A very poor report. Going through it I really got emotionally involved and I want to apologize for some of my writing that might be far from politically correct. I put many hours into it and hope it will help the project team in the future. I think a lot of work has to be dedicated before DG SANTE can accept these contents.
Implementation Study for EU Tobacco Traceability – Initiation Report

Pages 3 to 8 are removed as they fall outside the scope
1. EXECUTIVE SUMMARY

This document lacks structure and it shows it from the very beginning. Here, for example, you refer to Work Package 1 without telling the reader what are the objectives of the overall project/contract, what structure the project will have and how WP1 fits in it.

Later on you keep saying: “This option will be addressed later on in WP2.” And the reader is left asking herself (“Why? Aren’t they supposed to address these issues now? Why later?”).

The objective of Interim Report I is to document all the findings of Work Package 1 – Completion of the technical knowledge base, in its two main tasks:

1. Technical reassessment of the Feasibility Study: Great. So no more technical reassessment later? By the way, what is a technical reassessment? Do you mean technological reassessment? You have to tell us what answers are you looking for!

2. Completion of the technical knowledge base acquired in the Feasibility Study. Same story here. What do you intend? With what you are going to give us we will have all the technological knowledge to complete the rest of the project? Now if this is the case, let me put it bluntly: you are far from having done it!

As can be seen in the tasks, the main input for Interim Report I is 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). The editing of the overall document is very poor. I will try to pinpoint some cases but I do not think I am the best person to do it. In any case, this is the first time you mention the Feasibility Study. I have seen that you like to use acronyms (too many for my own taste). In any case, here you should have indicated (FS).

The Feasibility Study (And here you should have use FS ... in a nutshell, use FS all the time or stop using it), published on the 7th of May 2015, contains two sets of four options for the Tracking and Tracing System and security features, which are the basis for the technical reassessment:

An important point: I really liked the FS. And think it is a solid and extremely well done document (even though I do not agree with some of its recommendations). The contrast with this Interim Report I is striking (in terms of quality of work, editing, etc.).
Figure 1: Summary of the options proposed in the Feasibility Study

The reassessment also has as an input the comments received during the targeted stakeholder consultation that was online between the 7th of May and the 31st of July 2015.

Despite having stated that the benefits outweigh the costs in all options proposed, the Feasibility Study did not choose a preferred option. When reviewing the options proposed for the Tracking and Tracing system, there were several concerns identified that made it impossible to choose one of the options of the Feasibility Study as such.

OK here is an important point. It is true that the FS did not choose and option but it really made an effort to document each one of them. Now, what are you supposed to do? Are you going to end up choosing? When? What do you need to choose? What have you done to help your client choose?

Despite the concerns identified in each option, it is possible to identify already some benefits and further complexities of implementing certain parts of the options in detriment of others. The main conclusion is that no solution is perfect, and there will be some trade-offs that have to be undertaken on the design of the optimal system. This paragraph is so naïve that it should have never been written (especially in the Executive Summary). “No solution is perfect”? Come on! They taught me that in my first course in my first year in Engineering school!

The same difficulty is present in the options for security features. There is first of all a concern with the fact that all options are applied as a paper stamp. That option is compliant with the TPD, and is operationally feasible, as it can rely on the tax stamps currently in operation in roughly 80% of the countries in the scope of the directive. However, so are other methods of application that were discarded, such as printing the security feature using inks directly onto the product, or a security feature combined with fingerprinting of unique material properties of the package (applied directly on the package, and not onto the paper stamp). I think that here you do not make your point clear enough. I think that the team (according to what I heard in our meeting in Brussels) and most of the relevant stakeholders consider the paper stamp an option...
that should be discarded (and maintained only as an option during an initial period of time if some member states have difficulties to adapt). The specific technologies to be used in each component of the security feature – overt, semi-covert, covert, and forensic – will have to be further analysed (“Further analysed”? why? I thought this was the objective of this WP1. Reduce the options. Give your opinion. Otherwise WP2 –and perhaps 3 and 4 and 5- will continue to be dragging the options), as this is a very fast-paced market, and new solutions may arise on the course of the Implementation Study.

The completion of the technical knowledge base acquired in the Feasibility Study was segmented in three main components – the Tracking and Tracing system, data storage, and security features.

For the Tracking and Tracing system, it was first done a characterisation of the logistics performance of the European Union¹, with a focus on the ability of the Member States to track and trace consignments. The ability to track and trace consignments is a component evaluated on a scale from 1 to 5, in which Germany was the best MS (4.21), and Cyprus and Bulgaria were the worse (2.84). Despite these differences, the Member States appear to be in a good position to implement a T&T system. As I pointed out in Brussels this part here should be eliminated. It makes no sense at all. “Germany is the best Member State with a grade of 4.21 and Bulgaria the worst with 2.84”. So what? Tell us if the tobacco supply chain is capable of handling what the European Commission and Member States want them to do! Can it be done in Bulgaria? Yes, ok then forget about this issue. No? Ok tell what will it require. For example, in Brussels we mentioned that large supermarket chains would probably be unable to read some 2D barcodes. This is important.

When analysing these results, it is possible to identify five main sets of countries, separated by the gaps on their scores (e.g. from UK to Ireland there is a gap of 0.12; from Italy to Spain there is a gap of 0.09; from Portugal to Hungary there is a gap of 0.15; etc.). Grouping the countries as such, the “map” of Europe looks as follows:

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These groups are not definitive, and are subject to further review [Do not do that!] in the next Work Packages of the project, but they may constitute a baseline to start defining the readiness of the distribution chain to implement the T&T system.

There is also an analysis of the item identifiers defined in the Feasibility Study. The Study presented four examples of marking technologies used to provide a unique identifier, and each one was here developed, to provide a better characterisation of the specific technologies that can be applied. [It's true, the FS presented –p.64 and 65- four examples. I do not see in the WP1 a big leap in terms of knowledge in this area –with the exception of 4 paragraphs dedicated to blockchain.]

What is really shocking is the main conclusion extracted from the supposed analysis “With a general understanding of the main types of item identifiers available, it will be possible to make an informed choice as to which is better to identify tobacco products” (p.53 of WP1).

Really? What additional information has been supplied in pages 50, 51, 52 and 53 that now allows you to make an informed choice? What was not already presented in the FS pages 65, 66,67, 68, 69, and 70?

Apart from these, the main conclusion [your conclusion? The FS also pointed it. In fact if I am not wrong it would be illegal for the EU to push for a solution non-compliant with standards] to be drawn is that the T&T system for tobacco products should rely on open standards, because otherwise it may block the innovation in logistics and close the doors to system integration.

Another conclusion that can be drawn is that in the future goods will move even faster and more frequently within logistic networks, which speaks in favour of the real-time (or near real-time) reporting within the T&T system. [This is a shocking conclusion coming from out of the blue. In your document there is no place where info is presented and conclusions extracted as to this is true. First, “future of goods will move faster”. Are you sure? With congestion? Tobacco products are going to move faster than today? Do you know how fast they move today? Is transportation speed and issue today? “Tobacco products will move more frequently”. What do you mean? Frequency? Do you mean that products will move in smaller batches? Are you sure? With the concentration in the industry it might well be the opposite. In any case, what “speaks in favour of real-time (or near real-time) reporting? We want to fight contraband! We want to be sure that only legal products are distributed and sold!]

For the data storage, the completion of the knowledge contained in the Feasibility Study focused on the data storage contracts, regarding the following topics:

1. Improvements on the sizing estimation of the data storage;
2. Inclusion in the “Bid Process Considerations” section of the possibility to have computing resources close to the traceability data.
3. Inclusion in the “General requirements for software/hardware/hosting services” section of requirements related to the communications network performance.

Yes, I read your Table of contents. But this is an Executive Summary. Tell me what is relevant in these three topics! The FS did a top-down sizing approach. You do not seem to like it. Ok, fine. What do you propose? That you will look into it later? Are you sure that their estimated size of 24.11 Kb is really off? by a factor of 10? 100? A million? Have you done a back of the envelope calculation of what the future system will require? When are you going to do it?
You recommend (in the main text p.62) “to request a flexible approach in the agreements and configuration of the performance requirements in order to assure that the Data Storage response times keep sustained rates irrespective of the evolution of the system”. Really? I prefer the FS approach: at least they have thought a little and presented me with a number. But perhaps you are right. The tobacco industry is like space exploration, the deep unknown, and the future system will be Sentinel-2 where Member States, customs and other officials will operate like European physicists looking for new constellation and hidden black holes.

For security features, the Feasibility Study covered a great deal of security features’ options and specific technologies – in a way that there is no need to add any further knowledge at this moment. Really? In fact I think this port of the WP1 is the one where I felt more contribution was done. However, given the pace in which the security technologies change, there is no guarantee that all available features are presented in the Study. Which Study? The FS? Your study –WP1? Technologies change but the Commission will have to say something. In fact they ask you to propose. We are in the Executive Summary. OK. What do you tell me? That you have no clue? Come on!

Additionally, there is also a section on the completion of knowledge regarding the variety of tobacco packaging. This section was added to highlight the differences in the existent packaging options for different tobacco products, and how it may impact the application of serialised unique identifiers. Mentioning this in an Exec Summary is ridiculous. The content of pages 63-68 is unbelievable. Come on you tell me how a pack of cigarettes looks like! Or a pallet!

Concluding, a major recommendation to the high level design of the T&T system is the consideration of alternative options, as per the Inception Impact Assessment:

Two considerations here. A) Are you going to conclude, wrap-up your exec summary. Or are you just throwing another piece of info? B) You mention for the first time the Inception Impact Assessment. You should, at least in the footnote, tell us what is it, how this document fits with the FS and your project.

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### Tracking and Tracing

<table>
<thead>
<tr>
<th>Governance model</th>
<th>Data storage location</th>
<th>Allowed data carriers</th>
<th>Allowed delays in reporting events</th>
<th>Method of adding a security feature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Option A1</strong>: Industry operated solution</td>
<td><strong>Option B1</strong>: Centralised data storage</td>
<td><strong>Option C1</strong>: System with a single data carrier</td>
<td><strong>Option D1</strong>: Real-time (or limited delay) reports</td>
<td><strong>Option S1</strong>: Affixing</td>
</tr>
<tr>
<td><strong>Option A2</strong>: Third party operated solution</td>
<td><strong>Option B2</strong>: Decentralised data storage</td>
<td><strong>Option C2</strong>: System with a limited variety of data carriers</td>
<td><strong>Option D2</strong>: Once daily reports</td>
<td><strong>Option S2</strong>: Printing or integrating through a different method</td>
</tr>
<tr>
<td><strong>Option A3</strong>: Mixed solution (industry and third party)</td>
<td>N/A</td>
<td><strong>Option C3</strong>: Free system allowing any existing data carrier</td>
<td><strong>Option D3</strong>: Once weekly reports</td>
<td><strong>Option S3</strong>: Any method</td>
</tr>
</tbody>
</table>

**Table 1: Alternative policy options of the Inception Impact Assessment**

OK, if I understand you well, this is not yours, this table is contained in the Inception Impact Assessment.

What comes later, is also part of this Inception Impact Assessment? Or is it your contribution? The blocks of options A, B, C, D, and S are largely independent from each other, and all their combinations should be possible. This way, the optimal solution can combine elements that were found on Options 1 and 2 of the Feasibility Study, for instance, ensuring the compliance with all of the TPD requirements.

When all the options are presented in this format, a new, individual analysis has to be conducted, considering the trade-offs that each one presents (e.g. concerning (B) Data storage location, a decentralised data storage may be easier to implement and maintain, but with a centralised data storage it might be easier to treat information and generate reports).

So you finish this Exec Summary telling me we are back in step one? Again I do not want to sound harsh but what have you been able to pull out of all this phase (WP1)?

With the reassessment conducted [a very poor assessment], and with the additional [none or practically none] knowledge gathered, the project team is confident regarding the execution of the next phase, namely the high level design of the optimal system.

I think this project should go through a radical revision. I think there is a lack of understanding of the issues and a very poor management of the project team. This Executive Summary summarises in fact my evaluation:

- Lack of structure
- Poor quality (I frankly think that no effort was put into the job)
- Sloppy edition (it looks like there is no owner of the document but just some cut and paste done in a hurry)

I am not “confident regarding the execution of the next phase”. I sincerely hope I am wrong.
2. INTRODUCTION

The Implementation Study is closely linked with 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 (hereafter the Feasibility Study).

The Feasibility Study\(^4\), published on the 7th of May 2015, contained, among other aspects, four options for the Tracking and Tracing system, four options for security features, some considerations on the necessary data storage contracts, and a cost/benefit analysis of the whole system. These aspects were then assessed during a targeted stakeholder consultation, which was online from the 7th of May 2015 to the 31st of July 2015.

The options proposed in the Feasibility Study are summarised below.

The first work package of the Implementation Study – WP1: Completion of the technical knowledge base – makes the link between the Feasibility Study and the additional work required to reach an optimal system and define its technical requirements. This is clear in the two tasks that compose Work Package 1:

1. Technical reassessment of the Feasibility Study; \textit{I will sound repetitive but the technical reassessment is neither}

\(^3\) Chafea’s call for 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, \url{http://ec.europa.eu/chafea/health/tenders_H11_2013.html}

2. Completion of the technical knowledge base acquired in the Feasibility Study. **OK, but what have you brought new to the table?**

The main objective of task 1 is to check the completeness and coherence of the options proposed in the Feasibility Study. So, **technical reassessment means that you will go through the 4 options, see what they lack and check if they are coherent. Now coherent with what? With who?** To achieve this goal, the project team reviewed the comments received in the targeted stakeholder consultation and the Feasibility Study, and discussed its analysis during the first expert workshop (the workshop was confined to the review function). **But the stakeholders were not only reacting to the 4 options.**

The outcomes of this task include a non-confidential review of the comments from the targeted stakeholder consultation, and a critical review of each option proposed in the Feasibility Study.

For task 2, the main objective is to complete the technical knowledge base contained in the Feasibility Study. **I might be wrong but I think this is not the case. Section 13 covers basically “traceability and security features considerations” and “cost benefit analysis considerations” and your task 2 (chapter 5) covers other issues.**

As an outcome, this task produced commentaries, analytical notes, and necessary revisions of the options proposed in the Feasibility Study.

As the document that summarises all the findings or Work Package 1, the Interim Report I follows the same structure as the work package. The summary of the methodology applied to complete this document is presented below.

Figure 4: Summary of the methodology applied to complete Interim Report I

The non-confidential review of the comments from the targeted stakeholder consultation is summarised in the next chapter, and presented in full in ‘Annex A. Non-confidential review of the targeted stakeholder consultation’. The critical review of each option proposed in the Feasibility Study is summarised in chapter 4, and detailed in Annexes B and C (for Tracking and Tracing options and security features, respectively).
3. REVIEW OF THE COMMENTS RECEIVED FROM THE TARGETED STAKEHOLDER CONSULTATION

The basis for the targeted stakeholder consultation was the Feasibility Study, published on the 7th of May 2015. The targeted stakeholders, namely manufacturers and importers of finished tobacco products, wholesalers and distributors of finished tobacco products, providers of solutions for operating traceability and security features systems, and governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade, were advised to review the Feasibility Study before responding to this consultation, which was online from the 7th of May 2015 to the 31st of July 2015.

The Annex does a better job at presenting the review of the comments received from the stakeholders. This chapter 3 should give a clearer synthesis. For example why do you tell us that 1/3 of the responses come from UK, Belgium and Ireland? How does this help us in WP1?

Overall, the consultation generated 110 contributions, which illustrates a great interest in the subject. The stakeholder group with more responses were the manufacturers of tobacco products destined for consumers (finished tobacco products), but overall, all stakeholders' groups had a good representation. The responses are more centralised geographically, where the United Kingdom, Belgium and Ireland alone count for more than 1/3 of the responses, on a universe of 25 countries represented.

The contributions received from various stakeholder groups are reported in Annex A without additional commentaries. Their proper interpretation requires taking into account specific perspectives represented by individual stakeholders and their groups, including their economic interests related to the development of an EU system for tobacco traceability and security features. This is obvious. The question here is: have you done it? Have you been able to distil what issues or opinions have to be taken into account or which ones have to be discarded?

Most of contributions were based on opinions and views, which are helpful in scrutinising the existing policy options, but given the forward-looking character of the project could not always be supported in hard facts or evidence. What do you mean? There were no hard facts and evidence because they cannot be supplied or because the set-up of the consultation was not providing the means to gather them. The question here is was it worth it and how have you incorporated these views.

Regarding the options proposed in the Feasibility Study, it is difficult to draw firm conclusions from the outcome of the targeted stakeholders' consultation procedure.

I disagree. I have not gone through them as you have but, if you read the feedback from the big manufacturers, it is very easy to draw a conclusion on their points of view.

On the options for Tracking and Tracing, no solution is considered appropriate (by everybody? There is probably no consensus but you knew that would happen), but the comments provided by the respondents enable understanding how each part of the T&T system can be implemented (Great. just tell us. How is each part going to be implemented?). On the options for security features, the main concern is with the fact that all solutions proposed are based on a paper affixed onto the pack. Again, the respondents provided several ways to overcome this issue, via
different technologies being defined at overt, semi-covert, covert and forensic level. And what is your opinion? What do you recommend?

On the cost-benefit analysis there is a general disagreement with the values presented. The respondents (all of them?) consider that the benefits are overestimated, mainly because of the assumptions taken (e.g. all options generating the same benefits, reducing illicit trade in all its components). On the other hand, the costs are considered to be underestimated, because of the assumptions taken and the lack of detail on the calculations taken on each party impacted, especially the manufacturers and operators involved in the supply chain. Do you agree? Do they have a point or is it just them defending their turf?

Regarding the “additional questions” of the Feasibility Study, the responses are, in general, less dispersed, and allow to draw some recommendations on how to progress:

• For the generation of a serialised unique identifier, the majority (what does the minority say) of respondents believe that a single standard provided by a relevant standardisation body is the most effective option, especially with an EU wide standardisation, and using the GS1 standard.

• For the data carriers for a serialised unique identifier, the analysis is segmented onto two items:
  o On the way to implement the data carriers for the serialised unique identifier, the respondents are divided (how are they divided? All manufacturers agree a given solution should be implemented and all the NGOs think the opposite? Do we have 90% agreeing? Is it 50-50%?) between a solution based on a single data carrier (e.g. 2D data carriers, such as DataMatrix and QR Codes, or RFID tags), and a solution based on the minimum technical requirements that allow for the use of multiple data carriers.
  o When evaluating if the system should operate only with machine readable codes, or both with machine and human readable codes the outcome leaves no doubts: the majority (majority meaning? JTI has the same weight as a little NGO from Canada?) of respondents prefer a system operating with both machine and human readable codes, allowing for the consumers to also verify the authenticity of the tobacco packs bought.

• For the physical placement of a serialised unique identifier, most respondents prefer the placement after the pack is assembled and filled with products. There are also comments regarding the physical location of the unique identifier, stating that there needs to be clear requirements regarding this point, as different types of tobacco products will have different packaging methods, and that it must ensure that it doesn’t interfere with any other elements required by legislation, such as tax stamps.

• For the entities responsible for each step of the application of serialised unique identifiers, the majority of respondents consider best to have an “Economic operator involved in the tobacco trade supervised by the authorities” performing all the tasks identified but one – the aggregation of products – in which an “Economic operator involved in the tobacco trade without specific supervision” is preferred. This result points to the notion that control can be achieved through a strict supervision of the economic operators’ activities.
As you can see there is no effort to structure your analysis. Everything has the same weight. You seem to follow the order used in the consultation. You have to make an effort (I think) to help your client: sip through the data and structure it.

For the method of putting the security feature on the pack/ tin/ pouch/ item, there is no one preferred solution, although 'a security feature is printed' was the one selected the most. The respondents justify this choice with the fact that any affixed feature secures only the fixture, and not the product itself.

For the independent data storage, the majority of respondents prefer an accreditation or similar system for multiple interoperable storages (e.g. organised per manufacturer or territory). The respondents consider that a single EU system would have some advantages, but would have massive storage requirements. There were also some critics to a decentralised system (decentralized from a topology point of view?), due to the increased complexity that this would bring to the system.

For the development of reporting and query tools, the responses are split between a provider of solutions to collect the data from the manufacturing and distribution chain, and a provider of data storage services. Actually, many respondents claimed no preference between the two, as long as they have a thorough and sound knowledge and understanding of both the tobacco industry manufacturing/ processes (including IT landscape) and of database concepts.

For the empowerment of individual consumers to decode and verify a serialised unique identifier with mobile devices (e.g. smartphones), the majority of respondents agree with this premise, as it can increase the awareness on the issue of illicit trade, and improve the tools at disposal of the authorities working against illicit trade. There is also the recommendation to combine this system with social campaigns to increase citizens’ knowledge and awareness about the issue of illicit trade.

The inputs gathered in reply to the consultation are of major importance to the technical reassessment of the Feasibility Study. The figure below outlines the main concerns identified, to be considered throughout the rest of the document.
Here is a better example of what I mean. It’s a magma. 17 Pressing concerns! 17 rabbits! You’ll never catch them. You have to prioritize (by nature, in time, ...).

The detailed analysis of responses, where the concerns and recommendations are identified per stakeholder, can be found on ‘Annex A. Non-confidential review of the targeted stakeholder consultation’.

I would really appreciate knowing how this part of the project has helped achieve the objectives of WP1.
4. TECHNICAL REASSESSMENT OF THE FEASIBILITY STUDY

4.1. Critical review of the options proposed for the Tracking and Tracing system

The Feasibility Study proposes four options for the Tracking and Tracing:

- **Option 1** is an industry-operated tobacco traceability solution, with the tobacco manufacturers marking the products in the production line (data storage is done by an independent data storage provider).
- **Option 2** involves one or more solution providers marking the products directly on the production line.
- **Option 3** is a blended solution where each Member State (MS) decides between option 1 and 2.
- **Option 4** is a solution that combines the traceability solution with security features by adding a unique identifier to the security feature. This option is strange, to say the least. Shouldn’t you comment it?

To enable a better understanding of each option, the key principles that define them are presented below:

<table>
<thead>
<tr>
<th>T&amp;T Options</th>
<th>Key principles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Option 1</strong></td>
<td></td>
</tr>
</tbody>
</table>
| - The tobacco industry is responsible for operating the tobacco traceability solution on their sites, making the required data accessible to competent authorities. Generation, application and recording of the unique identifier on tobacco units, including aggregation and shipment events, is performed by the manufacturer using their own and/or industry-developed solution.  
- The economic operators record and submit tobacco tracking events either using their own systems (using the prescribed form for data exchange) or using a solution/device provided by the tobacco manufacturers.  
- Data storage is provided by third party data storage providers (independent of other economic operators) with measures in place to guard against data losses or amendment by unauthorised parties. |
| **Option 2** |  
| - The solution is operated by one or more solution providers that are independent of the tobacco industry. The solution providers implement technology components responsible for serialisation of tobacco items, recording aggregation events, and submission of traceability data to a single European data repository for storing traceability event, with EU Standards ensuring interoperability of the whole solution components.  
- The system provides standard interface for economic operators with automated systems to submit traceability data (receipts and dispatches) to the EU event repository. Alternatively, the providers offer a stand-alone solution component for non-automated/SME distribution chain operators to record the receipt and dispatch of tobacco products, which is also uploaded to the central European event repository.  
- The competent authorities have access to a central EU event repository for monitoring and analysing tobacco traceability data. A further option for Member States may be the replication of this data to support national monitoring activities. |
| **Option 3** |  
| - Option 3 considers a solution where MS decides between option 1 or 2, i.e. whether operated by the industry or a solution provider independent of the industry, and that applies to all tobacco manufacturing and tobacco movements and sales within the MS.  
- The competent authorities have access to a Member State’s tobacco traceability data under controlled circumstances to support risk management, enforcement and investigation activities within the EU community. |
Each MS appoints a data storage provider as the repository for national tobacco traceability data.

European Commission access to data will be limited to providing a mechanism for data queries to operate across MS data repositories. Detailed data analysis will be based on requests to the MS for access to relevant data.

Economic operators operating within a particular MS record distribution chain events either using their own systems then submit to the MS repository using prescribed industry data exchange standards, or use a solution offered by either the tobacco industry or independent solution provider, as applicable for that MS.

Two variations of this third option are considered:

- Option 3a considers the scenario that different Member States may appoint tobacco manufacturers to operate the tobacco traceability solution.
- Option 3b considers each Member State appointing their own solution provider (independent of the tobacco industry).

Option 4

- Synergies between the traceability solution and security feature can be realised. Further synergies and cost savings for those MS that have tax stamps that will fulfill the requirements of the security feature presented in Article 16 of the TPD, and therefore will enable these to be used for this purpose.
- A tobacco control traceability solution which requires that some critical elements be controlled by the MS, whilst less critical functions can be delegated to an independent provider or other players:
  - MS retain key responsibilities considered critical for a tobacco control regime and establish solution components and standards for recording the unique identifier of the secure label applied during manufacture. This equipment is installed in manufacturers’ premises but operated and serviced by a provider independent of the tobacco industry. A data exchange mechanism is specified for manufacturers to provide additional data at time of manufacture (e.g. intended shipment route).
  - Solution components that are considered lower risk such as recording distribution chain events from manufacture to last point prior to retail are operated by the industry and data is submitted to the independent data storage provider using prescribed industry data exchange standards.
- The competent authorities have access to this data under controlled circumstances to support risk management, enforcement and investigation activities within the EU.
- An independent data storage provider stores traceability data (recorded at the time of manufacture or import, and received from the distribution chain operators).
- The Commission operates a query messaging service for the routing of tracing queries that span across multiple Member State data repositories.

Figure 6: Key principles of each option proposed for the Tracking and Tracing system

The assessment of the Tracking and Tracing options is performed from an operational (what do you understand by operational?), technical, legal and financial standpoint. The summary of the review is presented below, while the detailed analysis can be found on Annex B. Detailed review of the options proposed for the T&T system.

4.1.1. Operational analysis

At an operational level, a large part of the requirements are common to all four options. In order to enable a full understanding of the review, the transversal concerns are presented according to the impacted stakeholder.

Manufacturers
Again I think you are not doing a good job here. Do you really mean that packaging design is the main transversal concern of the manufacturers? You need to structure!

One of the main common requirements concerns the packaging design. The unique identifier needs to be accessible during aggregation operations, and needs to comply with the space required for any other legal warnings and tax stamps (where applicable).

Also, different levels of packaging require different localisations for the unique identifier (a detailed description of these can be found on chapter 5.4.1. Variety of tobacco packaging).

These requirements should cover any need for aggregation that may come from the economic operators of the tobacco industry.

The manufacturers are required to have business processes to support the submission of commercial event data (order, invoice and payment records) to the third party data storage providers. In order to automatize these operations, the optimal system should contemplate open standards that enable the integration with ERP and invoice systems.

OK. Now have you read in the manufacturers answers any concern about it? Is there a problem from their side that would not allow them to exchange commercial event data using open standards?

The manufacturers are required to have exception processes in place, with their own system or a system provided by the solution providers, to record damaged or unsellable goods (at various stages of aggregation) that already have unique identifiers assigned to them.

Manufacturers must also use quality control measures that include a rejection process for tobacco items where the unique identifier is absent or unreadable. These controls span downstream in the supply chain, as all economic operators are required to have processes in place to record traceability events for tobacco cartons and packs that may be returned - back to wholesaler, distributor and/or manufacturer (reverse logistics).

Is this point something relevant at this stage? What is your opinion?

When having third party equipment installed in each production line, apart from this equipment, the manufacturers need to provide a secure space to hold the servers and communication equipment operated by the solution provider, and to provide for network connectivity at each production site, for use by the solution providers systems. There may also be the need to accommodate representatives of the solution providers on the production lines for the operation, maintenance and support of the tobacco traceability solution components.

These will require that the infrastructure of the solution providers guarantees the security of all interfaces with the manufacturers' systems, and that all third party representatives present at the production lines need to be placed under the same level of control as the workers of the tobacco industry.

I was surprised when I did not find an important transversal concern (I frankly do not know if grounded on solid facts) that all major manufacturers put forward: the idea that some proposals were illegal (or not in accordance with the letter or spirit of the directive). Now this is serious. Did you check that? Why did you not present this here?

I have not read the 100+ responses but having read 4 or 5 and seeing that you are reflecting their major concerns, leaves me rather nervous.
SME Manufacturers

For SMEs with specific tobacco packaging requirements that may impede the use of direct marking methods for applying the unique identifier, it is proposed to have the solution providers providing an alternative mechanism where the unique identifier is printed at the time of manufacture onto a label, which is then applied to the product.

The utilisation of a label is a good solution even for the variety of packaging units associated with other tobacco products (e.g. hand-packaged cigars), although in these cases the date and place of manufacture may not be so evident.

SMEs can use handheld devices capable of reading the machine-readable unique identifier on unit packets of tobacco to support manual aggregation processes, and the main operational impact envisaged is the additional time required to scan each item during packing operations.

This is a little confusing. You mean that these SMEs operate without any sort of system. They do cigarillos one by one and put them in a home made box?

How many of this sort of really really small companies exist. Are you going to dedicate to them in this WP1 the same amount of paragraphs as JTI and the other three?

Just say if these SME's (how many in Europe) are going to be an issue or not.

In very small operations this may work, but each economic operator will have to assess the risks to operate without redundant devices (e.g. no matter how small the operation, a manufacturer should not rely only on one uTrack device, because if that device breaks down, the whole operation is stopped).

Also, SMEs with low levels of systemisation and/or use of consumer invoicing and accounting software, and with little opportunity for extension and customisation, can operate a stand-alone system for the capture of information required for tobacco traceability purposes.

According to the TDP, supplying the economic operators with a system and equipment for T&T is the responsibility of the manufacturers. This requirement, however, should be applied proportionally, and so, in principle, SMEs will only be covering a very limited part of the costs related to equipping wholesalers and distributors.

So what? What are you telling me? If the conclusion is that we can forget about it, just say it at the very beginning and put in a footnote or an Annex the rest.

Data Storage Providers

The Data Storage Providers will provide a data hosting service in the EU in line with contracts approved by the Commission. When using the information stored, whether for audits, or for standard generation of reports, the Data Storage Providers must ensure that all commercial/trade information is kept safe. Have you read what you have written here? Of course a Data Storage Provider provides data hosting services and they have to keep the information safe. Yes. And a firefighter is suppose not to burn a house.

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1 One uTrack is defined as one PC, two scanners, and all the related software.
Nothing else from the Data Storage Providers? Nothing? If this is really the case, do not mention them!

Economic Operators

Economic Operators (Eos) will be required to scan receipt and dispatch of tobacco products. Do you know if they already do it? (Most probably) The TPD (15.5) also includes “intermediate movements” until unit packets exit their possession. This will include unpacking/ repacking operations, in order to maintain the integrity of the aggregation hierarchy.

EOs will also be responsible for tracking the potential reuse of master cases for new shipments unrelated to the previous master case contents. To ensure integrity of the aggregation hierarchy, the items removed from the original master case would need to have been recorded as such, and the new contents should be scanned if the original label and identifier were to be reused.

You just describe what the TPD requires; but I thought you were presenting the “transversal concerns”. What concerns have appeared?

European Commission

The responsibilities of the European Commission are mainly as defined in Articles 15 and 16 of the TPD. I think you should briefly present them. They are important.

Has somebody from the European Commission responded? What are their transversal concerns? And who are they? What DG?

The Feasibility Study proposed as a requirement in options 1 and 3a to facilitate a joint Government and Industry working group to support the definition of specifications and standards. A critical function of the group during solution development implementation and post implementation is to provide a platform for economic operators to resolve identified issues and track implementation progress.

Nonetheless, the Feasibility Study does not suggest any proper Governance body for the T&T system. Is this your concern or the EU’s concern?

The T&T is a complex and long-term project, with many stakeholders, public and private, and many EU-wide systems to be integrated. The Implementation Study recommends that such challenging environment would be led by a Governance body that engages representatives of all the stakeholders in order to ensure their commitment and that all members’ view are taken into consideration (i.e. the stakeholders are consulted, but decisions linked to implementation lie solely with the Commission in accordance with Article 15 of the TPD).

Such Governance body would manage and coordinate in the medium-long term all the T&T aspects (e.g. technical specifications, reference implementations, operational, economical, legal, political, etc.) through specialised working groups. Moreover, this Governance body could manage external synergies with similar systems such as the implementations of the FCTC Protocol done by other countries that do not belong to the EU. It is envisaged that the implementations of a) the FCTC Protocol, and b) the Articles 15 and 16 of the TPD, have many things in common because they share goals and requirements. Thus, such Governance body could coordinate the exchange of experiences related to those systems in order to benefit all
stakeholders involved. Also, synergies with other similar EU-deployments could be explored as well, such as the pharma domain shall realise in the near future to accomplish the 2011/62/EU Directive.

I do not know if you realize you have not done what you pretend to have done!

Member States Authorities

One of the Member States authorities regular activities are the conduct of market surveillance campaigns to ensure tobacco items are correctly and legibly marked. All options require that these campaigns would also need to verify compliance of products on the EU market and assess levels of illicit items on the internal market, if the traceability solution is to be effective to aid in detection of non-conformant tobacco products on the internal market.

In the case when each MS may operate with a different system, this control will be more complex, because it is normal for the authorities to find tobacco products from other countries, and they will need to be able to authenticate these products. On the other hand, the Member States can keep in contact, so that these products can be easily authenticated, and possible illicit trade schemes may be identified.

Same story here. Member States are an important bunch of stakeholders. Have they answered in one way or another? Or are these two paragraphs just what they look like: a pretty general and superficial consideration of the WP1 team?

Consumers

Across all four options, the Feasibility Study never expects to have any material implications on the consumers.

What do you mean?

Have NGOs or consumer groups said anything? No concerns? At all?

And, if I remember well we do expect consumers to have material implications (whatever “material implications” mean to the authors of this WP1). Concretely, we want to influence their consumption of tobacco and, thinking more “materially”, we could consider them scanning with their phones products to check their legality.

Comments specific to each option

Apart from the transversal impacts, there are also impacts concerning each specific option proposed. The editing of the whole WP1 is very poor. Here is an example (but there are many others). You are going to present the comments to specific options. OK. Now, why don’t you have a section for each one of the 4 options? As stated previously, Option 1 is almost (I agree with you; shouldn’t you specify what part of the system is not operated by the manufacturers) fully operated by the manufacturers, which limits the impact on the supply chain, and leverages on the investments already done by the main producers of tobacco products.

Subject to several alternations (alternation? Does not make any sense), this option may guarantee that the control is maintained by the Commission and the competent authorities. The main point of concern (for who?) to be addressed (by who?) is the fact that the generation of
the unique identifier is performed by the manufacturers. In order to comply with the TPD, and with the FCTC Protocol, the generation of the serialised unique identifier should be the responsibility of the Commission, or a selected third party. This approach is more in line with what happens today in the pharma industry (“more in line”? Is it what the pharma industry does? Can we do what they do? Why not? Or why should we do it?).

The question here is can the codes be generated at the manufacturers facilities and, at the same time, have a 100% guarantee that they cannot be tampered with by the manufacturers. The FS provides already alternatives (p215-216). Here again the WP1, coming after an FS report that has done a pretty significant amount of work, instead of building on their accomplishment (perhaps correcting/ MODIFYING/enriching them) just falls in an exposition of banalities.

After being provided with the codes, the manufacturers can apply and scan them, to perform the aggregation of the products. This way, the manufacturers have control over the aggregation and shipment activities, and the competent authorities have checkpoints after the first scan of the products, after their aggregation and shipment, and throughout the whole supply chain.

The economic operators can then record and submit tobacco tracking events either using their own systems or using a solution/device provided by the manufacturers. Either way, the competent authorities shall receive information at the entry and exit point of each operator, and about the movements (e.g. disaggregation of products) that are done within the boundaries of an operator.

No more concerns from Option 1? The only concern is the generation of the unique identifier? Really?

As opposed to Option1, Option 2 involves the appointment of one or more solution providers to implement an EU wide tobacco traceability solution.

I might be wrong but the following paragraphs seem to indicate that the only concerns related with Option 2 come from manufacturers and Economic Operators. I have read the concerns expressed and, frankly, I do not see them reflected here.

Option 2 requires having third party equipment installed in every production line of the manufacturers, including production lines outside the EU producing to the European market. This way, there needs to be an interface with the manufacturers’ production systems, and ERP and financial systems, to guarantee the availability of all the information required on the unique identifier.

To minimise the impact on manufacturers, a mechanism should be in place for solution providers to monitor all operating sites to ensure tobacco traceability equipment is operating within acceptable parameters, receive alerts, and schedule any required and/or preventive maintenance.

This monitoring system is necessary, but there also need to be SLAs, and penalties in place for when those are not met. Given the volume of tobacco products manufactured for the European market, having a production line stopped because of problems in the solution providers’ systems, even for one hour, has significant impact on the industry.

It is proposed [this is not clear: who proposes the WP1 team or the manufacturers or another stakeholder. You have announced that you were going to put forward the concerns and here comes a few paragraphs that seem to offer your response to these concerns. It is messy. You should clarify what is what] that, during the implementation, the service providers may provide
support to economic operators. This support may include the definition of requirements that outline the necessary preparations to be made by the manufacturers, or support in complying with packaging design and line operations compatible with the T&T system. The solution providers can also work with the economic operators choosing to configure/ enhance existing systems to electronically submit tobacco traceability events.

This support is essential for the implementation of a third party operated system, but the time available for the implementation of Articles 15 and 16 of the TPD may not allow for such a work with all economic operators.

It is also proposed that the economic operators use equipment provided by solution providers for the scanning and recording the receipt, dispatch and logistic operations (disaggregation, re-aggregation). This may work for smaller operators, but usually larger operators have their operations automated, and this may require additional implementation or integration efforts and support from the solution providers.

Despite all the standardisation and interoperability requirements designed by the Commission, option 3 may be the most complex option to operate.

For example, on the manufacturers' side, production lines producing for different MS will need to accommodate as many systems as these MS have chosen. Economic operators operating through different Member States will also have to submit information according to each MS chosen system.

Since option 3 divides itself into either option 1 or 2 per Member State, the main operational concerns are presented on the option 1, option 2, or on the comments transversal to all options. Not clear. It looks like you pretend that Option 3 is identical to option 1 or 2 depending on what a MS decides.

On option 4, manufacturers will be required to source and operate a mechanism for application of the combined security feature and unique identifier on their production line. Where combined with the MS tax stamp requirements, it is anticipated this will have limited additional impact on most manufacturers with tax stamp applicators already fitted on most production lines producing for the EU market. Exceptions will be those markets not currently requiring tax stamps (approximately 20% of tobacco market).

However, to serve as a unique identifier, the tax stamp needs to be placed in an area where it can be easily scanned, and it implies the utilisation of a data carrier that contains all information required by Article 15 of the TPD, which may require modifying or adjusting both the application equipment in each production line and the tax stamp itself.

Solution providers (SPs) will be responsible for maintenance and upkeep of their tobacco traceability related equipment and required operation consumables, and will be required to provide support to economic operators where necessary.

The previous two paragraphs look like a description of option 4. I want to know the non-transversal impacts associated with this option!

To minimise impact on manufacturers, mechanism should be in place for SPs to monitor all operating sites to ensure tobacco traceability equipment is operating within acceptable
parameters, action operational alerts, schedule required and preventative maintenance. As on option 2, there need to be SLAs and penalties in place, to ensure the effectiveness of the system.

4.1.2. Technical analysis

Concerning the technical requirements, as with the operational ones, a large part of the requirements are common to all four options. The main technical topics analysed are presented below.

4.1.2.1. Standardisation

The Commission, by means of implementing acts (Articles 15(11), 15(12) of the TPD), will shape the rules laid down in the TPD by defining the applicable technical specifications with respect to the T&T system and defining the key elements of the data storage contracts.

The overall recommendation is that these specifications are based on standards to the greatest extent possible. Standards promote interoperability, enable the system to be future-proof, and allow for open and fair competition between providers and stakeholders. A standard based system would facilitate the integration with external systems such as international FCTC implementations. Extensions and tailored profiles are recommended just in case current standards do not fulfil entirely the project needs.

Along the technical specification of requirements of the FS, a set of relevant standards and organisations were identified as follows (depending on the option, the standards are required to different stakeholders):

<table>
<thead>
<tr>
<th>Topic</th>
<th>Relevant standards referred in the FS requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifiers</td>
<td>GS1 Global Location Number (GLN) and GLN extension as standard that provides specific prefixes and numbers. This would help on achieving a unique identifier throughout the distribution chain.</td>
</tr>
<tr>
<td></td>
<td>GS1 Serial Shipping Container Code (SSCC) or Global Trade Item Number (GTIN) as tobacco traceability identifiers.</td>
</tr>
<tr>
<td>Record data into the repository</td>
<td>GS1 EPCIS standard with agreed extensions to accommodate TPD Article 15 data elements to transmit data to 3rd party data storage providers in a standard way. The EPCIS standard defines the Capture interface to upload events into a repository.</td>
</tr>
<tr>
<td></td>
<td>Electronic Data Interchange (EDI) format to receive commercial information (e.g. invoice, order, delivery note and payment records).</td>
</tr>
<tr>
<td>Serialisation and data aggregation</td>
<td>Pack / carton / master cases / pallets marking with standards such as DotCode, GS1 data matrix or GS1-128 barcode. Further details can be checked in section Error! Reference source not found.</td>
</tr>
</tbody>
</table>

The suitability of these standards for the T&T system will be further analysed in Work Package 2.
Again a pretty disappointing section. The FS already provided a pretty good introduction on this sort of standardization (p.69 and p. 82-91). What has this half page brought to the table?

4.1.2.2. Integration

The Article 15 of the TPD requires not only traceability information but also commercial information related to invoices, orders, purchasers and payments. In order to comply with the data requirements of the Directive, economic operators will need to add information that is found on their ERP’s, commercial systems and financial systems, among others. You already said that.

In order to provide such commercial information, the economic operators will need to perform integrations to link the T&T system and their native systems. Depending on the degree of automation of their systems, the integration would require a substantial effort to be developed. Come on! This last sentence is empty. This is the sort of things one was hearing about ODETTE in 1986!

To facilitate this integration task, the T&T system will be based on open standards and data models, giving the economic operators the freedom to integrate their systems as appropriate (e.g. using an Enterprise Service Bus that implements out-of-the-box integration patterns between different applications).

4.1.2.3. Database alternatives (distributed vs. centralised)

Not my field but I feel more comfortable with FS point 4.4 (p.92 to 100). One of the fixed decisions of Options 1, 3 and 4 is to have distributed databases (as per TM managed by a 3rd party Data Storage Service Provider or per MS).

It should be noted that the term “distributed” refers not only to the physical location but also to the contents stored in the repositories. As such, the traceability data of each tobacco product should be solely stored either in the database repository of its manufacturer (Options 1 and 3a) or in the database repository managed at Member State level (Options 3b and 4).

The distributed data alternative has the following major implications:

- **Record of traceability movements**. In this distributed alternative, the traceability events should be properly notified to the target repository (i.e. TM for Options 1 and 3a/MS for Options 3b and 4). Thus, the following stakeholders would require to adapt their event notification processes accordingly: TMs because they record the creation and aggregation events on the manufacturing processes, and DCOs because they record logistic event updates (e.g. shipments at a TM/MS or multi-TM/MS level, aggregation, re-packaging, reverse logistics, etc.). If dealing with Option 1 or 3a, it is expected that the TMs can re-use to a great extent their current infrastructure. On the DCOs side, it can be anticipated that the impact is high, irrespective of the option, because they will have to notify events to multiple repositories. However, the complexity of selecting the target repository could be moved to a new central component (i.e. Discovery Service).
which needs to be aware of all the TM/MS repositories and route each event according to its contents.

- **Surveillance.** In this distributed alternative, a global view of the products movement at EU level most probably will require to access multiple repositories (i.e. TM for Options 1 and 3a/MS for Options 3b and 4). Competent authorities will need to conduct traceability data analysis of the events recorded to perform surveillance activities. Thus, a central component (i.e. Discovery Service) is required to span the traceability searches across all these repositories. It can be anticipated that this component most probably will introduce response delays compared to a search in a centralised repository. Hence, there is a performance impact on the surveillance with distributed repositories.

- **Costs** are expected to be higher than a centralised database configuration. The fact is that the distributed database configuration requires the following at a TM/MS level: individual infrastructures and bidding processes (economy of scale cannot be maximised and the small TMs may achieve worst economic conditions from the 3rd party Data Storage Service Provider), cost of sharing algorithms, additional integration processes between repositories and additional auditing procedures. Moreover, the central Discovery Service component has to be developed, deployed and maintained.

- **Risks.** Some high level risks can be anticipated: the required central Discovery Service is complex, the export and integration complexity increases along with the number of repositories, additional complexity in the operational procedures of the economic operators with regards the recording of tobacco movements, and the possibility that a monopoly provider is established.

Concerning the **centralised** data alternative, the main implications are as follows:

- **Record of traceability movements.** The traceability events have to be notified only to one central repository. Thus, the notification mechanisms of the TMs and DCOs stakeholders would be simpler than with the distributed.

- **Surveillance.** In this centralised alternative, a global view of the products movement at EU level could be instantly provided by the central repository. Since there is a unique search engine, there are no additional response delays. Also, the data access implementation is simpler as well: no Service discovery is needed and the implementation of any data related functionality is simpler because no extra logic is needed to maintain the integrity of the information. Hence, the competent authorities can outperform surveillance activities since this database configuration does not pose any functional or technical disadvantage.

- **Costs** are expected to be lower than for the distributed alternative. The main factor is that the number of components are reduced to a minimum as per the
central database. Thus, bidding, maintenance, and integration are simpler and require lower investment (this is coffee/cheap talk).

It should be remarked that the analysis of advantages and drawbacks of each database alternative will be further developed in WP2 because it will be necessary to decide on this topic.

4.1.2.4. Printers and scanners

Regardless of who’s responsible for the operation of the system (the industry or a third party), on the manufacturers’ side, each production line will need printers and/or label applicators to apply the serialised unique identifiers on packs, cartons, master cases and pallets, and scanning equipment to validate the identifiers. This is mind-boggling! Off course we will need printers and scanners! The question might be can the ones already existing be used? How many should be changed? Order of magnitude of investments needed. You tell us nothing! I read this and I feel you make me waste my time, frankly!

These requirements continue to other economic operators in the tobacco supply chain. Wholesalers and distributors will also need scanning equipment, either fixed on automatized environments, or handheld for smaller operations. These requirements could be slightly different according to the economic operator size and its automation level (e.g. a high-speed printer would not be necessary for small distributors).

Standard IT infrastructure and software will also be required, along with connectivity to the third party data storage provider.

The way all these elements impact the T&T system will be further analysed (further analysed! What sort of analysis have you done so far! My impression is that you do not know what you are talking about!), during the course of Work Package 2. However, some of the points that need to be taken into consideration are already identified (obvious these issues have to be taken into consideration):

- **Data carrier**: First, the data carrier chosen needs to fit in the packages’ available space, concerning the information required in Article 15 of the TPD, and as per the TPD packaging requirements. Also, different data carriers have different printing/application speed limits, and this needs to be assessed, to minimise the impact on the production lines (some manufacturers have reported on production lines producing cigarette packs at a rate of 1,000 per minute).

- **Printing techniques**: There are a set of printing techniques available, but the speed of the production lines needs to be taken into account when choosing these. WOW! That’s all you can tell me?

- **Label application**: Most of the manufacturers already have the means to apply labels (in this case, tax stamps), but the current placing may complicate the aggregation activities. This way, the applicators may need to be adjusted, in order to place the stamps on the top of the packs, where they can easily be scanned on the production lines. This shouldn’t have an impact on the speed of the production lines, as most of the manufacturers are currently doing it already.

- **Scanning**: The scanning of unique identifiers requires the reading of the information contained in them, which may pose an impact on the production lines speed. A specific
assessment of the available equipment needs to be conducted, in order to evaluate the speed limits for each of the item identifiers outlined. Again, you tell me nothing at all! These and other questions will be assessed on WP2: High level design of the optimal system.

4.1.2.5. General comments

Technically, there are some global points of concern on the Feasibility Study, namely:

- The fact that the Feasibility Study did not develop the Options on the basis of a common ground of requirements (what do you mean?) led to the situation that the stakeholders’ requirements are not consistent between options (e.g. Option 1 states less requirements to the MS Authorities than in Option 2 where “a business intelligence tool” is expected to be provided). Come on! They are different options! One will oblige MS to do something and another, different, will require MS to do other things. I really have a hard time following your way of thinking.

- The Feasibility Study presents each option as a complete and vertical solution. Each one poses fixed alternatives related to architecture (e.g. centralised database vs. distributed) or governance (e.g. TMs vs. SPs as responsible of the unique identifier serialization). Thus, the Feasibility Study did not explore other combinations of common T&T components (e.g. Data Storage) that may be feasible (e.g. TMs responsible of the unique identifier serialization but using a centralised EU-wide data repository). My understanding is that this is your job! The impression is that the traceability options of the Feasibility Study are driven by the stakeholders’ requirements involved in each option. Well I think the FS did a good job showing what system each of the key stakeholders would prefer. Now it is your job to find commonalities, designing the solution that we will be able to implement.

- Timeliness of records transmission. According to Article 15.7 of TPD, the economic operators shall transmit the recorded data electronically to a data storage facility. As can be seen, the TPD states the requirement of transmission but does not specify the timeliness of such transmission. Nor the FS introduces the timeliness topic and only requires from the economic operators to be able to accommodate temporary interruptions (offline) in connectivity to retry the transmission of events. However, it can be anticipated, as the Inception Impact Assessment also suggests, that at least, two different transmission priorities would be needed in the T&T system: real-time and non-real-time (e.g. daily, weekly, etc.). This topic will be addressed in WP2 when the high level design of the T&T will be developed. It would require exploring optimizations with regards the data transmitted (e.g. aggregate messages), the protocols used (e.g. EPCIS Capture service) and the communication channel infrastructure (e.g. minimum required bandwidth for real-time communications). Why don’t you start addressing this issue?

4.1.3. Legal analysis

The primary requirement of the traceability solution adopted for the tracking and tracing system of tobacco products is the full compliance with Articles 15 and 16 of the TDP; as well as the Article 8 of the FCTC Protocol. The TPD establishes a legal framework with whom the solution
must comply, as it provides concrete details on the content of the unique identifiers, the requirements of the security features, and scope and governance of the system, among others.

With these legal requirements in mind, a critical review of the four traceability solution options proposed in the Feasibility Study has been performed from a legal point of view. The main finding is that there are critical issues (how many? Can you list them now?) in the four options proposed, and all of them need some adjustments or modifications in order to be fully compliant with the legal framework.

One of the main requirements is independence, which is included in article 15(8) of the TPD and in article 8.2 of the FCTC Protocol:

"Each Party shall establish, in accordance with this Article, a tracking and tracing system, controlled by the Party for all tobacco products that are manufactured in or imported onto its territory taking into account their own national or regional specific needs and available best practice".

This requirement discards all the options based on solutions entirely operated by the industry such as Option 1 and Option 3a. Are you sure? This is very similar to some systems already in place in the tobacco industry that have shown themselves inefficient to fight against illicit trade.

A solution owned by the tobacco industry shall be acceptable as far as the competent authorities remain in control of the system – for example, by generating the unique identifier codes that are later applied to the packets, cartons, master cases or pallets by the manufacturers and other control measures. OK. Therefore it looks like something can be done. Can these UICs be generated by the authorities, etc.

You can not as a professional consultant tell your customer in one paragraph “This requirement discards all the options based on solutions entirely operated by the industry such as Option 1 and Option 3a” and then in the following paragraph that yes it could be possible if the generation of a code was properly addressed.

On the other hand, the Feasibility Study brings the attention to the fact that Option 2, Option 3b and Option 4 are based on a system where the solution is provided and operated by an independent solution provider(s), and questions the ‘legal basis’ for granting access to this independent solution provider(s) to the manufacturers’ premises to install and maintain their equipment. However, the mandate of the TPD to establish a tracking and tracing solution for all tobacco products is clear, and economic operators that do not comply with the requirements of the solution will not be authorised to commercialise their products in the EU. The ‘legal basis’, as called by the Feasibility Study, is the TPD itself. If the system to be implemented implies the participation of an independent solution provider, economic operators will need to grant them with access to install and maintain their equipment. Have you read what you have just written?

A third element that should be taken into consideration from a legal standpoint are the liabilities of the solution provider(s). In Options 2, 3b and 4, where the solution is provided and operated by an independent solution provider(s), a clear framework of liabilities needs to be defined in case of:
Any of the two situations described above may have a negative impact on the production lines of the tobacco manufacturers.

Table 2: Summary of the legal review

Any first reflection on these critical legal points?

4.1.4. Financial analysis

The Feasibility Study includes a detailed cost/benefit of the four traceability solution options proposed. When assessing the impacts of the T&T system on economic operators, the FS took the following costs into account:

- Installation of marking/label applicator equipment on production lines;
- Independent line monitoring equipment;
- Monitoring/scanning equipment required for data aggregation;
- Estimated cost for system development effort for manufacturers to provide information required for aggregation (packs, cartons, master cases and pallets), and;
- Cost for compliance monitoring activities.

On the other hand, and although it is unclear to what extent individual Member States will implement additional capacity to oversee a tobacco Tracking and Tracing solution, the costs for Member States include:

- The additional labour force requirements to conduct audits, inspections and enforcement activities, and;
- The development and maintenance of an information system to administer the proposed traceability solution.

Assessing the above costs included both fixed and operating costs for implementation and operation of the solution:

- **CAPEX (Capital Expenses)**:
  - Investment costs associated with implementation of equipment at manufacturing sites, production lines and within the distribution chain. Also included is the required technical infrastructure for data exchange and implementation of the required data storage.

- **OPEX (Operational Expenses)**:
  - Operating costs associated with marking items, packaging materials and associated per-unit costs incurred for process and business activities required to enable the traceability solution. Further, operating costs associated with the information technology infrastructure.

Figure 8: Summary of the fix and operating costs for the T&T system

Benefits wise, the analysis was conducted considering two quantitative factors:

- Public health savings
  - By reducing the supply of under-priced illicit cigarettes, using price elasticity estimates, a reduction in smokers is expected. In addition, academic literature
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proposes a corresponding decrease of expected Non Communicable Diseases (NCD), with an associated reduction in the NCD economic burden for the 28 Member States. Projected public health savings were calculated for each Member State.

- Increased fiscal revenues
  - For each percentage of the current tobacco market that is illicit, a potential tax loss amount can be calculated. Again, depending on price elasticity figures available, tax benefits of implementing a traceability solution can be estimated, given distinct levels of impact – low, medium or high - that such solution could have on illicit trade.

From a qualitative perspective, improving the functioning of the internal market and it [wording makes no sense] aids the objectives of the TPD. A reduction of tobacco consumption could in turn result in consumers smoking less or quitting smoking altogether. If there is a reduction in consumption this could mean less absenteeism from work on a daily basis and possibly a decrease in the number of people retiring early, due to smoking-related health issues. Furthermore, a reduction in smoking will impact the life expectancies of these smokers, thus prolonging their lives to the levels of non-smokers.

Other benefits may include increasing the effectiveness of national tax and health policies, which include curbing tobacco demand and meeting supply objectives, promoting consumer protection and health improvements, fighting illicit trade and criminal organisations and supporting fair economic practices for legitimate tobacco companies and distributors.

The benefit analysis offers a comprehensive approach to all options, showing that 1.32% of the tobacco products in the single market would be affected by the regulation. This production would result in 0.79% of the consumption going legal, and other 0.53% abandoning the habit of smoking.

As a result, the FS estimates 870M euros in public benefits, considering 134M as a reduction of public health expenses and 736M from new tax revenue. Overall, no matter what option chosen, the Feasibility Study concludes that the benefits of its implementation will always outweigh the costs.

Before going any deeper in the analysis, one should bear in mind that a cost/benefit analysis in a preliminary stage is a modelling exercise to estimate the economic benefits and costs of the impact of the implementation of the TPD, and it is challenging to anticipate all of the potential benefits and costs of the system. We know the limitations of any cost/benefit analysis. The question here is will the fundamental decisions be made based on Cost-Benefit models? In this particular case I do not think so.

When performing the initial technical review of the analysis, several areas have been highlighted and should be studied in detail in the analysis of the traceability solution that will be recommended in the Implementation Study, as they may have an important impact of the output of the analysis. What do you mean? That the costs of certain options might end up being higher than forecasted?
4.1.4.1. Technical review of the benefit analysis

Sizing the illicit tobacco trade

One of the first steps of the benefit analysis is to size the volume of the illicit trade of tobacco products in the EU, as one of the main benefits of the implementation of the traceability solution and the security feature is the reduction of the illicit trade.

The Feasibility Study, while recognising that there are studies stating that the illicit trade of tobacco is between 8% and 12% of the total EU market, decided to quantify it in 8.25%.

This figure is mirrored in the TPD Impact Assessment (illicit trade in FMC currently accounts for 8.25% of total trade in the EU (2010) and is estimated to increase by 1% per year in the next five years (Euromonitor data presented in Matrix 2012)).

However, the authors of the Feasibility Study seem to have ignored the estimated increase of 1% per year for the next five years. As the data provided was for 2010, it could easily be inferred that for 2015 the share of illicit trade of tobacco is higher than 8.25%.

In this line, the Inception Impact Assessment also states that “it is estimated that the illicit trade accounts for around 13% of the total consumption of cigarettes in the EU”, as seen in the table below.

<table>
<thead>
<tr>
<th>Illicit trade estimates of cigarettes</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual consumption in million sticks</td>
<td>734,627</td>
<td>705,303</td>
<td>665,839</td>
<td>635,639</td>
<td>596,014</td>
</tr>
<tr>
<td>Illicit trade in million sticks</td>
<td>64,397</td>
<td>73,664</td>
<td>65,612</td>
<td>66,883</td>
<td>67,780</td>
</tr>
<tr>
<td>% penetration of illicit trade</td>
<td>11.39%</td>
<td>13.88%</td>
<td>12.60%</td>
<td>12.79%</td>
<td>13.21%</td>
</tr>
</tbody>
</table>

*Note: figures exclude Cyprus, Luxembourg and Malta*  
*Source: Euromonitor*

Table 3: Illicit trade estimates of cigarettes

Therefore, the selection of 8.25% as the value of the illicit tobacco trade in the EU does not seem the most accurate. A figure around 12-13% could provide a more precise sizing of the illicit tobacco trade, which is crucial to estimate the impact of the benefits of the solutions implemented. Great, but another issue is by how much the illicit trade will go down as a function of the solution picked. My impression is that this percentage might fluctuate much more than the estimate of the future illicit trade. In a nutshell, do not waste too much time here.

Benefits of the different proposed options

According to the Feasibility Study, the benefits resulting from the implementation of the TPD are the same irrespective of the option. This casts some doubts on the FS’s consistency since each option has its own particularities and implications, which may lead to different scenarios.

Well, be my guest. You think that you are going to be able to do a better job? I think the FS did a pretty honourable thing: give an estimate and recognize they have no way of saying if option 1 or option 3, for example, are going to be more effective in fighting illicit trade. My impression...
is that you want to say that any of the 4 options can be made waterproof and that all of them can provide the same level of service to the law enforcing units fighting illicit trade.

If you think this is not so, then tell us and tell us why.

First, the FS recognizes that “there is no effective way to differentiate the benefits from one option to another”. At the same time, it points out that, to a degree, there are a series of variables that may affect the prospective benefits. Therefore, this holistic and comprehensive view brings some vagueness into the analysis and it does not help shed light on the benefits attained.

Secondly, the structure of the illicit market is different in each Member State. This way, even if there are no differences in the benefits generated by each option, it is likely to have different benefits per country. This analysis will be further refined in Work Package 2. My personal view is that it will be very, very related to the instruments each MS puts into fighting this sort of trade. Even if all of them have the access to the same T&T system, the use of it will vary. You should not enter in this discussion.

In such a context, the FS establishes that 1.32% of the market, accounting for 368.9 M packs, all illicit trade, will be affected by the new regulation. However, since this is the outcome of the FS’s chain of assumptions, this percentage is expected to vary.

Overall, this approach towards benefits does not provide enough details for further examination and assessment of the different options, which was the ultimate purpose of the FS. You are hanging yourself. If I was DG Sante I would now ask you to do for me this analysis. You would have a lot of fun.

Impact of the solution in the different modalities of illicit tobacco trade

The benefit analysis of the Feasibility Study states, based on data provided by the TPD Impact Assessment, that an effective T&T system and security features could have the following impact on the illicit trade:

- 30% reduction on contraband;
- 10% reduction on counterfeit;
- 10% reduction on illicit whites.

While the positive impact of an effective system in the reduction on contraband seems feasible, this is not straightforward for counterfeit and illicit whites. It is worth noting that these products could be manufactured outside the European Union and then smuggled into EU territory, escaping the TPD regulation while circulating in the single market. In such a context, the lack of a unique identifier would reveal the illicit nature of the product, but at the same time, it would be an unsecured and cheap product available for consumers. Well this is pretty obvious, right? We all know that a product without a Unique Identifier can always be unloaded in the Port of Barcelona. So what?

This can, however, be offset by the fact that a better monitoring of the legal market will provide the means to precisely determine new inflows of illicit products (given the largely stable demand for tobacco), and hence will provide the enforcement agencies with highly valuable intelligence to work against illicit trade.
This estimated impact on illicit trade reduction has a big influence in the calculation of the total quantification over total market. Thus, these estimations need to be carefully reviewed in order to perform a more accurate benefit analysis.

Do you think that you can come up with a different number, so different that the system will not be built or built differently? I do not think so. Do not waste more energy here. Design the best system to fight illicit trade. Full stop.

**Price elasticity of the tobacco demand**

Assuming a price elasticity of -0.4 for all countries, the Feasibility Study states that, after the implementation of the T&T system, 60% of the current consumers of illicit products will embrace the legal production, assuming the higher costs of these licit products. The remaining portion (40%) will stop smoking or reduce the habit.

The FS's price elasticity is based on scholarly research that recognizes the evidence of higher revenues for the state as the consumers react to the new regulation. These studies stressed that the cigarette demand is characterized by a low price elasticity, which leads to increased tax revenues in terms of tax.6

The price elasticity points out the customer demand degree of response for a given price change. The higher the absolute number, the more reactive customers are to price fluctuations. The chosen rate of -0.4 is consistent with the scholarly research in this area. For comparability purposes, the rate chosen in certain studies for the United States tobacco market, was -0.374, in accordance with the WHO.7

On the other hand, the purchasing power differs between MS, which may lead to differences in the price elasticity registered. This effect will be further analysed during the course of Work Package 2.

Same consideration here. We got the green light for launching a system. We know it is a good thing. Leave it and build the thing!

**Impact of the implementation of the TPD on RSP**

The Feasibility Study relies on the assumption that the implementation of the TPD will not result in an increase of the Retail Sale Price (RSP). However, tobacco manufacturers are likely to weigh some alternatives in response to the new regulation. One of them is the increase of RSP, which may lead to a decrease of the consumption and, consequently, an increase of the expected benefits in terms of the public health objective. The Member States can leverage their influence in prices as well. Through the tax system, the MS could generate higher prices for the final consumer, changing the post-TPD scenario of the FS. With this process, and although the tobacco products’ consumption is decreasing, the Member States can generate more revenues from licit trade, and more savings for the public health systems across the EU. I lost you. You

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7 WHO Factors affecting consumer behaviour, http://www.who.int/tobacco/economics/2_1ffactoraffectingconsumerbehavior.pdf
want to predict how the tobacco market will react to the system? Be my guest! Again, this is a non-relevant point now. You have the political decision, the green light. Build the system!

4.1.4.2. Technical review of the cost analysis

Same cost approach for Options 1-3

The cost analysis of the Feasibility Study is based on the assumption that traceability solution options 1, 2 and 3 represent roughly the same costs. These three options share the same Capital Expenditures and depreciation, and same Operational Expenditures. Although additional costs vary, as well as the annualized total costs, differences are minimal across these three options in the FS. On the other hand, option 4 presents a completely different set of numbers. Following the study’s approach, it is necessary to consider option 4 comprehensively, since the costs are integrated in both the security and traceability components.

Given the different nature of the option 4, the usage of another cost system seems justifiable. Nonetheless, the first three options accounting for almost the same costs cast doubts on the methodology used.

This estimation has not considered the developments of the tobacco producers’ internal traceability system, which is in many cases already operative. Why is that? Do you think this is right? This would entail a completely different picture for the option 1, the industry-operated solution. Considering that cost estimates of options 2 and 3 are based on option 1, these estimates are likely to be unrealistic.

Regarding the other costs of the economic operators, the FS considers them to be the same for all options. This costs standardization for the first three options seems rather a simplification, since the specifics of each option are not taken into account. Likewise, costs associated to the design and implementation of the manufacturer’ solution, and the costs of manufacturers’ sales force are not included.

Cost analysis of the whole supply chain

The Feasibility Study has considered the manufacturers, the wholesalers, and the distributors or other commercial agents in their cost-benefit analysis, which are the economic operators in the scope of the TPD. However, not all the supply chain costs have been factored in.

First of all, the FS has not taken into account the costs associated with the integration of the tracking and traceability solution with all the existing systems of the supply chain. This integration shall allow the different stakeholders to channel all the information required by the TPD in systems such as accounting, invoicing, manufacturing or warehousing.

This technical infrastructure is likely to cover all the payment records, invoice numbers, and movement information. The costs of this infrastructure are likely to be important, according to several stakeholders, since the information must be recorded from manufacturing to the first retail outlet.
Secondly, the FS has considered hardware costs throughout the supply chain, but at the same time, related costs such as testing, research and development, interfacing or technical support have been disregarded (again, order of magnitude? Is it more like 10% of the total investment or 30%? Do has the FS taken into account the overall operation. Some of the stakeholders indicated that the costs for the MS interested in exploiting this T&T would be very important and that, in fact, many countries would not be able to beef up their “tracking teams”. This would concern me. In fact, imagine that you (MS) get access to the accounting, invoicing info of a multinational like Imperial. Is it going to be easy for a civil servant to understand how a partial delivery was managed, etc. These costs can be so huge that, I think they should influence the design of the overall system).

Also, automation and adaptation of distribution lines for the required equipment has not been recognized by the FS (my gut feeling is that this issue in particular is going to be “easy” to tackle). This is particularly relevant since large wholesalers can benefit from economies of scale due to the volumes they manage. However (I do not follow your reasoning. Large wholesalers can benefit from economies of scale. OK. But then you mention an alternative not foreseen?), investments in this kind of equipment exceed by a large margin the FS’s estimation, given that the study did not foresee this alternative.

In this sense, it is worth noting that retailers across the EU are mostly medium size companies, which normally operate just in one country, with limited resources, and different business models (wait a minute! The system does not include retailers. Does it?). Large distributors across the EU are characterized by their heterogeneity and diversity, which introduces another element of complexity in calculating costs which was not contemplated by the FS.

**Missing elements in the cost analysis of the traceability solutions options**

From a technological point of view, one should consider to take into account several elements that are missing in the cost analysis of the Feasibility Study.

- **Communications network**: It will be necessary to setup a low latency communication channel(s) in the recipient side (i.e. Data Storage Infrastructure) that are able to cope with the demanding throughput of the T&T events (I really think you are making a BIG MISTAKE here. Low latency? Why? Or more specifically, low latency where? You probably want to have a system that can not be tampered with. You load a pallet into a truck and the truck gets stopped and we must be able to check, perhaps with some delay, that the pallet was there. I probably do not need to be able to have a instantaneous capability of knowing where every pack of tobacco is. This, I think, makes no sense). The low latency communication channel(s) should be established with the facilities of the economic operators, which send the events to the storage infrastructure. Although in the sender side a normal broadband connection (DSL, Optical Fibre …) could be enough, it has to be stable to ensure the low latency and the connectivity to the recipient. Moreover, in the recipient side, the communication channel(s) should be properly sized to support the huge workload due to the notification of the T&T events.

  You complain that the communication network costs are not factored in in the FS, OK, but can you tell us an order of magnitude. At least, how do they compare (even if later you say that you’ll need to look at them with more detail) with the manufacturers’ labour costs, for example
Another important, I think, reflection. You are going to do a Cost Benefit analysis. Great. From which point of view? The European Commission? Imperial? The Kingdom of Spain? Having done many of those for Public Administrations I would recommend to present the analysis in three levels (Financial Cost-Benefit, Economic Cost-Benefit and Social Cost-Benefit). Do not mix them!

Manufacturers’ labour costs, related to training of the teams who will be involved in the new traceability processes: labelling and event notification. No way. The training is going to be peanuts compared with the increased operating costs. Training is going to be something you do at launching. Might be important. But will be a one of investment. What you have to look in detail is how much more personnel are they going to need to play their role (whichever it is) in the new system.

What I really will have any private stakeholder very worried is going to be the effects of sharing commercial info. Who is going to know if we did a rebate to TESCO? Just making sure leakages of sensitive info like this do not happen is going to be expensive.

Distribution chain operators’ labour costs, related to training of the teams who will be involved in the new traceability process: event notification when a product movement has to be recorded in the T&T system. Same comment.

Update of the manufacturers’ production line procedures. Some of the procedures of the product lines will change because of such new traceability processes. Thus, the documentation and procedures have to be updated and verified accordingly. Are you going to be able to calculate this? I remember a course I took many years ago in Berkeley on cost benefit methodologies. We studied in great detail a particular project (a new airport in London). The whole think went very wrong just because there was no feeling on the level of detail needed to be able to discriminate and support a decision process. Reading you document I have the feeling that you are falling in the same trap.

Manufacturers’ costs of integration with internal IT systems, reporting, evolution of current T&T to new T&T, adaptation of MRP (Manufacturing Resource Planning) Here you surprise me again. First, and MRP (for almost anybody is a Material Requirement Planning system. How is your MRP going to be affected?), accounting, invoicing and warehousing systems in order to provide information such as: customer, order and invoice numbers and payment records.

Manufacturers’ maintenance costs of the new equipment (software and hardware) for printing/ labelling and event notification. The system that will finally be picked will have a minimum impact on the maintenance cost of the equipment. Come on, per pack, knowing what these guys are already printing, how much is additional maintenance going to represent (my feeling is that it is going to be 0). In any case, compared with other costs, I bet my salary it is irrelevant. Put yourself in the shoes of the COO of Imperial. She is probably looking at this project very seriously. Do you think he is thinking about the increase in maintenance costs in her production lines? Well if she is not even thinking about it you shouldn’t either! Give me a break!

Distribution chain operators’ maintenance costs of the new equipment (software and hardware) for printing/ labelling and event notification.
4.1.5. Main conclusions of the assessment of the Tracking and Tracing options

The review of the Tracking and Tracing options proposed in the Feasibility Study presents several concerns with their implementation, and the fact that each option is presented as a complete and vertical solution makes it impossible to choose one of the options of the Feasibility Study as such. Can you at least discard one option? Can you rank the options? Nothing? Well it looks as if your job so far has not been terribly helpful.

When choosing the optimal system, it will be required to explore other combinations of common T&T components (e.g. data storage) that may be feasible (e.g. the manufacturers may be responsible for printing the unique identifier (as per Option 1), but using a centralised EU-wide data repository (as per Option 2)). And why haven’t you started to do it?

When assessing each option individually, Option 1 is completely operated by the manufacturers, which maintains the same concern that exists today with Codentify: the Commission has no control over the generation of unique identifiers and other aspects of the system. Since the generation of codes can be manipulated, it hampers any control (this is not true and the FS was even showing it) that is performed onwards.

Technically, the option to have distributed databases (one per TM another editing recommendation: in the previous paragraph, not very far away, you talk about "manufacturers"; now you use TM and your reader has to stop and think "who the hell are these TM". Be nice to us. Use manufactures or TM for the whole document!) may hamper functionalities that requires access to data (e.g. cross repository search, traceability of multi-TMs pallets, shipments of multi-TMs, re-packaging, etc.). Since the information is spread across repositories, a relatively complex central Discovery Service is required to deal with this data partitioning. Despite the complexity, this option can benefit from the fact that the current TM infrastructure, equipment and software can be re-used to a great extent.

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. AS you mentioned in Brussels, you are going to look into it by gathering legal council. Now, this is a key issue. Do not put effort in describing systems, evaluating (which fortunately you haven’t done so far in great depth) and then later have a good lawyer telling you it is a no go. Go to the lawyer first and let’s not waste our time here!

It is important to notice, though, that control is not ownership or the fact of carrying out certain operational functions, and if the generation of the unique identifiers is performed by the Commission (or an independent third party supervised by the Commission), the manufacturers can apply and scan them, to perform the aggregation of the products. This way, the manufacturers perform the aggregation and shipment activities, and the Commission has checkpoints after the first scan of the products, after their aggregation and shipment, and throughout the whole supply chain, which provides the appropriate level of control.

Option 2 is, in many ways, the perfect opposite of Option 1. In Option 2, one or more solution providers is appointed to implement a community-wide tobacco traceability solution. This means having third party equipment installed in every production line, including the ones that are outside the EU producing to the European market.
Technically, this option runs on a centralised database, which simplifies the implementation of any data related functionality because no extra logic is needed to maintain the integrity of the information. Also, the business intelligence applications can outperform on surveillance tasks, because they have instant access to all the event data. This solution has as a major drawback the higher risk of unavailability, because unexpected issues may arise (e.g. connectivity) and there is a unique access point.

Regardless of the sub-option chosen – 3a: industry operated solution, or 3b: third party operated solution – Option 3 configures itself as the most complex option to operate (e.g. on the manufacturers’ side, production lines producing for different MS will need to accommodate as many systems as these MS have chosen; on the competent authorities side, the technical monitoring and the enforcement activities will also become more complex, as each MS may receive products from other MS, with different data carriers, that still need to be validated).

Technically, and as in Option 1, the databases are distributed, but the similarities end here. The final database scenario of Option 3 is even more complex than in Option 1, because the countries that chose Option 3a may have several databases (one per TM), while the countries that chose Option 3b may have one database with the information of all their TMs. Therefore, in Option 3 the vertical data partitioning would not only depend on the TM, but also on the MS, making the Discovery Service extremely complex.

From a legal perspective, the concerns are the same as in Options 1 or 2, whether the MS chose Options 3a or 3b, respectively.

On option 4, manufacturers will be required to source and operate a mechanism for application of the combined security feature and unique identifier on their production line. Where combined with the MS tax stamp requirements this option has limited impacts, but these MS are only 80% of the total of countries impacted by the TPD.

As with Option 1, this option fixes a set of distributed databases, but at MS level. Option 4 comes with the drawbacks of distributed databases that were already anticipated in Option 1, but the complexity when accessing data is dependent on the specific MS.

You have already explained all of this. I think that a simple table would be more than enough to summarize your views.

Despite the concerns identified in each option, it is possible to identify already some benefits and further complexities of implementing certain parts of the options in detriment of others. The main conclusion is that no solution is perfect, and there will be some trade-offs that have to be undertaken on the design of the optimal system. Yes you love this sentence and you have used it also in the Executive Summary. Again, I would get rid of it, fast.
4.2. Critical review of the options proposed for the security features

For the security features, the Feasibility Study also proposed four options, all applied as a label or paper stamp:

- Option 1: A security feature using authentication technologies similar to a modern tax stamp.
- Option 2: Reduced semi-covert elements as compared to Option 1.
- Option 3: The fingerprinting technology is used for the semi-covert and covert levels of protection.
- Option 4: Security feature is integrated with unique identifier (see Option 4 for traceability).

The specifics of each option are presented below, in order to enable a better understanding of the options proposed.

<table>
<thead>
<tr>
<th>Option</th>
<th>Level 1 (Overt)</th>
<th>Level 2 (Semi-Covert)</th>
<th>Level 3 (Covert)</th>
<th>Level 4 (Forensic)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Optically variable device (Option 1A) or optically variable ink (Option 1B)</td>
<td>• Micro text</td>
<td>• Laser or Machine Readable Taggant</td>
<td>• Forensic Marker</td>
</tr>
<tr>
<td></td>
<td>• Overt guilloche pattern (Security Print Technique)</td>
<td>• UV inks with bi-fluorescence reaction</td>
<td>• Laser or Machine Readable Taggant</td>
<td>• Frangible Paper and adhesive, Die cuts (Kiss cuts) for self-adhesive labels</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Covert Holographic Feature (1A) or Semi-covert Ink Effect (1B)</td>
<td>• Use Track and Trace Serialisation (using traceability options 1, 2 or 3)</td>
<td>• Dry Label and Self Adhesive label</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Fingerprinting Technology</td>
<td>• Available as stacks or reels to suit manufacturers preferences</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Laser or Machine Readable Taggant</td>
<td></td>
</tr>
</tbody>
</table>

The assessment of the options for security features is performed from an operational, technical, legal and financial point of view. The summary of the review conducted is presented below.

This section of the WP1 is very different from the rest of the document. I think the team should use it as a model on how to approach the project.
6. Finally, a flexible approach may make it easier to reach a qualified majority in the Committee (which is what is required for an implementing act).

Despite the reasons for a flexible approach presented here, there are also some challenges when choosing such a system. Primarily, there is the challenge of uniformity, as even with the requirements being set by the Commission, there is still the possibility to have small differences between MS. This may then lead to compatibility challenges, particularly when taking into account that we are operating within an internal market directive.

4.2.1.2. The Minimum Elements for a Compliant Security Feature(s) Solution

The solution selected to implement the security features would consist of the following elements:

1. Unique Identification Number (part of Article 15 of the TPD);
2. Machine readable code as selected by the Commission or Member State (e.g. DataMatrix or QR code);
3. Overt Security Features as selected by the Commission or Member State;
4. Optional Semi-Covert Security Features as selected by the Commission or Member State;
5. Covert Security Features as selected by the Commission or Member State.

Specific recommendations on how to implement each one of these elements can be found on the Feasibility Study. For the specific case of the machine readable code, the knowledge contained in the FS was completed and can be consulted on chapter 5 of this document.

4.2.1.3. Analysis of Member State Systems Already in Place

As part of the research of the potential solutions for the security features, extensive investigation was conducted into the current solutions and security features implemented among the different Member States. As part of this process of looking at security features, 22 European Union Member States were researched with respect to their use of overt, covert and semi-covert security features (these elements are almost all related to the use of current cigarette and tobacco tax stamps). Out of the 22 Member States studied:
1. 15 of the Member States studied already have a visible Unique Identification Number as part of the security feature and 1 Member State has an invisible (covert) Unique Identification Number (thus, of those studied, 73% already use visible or invisible Unique Identification Numbers);

2. 4 Member States studied use a visible (overt) 2D barcode or matrix on the tax stamp (with 1 Member State using a QR code and the 3 others using a 2D matrix) and 1 Member State uses a covert (invisible) 2D matrix code (thus, of those studied, 23% use a visible or invisible 2D barcode).

The national Member State systems studied were as follows: Belgium, Bulgaria, Croatia, the Czech Republic, Denmark, Estonia, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain.

Below are some examples of the visible 2D matrix code and visible QR code on Member State implementations:

<table>
<thead>
<tr>
<th>Country</th>
<th>Type</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hungary</td>
<td>2D matrix</td>
<td><img src="http://www.tax-stamps.com" alt="Image" /></td>
</tr>
<tr>
<td>Italy</td>
<td>2D matrix</td>
<td><img src="http://www.tax-stamps.com" alt="Image" /></td>
</tr>
<tr>
<td>Romania</td>
<td>2D matrix</td>
<td><img src="http://www.tax-stamps.com" alt="Image" /></td>
</tr>
<tr>
<td>Slovakia</td>
<td>QR code implementation</td>
<td><img src="http://www.tax-stamps.com" alt="Image" /></td>
</tr>
</tbody>
</table>

Images from public source: [http://www.tax-stamps.com](http://www.tax-stamps.com)

### 4.2.1.4. Impact on other aspects of the solution

The following paragraphs point out some important considerations regarding the impact of the security features on other aspects of the global solution.

- **Security Features Links with Tracking/Tracing:** One of the more interesting aspects is the coherence of the security feature(s) with the requirements for tracking and tracing. With a Unique Identification Number already being used within 16 of the Member States (15 visible, 1 invisible), this also has an application for tracking and tracing. And in
addition, the 2D barcode (used in 5 Member States – one invisible and 4 visible) can also be one of the key features which can address the tracking and tracing aspects. However, the Unique Identification Number used on tax stamps is unlikely to meet the TPD requirements, as certain obligatory information is available only at the moment of manufacturing, and the 2D barcodes used on tax stamps may not be suitable for printing with sufficient speed for the manufacturing lines of large manufacturers. Both these points will have to be further analysed.

- **Costs Involved**: The cost for implementation and operation of a system will differ significantly from Member State to Member State depending upon existing systems, national solutions providers or parastatal corporations involved in the components and solutions. And as such, it is not possible to generalize such cost estimates. However, there is one well-publicized set of World Health Organization (WHO) information from the Turkey implementation, which indicates that the cost of such overt/covert security features (specifically addressed in the tax stamp) was in the range of $0.10 US dollars per packet of 20 cigarettes. That’s it. This is the sort of info you have to provide. Good Job!

**4.2.1.5. Summarizing the Benefits of a Flexible, Hybrid, Combined, and Member State Decided Solution**

The benefits of a flexible, hybrid, combined and Member State decided solution are manifold, as mentioned here below:

1. Member States can start with existing systems in which they have made considerable investments in some cases, and add-on necessary features in order to achieve full compliance with the TPD;

2. This approach assures solutions neutrality – no one overt/ covert/ semi-covert security features solutions provider or group of solutions providers is favoured over another. This approach allows even solutions which may have been minimized in the Feasibility Study to be considered and be utilized by the Member States;

3. There can be no accusations of “heavy handed” central regulation and control as Member States make their own decisions in compliance with the TPD, keeping in mind that this is an internal market directive, and that a certain amount of harmonisation is relevant, if not desirable;

4. This solution can be and will be coherent with and contribute to tracking and tracing requirements.

**4.2.2. Legal analysis**

The legal framework for the security feature is determined by article 16 of the Tobacco Products Directive.
Very good too. Simple, clear. Loved it!

A detailed analysis of each Method may be found in Annex C. Detailed review of the options proposed for security features of this Report.

In general, three out of the five methods of application of the security feature are compliant with the legal framework. One of them is clearly not compliant and another is too vague in order to be assessed in a conclusive manner.

It is important to highlight that the options analysed are different methods of application of the security features in the packaging, and not security feature configuration themselves. The compliance of each security solution or configuration will need to be assessed individually.

4.2.3. Financial analysis

The Feasibility Study provided a cost analysis of the security features taking into account the four different options defined. For the security features, two main cost dimensions were derived for each package:

- The costs of producing the security features, and;
- The costs of applying such security features to a single production line.

For the first cost dimension, the methodology adopted derived a base scenario that allowed the solution providers to provide a cost range for options 1 and 2. This was applied to all eligible survey respondents (those that were able to provide both overt and covert security features).
production lines are located outside the EU but produce for the European market. This could result in a further rise in costs estimations.

5. On option 4 the FS only suggests production costs, but having in account that approximately 20% of the EU countries do not work with tax stamps, more costs for machinery should be considered for implementing the stamp system in these countries.

6. Additional costs per packaging unit are not the same for all the tobacco products. Given that certain products are manufactured in smaller amounts, the costs are higher for being compliant with the requirements. This has not been taken into account.

4.2.4. Main conclusions of the assessment of the security options

The requirements present in Article 16 of the TPD point to a solution than contain overt, semi-covert (optional), and covert security features. The Feasibility Study provided a thorough analysis of the options available at each of these levels – knowledge that can be reused for the high level design of the optimal system.

The security features, however, are not all contained in Article 16. The serialised unique identifier, which can work as a human readable code, and the machine readable code that come from Article 15 of the TPD can actually also function as security features, authenticating the legality of the tobacco products.

Regardless of the security features chosen for each level, there is the matter of their application onto the packs, pouches or tins. In the options proposed for security features, the Feasibility Study always assumed the application as a paper stamp. That option is compliant with the TPD, and is operationally feasible, as it can rely on the tax stamps currently in operation in roughly 80% of the countries in the scope of the TPD. There may be the need to adapt/upgrade the tax stamps in operation, but that can have a reasonable impact, with added benefits for the Member States.

This option, however, was severely criticised on the stakeholder consultation, where many of the stakeholders pointed to fact that a stamp only secures the stamp itself, and not the product it is applied to. This claim is backed by the fact that many countries currently operate with tax stamps, and illicit trade still occurs.

The concerns with this method of application lead to the analysis of other methods, provided in the Feasibility Study, and that meet the requirements of the TPD, such as printing the security feature using inks directly onto the product, or a security feature combined with fingerprinting of unique material properties of the package.

There may be benefits to let each Member State decide on the security features they want to implement, granted that they follow the requirements defined by the Commission, and that the elements that are part of Article 15 of the TPD are kept interoperable, to ensure a proper integration between Member States.

Much better than the other chapters!
5. COMPLETION OF THE TECHNICAL KNOWLEDGE BASE ACQUIRED IN THE FEASIBILITY STUDY

5.1. Comments, notes and reviews of the options proposed for the T&T system

5.1.1. Characterisation of the logistics performance of the European Union

As I mentioned, this is a useless piece of information. It should be eliminated from the final version of the WP1.

The logistic operators that will be affected by the T&T requirements that we are discussing are so special that whatever Logistics Performance Index you can pull from your sleeve is useless. For example, I just learned that the LPI of Spain is 3.74 and that Denmark is behind us (3.70). What is this telling me? I do know that the logistic systems used by the tobacco industry in Spain is extremely performant.

I think you should go and find out if the logistics performance of the tobacco industry/Supply Chain in each country is ready. Off the bat I do not see a major issue because this is an industry that has been looking for high levels of logistic performance for years (due to the sort of product the deal with, the margins, the controls required by the different States).

The Logistics Performance Index (LPI)\(^9\) is a benchmarking tool created to help countries identify the challenges and opportunities they face in their performance on trade logistics. The LPI is based on a worldwide survey of operators on the ground (global freight forwarders and express carriers), providing feedback on the logistics performance of the countries in which they operate and those with which they trade. Feedback from operators is supplemented with quantitative data on the performance of key components of the logistics chain in the country of work.

The 2016 edition of the LPI allows for comparisons in 160 countries, including all 28 Member States, and across six components:

- The efficiency of customs and border management clearance;
- The quality of trade and transport infrastructure;
- The ease of arranging competitively priced shipments;
- The competence and quality of logistics services;
- The ability to track and trace consignments, and
- The frequency with which shipments reach consignees within scheduled or expected delivery times.

These components are mapped into two categories – areas for policy regulation, indicating main inputs to the supply chain (customs, infrastructure, and services), and supply chain performance outcomes (timeliness, international shipments, and tracking and tracing) – which are aggregated into a single indicator, the overall LPI score. The figure below illustrates the overall view of the LPI.

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Figure 13: Grouping of Member States per ability to track and trace consignments

These groups are not definitive, and are subject to further review in the next Work Packages of the project, but they may constitute a baseline to start defining the readiness of the distribution chain to implement the T&T system.

In theory, the group of countries with a very high ability to track and trace consignments (Germany, Sweden, Belgium, Austria, the Netherlands, and the United Kingdom) should be better prepared for the implementation of the T&T system than the remaining countries. Spain is leading Europe in terms of logistics of civilian explosives. The reason? We had a military threat on them for years. But we also lead the service performance of the physical distribution of pharmaceuticals. Why? Because our retail is very fragmented but, at the same time, our drugstores own (in cooperatives) some very large wholesalers. So who says that Bulgaria is not at the forefront of tobacco logistics performance for some sort of unknown to me reason? However, there are more factors concurring to the readiness of the distribution chain, such as the design of the distribution chain of tobacco products in each country, that need to further reviewed in the following Work Packages of the project.

Despite the additional work that will be done, the LPI provides a baseline to start defining the readiness of the distribution chain to implement the T&T system. From these results, it is possible to make some changes and adjustments to the countries’ groups, enabling the definition of requirements that are in line with the reality of each Member State (or group of Member States) (do you mean that the system will not be implemented across Europe in the same way because of the differences in maturity of the whole of the transport sectors?).

5.1.2. Item identification

The Feasibility Study presented four examples of marking technologies used to provide a unique identifier. The objective of this section is to further develop each one, presenting the specific technologies that can be applied.
Other reason that it has taken so long for RFID to come into common use is the lack of standards in the industry.

NFC stands for Near Field Communication, and, as the name implies, it's a set of close-range wireless communication standards. NFC and RFID are sometimes used interchangeably, but NFC is really a newer version or extension of RFID. NFC also allows two-way communication, as opposed to RFID's one-way reading technology.

NFC tags do not need to be positioned precisely to the scanner, but they need to be close to it (approx. 10 centimetres). The technology allows for 2-way communication between the reader and a single tag. Although present in many smartphones, the technology is still rather costly to use in the industry.

The technology allows for 2-way communication between the reader and a single tag.

Although present in many smartphones, the technology is still rather costly to use in the industry.

Table 8: Examples of radio wave based tags (RFID and NFC)

What you have provided is a little more extended than what p.66 of the FS had already offered.

5.1.2.5. Main conclusions of the analysis

With a general understanding of the main types of item identifiers available, it will be possible to make an informed choice as to which is better to identify tobacco products (really?).

The unique identifier does not need to be implemented with the same technology for all products and/or levels of packaging (e.g. individual packs, pouches or tins can be identified with a 2D barcode, and subsequent levels of aggregation with an RFID tag). Important is to make sure that the technologies used are the ones that best suit the requirements of Article 15 of the TPD, and that will enable an effective scanning throughout the tobacco products supply chain. Such considerations include:

- Which character set needs to be supported? With alphanumeric characters, GS1-128 or QR Code can be the best fit.
- How much space is available on the product packaging? For small packs, UPC, EAN and DataMatrix all offer smaller form factors.
- In which material will the identifier be printed on? For material such as corrugated cardboard, ITF is probably the best option.
- How much data does the identifier need to support? For large amounts of data, PDF147 or RFID tags offer the most storage capacity.
- Will the identifier be also used as a security feature? Although any serialised unique identifier can be considered as a security feature, RFID tags are the best equipped to maintain the security of the products.
- (...)

The answers to the questions above can help guide the selection of the best types of item identifiers for each product and/or level of packaging.
5.1.3. Current industry trends

This section presents additional technological concepts, standards, or initiatives which are worth to be taken into consideration when designing the optimal solution during the completion of WP2.

5.1.3.1. Blockchain as storage alternative

5.1.3.1.1. High level description

Blockchain technology went live in January 2009 being the core of Bitcoin, an open-source project for a transactional internet payment protocol over a decentralized network, with remarkable transactional features: Instant and p2p, low-cost or near zero processing fees, with public auditability and strongly protected.

A blockchain is a structure designed to hold transactions in cryptographically secured sealed structures called blocks that are linked one after another (thus its name). This database is distributed and validated among all the participant nodes of the decentralized network. From a traditional point of view it is like a distributed account ledger where every transaction is an entry signalling movements among accounts plus metadata and even a so-called smart contract. The accounts of the participants are cryptographically tamper-proof identifiers that allows almost anonymous usage.

The public and decentralized nature of a blockchain serves for the first time ever as a digital trust source among untrusted parties allowing to interact with each other without requiring a central party.

After its inception, many other projects have started iterating over the blockchain technology apart from Bitcoin such as Namecoin, Litecoin, Ethereum and Ripple. Every project has its strengths and weakness but for a mature perspective only Bitcoin and Ripple can be checked for this proposal as the public decentralized notary-like part. There should be also needed a central private part (e.g. EU Tobacco T&T agency) to give system access to the recognized supply-chain actors and store private data.

5.1.3.1.2. Applicability to the T&T system

The transactions registered within a blockchain are protected by using digital signatures and naturally forms a continuous trace of asset movements in time. So many use cases arise changing the asset meaning: funds, ownership, shares, etc. Regarding T&T the assets could be registration and ownership transfer events of every tracked item, for instance:

- Manufacturer A registers a production set of pallets Pa, Pb, and Pc within the metadata part of many transactions signed by itself.
- Wholesaler B buys Pa and Pc from A. A registers an ownership transfer transaction of those pallets to B.
- Distributor C buys Pa from B. B registers an ownership transfer transaction to C.
And so on down to the chain, all the events are secured, audit-enabled and non-modifiable but for the owner of the tracked items. At any time items can be queried and show their provenance and public details, for instance, and end-user that scans a QR code from a pack of cigarettes.

5.1.3.2. EPCIS through REST

5.1.3.2.1. High level description

The aim of this section is to introduce the promising approach of having EPCIS services bound to REST in order to achieve better performance. Further analysis on the benefits and drawbacks of such possibility should be undertaken in WP2.

The FS had done a pretty good job (p. 68 to 91). Why don’t you pick up from there and tell us about REST?

EPCIS is the reference standard used in many supply chain systems to share information about the physical movement (i.e. events) and status of products as they travel throughout the supply chain. Many of the EPCIS interfaces are bound to the SOAP (Simple Object Access Protocol) Web services protocol that is based on the XML (eXtensible Markup Language) standard as data format.

As the XML messages introduce some payload, the REST (Representational State Transfer) architectural style was defined to tackle this issue. Currently, REST represents over 70% of public web services. The predominant data format used with REST is JSON (JavaScript Object Notation) which is more efficient than XML.

Concerning security, it should be noted that SOAP and REST do not provide the same security capabilities. Both SOAP and REST support HTTPS/SSL security at transport level, providing security with encryption over the wire. But when the message arrives to the application, only SOAP provides out-of-the-box standard security at message level through WS-Security. So, with WS-Security, even though the message leaves the transport channel it will be still protected.

Although SOAP provides a more complete set of security mechanisms, many private and public companies such as the American National Security Agency (NSA) are coming up with their own security practices over exchanging data with REST services leaving behind the SOAP approach.

5.1.3.2.2. Applicability to the T&T system

Many events will be exchanged through the T&T system. Therefore, any improvement related to this topic, even if it is small, would mean a significant performance improvement in the T&T system for the long term.

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11 OASIS SOAP 1.2 specification, https://www.w3.org/TR/soap/
12 W3C XML specification, https://www.w3.org/XML/
14 https://www.nsa.gov/ia/_files/support/guidelines_implementation_rest.pdf
Ok if I understand you well, using REST would allow to gain a little on performance. Good, I would just say that.

In order to improve the performance of the EPCIS’ client applications, some efforts have been already done to map EPCIS SOAP interfaces to REST. In particular, these efforts addressed the mapping of the EPCIS Core Query interface. These EPCIS mapping efforts are referred below:

- SAP and academia joint research initiative: Giving RFID a REST: Building a Web-Enabled EPCIS15.
- Free and Open Source Software for Track and Trace (FOOSTRACK) EPCIS – REST adaptor16.
- Drupal EPCIS – REST specification17.

Taking into account the T&T needs, the EPCIS Core Capture interface is expected to be widely used because it defines the service that will receive all the traceability events of the tobacco products along the supply chain. Hence, the EPCIS Capture interface is a likely candidate to be mapped to REST/ JSON as well.

It should be noted that the EPCIS Core Capture interface has a HTTP binding based merely on a POST in order to optimize the exchange of data, without any SOAP WSDL definition. However, the EPCIS Capture server expects XML data. This is the point where an optimization can be introduced, receiving JSON data instead of an EPCIS XML event. Afterwards, the JSON event could be transformed to a formal EPCIS XML event.

Regarding security, at the time of writing, is not specified yet the level of security required when exchanging events. So, this approach will be further analysed taking into account all the pros and cons in WP2 when more detailed information would be available.

5.1.3.3. High throughput message broker

5.1.3.3.1. High level description

A key component to foster scalability when dealing with highly concurrent and demanding systems is a high throughput message broker. This component acts as a shock absorber between the flood of events received and those who want to consume them (i.e. the storage system).

Apart from managing large chunks of data, this component also allows connections among a disparate set of systems and platforms, converting them into a single end-to-end standardized and unified platform. Thanks to the pull-based consumption model, it allows the consumers to process the messages at the appropriate speed providing the ability to support streaming data, low latency consumers and even the ones which are offline.

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In essence, it is a publish/subscribe message queue conducted by a distributed transaction log and supported by a highly scalable architecture that ensures low latency end-to-end event communication, guaranteeing high availability and fault tolerance by replication and persistence methods to prevent data loss.

5.1.3.3.2. Applicability to the T&T system

A high throughput message broker, such as Apache Kafka, acting as a data backbone will ensure processing hundreds of millions of events a day and will enable horizontal system demanding scalability to meet the stability and performance needs with commodity hardware — up to 2 Million writes per second on a three commodity machines cluster.

All this is very good. But you have not told us if the T&T will process hundreds of millions of events per day or hundreds of billions, or just millions (or tens of millions). Do you think the order of magnitude is something to address pretty early in a project like that?

Furthermore, as a distributed, partitioned, replicated commit log service, Apache Kafka provides a publish-subscribe messaging based on feeds called topics that can be published and processed by several producers and consumers, respectively.

For the characteristics described above, a solution based on Apache Kafka will be able to receive and smoothly process tobacco movements generated by all stakeholders involved in the manufacturing and distribution chain. Its capabilities are accredited in several well-known enterprise projects, starting with LinkedIn, for which it was developed as central data pipeline in 2010, but also in many other large-scale enterprise systems such as Yahoo, Twitter, or Netflix.

5.1.3.4. Physical Internet

5.1.3.4.1. Description (high level)

Companies constantly strive to improve the efficiency of the logistics networks that move their products. Although performance levels have increased significantly over the years, they are far from satisfactory. For example, far too many containers and freight vehicles transport empty space or are idle because of operational delays. All too often, disruptions prevent products from reaching consumer markets, adding to the waste that pervades many logistics networks.

The Physical Internet proposes to eliminate these inefficiencies in the same way that the Internet transformed the flow of information around the globe.

Before the arrival of the Internet data networks were highly fragmented. Communicating data across companies, especially on an international scale, was relatively costly, slow, and hampered by capacity limitations. Then came the information superhighway, a metaphor taken from the transportation space. The digital highway swept away these barriers by providing a standardized pathway for data transmissions that encircled the world. With a modest investment in equipment, any organization could join the highway. The speed and volume of data flows grew exponentially, as did the rate of innovation in data communications.18

The Physical Internet is a concept that proposes to emulate the “Internet world”, and create a universal, open logistics network that is economically, environmentally, and socially efficient and sustainable.

The main driver of this idea is the Physical Internet Initiative\textsuperscript{19}, a major supply chain project with contributions from both the academia and large supply chain operators (e.g. Boeing, Volvo, Walmart, etc.). In Europe, the Alliance for Logistics Innovation through Collaboration (ALICE), launched by the Commission in 2013, has adopted the concept and is working towards a real-world Physical Internet by 2050.

### 5.1.3.4.2. Applicability to the T&T system

Although a complete Physical Internet is far from being operational, the T&T system needs to take into account its future implications, where the number of steps until reaching the final consumer can increase exponentially [Which steps will increase exponentially?]. The control of the supply chains can, however, be simplified, and tracking and tracing capabilities can be used in more industries than the ones that currently do so.

In a simple way, the Physical Internet aims at replicating what happens on the digital internet. For instance, when an e-mail is sent, that message may be broken up into a bunch of individual packets that are sent separately and then reassembled when the message is delivered.

The Physical Internet could do the same thing by breaking a delivery into packets, or legs. By breaking a trip into legs of 300 kilometres, for instance, each trucker could drive round trip in a day and probably get a return load. Meanwhile, the load itself would be kept in motion, reducing delivery time by 40 or 50%. Transport packaging and space would be modular and standard, which would allow for more efficient and cost effective materials and materials handling equipment. Each of the warehouses and distribution centres in the market would become potential drop-off or pickup locations.

The Physical Internet still has a long way to go before being fully developed, but the commitment made from both public and private organisations may expedite its development and make it a reality before 2050.

The Physical Internet will be further explored and reviewed in WP2 in order to identify if some approach of this initiative could be applied or considered for the long term in the T&T system.

Do you really consider to throw the project into this mess? Just fight the battles you need to fight. Leave the Internet of Things to who it belongs. Tobacco products, and explosives, and bank notes will continue to be distributed in networks that will not look like a digital network distributing bytes. Again, in chapter 4.3 you showed an understanding of the dynamics of this industry and you proposed alternative approaches to make this T&T system a reality. The member of the team that wrote this piece on “The Internet of Things” should need to go a have a coffee with the colleague that wrote 4.3. He will, I am sure, decide not to mention the Internet of Things for the rest of the project!

\textsuperscript{19}Physical Internet Initiative, \url{http://physicalinternetinitiative.org/}
At the time of writing, it is not detailed yet the information that should be stored. Neither the overall information flow, nor the business processes have been defined yet. Thus, in order to provide a more accurate result, the storage sizing estimation will be done in WP2 once the high level design of the T&T system is accomplished.

With the approach introduced below, it is easy to anticipate which entities are the more demanding, how the functional behaviour influences the storage needs and where performance optimisations can be introduced. Also, this approach supports the simulation of different user scenarios, which could be very useful because there are no EU-wide references of systems at this scale and complexity. It is worth to mention that such type of approach is widely used at an enterprise level.

24,11 Kb was a number, something to joggle with. You tell us it is wrong. We do not know if very wrong or just a little wrong. You just tell us it is important to recalculate it, with another approach. I hope you are right and that the extra effort will be worth the wait. Imagine that, as you say in point 7, your new approach reassesses the value by an extra 10% but then you propose (as any good engineer would do) to go for some safety factor of 2 (the sort of things we do when doing pavement or structural design)!

Having a lot of Spaniards in the project (I think) let me share with you what a prof in last year in Civil Engineering told me 35 years ago. I was struggling with some calculations and I told him ("Es que no me cuadra" – “I can't get it exactly right!- The guy look at me and said “Pues redondea” – “Well then round it out”.

5.2.2. Additional bid process consideration

5.2.2.1. Computing resources close to the traceability data storage

The Implementation Study recommends to consider, as part of the bid process, the possibility of having computing resources close to the traceability data storage that also support the deployment of T&T business intelligence applications.

Once the traceability events of the tobacco products are available at the Data Storage of the DSP, the competent authorities would have to develop T&T business intelligence applications to detect and prevent abnormal situations in the tobacco supply chain of the EU market. Moreover, other capabilities such as reporting, alerts or monitoring could be realised by these applications.

In order to foster the T&T applications’ performance and qualitative outcome, it is of great importance that these applications run close to the traceability data (close means in the same facility?). Some advantages of this approach can be anticipated hereafter:

- Users save download time and local storage capacity.
- Export errors are avoided because this intermediate stage is removed.
- Performance increases because the business intelligence applications have a quicker access to the event data (since they are running in the same hosting facility). Quicker? How much quicker? Again we suffer here from not knowing what performance we want the T&T system to have. Again to “detect and prevent abnormal situations” I do not think instantaneous response is needed. You should talk to a cop or a custom official.
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- **Qualitative improvement** of the outcome of the business intelligence applications because:
  - **Reactive notifications to abnormal situations** could be realised in near-real time due to the instant access to the events recently received. Is this useful? How much will it cost to be able to have that response?
    - There is no intermediate export process that takes time and prevents from reacting fast.
  - **More accurate patterns can be analysed** and deducted because the applications have access to the events historical data within the same hosting facility. I do not get it. Data can be in different places and I am sure you can always combine it. Perhaps it’s faster to have it in a single site.

As a reference, it is worth to mention the Grid Processing On-Demand (G-POD) platform from the European Space Agency (ESA). G-POD is a platform for grid processing on demand to promote the access and use of Earth Observation satellite data available at ESA. Scientific users deploy and run Earth Observation applications which have access to the satellite data through the G-POD processing platform. Why do you think this T&T system will have something in common with this ESA platform? Why not an application of a major bank or the actual T&T systems of the tobacco manufacturers?

### 5.2.3. Additional general requirement for software/hardware/hosting services

#### 5.2.3.1. Communications network

This section elaborates on the completion of the technical knowledge base with regards the communications network requirements. The IS considers that the communications network requirements are of great importance because a huge amount of traceability events should be notified to the T&T Data Storage system. As such, many concurrent events could occur at the same time and the communications shall to be designed to support seamlessly the inbound events flood.

Thus, a set of main communications network categories of indicators are introduced hereafter:

- **Effectiveness**: Effectiveness is the capacity of the network to achieve end to end communications in the most effective manner. It is important to know how the network is running and if it would have the ability to deal with high on-demand services with millions of concurrent connections without affecting on it. Some of the key aspects to consider when specifying the effectiveness are: network utilization, link bandwidth, or response time.

- **Performance**: Network performance is the analysis and review of collective network statistics, to define the quality of services offered by the underlying computer network. It is a qualitative and quantitative process that measures and defines the performance level of a given network. This information helps with the improvement of network

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20 ESA G-POD grid processing on demand, 2016, [https://gpod.eo.esa.int/](https://gpod.eo.esa.int/)
21 ESA, 2016, [http://www.esa.int/ESA](http://www.esa.int/ESA)
services. Some of the key aspects to consider when specifying the performance are: data loss, network errors or the amount of data successfully transferred over the network in a given time.

- **Availability**: It is the amount of time over a one-year period that the network remains up and running. This measurement suggests the need to change some aspects of the infrastructure in case of downtimes. Availability can be measured relative to "100% operational" or "never failing." A widely-held but difficult-to-achieve standard of availability for a system or product is known as "five 9s" (99.999 percent) availability.

- **Connectivity**: Network connectivity stands for the process of connecting various devices to a network. Some key aspects to consider related to connectivity are: link bandwidth and redundancy.

At this moment, and during a certain period of time, it would be very difficult to anticipate which will be the workload of the Data Storage and the stakeholders' behaviour. You are capable of knowing how many packs, boxes and pallets the big 4 have managed last year in Europe. You can have an approximate number for a few major wholesalers and small ones. Then extrapolate. If you do not have a difficult, unsurmountable problem, you'll need to do it sooner or later. Do it now and keep refining. In principle, it is expected that the majority of accesses will be for writing purposes, because many events are to be notified to the repository (e.g. aggregation, shipment of products, etc.).

Hence, it is recommended to request for a flexible approach in the agreements and configuration of the performance requirements in order to assure that the Data Storage response times keep sustained rates irrespective of the evolution of the system. In this regard, the Implementation Study anticipates that a phased deployment approach could be necessary. This approach is based on iterative deployments which deliver new functionalities or components in an incremental way and it allows deploying and focusing on the test and integration of the new delivered component or functionality, ensuring their correct integration with the rest of the system. In this way, the performances of the T&T system can be verified after the deployment of any new component or functionality. Additionally, this approach permits to establish priorities (e.g. develop mandatory functionalities first).

Therefore, a monitoring strategy would help on tracking, learning about the T&T system (e.g. read/write usage, peak workloads, etc.), and conclude on usage patterns that will help optimising the system sizing and configuration.

Such monitoring strategy is also used at ESA, which monitors the access to Sentinel-1 Earth Observation data. With the observations made, ESA is able to size the system accordingly, adopt preventive actions (e.g. assure required network performance or identify burdensome capabilities: download or query) and establish realistic scenarios (e.g. access to data older than one month may be marginal in volume).
5.3. Comments, notes and reviews of the options proposed for the security features

Given the pace in which the security technologies change, there is no guarantee that all available features are presented in the Feasibility Study. However, the study covers a great deal of security features’ options and specific technologies – in a way that there is no need to add any further security features at this moment.

On a generic level, all the relevant security features can be found in the Feasibility Study. Chapter ‘4.2.3 Overview of security feature categories’ contains an analysis of overt, semi-covert, covert and forensic security features, as well as an overview of tamperproof and tamper evident features and the main emerging technologies.

On a specific level, a large number of technologies are assessed on chapter ‘7.2.2 Assessment findings of security features’. Despite the concrete assessment made, on the specific level there is a constant evolution of new features which cannot be guaranteed to be found in the Feasibility Study and may even emerge on the market during the course of this current project.

As such, new features might be considered for the implementation of Article 16 of the TPD, even if they don’t appear on the current list, and even if they don’t fit into the current generic categories.

5.4. Other comments and notes

5.4.1. Variety of tobacco packaging

5.4.1. Get rid of this subchapter!

The variety of tobacco packaging is one of the key points of analysis on the implementation of the tobacco T&T system, as the differences in format, shape and material used to pack tobacco products may require different ways to apply the serialised unique identifier, and even the security features.

This chapter highlights the main types of tobacco packaging, with special focus of the first products where the T&T system will be implemented, namely cigarettes and RYO. The information presented is based on Chafea Service Contract 20147102 – Proposals and technical specifications for the use of warning messages on tobacco packages22 – and intends to bring to light some of the information contained in that report.

5.4.1.1. Cigarettes

In Europe, and after the entry into force of the TPD, all packs must have at least 20 cigarettes to leave room for health warnings, which must cover 65 per cent of the front and back of every pack of cigarettes.

The main types of cigarette packs are flip-top and soft packs, as illustrated below.

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5.4.1.6. Water pipe tobacco

Water pipe tobacco has to follow the full regime of the TPD, meaning that this type of tobacco product should display combined health warnings, the general warning and information message.

There are no requirements for package shape and size, but water pipe tobacco is usually sold in fold box, with top tuck, flip-top box, and buckets.

![Fold box of water pipe tobacco](image)

The next levels of aggregation of water pipe tobacco are bundles, master cases, and pallets.

5.4.1.7. Smokeless tobacco, including chewing, oral and nasal tobacco

Smokeless tobacco, such as chewing tobacco, oral tobacco and nasal tobacco are usually sold in tin cans.

Smokeless tobacco, regardless of its specific individual packaging, is further aggregated into bundles, master cases, and pallets.

This point really looks like a bad high school project!