Case Id: f6db8f9c-4240-45ed-8c94-8c440ccc7b52

Date: 29/07/2015 16:08:49

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

Fields marked with \* are mandatory.

This is a targeted stakeholder consultation. The purpose of this consultation is to seek comments from stakeholders:

- directly affected by the upcoming implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the new Tobacco Products Directive (Directive 2014/40/EU), or
- considering to have special expertise in the relevant areas.

In the Commission's assessment, the following stakeholders, including their respective associations, are expected to be directly affected:

- 1. manufacturers of finished tobacco products,
- 2. wholesalers and distributors of finished tobacco products,
- 3. providers of solutions for operating traceability and security features systems,
- 4. governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade.

Not directly affected are retailers and upstream suppliers of tobacco manufacturers (except the solution providers mentioned in point 3 above).

The basis for the consultation is the Final Report to the European Commission's Consumers, Health and Food Executive Agency (CHAFEA) in response to tender n° EAHC/2013/Health/11 concerning the provision of an analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereafter the Feasibility Study). The Feasibility Study was published on 7 May 2015 and is available at <a href="http://ec.europa.eu/health/tobacco/docs/2015\_tpd\_tracking\_tracing\_frep\_en.pdf">http://ec.europa.eu/health/tobacco/docs/2015\_tpd\_tracking\_tracing\_frep\_en.pdf</a>. 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
  viv) 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

Cigars, specifically Premium Cigars - 100% hand made with high quality, aged tobaccos and 0 additives.

\*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

Premium Imports Inc.
123 San Lorenzo Avenue
Coral Gables, FL 33146

(305) 443-7995

- \*A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):
  - Yes
    No
- \*A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.
  - · c1516305-0deb-40bc-9f40-df7ce0631484/2015 Annual Company Certificate.pdf

# B. Options proposed in the Feasibility Study

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

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	•	0	0	0	0	0
*Interoperability	•	•	0	0	0	0
*Ease of operation for users	•	©	0	©	•	0
*System integrity (e.g. low risk of manipulation)	0	©	0	0	0	•
*Potential of reducing illicit trade	0	•	0	0	•	0
* Administrative/financial burden for economic operators	0	©	•	©	•	0
* Administrative/financial burden for public authorities	0	©	0	•	•	0

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	0	•	0
*Interoperability	0	0	0	0	•	0
*Ease of operation for users	0	•			•	0
*System integrity (e.g. low risk of manipulation)	0			•	0	
*Potential of reducing illicit trade	0	©	0	0	•	0
* Administrative/financial burden for economic operators	0	©	0	0	•	0
* Administrative/financial burden for public authorities	0	©	0	0	•	0

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	0	•	0
*Interoperability	0	•	0	0	•	0
*Ease of operation for users	0	•	0	•	•	•
*System integrity (e.g. low risk of manipulation)	•	•	•	•	•	•
*Potential of reducing illicit trade	0	•	0	•	•	•
* Administrative/financial burden for economic operators	0	•	•	•	•	0
* Administrative/financial burden for public authorities	0	©	0	©	•	0

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	•	0	0
*Interoperability	©	•	0	•	0	0
*Ease of operation for users	0	•			•	•
*System integrity (e.g. low risk of manipulation)	•	•			•	•
*Potential of reducing illicit trade	0	•	0	•	•	•
* Administrative/financial burden for economic operators	0			•	•	0
* Administrative/financial burden for public authorities	0	©	0	©	•	0

- B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)
  - 1d48de62-91d7-4906-b827-c5654c3379bb/1.pdf
  - B.2. Please rate the appropriateness of each option for security features set out in the Feasibility Study in terms of the criteria listed in the tables below

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	0	•	0
*Interoperability	0	•	0	0	•	0
*Ease of operation for users	0			•	0	
*System integrity (e.g. low risk of manipulation)	•			•	•	
*Potential of reducing illicit trade	0	•	0	0	•	0
* Administrative/financial burden for economic operators	0	•	0	•	•	0
* Administrative/financial burden for public authorities	0	©	0	0	•	0

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	0	•	0
*Interoperability	©	•	0	0	•	0
*Ease of operation for users	0			•	0	
*System integrity (e.g. low risk of manipulation)	•			•	•	
*Potential of reducing illicit trade	0	•	0	•	•	0
* Administrative/financial burden for economic operators	0	•	0	©	•	•
* Administrative/financial burden for public authorities	0	•	0	•	•	0

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	0	0	•	0
*Interoperability	0	•	0	0	•	0
*Ease of operation for users	0			•	0	
*System integrity (e.g. low risk of manipulation)	•			•	•	
*Potential of reducing illicit trade	0	•	0	0	•	0
* Administrative/financial burden for economic operators	0	•	0	•	•	0
* Administrative/financial burden for public authorities	0	©	0	0	•	0

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

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	0	0	•	0	0	0
*Interoperability	0	•	•	0	0	0
*Ease of operation for users	0	•	•	0	0	0
*System integrity (e.g. low risk of manipulation)	•	•	•	•	•	•
*Potential of reducing illicit trade	0	•	0	©	•	0
* Administrative/financial burden for economic operators	0	©	0	©	•	0
* Administrative/financial burden for public authorities	0	©	0	©	•	0

- B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)
  - 8a179015-ac3f-48e5-9067-73532f1fc408/2.pdf

# C. Cost-benefit analysis

# C.1. Do you agree with?

	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	No opinion
*The benefit analysis presented in section 11.3.1 of the Feasibility Study	•	©	•	•	•	©
*The cost analysis presented in section 11.3.2 of the Feasibility Study	©	©	©	©	•	©

- \*C.1.1. If you selected option "Disagree" or "Somewhat disagree" in the previous question, please upload your main reasons for disagreement (max. 5 pages)
  - f074f1f0-691a-4a15-bdfe-6970f1afe099/3.pdf

# D. Additional questions

The questions in this section relate to different possible building blocks and modalities of the envisaged system (questions D.1, D.3, D.4, D.6, D.8, D.10, D.12, D.14 and D.16)

When replying please take into account the overall appropriateness of individual solutions in terms of the criteria of technical feasibility, interoperability, ease of operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities.
*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier, see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)?  ☑ 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
Standardization on the EU level.
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)

- 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

Text of 1 to 400 characters will be accepted
The preferred data carrier depends on the level/packaging unit
*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)?  ② a) System only operating with machine readable codes;  ⑤ b) System operating both with machine and human readable codes;  ⑥ c) No opinion
D.5. Please upload any additional comments relating to the options for (a) data carrier(s) for a serialized unique identifier referred to in questions D.3 and D.4 above (max. 2 pages)
*D.6. Regarding the physical placement of a serialized unique identifier, when should it happen (multiple answers possible)?  a) Before a pack/tin/pouch/item is folded/assembled and filled with products;  b) After a pack/tin/pouch/item is folded/assembled and filled with products;  c) No opinion
D.7. Please upload any additional comments relating to the placement of a serialized unique

- identifier referred to in question D.6. above (max. 2 pages)
  - 89d9ce5b-63b2-4766-9478-cb0e44b19f23/4.pdf

D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	0	0	•	0	©
*Marking products with serialized unique identifiers on the production line	•	•	•	•	0
*Verifying if products are properly marked on the production line	•	•	•	•	0
*Scanning products upon dispatch from manufacturer's/importer's warehouse	•	•	•	•	0
*Scanning products upon receipt at distributor's/wholesaler's premises	•	•	•	•	0

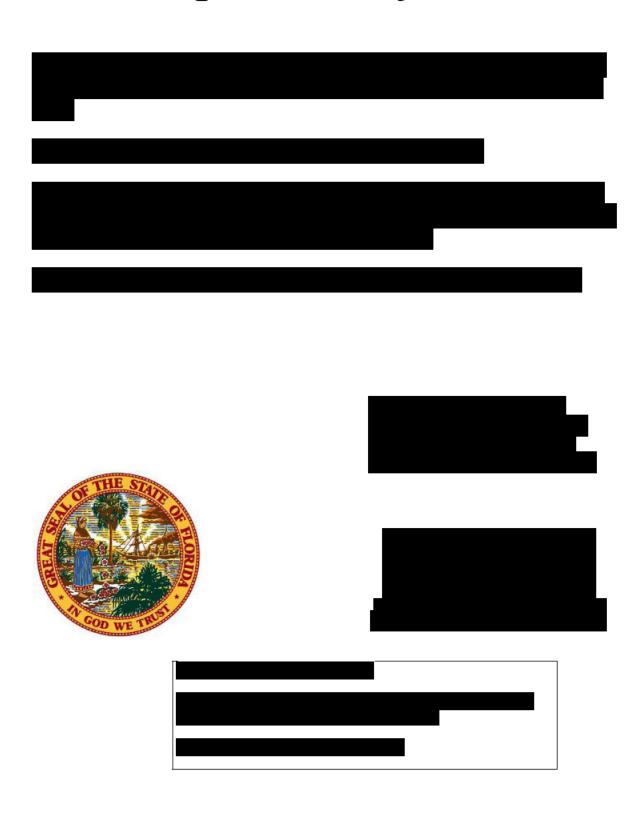
*Scanning products upon dispatch from distributor's/wholesaler's premises	•	•	•	•	•	
*Aggregation of products	•	0	0	0	0	

D.9. In relation to question D.8. above, please specify any other measures that your organisati considers relevant	on
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 the following solutions do you consider as appropriate (multiple answers possible)?  ② a) A security feature is affixed;  b) A security feature is affixed and integrated with the tax stamps or national identification marks;  ② c) A security feature is printed;  ② d) A security feature is put on the pack/tin/puch/item through a different method;  ② e) No opinion	of
*D.10.d. Please explain your other method  Text of 1 to 800 characters will be accepted	
Cigars are produced in small volumes and in a large variety of models, sizes, and brands. As a result, production runs are slow and small.  Manufacturers require as much flexibility as possible in order to be able to chose the best solution depending on the type of packaging and on the production volume.	
D.11. Please upload any additional comments relating to the method of putting the security feature on the pack referred to in question D.10 above (max. 2 pages)	
*D.12. Regarding the independent data storage as envisaged in Article 15(8) of the TPD, which 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 referre	d to

in question D.12. above (max. 2 pages)

D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)?
<ul> <li>a) Provider of solutions to collect the data from the manufacturing and distribution chain;</li> </ul>
<ul><li>b) Provider of data storage services;</li></ul>
C) Another entity
✓ d) No opinion
D.15. Please upload any additional comments relating to the development of reporting and query
tools referred to in question D.14. above (max. 2 pages)
*D.16. Do you consider that the overall integrity of a system for tracking and tracing would be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones)?
a) Yes
<ul><li>b) No</li></ul>
© c) No opinion
D.16.b. If no, please explain your considerations
D.16.b. If no, please explain your considerations  Text of 1 to 800 characters will be accepted
Text of 1 to 800 characters will be accepted  D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)
Text of 1 to 800 characters will be accepted
Text of 1 to 800 characters will be accepted  D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)
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D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)  • 4440dc7a-d14a-40c2-bdfd-d4c48e6fa238/5.pdf

# State of Florida Department of State



The hand rolled premium cigar industry is and has always been largely made up of small, family owned operations just like ours. We. like most other premium cigar manufacturers, produce less than 4 million cigars per year. Our products are unlike cigarettes, they are 100% hand made with high quality, aged, long filler tobaccos and include zero additives of any kind. Our cigars are rolled by skilled craftsmen and blended to be savored and enjoyed by adults much like a fine wine would be. Our products are not marketed to children nor are they priced in a range which is accessible to them. It is important to take into account, before getting into details, that the cost of these regulations will eliminate brands like ours from the European market and create conditions in which only a few very large multinational corporations whose sales derive mainly from cigarettes can survive. These types of regulations will not only harm small businesses but can severely harm the centuries old Dominican culture and tradition of hand crafted cigars and cause significant job loss and economic damage to an already very poor country.

And hundreds of thousands of jobs in a country that is already poor. The illicit trade in cigars is negligible/ non-existent in the EU. In June 2013 the European Commission published 'Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products: A comprehensive EU Strategy' (COM(2013) 324 final). Regarding the illicit trade in tobacco products other than cigarettes the Commission noted that "The seizures reported by the Member States confirm that cigarettes constitute by far the biggest part of seizures of tobacco products, although some significant seizures of Hand Rolling Tobacco (HRT) were also recorded. Other tobacco product types, such as cigars, do not appear in significant numbers." (paragraph 2.2). Also other, more recent publications such as the 'Fight against Fraud Annual Report 2013 (July 2014), the 'Evaluation of the Hercule II Programme' by Ramboll Management Consulting A/S (May 2015) and the OLAF report 2014 (June 2015) do not contain any references to the existence of illicit trade in cigars.

Due to the fact that illicit trade in cigars is negligible / non-existent, we consider the 'potential of reducing illicit trade' in cigars of all 4 options to be 'inappropriate'.

We also consider the 'administrative/financial' burden for cigar manufacturers to be 'inappropriate' in all 4 options. In its September 2010 final report 'Assessing the Impacts of Revising the Tobacco Products Directive', RAND Europe calculated the labelling costs for the tobacco industry and concluded: 'It is important to note that whereas total costs accruing to cigarette manufacturers are much larger than those accruing to cigar manufacturers, the relative burden of compliance (e.g. costs per revenue) is much higher for cigar manufacturers as cigar manufacturers' brands are typically of much smaller quantities. Costs therefore fall on a much smaller number of units sold'. The same is true for the administrative/financial burden for cigar manufacturers in the case of the traceability and security feature pursuant to Article 15 and 16 of the tobacco products directive

#### Attachment B.2.5

The illicit trade in cigars is negligible/ non-existent. In June 2013 the European Commission published 'Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products: A comprehensive EU Strategy' (COM(2013) 324 final). Regarding the illicit trade in tobacco products other than cigarettes the Commission noted that "The seizures reported by the Member States confirm that cigarettes constitute by far the biggest part of seizures of tobacco products, although some significant seizures of Hand Rolling Tobacco (HRT) were also recorded. Other tobacco product types do not appear in significant numbers." (paragraph 2.2). Also other, more recent publications such as the 'Fight against Fraud Annual Report 2013 (July 2014), the 'Evaluation of the Hercule II Programme' by Ramboll Management Consulting A/S (May 2015) and the OLAF report 2014 (June 2015) do not contain any references to the existence of illicit trade in cigars.

Due to the fact that illicit trade in cigars is negligible / non-existent, we consider the 'potential of reducing illicit trade' in cigars of all 4 options to be 'inappropriate'.

We also consider the 'administrative/financial' burden for cigar manufacturers to be 'inappropriate' in all 4 options. In its September 2010 final report 'Assessing the Impacts of Revising the Tobacco Products Directive', RAND Europe calculated the labelling costs for the tobacco industry and concluded: 'It is important to note that whereas total costs accruing to cigarette manufacturers are much larger than those accruing to cigar manufacturers, the relative burden of compliance (e.g. costs per revenue) is much higher for cigar manufacturers as cigar manufacturers' brands are typically of much smaller quantities. Costs therefore fall on a much smaller number of units sold'. The same is true for the administrative/financial burden for cigar manufacturers in the case of the traceability and security feature pursuant to Article 15 and 16 of the tobacco products directive

### Attachment C.1.1

We disagree with the 'benefit analysis' presented in section 11.3.1 of the Feasibility Study. According to this paragraph, 'the four solution options for both traceability and security features are designed to address most of the issues identified in the problem statement'. As stated above, illicit trade in cigars is negligible / non-existent, i.e. no benefits will be achieved by applying an EU system for traceability and security features pursuant to Article 15 and 16 of the tobacco products directive to cigars.

We disagree with the 'cost analysis' presented in section 11.3.2 of the Feasibility Study. In its September 2010 final report 'Assessing the Impacts of Revising the Tobacco Products Directive', RAND Europe calculated the labelling costs for the tobacco industry and concluded: 'It is important to note that whereas total costs accruing to cigarette manufacturers are much larger than those accruing to cigar manufacturers, the relative burden of compliance (e.g. costs per revenue) is much higher for cigar manufacturers as cigar manufacturers' brands are typically of much smaller quantities. Costs therefore fall on a much smaller number of units sold'. The same is true for the costs for cigar manufacturers in the case of traceability and security feature requirements.

In our view the impact of the traceability and security feature requirements should be assessed following the Commission's Better Regulation Agenda, on the basis of which impact assessments are conducted throughout the legislative process, not just when the Commission prepares its proposal. An ad hoc and independent technical panel should be set and should analyse whether Articles 15 and 16 are practical to implement and avoid disproportionate costs for the cigar sector.

### Attachment D.7

The date and place of manufacturing is not so evident in the cigar industry. Over 200 pairs of hands are involved in the hand crafting of a hand made cigar in Nicaragua, Dominican Republic, Honduras and several other Central American countries.

The process of making a cigar from start to finish can take several years, including the fermentation and aging of the tobacco before the cigar is crafted. Finished, and even once made, the cigars can be rested and aged again for several years before release. It would be impossible to identify the destination country each cigar is destined for at the end of each 'manufacturing stage.

Hand made cigars are packed by hand into wooden boxes, cardboard boxes and cardboard shell & slide packs, and metal tins. The packed cigars are put on (a) pallet(s) till the batch is finished. The pallet(s) may be stored in the warehouse for months, until it is known to which country the cigars will be sold.

Hand made cigars are then primarily exported to their distributors in each designated territory, for the placement of Health Warnings, tax stamps and EAN-code labels to comply with local regulations.

We should define 'the moment' when the unique identifier is physically added to each box as when the consumer packs are finished with the health warning labels, tax stamp and EAN-code label.

### Attachment D.17

The illicit trade in cigars is negligible/ non-existent. In June 2013 the European Commission published 'Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products: A comprehensive EU Strategy' (COM(2013) 324 final). Regarding the illicit trade in tobacco products other than cigarettes the Commission noted that "The seizures reported by the Member States confirm that cigarettes constitute by far the biggest part of seizures of tobacco products, although some significant seizures of Hand Rolling Tobacco (HRT) were also recorded. Other tobacco product types do not appear in significant numbers." (paragraph 2.2). Also other, more recent publications such as the 'Fight against Fraud Annual Report 2013 (July 2014), the 'Evaluation of the Hercule II Programme' by Ramboll Management Consulting A/S (May 2015) and the OLAF report 2014 (June 2015) do not contain any references to the existence of illicit trade in cigars.

Due to the fact that illicit trade in cigars is negligible / non-existent, we are of the opinion that the overall integrity of a system for tracking and tracing would not be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices.