Expert Revision of the Draft Interim Report I from the Implementation Study on Traceability and Security Features in the Field of Tobacco Products.

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I have read the draft Interim Report I v0.2 ('Interim Report') titled Implementation Study for EU Tobacco Traceability (N° Chafea/2015/Health/40) issued by the consortium of PwC and Everis (hereafter "the consortium") 13/09/2016 The main inputs for the Interim Report are the Feasibility Study (Chafea's 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) published on the 7th of May 2015 and the Inception Impact Assessment published by the European Commission on the 5th of July 2016.

I have participated (via teleconference) in the one-day workshop with other independent experts, the representatives of the consortium, and the representatives of the Directorate-General for Health and Food Safety of the European Commission (DG SANTE).

This document contains my written comments on the draft Interim Report according to the specifications of purchase order SANTE/2016/B2/045/2 issued after tender n° 2016/B2/035 Expert revision of the Draft Interim Report I from the Implementation Study on traceability and security features in the field of tobacco products.

My remarks made during the workshop and comments provided in this document are based on my knowledge and experience as an economist working on tobacco control issues for over 18 years. I have specific knowledge and expertise in at least three areas relevant for the task under tender n° 2016/B2/035. I have specific knowledge about the illicit trade in tobacco products, I understand and conduct cost/benefit assessments related to public health interventions, and I am familiar with the traceability concepts and solutions proposed to design and implement tracking and tracing for tobacco products.

I have checked the draft Interim Report for completeness, comprehensiveness, quality, and consistency in view of the tasks specified in N° Chafea/2015/Health/40.

The Interim Report builds nicely on the wealth of information provided in the Feasibility Study. It summarizes the main findings of the Feasibility Study and points to advantages and disadvantages of each Option. It also provides additional information and data and presents them in a format that will be useful for moving the project forward towards the Final Report (Work Package 4).

The Interim Report points out that no solution offered in the Feasibility Study is perfect and highlights incoherencies between different Options' implications in the Feasibility Study (p. 27). I concur with the conclusion of the Interim Report on this point.
I also concur with the Interim Report's legal analysis on p. 28 where it states that the requirements of Directive 2014/40/EU of the European Parliament and the Council ('TPD') and of the WHO Framework Convention on Tobacco Control ('FCTC')

Protocol discard all the options based on solutions entirely operated by the industry such as Option 1 and Option 3a.

The TPD articulates a number of purposes for further regulating the manufacture and distribution of tobacco products and that regulation includes T&T. One purpose is to promote the smooth functioning of the internal market (Whereas clause (2), p.1). Another purpose of the TPD recognizes that, “Legislative action at Union level is also necessary in order to implement the WHO Framework Convention on Tobacco Control (‘FCTC’) of May 2003, the provisions of which are binding on the Union and its Member States.” (Whereas clauses (7) and (8)). Most important, the TPD spells out the reason for implementing a T&T system in Whereas clauses (29), (30), and (31), where it discusses illicit cigarette trade and stresses the importance of T&T’s independence from potential influence. These purposes for greater regulation of tobacco products would be thwarted if the tobacco industry were permitted to manage and implement T&T.

The potential risks posed by industry-operated T&T are too great, especially given the industry’s propensity to divert product into illicit channels (see, for example, the recent case in which British American Tobacco was fined £650,000 by the U.K. government for oversupplying cigarettes into the low-tax Belgian market, from which they could be smuggled back into the U.K.(Reuters, Nov. 13, 2014). If a tobacco company, in operating T&T, somehow failed to subject products to all features of the T&T system so that they could be diverted, the system would be rendered ineffective as to those products.

The Interim Report states, "From a legal standpoint, an industry-operated solution **may be in conflict** with Article 15.8 of the TPD and Articles 8.2 and 8.12 of the FCTC Protocol that require the system to be kept under control of the competent authorities." In fact, an industry-operated solution **is** in direct conflict with Articles 8.2 and 8.12 of the FCTC Protocol.

Option 3b would also undermine the smooth functioning of the internal market because different Member States (‘MS’) could choose different providers for T&T whose systems may present a challenge for compatibility, thus adding complexity to the solution and pushing up costs. Even though Option 3b would provide a lot of autonomy for the MS, it would also introduce a level of complexity that could jeopardize the functionality of the T&T system. For that reason, I favor a T&T system that would introduce a uniform standard across the EU, as the TPD indicates. Such a system will be more effective and easier and cheaper to implement. Data storing and processing should be centralized to simplify compliance and enforcement. The Interim Report adequately critiques the weaknesses of the Option 3 of the Feasibility Study.

Option 4 for T&T represents an outlier among the options in the sense that it answers a different question than Options 1 – 3. Options 1-- 3 deal primarily with governance (Who? in the Inception Impact Assessment), but Option 4 deals with the mechanism of implementation (How? in the Inception Impact Assessment). It confuses the issue of the "Governance model" with the "Method of adding a security feature". The Interim Report should critique Option 4 for T&T on these grounds in addition to the faults it addresses.

After reading and digesting the information provided in the Interim Report, I believe that the way forward is to further develop Option 2 for T&T described in the Feasibility Study, because it will best accomplish the purposes of the TPD. Given that illicit trade undermines both internal market functioning and health, and that the terms of the FCTC are binding on MS, it would be a mistake to pursue any option with an industry-operated solution. The Interim Report is explicit in this regard.

Other Comments
Most of the Interim Report‘s criticisms of Option 2 for T&T can apply to all the other Options as well. However, the Interim Report offers some improvements for Option 2. It suggests, for example, that the tobacco traceability query should be developed and maintained by the competent authorities (as opposed to the Solution Providers).

The Interim Report engenders some confusion by stating in one place that Option 2 features a distributed database (p.111) and elsewhere that Option 2 is the only one that suggests a centralized database (e.g. p 36, 109), while only Options 1, 3, and 4 feature a distributed database (p. 24). The Report then goes on to describe how, if access to data is not immediate and easy, data mining and analysis, and hence surveillance, will be difficult to perform properly (p. 111). On p. 116, this distributed data access complexity is attributed to Option 1 even though Option 3 is discussed on this page, which is a bit confusing.

Two aspects of the Options have the potential to impact this access issue: technical and governance. What is clear is that any T&T solution must meet or exceed the standards for performance and security. Whether to go with a distributed or centralized database should be decided on the basis of its ability to meet or exceed these standards. It is important to note that relevant authorities have already reported difficulty getting access to Codentify data[1] in countries where this industry solution has been piloted. I personally favor the centralized database, since the only potential weaknesses are the level of performance and security, both solvable given the current state of technology.

The issue of the database centralization/decentralization is separate from the governance issue. Any industry-operated solution runs the risk of being ineffective. This issue arises, for example, regarding who will provide the equipment for marking products, validation, and reading the unique identifiers on all forms of packages. The Feasibility Study assumes in Option 2 for T&T that the Solution Provider will provide this equipment. In some comments, the Interim Report also assumes that it will be the responsibility of Solution Providers (p.131, 133). However, the TPD states that the tobacco manufacturers will “provide” the equipment to all economic operators in the supply chain (Article 15.7). In this regard, the Interim Report introduces additional confusion on p. 109 where it interchangeably uses the words "equipment" and "infrastructure".
The Feasibility Study suggests that the Distribution Chain Operators provide "infrastructure and networks connectivity", but it does not seem to suggest that these

[1] European Commission. Study on the measuring and reducing of administrative costs for economic operators and tax authorities and obtaining in parallel a higher level of compliance and security in imposing excise duties on tobacco products; 2014.

operators would also provide the equipment. In my opinion, the Solution Providers should provide the equipment.

The Interim Report states that Option 2 for T&T will have a high impact on tobacco industry production. As far as I know this has not been the experience of countries where partial T&T systems have been implemented using a 3rd party provider (e.g. Kenya, Brazil, Turkey, etc.). It would be good to bring the experience of other countries in controlling their cigarette supply chain to this report to better assess the anticipated impact with empirical evidence.

The Interim Report could consider whether human readable codes (the data carrier) do need to apply to all packaging sizes. Perhaps human readability is important for packs and cartons, but not for master cases or pallets.

The Interim Report should mention that any solution for T&T needs to meet the guidelines proposed by European Interoperability Strategy (EIS).

The Interim Report lists EMCS in the Glossary and Terms of Reference, but does not mention it in the body of the text at all. What will T&T mean for EMCS?

Page 85 of the Feasibility Study mentions that the tobacco product supply chain already has a standard for data sharing. It would be beneficial to explore this a bit more, perhaps in the next phase of the project, so that the systems already in place are better understood.

I think that the Feasibility Study describes very well the characteristics of a T&T system on p. 82. It would be good to reflect on those characteristics either in the Interim Report or in future work packages.

The Interim Report handles the critique of the security features options proposed by the Feasibility Study quite well, leaving some room for further analysis, given the fast pace of this industry. I only disagree with the report's interpretation that the Feasibility Study only considers stamps as the data carrier. I do not see it that way. (See, for example, section 9.1.1. Method of Application on p. 240 of the Feasibility Study.)

One of the weakest parts of the Feasibility Study is its cost benefit analysis. It is criticized to some extent in the Interim Report, but the critique could go a bit further.

My main concerns with the cost benefit analysis are the following:

1. The expected efficiency of the T&T system according the Feasibility Study is low in my opinion. For example, it assumes that there will be a 30% reduction in contraband. This is based on information from the industry that an effective tracking and tracing system reduces illicit contraband by 30% in five years[2]. Why is it only 30% if the contraband represents legal industry products that leaked into the illegal supply chain? The experience in countries that have

[2] Cited in the Inception Impact Assessment, but taken from the TPD Impact Assessment, p. 108.

implemented even partial T&T systems shows much greater reductions in contraband.

2. The assumptions behind many of the calculations are not explicit. For example, we do not know how the analysis splits the impact between quitting/non-initiating and reduced consumption (among those who will continue to smoke). There are no details about the cost saving calculations and the assumptions used either.

3. The calculation assumes that a smoker dies 14 years earlier than people who never smoked. No citation is provided. The latest evidence presented in the US Surgeon General Report 2014 states that this loss is 12 years for males and 11 years for females, for example (http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html).

4. The calculation estimates higher tax revenue, but forgets to estimate higher industry profits from the reduction in the supply of counterfeits and illicit whites.

On a few occasions, the Interim Report is concerned about the costs to tobacco manufacturers. Just a side note: if the goal of the TPD is to improve public health, the costs to tobacco manufacturers should be regarded as a plus (not as a minus), since these costs will increase product prices, and thus reduce their consumption.

Minor comments:

Not all abbreviations are listed in Annex D: Glossary and Terms of Reference – e.g. SLA (p. 22 and elsewhere), IS (p. 61). The terms in Annex D are not in alphabetical order – e.g. SME is below TPD.
Typos – e.g. p. 106, 110 (DSPDSPs), p. 108 (ore)
Missing reference p.24, Figure 7
The report uses both "decentralised" and "decentralized".