

**From:** [redacted]@sicpa.com>  
**Sent:** vendredi 16 décembre 2016 16:49  
**To:** SANTE TT SW  
**Subject:** DG SANTE - Stakeholders Workshop - Letter from SICPA - 16Dec16  
**Attachments:** DG SANTE - Stakeholders Workshop - SICPA Letter - 16Dec16.pdf

**Sensitivity:** Confidential

**Categories:** Blue Category

Dear Sir, Madam,

Please find attached a letter for your attention, related to the stakeholders workshop on the implementation of Directive 2014/40/EU articles 15 and 16, that occurred on 12 December 2016.

Yours Faithfully,

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**EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY**

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Prilly, 16 December 2016

**Subject: Stakeholders Workshop on the Implementation of Articles 15 and 16 of Directive 2014/40/EU**

Dear Sir, Madam,

Further to the stakeholder workshop on the implementation of Articles 15 and 16 of Directive 2014/40/EU organized by DG Health and Food Safety on 12 December 2016 in Brussels.

SICPA is grateful to have been offered the opportunity to attend this workshop as a provider of solutions for traceability, security features and data storage systems for governmental organizations in the area of tobacco control and the fight against illicit trade.

SICPA is also pleased to note that the importance of the World Health Organization Framework Convention on Tobacco Control FCTC and its Protocol to Eliminate Illicit Trade in Tobacco Products ratified by the EU on 24 June 2016 (hereinafter the Protocol) was highlighted during the discussion. It is essential that the implementing measures take account of the intent and spirit of the Protocol. The provisions of the Protocol make clear that only a third party solution meets its requirements i.e. for a Party to be in control of the generation, the printing and the scanning and verification of the unique identifier: only Option A2 is compliant with the Protocol.

The Protocol provides the basis for effective interaction of the European Union system with systems to control non-EU sources of illicit product and is a crucial element in tackling the EU's problems. Furthermore, since the EU is the first regional area to decide on regulation for tobacco track and trace, it is essential that it sets the right example and enables a globally integrated approach as foreseen by the WHO. Some parties have raised doubts about the interpretation of the WHO Protocol and FCTC. We believe these doubts can be clarified by referring to the documents published by the WHO regarding the best practices available around the world such as the *WHO Report on the Global Tobacco Epidemic, 2015*<sup>1</sup>; the *Protocol to eliminate illicit trade in tobacco products: Questions & Answers*<sup>2</sup>.

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<sup>1</sup> <http://www.who.int/fctc/protocol/faq/en/>

<sup>2</sup> <http://www.who.int/fctc/protocol/about/Protocol-to-Eliminate-Illicit-Trade-in-Tobacco-QA-EN.pdf?ua=1>

SICPA has significant experience in designing, deploying and implementing successful tax collection and product authentication systems.

We advise the following choices:

- A2: A third party operated system aligned with the WHO FCTC and its Protocol;
- B3: Data storage on a sovereign country basis, knowing that these must be linked in a way that operates as a single virtual data store that can provide Big Data dividend for enforcement;
- C3 or C4: A limited variety of data carriers. We believe tax stamps, already in place for many countries and therefore free in marginal cost terms, provide a way of combining the security feature and the data carrier requirements, especially for small and medium producers. Secured direct on-line marking is a good option for high volume/high speed production lines to meet Article 15 requirements;
- D1: Near real-time is the best option to enable effective enforcement; and
- S1: Affixing. Tax stamps are the best and proven method of providing multi-layered security which protects against counterfeiting.

Our real-life experience demonstrates it is complex, but possible, to make such systems work in practice in the very varied industry contexts; ensuring a level playing field for all industry stakeholders. We stand ready to facilitate your access to existing operations of relevance.

We are confident that provided decisions are taken as planned in 2017, there is no reason why an efficient Protocol compliant system should not be in place as required by the Directive by May 2019.

Yours Faithfully,



SICPA SA