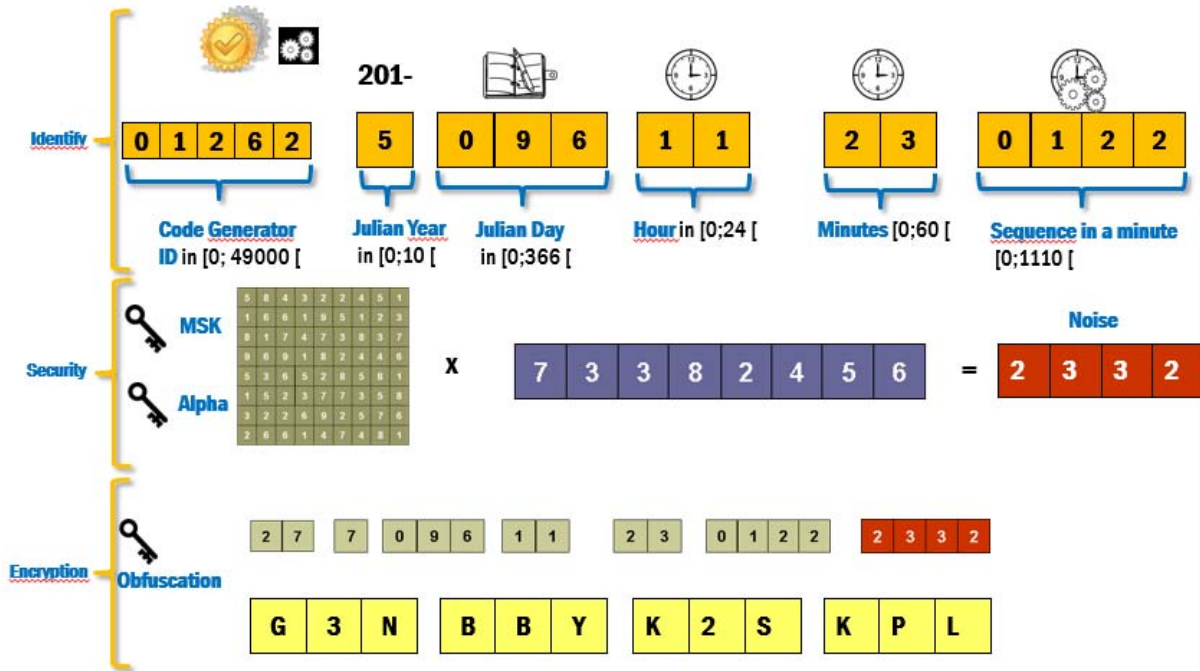
Any additional information or document, known to PMI at the time of production, can form part of the unique identifier or be linked to it.

The second step creates the security element. Two dynamic encryption keys, which are unique per production batch, create the security noise. They are not stored, except by the entity designated by the authorities that maintains the central system.

The third step merges the identity part with the security part. As an additional security measure, PMI applies obfuscation to both sets of information using a static key.

If additional information must be securely linked with the unique identifier, it can be referenced during the second step, creating noise that is based on this information and therefore preventing the possibility to modify the information's content.

The diagram below graphically presents the three steps used to form the unique identifier.





To be effective, data carriers for a serialized unique identifier must be highly compatible with and usable by all operators across the tobacco supply chain as well as the logistic service providers. Only widely-accepted solutions will have a chance to be globally interoperable, as required under WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

GS1 is the only global traceability standard accepted and used across all industries requiring logistic services. According to the Analysis and Feasibility Assessment (“Assessment”), “GS1 standard offers a framework to establish a holistic view of the supply chain and create a bridge between the physical and the information flow. Its neutrality and general acceptance makes it well positioned to appropriately respond to traceability system design and implementation requirements.” (pg. 91) We urge the Commission to require in the implementing acts that GS1-compliant solutions are recommended to be data carriers for serialized unique identifiers.

Incorporating GS1-compliant solutions into Article 15 TPD technical requirements would lower costs and permit timely implementation by the manufacturers, who are already equipped with the necessary coding equipment, and the supply chain, which is already using these standards.

PMI uses two types of data carriers for serialized unique identifiers: (i) human readable, and (ii) machine readable. The human readable unique identifier is applied in alpha-numeric format, and looks as follows.

ABC DEF GHI JKL

The machine readable data carrier of the unique identifier is applied in different formats, depending on the packaging level. The reason for applying different formats is linked with: (i) manufacturing speed, and (ii) limited printing space on unit packets.

At high manufacturing speeds manufacturers must use data carriers that can be applied to unit packets without sacrificing readability. In addition, PMI uses data carriers that are readable even if damaged, either in printing (e.g., clogged printing nozzle), or when retrieved on discarded empty packs. This capability is used for the purposes of empty pack surveys. DotCode meets and exceeds the requirements of modern-day high speed manufacturing. DotCode uses the GS1 128 coding standard, strengthened by the Reed-Solomon error correction. DotCode, like GS1 128, can store GS1-formatted data messages.

DotCode is an Automatic Identification and Mobility (AIM) Standard.¹ It is expected to be recognized as GS1 standard, following a statement of business need submitted by leading Fast Moving Consumer Goods industry players including PMI, British American Tobacco, Japan Tobacco International, Imperial Tobacco, Unilever, SAB Miller and Societe des Brasseries et Glacieres Internationales (B.G.I.).² As described by the AIM, “DotCode is a rectangular matrix symbology designed to produce machine-readable coding with existing high-speed industrial

¹ For more information about AIM please visit: https://aimglobal.site-ym.com/?page=About_AIM.

² The statement of business need to adopt the AIM DotCode as an approved GS1 symbology was submitted on 19 May 2015.



printing equipment. DotCode is ideally suited for high-speed industrial ink jet and laser marking because it does not require continuous lines or touching elements.” DotCode looks as follows.

LASER



INKJET



Higher packaging levels do not have such demanding manufacturing speed or readability requirements as unit packs. Any GS1-compliant format currently used by supply chain operators is acceptable. For example, PMI uses GS1 DataMatrix to mark cigarette bundles (usually comprising 10 packs), and GS1 128 barcode supplemented by GS1 DataMatrix to mark cigarette master cases (usually containing 50 bundles). Examples of bundle and master case marking are as follows.

MASTER CASE



BUNDLE





PMI places the serialized unique identifiers where they can be read and aggregated into a higher packaging unit. For cigarettes that is usually the bottom of a pack. This placement also ensures that unique identifiers do not interfere with any other elements required by legislation, such as tax stamps. The following images depict the location of unique identifiers on PMI cigarette packs.

FLIP-TOP PACKS

A	B	C	1	2	3		D	E	F		4	5	6							
T	E	X	T		T	E	X	T		T	E	X	T							



SOFT PACKS

A	B	C	1	2	3		D	E	F		4	5	6							
T	E	X	T		T	E	X	T		T	E	X	T							



Because the production line, for other technical reasons, is already configured in such a way that the bottoms or tops of the packs are in a readable position, placing the unique identifiers on pack bottoms or tops enables cameras to read the codes.

Reading all the codes applied on products contained in a higher packaging unit is essential for aggregation purposes, creating the so-called parent-child relationship. This ensures that each lower packaging unit (child) is linked with a unique higher packaging unit (parent).

The following depicts a bundle of 10 packs of cigarettes and the position of unique identifiers. They are placed in the same position on a production line, ensuring that all the codes are read. Once read, they are aggregated into a higher packaging unit (bundle), which is uniquely marked. Images of a bundle of 10 cigarette packs, and a label with unique identifier attached to the bundle, are depicted below.



The placement of unique identifiers on bundles of cigarette packs is as important as placement of identifiers on the packs themselves. The identifiers are placed on the shorter side of a bundle to allow them to be read before they are placed in a master case. Practically, locating



the unique bundle identifier on the bundle's side allows efficient verification of codes that are contained in a master case, during quality controls and inspections of seized goods.





To ensure its effectiveness, and to be admissible in court to authenticate the, the security feature must be part of the product's packaging. As an example, tear tapes are an integral part of cigarette packaging. Once removed, they cannot be re-applied and thus make clear that the product they secure has been tampered with. In our experience, tear tape evidence is generally admissible in court as evidence that the product is counterfeit. In contrast, labels or other external features do not fully secure products they are meant to protect and can be mimicked, creating a false sense of security.

We understand that under Article 16 TPD the Commission may allow Member States the use of existing tax stamps to fulfill requirements of security feature. At the same time, we hope that this is an interim stage and that those outdated solutions will be phased out over time.

A number of technologies exist for adding security features as part of the packaging. We discuss three below: printing, fingerprint technology, and tear tape. Without proper justification, however, the Analysis and Feasibility Assessment ("Assessment") rejects or criticizes all those methods.

The Assessment also rejects the ability to use a printed unique identifier as the visible element of the security feature, stating that it "fails to meet requirements of an overt security feature." (pg. 22) As we explain in sec. D.17., however, the Assessment's analysis errs because Article 16 TPD requires "visible" elements, not "overt" elements, where overt is a specialized term that requires more than to be visible.

In addition, printed security features are broader than just unique identifiers and include anything printed on a pack. PMI completed trials with invisible printed markers that could be used on any cigarette pack. The technology is mature, and ready for implementation.

The Assessment recognizes fingerprint technology as a valid option for the invisible element of the security feature. Fingerprint technology forms part of security feature Option 3 but, unfortunately, only as part of a label applied to a product, or linked to a label carrying the unique identifier. This defeats the objective of material fingerprinting, i.e., the ability to recognize the nano-structure of the product it is intended to protect. Instead, the process should be completed without using any ancillary surface. We discuss fingerprint technology further in our response to sec. B.2.5.

Tear tape has been a part of cigarette packs for more than 13 years. Together with a clear overwrap, it ensures the product's integrity. Once removed, it cannot be re-applied, thus showing clearly that the product has been tampered with. According to the Assessment "[t]o comply, sections of the overwrap or tear tape would have to be permanently affixed to the tobacco packaging and designed to separate during removal" or a "second tear tape applicator [would have] to be installed on each production line." (pg. 241) This is incorrect. Tear tape is permanently attached to a pack, as it cannot be removed without tampering with the product it protects. Any additional tear tape would only repeat this function.



Another way to apply a security feature - one of the latest innovations in this area - is to spray invisible substance over products. The technology is extremely difficult, if not impossible, to mimic, and relatively cost-efficient, as it is applied to the outer packaging during its printing. In combination with other security features, such as the unique identifier, it is a robust way of securing products.



Option 1 is the only one of the options discussed in the Analysis and Feasibility Assessment (“Assessment”) that is readily consistent with Article 15’s provisions regarding data storage, as we explain in our response to sec. D.17. Below, we explain why the legislative plan for data storage as expressed in Article 15 TPD also makes most sense from a technical viewpoint. Only Option 1 can yield easy to operate and relatively easy to manage traceability databases with any reasonable degree of certainty. The Assessment provides no assurance that Options 2, 3 and 4 would be manageable at a reasonable cost.

Option 1. According to Article 15(8) TPD and Option 1, tobacco manufacturers select independent third party data hosts and auditors, subject to the Commission’s oversight over the data storage process, including the approval of data storage contracts. This provision makes sense, as large scale data storage is technically demanding. We have significant experience with processing large tracking data ourselves and know which performance indicators are important. Data storage hosts must provide robust, flexible and cost efficient solutions. Several tobacco manufacturers already operate their own databases, including all the tracking events captured over the last years. Option 1 builds on this experience and allows easy replication.

Option 1 limits each manufacturer to one database. This is not a major constraint to PMI, but we note that there is no basis for such a limitation in Article 15 TPD. Two or more data hosts may be cost-efficient for some manufacturers and should be permitted if approved by the Commission.

Option 2. The Assessment underestimates the complexity of data management, relying only on database volumes. (pg. 20) To measure the data complexity and size, the Assessment considers data processed by the manufacturers, but disregards the vast amount of data that would be generated by the supply chain operators. In our experience, managing PMI data is itself challenging; managing PMI data across the entire supply chain until the last economic operator before the first retail outlet, required under Article 15(5) TPD, will be a substantial challenge. Option 2 prescribes a single database for the entire EU – an unprecedented challenge given that more than 200 tobacco manufacturers operate in the EU.

Option 3-4. Options 3 and 4 prescribe 28 separate Member State databases. This would create a need for data replication, or not yet developed Commission-level software, to permit information to be pulled from the different data bases. The approximate size of such a repository would be more than 12 TB per year,¹ assuming that PMI first level customer tracking database—without data compression—would amount to more than 4 TB per year.

Regardless which traceability option is selected, PMI must be able to retain a copy of data related to our products, including manufacturing data. This is, among others, a requirement in certain jurisdictions where we must provide law enforcement with traceability information related to our genuine products that were seized.

¹ The Assessment miscalculates the database size requirements to be 2.21 TB per year. (pg. 261)



This section summarizes important practical and legal considerations that may inform the way forward following this Analysis and Feasibility Assessment (“Assessment”). An important guidepost is the timeline. The Commission’s indicative timeline to adopt implementing and delegated acts under Articles 15 and 16 TPD is Q2 2017.¹ By that time, public consultations, a follow-up study and Member State/Expert Group consultations should be completed. Articles 15 and 16 require compliance for cigarettes and roll-your-own tobacco from 20 May 2019.

Track and Trace – No Reason to Abandon Existing Traceability Experience and Investments

OPTION 1 – Government Oversight Approach

Option 1 provides the Commission and the Member States with a clear path to implementing Art. 15 TPD in a way that takes advantage of an already existing, proven and reliable traceability system, which with an acceptable degree of certainty can be implemented by 20 May 2019. Option 1 is also the best fit to ensure interoperability with a future global traceability system resulting of the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products (“AIT Protocol”). Option 1 proposes a familiar model of regulation, based on government standards and oversight, and industry accountability for operational details. Implementing acts for Option 1 can straightforwardly incorporate references to open standards and will foster a market approach based on free competition, to encourage innovation. Because Option 1 is fully consistent with Article 15, the Commission has the power, if exercised appropriately, to use it as a basis for implementing acts in accordance with Art. 15(11). Moreover, Option 1 does not introduce the range of thorny practical and legal issues Member States would face under Options 2 through 4, which all rely on government-mandated in-factory third parties and are not consistent with Article 15’s plain language.

Option 1 is effective. As the TPD Impact Assessment and the Commission have recognized, existing industry traceability solutions are working towards the objective of reducing the illicit trade in contraband. The TPD Impact Assessment (108-09) observed that “the largest tobacco manufacturers are already implementing some of the requirements” of a traceability solution and existing traceability solutions “improve[] compliance with the FCTC.” The Commission stated that “[t]he measures implemented by the four big manufacturers under the Cooperation Agreements, such as tracking and tracing of tobacco products, due diligence in relation to customers and prevention of money laundering, have clearly led to a significant reduction in the presence of these companies’ products on the illicit market.”²

Option 1 is feasible. Because it builds on existing and tested technology and a familiar regulatory oversight model, Option 1 is the only one of the Assessment’s suggested traceability options that creates an acceptable level of certainty that it can be completed within the

¹ http://ec.europa.eu/health/tobacco/docs/implementation_plan_en.pdf

² Communication from the Commission, *Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - A comprehensive EU Strategy*, COM(2013) 324 final, pg. 8.



timeframe of Article 15. The TPD Impact Assessment recognized that building on existing industry traceability solutions would make implementation more straightforward; this “creates a level playing field between different operators (currently only the biggest four tobacco manufacturers are bound to develop and use tracking and tracing systems) and would be beneficial for them (unless they are themselves involved in illicit trade). . . . This will allow small business to adapt and learn from bigger companies.” (pg. 112) Thus, as acknowledged by the Legislature and Commission, a functioning system exists that has been proven effective in reducing illicit trade, and with which the industry and Member States are familiar. It can readily be extended, including to smaller companies, to fully meet the Article 15 requirements.

Option 1 is scalable and adaptable. Option 1 also has the advantage of relying on competition and market participants rather than awards to select solution providers. It can be implemented based on widely-accepted open coding (DotCode and GS1) and data transfer (EPCIS) standards, which should encourage development and adoption of innovative solutions and promote still greater effectiveness over time. (pg. 91: “By defining a shared minimum requirement and showing what action is required from trading partners, the GS1 traceability standard enables maximum interoperability between traceability systems across the supply chain whilst accommodating specific commercial, industry sector or legislative requirements.”) This adaptability is especially important because many other countries outside the EU will be introducing traceability systems as a result of the AIT Protocol, with which the system operated in the EU should be made compatible—both to increase effectiveness in fighting illicit trade and minimize potential trade barrier effects.

Option 1 is cost effective, as the Assessment acknowledges. The Assessment finds that Option 1 offers benefits equivalent to the other options, at lower cost, even though it did not recognize the cost savings from tobacco manufacturers’ past investments in traceability implementation. According to the Feasibility Assessment, “the combination of traceability Option 1 + security feature Option 2 solution would have the lowest cost impact on manufacturers and distribution chain operators.” (pg. 281) The cost advantage of Option 1 would be even larger if the Assessment had not assumed—contrary to fact—that there was no traceability system already in place.³ The Assessment’s benefit/cost calculation contains a number of inconsistencies and inaccuracies. But certainly the Assessment’s cost benefit calculation suggests no reason for the Commission and Member States to take on the complex legal problems presented by Options 2 through 4.

³ Despite assuming that that the existing traceability systems should not be included in the cost benefit analysis, the Assessment authors recognize that “[o]ne of the largest companies is expected to have Codentify [traceability system compliant with Option 1] fully operational (pack and carton level coding, supply chain traceability) by December 2014.”



Option 1 avoids legal problems. Option 1 is the only option consistent with Article 15 and, as such, is the only option that the Commission has the authority to adopt by implementing act without reopening the TPD. In contrast, Options 2 through 4 are inconsistent with Article 15, as explained below. And, for Options 2 through 4, the Assessment flags for “potential legislative consideration” the “[l]egal basis of fitment of tobacco traceability components on manufacturer’s production lines.” (pgs. 165, 186, 203) But the Assessment fails to consider the substantial legal problems that would arise. Options 2 through 4 would impose very serious restraints on tobacco manufacturers’ ability to conduct their day-to-day operations.

WHAT IF:

- *A TRACEABILITY EQUIPMENT MALFUNCTION SHUTS DOWN PRODUCTION LINES FOR TWO WEEKS?*
- *THIRD PARTY INSTALLATIONS DAMAGE MANUFACTURING EQUIPMENT AND IMPAIR OEM WARRANTIES?*

DO MEMBER STATES PAY? IF NOT, WHO?

OPTIONS 2, 3B AND 4 ALL WOULD REQUIRE MANUFACTURERS TO PERMIT GOVERNMENT-MANDATED IN-FACTORY THIRD PARTIES TO IMPLEMENT AND MAINTAIN TRACEABILITY EQUIPMENT ON PRODUCTION LINES. THIS UNCHARTED REGULATORY TERRITORY RAISES MANY QUESTIONS. OPTION 1, WHICH RELIES ON GOVERNMENT OVERSIGHT AND LEAVES IN-FACTORY ACCOUNTABILITY WITH MANUFACTURERS, AVOIDS SUCH ISSUES.

The Assessment does not test whether such restraints are proportionate, or propose how to handle the practical legal questions that must arise.

Ultimately, though, it won’t be necessary for the Commission and Member States to wrestle with these tough legal and practical questions. Legislators need not deliberate the legality of severe interferences with manufacturers’ day-to-day operations. The Assessment provides no reason to abandon the accumulated experience and investments with existing traceability technology and start from zero in uncharted territory. Instead, its Option 1 provides the Commission and Member States with a strong foundation for an effective; feasible, even within the tight TPD timeframe; scalable; adaptable and efficient traceability system in the EU, fully in accordance with the plain language and legislative intent of Art. 15.

OPTION 2 – Centralized Approach

Option 2 proposes “a single Tobacco Traceability solution deployed as a standard harmonized EU Community system . . . operated by one or more [Commission-appointed] solution providers that are independent of the tobacco industry”. (pg. 27) Tobacco manufacturers would be “required to allow the solution provider(s) to implement systems and equipment on their production lines.” (pg. 161) Option 2 proposes a “central EU event repository” to store



traceability data (pg. 27), managed by one or more data management providers selected through a Commission-run bid and selection process (pg. 176), instead of data storage agreements concluded by the manufacturers. Option 2 would present the Commission and Member States with a number of challenges and is inconsistent with several elements of Article 15.

Option 2 is not consistent with the TPD. By its plain language, Article 15 does not contemplate a centralized EU system established by the Commission and run by a Commission-appointed third party service provider(s). Article 15 is precise in specifying the limited role for the Commission: approving the suitability of third party data storage hosts with which manufacturers and importers conclude contracts (Art. 15(8)), approving manufacturers' proposed auditors to monitor the data hosts' activities (id.), adopting delegated acts on key elements of data storage contracts (Article 15(12)), and determining "technical standards" in implementing acts, including to ensure that the "systems" used for the unique identifier and related functions are fully compatible across the Union (Article 15(11)). Article 15 does not give the Commission the power to appoint a single solution provider, or establish a central EU event repository instead of data storage agreements concluded by manufacturers.

Article 15 specifies only a single role for an "independent third party". Article 15(8) states that "Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data." The EU Legislature specified when an independent third party should be involved, and did not provide for independent third parties to be involved beyond data storage. They did not specify government-mandated third parties on manufacturers' production lines. Even for a matter less intrusive, data storage, the TPD gives manufacturers the right to select a provider, subject to Commission oversight.

Moreover, Article 15 does not provide for a centralized event repository to store traceability data, managed under a contract awarded by the Commission. Since the third party data storage host's activities are to be "monitored by an external auditor, which is proposed and paid by the tobacco manufacturer," it is plain that, under Article 15(8), each manufacturer may choose to contract with a separate "independent third party." Articles 15(8), para. 3, and 15(12) also make clear that the TPD does not provide for a single data storage provider but, rather, multiple storage contracts and facilities. TPD Recital (31) also makes plain that "manufacturers of tobacco products should conclude data storage contracts with independent third parties", where "parties" is plural, and the Commission's role is to approve their suitability.

The TPD Impact Assessment provides no basis to believe the EU Legislature intended to pursue a centralized approach managed by the Commission and which would abandon the traceability solutions already used in the EU. Instead, the TPD Impact Assessment affirmed tobacco manufacturers' legitimate expectations that the investments they made under their respective agreements with the European Union would be respected. (TPD Impact Assessment, pg. 108: "The proposed measure will be more burdensome for smaller operators who will possibly have to build up a tracking and tracing system from scratch. However, there are



possibilities to benefit from existing experience.”) Given Article 15’s unambiguous language and the clear legislative intent, the Commission lacks authority under Article 15 to pursue implementing acts in line with Option 2’s centralized approach.

Option 2 presents additional legal and practical challenges. Option 2 would present the Commission and Member States with a range of complex additional challenges, including potentially: (1) practical and legal challenges because Option 2 would compel manufacturers to accept a government-mandated third party into their factories (pg. 163; see, e.g., above); and (2) considerable doubt about whether they could solve legal issues, conduct public tenders, and provide for implementation of wholly-new technology within factories in time to meet a 20 May 2019 deadline.

Option 2 is more costly and may not be technically feasible, as the Assessment acknowledges. The Assessment itself determines that Option 2 would be more costly than option 1. (pg. 34) The Assessment also leaves unresolved the considerable uncertainty about whether there is a workable technical solution for a single EU data storage facility. For further discussion, please see our response to sec. D.13.

In sum, the Assessment provides no reason for the Commission to reopen the TPD to attempt to gain the authority to pursue this path, or for the Commission and Member States to take on the complex legal and practical problems that Option 2’s centralized approach presents.

OPTION 3 – Multiple Overlapping Systems Approach

Option 3 contemplates a heterogeneous T&T system whereby each of the 28 Member States may opt for its own solution requirements, including to appoint a solution provider to implement the system within tobacco manufacturers’ factories (or to permit tobacco manufacturers to implement their choice of system). Under Option 3, Member States rather than manufacturers would appoint third party data storage providers.

Option 3 is not feasible. In practice, Option 3 would potentially require multiple systems to be installed on a single production line, with multiple different Member State-mandated service providers needing on-going access to factories to maintain that service (pg. 183 (“to setup and capture information as part of shift set-up (e.g. intended market of retail sale)”)). For more information, please see our response to sec. B.2.5. Further, the only proposed “solution” to this problem appears at least as infeasible. The Assessment proposes that Member States enter into agreements to apply traceability solutions only to products **manufactured** in their territory. (pg. 217) But it does not provide guidance on the means to achieve such agreements; Option 3 instead leaves Member States to fend for themselves to satisfy their obligations under TPD Article 15. The Assessment does not explain how to trace products sold in a Member State but potentially subject to multiple different traceability technologies. It also does not explain which data storage facility would be utilized in relation to products shipped across multiple Member



States, and whether Member States that currently do not host cigarette manufacturing facilities would be required to have such data storage capacity at all.

Option 3 cannot be accomplished within the TPD's timeframe. Even if Option 3 were feasible, it is very unlikely to be accomplished within the Article 15 timeframe. If forced to comply with multiple overlapping requirements on their production lines, tobacco manufacturers would likely be required to substantially refit factories and potentially adjust supply chains throughout the EU and beyond during the period between Member State transposition, completion of tenders, and the 20 May 2019 date by which the entire supply chain must be ready to comply with Article 15.

Option 3 is not consistent with the TPD. Article 15 does not provide for Member States to appoint third party data storage providers. Article 15 only asks that Member States ensure that tobacco manufacturers conclude data storage contracts with an independent third party. Again, since the third party's activities are to be "monitored by an external auditor, which is proposed and paid by the tobacco manufacturer," it is plain, under Article 15(8), that each manufacturer may choose to contract with a separate "independent third party." Moreover, Option 3 seems contrary to the purpose of Article 15, to ensure a harmonized approach in Member States in anticipation of the AIT Protocol. (TPD Impact Assessment, pg. 112) The Feasibility Assessment itself identifies "fragmentation" and "risk of incompatibility" as drawbacks and fails to explain how the Commission's technical standards will be able to ensure full compatibility of an approach based on multiple overlapping requirements on the same production lines and fragmented Member State databases.⁴

Option 3 would present Member States with a range of practical and legal issues. Like Options 2 and 4, Option 3 raises a range of complex additional challenges. Legislators will need to solve the issue of how to compel manufacturers to admit government-mandated third parties into their factories, and the corresponding practical questions illustrated in the text box above. In a nutshell, when actions of government-mandated third parties result in damages, injury or business disruption, who will assume the liability? The Member States who appointed them? Clearly, this model of placing third parties into the factories of manufacturers on an ongoing basis would broach uncharted regulatory territory.

Option 3 is expensive with no additional benefit. The Assessment states that Option 3 is likely to be the most expensive approach. Even its flawed cost analysis (which assumes that CAPEX will be the same under Option 3 as under Option 1, which would permit tobacco manufacturers to continue to utilize current technology compliant with standards), concludes that Option 3 will involve 25% higher costs than Option 1. In addition to the costs associated

⁴ According to the Feasibility Assessment, the disadvantages of Option 3 are "[p]otential fragmentation of solution providers and data management providers . . . [that] increases costs." In addition, the Feasibility Study recognizes that Option 3 " . . . has very high dependence on interoperability amongst numerous providers and data integration across multiple sources", which leads to a "[r]isk of incompatibility and data integration issues during initial implementation" and "[p]otential system performance disadvantages when conducting tracing queries that span multiple Member State repositories." (pg. 195)



with factory and supply chain reorganization discussed above, the costs of setting up databases per manufacturer and per Member State would increase exponentially. As the Assessment recognizes “In Option 3, a single data management repository is considered for each Member State. . . . Considering there are 22 manufacturing Member States, . . . Option 3 will present higher costs due to the increased need of compatibility considerations between countries.” (pg. 302) Further, the Assessment points to no additional benefit to justify these higher costs.

In sum, the Assessment indicates that Option 3 provides no additional benefits over Option 1 at 25% higher costs and substantially higher risk that a feasible technical solution does not exist. The Assessment does not discuss how Option 3 could be implemented within the required statutory timeframe. Option 3 does not promote a harmonized EU approach or further AIT Protocol readiness of Member States.

OPTION 4 – Traceability Solution on Security Feature Label Approach

Option 4 attempts to combine the traceability solution with the security feature solution by adding a unique identifier to security feature labels. Option 4 proposes that Member States establish standards for recording the unique identifier on the secure label through a service provider independent of the tobacco industry. Option 4 again would require a third party to have ongoing access to manufacturer’s production lines. All data would be submitted to an independent data management provider appointed by the Commission and/or each Member State.

Option 4 is not feasible or is prohibitively costly. As explained in B.1.5, Option 4 would impose total production downtime that we estimate to exceed 60 years, if summed over all the production lines that would require rearrangement of label applicators, and cost more than EUR 300 million. Moreover, it can be done only if the Commission mandates standardized tax stamps and as described does not permit aggregation.

Option 4 is inconsistent with the TPD. As discussed above, any proposal that delegates to the Commission or Member States the power to appoint a data management provider or that mandates in-factory third parties, is not compliant with Article 15. Under Option 4, Member States would appoint a service provider to record the unique identifier on the secure label on manufacturer’s production lines. Either the Commission or Member States would appoint an independent data storage provider, contrary to Article 15.

Option 4 presents additional legal and practical challenges. Option 4 also would present the Commission and Member States with a range of complex additional challenges, including: (1) practical and legal challenges because Option 4 would compel manufacturers to accept a government-mandated third party into their factories (“TMs will need to accommodate within reason, representatives of the Solution Provider(s) being allowed access to production areas”)⁵,

⁵ The Assessment flags as an issue for “potential legislative consideration” concerning options 2-4 the “[l]egal basis required for fitment of tobacco traceability components on manufacturers production lines.” (pgs. 165, 186, 203).



some of which are detailed in the text box above; and (2) locking Member States into old paper-based security feature technology.

Option 4 is shown as less costly only because the Assessment makes unreasonable assumptions. The Assessment shows Option 4 as less costly than Option 1 but only because, among other flaws, it does not include the more than EUR 300 million that would be required to adjust label applicators under this Option and wrongly assumes that there is no traceability system already in place when estimating the costs of Option 1. (pgs. 278-9, 281) The Assessment does not cite any additional benefits to Option 4.

In sum, as with Options 2 and 3, the Assessment provides no good reason to abandon existing investments in traceability technology for an untested, unrealistic technical solution and intrusive regulatory model.

Security Feature – Only Labels and Stamps Considered

In Section B.2.5, we present our additional views about the Assessment's analysis of security feature solutions. Given the tight TPD time frame, which requires compliance for cigarettes and roll-your-own tobacco from 20 May 2019, the most realistic path to implementing acts for Article 16 may be to move forward with an approach that would maintain flexibility. Such an approach would permit Security Features on paper stamps for Member States wanting to continue them, and a combination of unique identifier as visible element and intrinsic solutions, such as packaging fingerprint or taggant in the tear tape, as the invisible element, for Member States that do not wish to revert to old technology.

As discussed in that section, we believe that manufacturers are best placed to secure their products and continually update that security to stay ahead of counterfeiters and illicit white makers. Here, we present some additional legal and practical considerations to demonstrate that the Assessment's paper-only approach should not be followed as the Commission and Member States move forward.

The Assessment did not consider whether government-mandated stamp-only solutions are feasible within the Article 16 timeframe. Unless manufacturers are given some flexibility to choose the security feature, they may effectively have less than a year to comply, which is not feasible. The limited time to comply with Article 16 requirements is not the only practical shortcoming of paper-based security feature. The proposed material for all the security features analyzed in the Assessment—frangible paper—has not been tested in actual production. In addition, if the solution could be tested on time, public procurement processes would have to follow, further delaying the time when manufacturers would be able to begin testing the proposed security feature in the manufacturing environment and addressing, among others challenges, the adjusting of equipment to apply the stamps.



The Assessment departs from Article 16's plain language and purpose to justify its favored stamp solution. The Assessment does not explain how a label or stamp can be tamper proof, and irremovably printed or affixed. But Article 16 explicitly requires these features, which are needed to fulfill Article 16's purpose of product authentication. A fiscal stamp can be authenticated in court by the stamp's maker. Authenticity information would, however, be limited to stamp only, not the product it is attached to. As a result, a brand owner could not authenticate its product based on the stamp only, since the stamp could have been stolen or lost and applied to non-compliant (e.g., counterfeit) product. The Assessment claims only that its Security Feature options "provide court-admissible forensic evidence of *security feature authentication*" (pg. 250, 252, 256, 259 (emphasis added)), not that the proposed options can actually serve to authenticate the *product*.

The Assessment relies on a term not contained in Article 16—"overt"—to discard the option that a portion or all of the unique identifier could form the visible element of the security feature. The Assessment equates the terms "visible"/"invisible" (used in the TPD) to "covert"/"overt" (pg. 71). To laypeople the terms may seem identical. They are not, and the distinction matters. "Overt" features are more than just "visible," they "provide the modicum of authentication by the consumer without requiring specialized equipment/devices." (pg. 18, listing "overt elements" as a "Critical Success Factor[] for Security Features" and 71). The Assessment then relies on the "overt" definition—not found in Article 16—to find that "the claim that an alphanumeric code applied to the tobacco packs provides an overt security feature for authentication . . . fall[s] short, as the proposed serialization technique by itself fails to meet requirements of an overt security feature" (i.e. consumer authentication without any additional tools, even a smartphone).

The Assessment counts responses to questionnaires and relies on unsupported assertions rather than analysis to discard any options not based on labels or stamps. Unsupported assertions from known experts with known qualifications would already be troubling. But unsupported assertions from unknown authors, with unknown qualifications, such as in the Assessment, cannot serve to provide a sound assessment of the different technical options for placing Security Features on tobacco products. The Assessment eliminates all but its favored label or stamp solutions, stating "[t]he solution provider survey responses showed there is a strong reference [sic] to apply security elements by means of a label to tobacco products" (pg. 22) and backing that up with a series of unsupported and apparently unanalyzed assertions about drawbacks of other options at pages 240 through 243.

In sum, we do not believe that the Commission can use the Feasibility Assessment as a basis for its decision in the implementing process.