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Health Unit

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TECHNICAL SPECIFICATIONS ATTACHED TO THE REQUEST FOR OFFER

**Request for services Chafea/2015/health/40 for the implementation of Framework
 Contract FWC DIGIT/R2/PO/2013/004 ABC III Lot 2**

**concerning the implementation analysis regarding the technical specifications and other
 key elements for a future EU system for traceability and security features in the field of
 tobacco products**

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1. Title of contract

Implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products

2. Purpose and context of contract

2.1 Purpose

The purpose of this contract is to provide services to and assist the European Commission in the design of a European Union (EU) system for tracking and tracing of tobacco products and for security features, as envisaged in Articles 15 and 16 of the Tobacco Products Directive¹, (hereafter "the TPD"), which was adopted on 3 April 2014.

2.2. Context

The service is to be provided according to the legal and technical requirements set in Articles 15 and 16 of the TPD, described below. In case of discrepancies, the original document takes precedence over the quotes in this document. The services will support the European Commission in developing the implementing and delegated acts envisaged by Articles 15 and 16 of the TPD. In addition, due attention shall be given to all other relevant legal and technical background related to tracking and tracing system and security features, from within the EU and at international level, which might have an impact on the legality, interoperability and general feasibility of the proposed solutions.

The ultimate responsibility for shaping an EU system for traceability and for security (features), as envisaged in Articles 15 and 16 of the TPD, remains in the hands of the European Commission, to avoid any kind of doubt.

With regard to the implementing acts, the European Commission will be assisted by a committee assembling Member State delegations within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers².

2.2.1 Background

a) Illicit Trade

¹ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127, 29.4.2014, p. 1-38.

² OJ L 55, 28.2.2011, p. 13-18.

Illicit trade is broadly defined as any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase, including any practice or conduct intended to facilitate such activity. In the context of the TPD, the main problem consists in the fact that illicit products do not comply with the requirements of tobacco product regulation, in particular with respect to ingredients and labelling rules. Illicit products also create an artificially cheap supply and make tobacco products more affordable. This imposes additional strain on health systems and weakens tax and other measures designed to reduce tobacco consumption. It leads to substantial revenue losses for governments around the world, but generates vast financial profits for illegal traders. These are often used to fund transnational criminal activity.

According to the information collected by **OLAF** (the Commission's Antifraud Office), the total loss in tax revenues amounts to € 10 billion³ annually. According to the calculations carried out for the purpose of the Impact Assessment underpinning the TPD, this corresponds to a market value in the legal supply chain (retail level excluding taxes) of € 3 billion.⁴ Two main types of illicit products should be distinguished: **contraband**⁵ and **counterfeits**⁶. The contraband products can further be divided into the contraband of genuine EU brands and 'illicit/cheap whites'⁷.

b) Articles 15 and 16 of the TPD

Considerable volumes of illicit products, which are not subject to the TPD requirements, are placed on the market. Such illicit products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation. Tackling this problem calls for adequate measures to fight illicit trade which would allow for greater control over the circulation of tobacco products and in turn over their compliance with the TPD.

With this aim in view, it has been decided that an interoperable tracking and tracing system and technical specifications for security features on unit packets of tobacco should be developed at EU level (Articles 15 and 16 of the TPD). For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the product security features. This is intended to enable manufacturers of other tobacco products to benefit from the experience gained prior to the tracking and tracing system and product security features becoming applicable to all remaining tobacco products.

In order to ensure independence and transparency of the tracking and tracing system, it has been decided that manufacturers of tobacco products should conclude data storage contracts with independent third parties. The Commission should approve the suitability of those

³ http://ec.europa.eu/anti_fraud/media-corner/press-releases/press-releases/2011/20110315_01_en.htm

⁴ Impact Assessment of the Proposal for the Tobacco Products Directive, SWD (2012) 452 final (see: http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf), p. 109.

⁵ **Contraband** – products which have been diverted into illicit trade, not respecting the legal requirements in the jurisdiction of destination.

⁶ **Counterfeit** – brand protected products which have been falsified without consent of the brand owner and are not respecting the legal requirements in the jurisdiction of destination.

⁷ **'Cheap whites / illicit whites'** - cigarettes produced (often legitimately) in their country of origin at very low cost, destined to be illicitly sold in other jurisdictions and not respecting the legal requirements in the jurisdiction of destination.

independent third parties and an independent external auditor should monitor their activities. The data related to the tracking and tracing system should be kept separate from other company related data and should be under the control of, and accessible at all times by, the competent authorities of Member States and of the European Commission.

For further details reference is made to Articles 15 and 16 of the TPD.

Article 15 of the TPD requires that all unit packets of tobacco products are marked with a unique identifier⁸ and that their movements are recorded so that tobacco products can be tracked and traced throughout EU. The requirement applies to all products manufactured in and destined for the EU market. The envisaged system covers all economic operators involved in the trading of tobacco products, from the manufacturer to the last economic operator before the first retail outlet.

Article 16 of the TPD requires that all unit packets of tobacco products, which are placed on the EU market, carry a tamper proof security feature composed of visible and invisible elements.

In order to make the system envisaged under the TPD fully operational, a series of implementing and delegated acts are foreseen by Articles 15(11), 15(12) and 16(2) of the TPD. The acts will shape the rules laid down in the TPD by defining the applicable technical specifications with respect to the operation of the tracking and tracing system, including the key elements of the data storage contracts, and the required tamper proof security feature.

c) World Health Organisation (WHO) Framework Convention Tobacco Control (FCTC)

The TPD also aims at meeting the obligations of the EU under the FCTC, which is binding for the EU and all Member States, and at formulating a consistent approach to non-binding FCTC commitments. In particular Article 15 FCTC (illicit trade in tobacco products) and the Protocol to Eliminate Illicit Trade in Tobacco Products, which is expected to enter into force in the coming years, are of relevance.

The Protocol to Eliminate Illicit Trade in Tobacco Products (thereafter "the Protocol") was adopted by the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC) in Seoul, South Korea, on 12 November 2012.

The Protocol among others envisages the establishment of a global tracking and tracing regime, within 5 years of the entry into force of the Protocol, consisting of national tracking and tracing systems controlled by the Parties for all tobacco products manufactured in or imported into its territory. One element of such a system consists of unique identification markings (on packaging of cigarettes and Roll-Your-Own within five years and other tobacco products within 10 years) which will assist in determining the origin and the potential point of

⁸ For the purpose of this tender specification, a unique identifier is construed as a serialised identifier which is guaranteed to be unique among all identifiers used within the envisaged system of tracking and tracing.

diversion and will enable the monitoring and control of the movement of tobacco products and their legal status (Article 8 – Tracking and tracing).

These articles are complemented by provisions on record keeping and security and preventive measures: Article 9 - "Record Keeping" requires that all natural and legal persons engaged in the supply chain of tobacco, tobacco products and manufacturing equipment maintain complete and accurate records of all relevant transactions. Article 10 - "Security and Preventive measures" requires that all natural and legal persons subject to licensing etc. take the necessary measures to prevent the diversion of tobacco products into illicit trade channels (including anti-money laundering measures, reporting of suspicious transactions etc.).

The compatibility of the future EU tracking and tracing system with the requirements of Article 8 of the future Protocol is an important factor in this contract and proposed solutions have to be compatible with the Protocol. This includes legal, as well as technical compatibility.

d) The Feasibility Study on the introduction of the system for traceability and security features

In the context of tender n° EAH/2013/Health/11, Eurogroup Consulting Portugal – Consultoria em gestão, LDA prepared a feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereafter "the Feasibility Study"). The Feasibility Study reaches a conclusion that full traceability of EU tobacco products is achievable.⁹ It also confirms that there are many solutions for security features that meet the TPD requirements.

The Feasibility Study presents four potential solutions for traceability and four for security features. Each of the proposed traceability solutions reflects the basic requirements made under the TPD, i.e. a unique identifier must be affixed to a unit packet at the manufacturing site, while information on a unique identifier along with additional information required by Article 15(2), which are generated during production and distribution of tobacco products, must be saved at an independent data storage facility.

The proposed traceability solutions are as follows:

- Option 1: an industry-operated solution, with direct product marking carried out by tobacco manufacturers; manufacturers are free to select an independent data storage provider;
- Option 2: a solution operated by a third party responsible for the product marking process on the production line; the system operates with one central independent data storage provider;

⁹ The Feasibility Study among others refers to two track and trace solutions for tobacco products that are currently in operation: (a) the SCORPIOS system used in Brazil for tobacco and beverage products and (b) the Codentify system endorsed by the four largest international cigarette companies under the banner of the Digital Coding and Tracking Association (DCTA). The latter system was initially developed by one of the four companies in the aftermath of the anti-contraband and anti-counterfeit agreement between the company and the EU authorities.

- Option 3: each Member State selects between Option 1 and 2 regarding the entity responsible for product marking (manufacture or independent solution provider); the system operates with multiple independent data storage providers;
- Option 4: a unique identifier is integrated with a security feature and affixed in the same process as a security feature; the system operates with (a) independent data storage provider(s).

Regarding the solutions for security features, each option includes several levels of protecting features: overt, semi-covert, covert and forensic. On the basis of various available technologies the Feasibility Study proposes the following four options:

- Option 1: a security feature using similar authentication technologies to a tax stamp;
- Option 2: reduced semi-covert elements as compared to Option 1, where the co-presence of a unique identifier is regarded as equivalent to the semi-covert level of protection;
- Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection;
- Option 4: a security feature is integrated with a unique identifier (see Option 4 for traceability).

The Feasibility Study concluded that no matter which traceability and security feature option is selected, the benefits clearly outweigh the costs from both economic and social perspectives. However, it also recognises that the above options may vary in terms of the likelihood of achieving the full benefits expected from the introduction of traceability and security features.

The Feasibility Study was published on 7 May 2015 (see the link below). The publication was followed by a **targeted stakeholder consultation** launched on the same date. The stakeholders were asked to express their opinions on a number of issues related to the envisaged system for traceability and security features. The stakeholder consultation closed on 31 July 2015.

References:

- Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127, 29.4.2014, p. 1-38.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_127_R_0001
- WHO Framework Convention on Tobacco Control (WHO FCTC)
<http://whqlibdoc.who.int/publications/2003/9241591013.pdf>
- The Protocol on the Elimination of the Illicit Trade in Tobacco Products
http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5_6-en.pdf
Certified True Copies under: http://treaties.un.org/doc/source/signature/2012/CTC_ix-4-a.pdf
- Feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features
http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf

- Targeted stakeholder consultation

http://ec.europa.eu/health/tobacco/consultations/2015_tpd_consultation_en.htm

3. Subject of the specific request for services

As indicated above, the main objective of the contract is to provide the Commission with the necessary input for development of the implementing legislation, based on Articles 15 and 16 of the TPD.

3.1. Scope

- As regards the **tracking and tracing system**, the scope of the contract is the design of an EU wide system for tracking (i.e. forward movement control of products) and tracing (re-constituting the product route back thorough the supply chain) of tobacco products, which have either been manufactured in the EU or are imported into the EU to be placed on the EU market. The scope covers the tracking and tracing of the smallest unit, which is on sale (e.g. packet of cigarettes) and covers the supply chain from manufacturing until the last economic operator before the first retail outlet. The scope includes the generating and marking with a unique identifier, the scanning and recording of a unique identifier, the processing and storing of related data, and the contracting of the data storage facility to an independent third party. The scope also includes the preparation of a model contract for the third party data storage. It is important that the authorities of the Member States and the Commission have access to the stored data, that the confidentiality of the data is ensured, and that adequate access, security, auditing and monitoring mechanisms are in place. Data privacy protection must reflect current EU policy. The entire system must reflect the highest levels of system uptime and failover to ensure no disruptions to industry.

Due attention shall be given to all other relevant legal and technical background related to tracking and tracing system and security features, from within the EU and at international level, which might have an impact on the legality, interoperability and general feasibility of the proposed solutions.

The contractor should look beyond the rules of the TPD to ensure compatibility with other regulations and requirements, such as in the areas of taxation and customs. It should look in particular into Trans-European Customs and Taxations Services, such as EMCS, VIES, Automated Export System. The proposed design of the system, including the minimal technical specifications, should take full account of activities of international organisations and bodies such as WHO, WCO, EUROPOL and INTERPOL, IEEE, OASIS and international standardisation organisations. In particular, the system should be able to manage enquiries through a global information-sharing focal point envisaged under Article 8(1) of the FCTC Protocol.

The options for the tracking and tracing system described in the Feasibility Study are a natural starting point for further design work. However, the contract is not restricted to the solutions described in the Feasibility Study.

- As regards the **security feature for tobacco products**, the scope of the contract covers in principle all available and suitable technologies in use or imminent.

The options for the security feature described in the Feasibility Study are a natural starting point for further implementation work. The contract is, however, not restricted to the solutions described in the Feasibility Study.

- The **geographical scope** of the contract is, in principle, the EU (all Member States). The contract covers the manufacturing in the EU and the manufacturing outside the EU, if the products are destined to be placed on the EU market.

However, as the phenomenon of illicit trade is a global one and international solutions are being developed, the contract also covers international compatibility/interoperability, in particular in view of Article 8 of the Protocol.

In relative terms, the international angle should count for around 5 % under the tasks of this contract, the rest being devoted to the EU dimension.

3.2. Objective of the contract

The objective of the contract is to supply the Commission with all necessary input in order to progress towards the development of the implementing legislation. In order to reach this objective the contractor shall provide:

As regard the tracking and tracing system:

- a technical reassessment of the options proposed in the Feasibility Study in view of the comments received in the targeted stakeholder consultation and in view of its own assessment (completion of the knowledge base);
- a proposal for optimal design including a system architecture diagram and data flows of the entire system with external systems interfaces for tracking and tracing, including the minimum technical specifications required for the establishment and the operation of the proposed system and describing how adequate levels of security and interoperability will be achieved;
- a proposal for optimal design and minimum technical specifications with respect to operating the independent data storage, including the key elements of the data storage contracts envisaged under Article 15(8) of the TPD. Key elements such as data access, security rights and privileges, data retention, archiving and data privacy should be covered.

As regards the security feature:

- a technical reassessment of the options proposed in the Feasibility Study in view of the comments received in the targeted stakeholder consultation and in view of its own assessment (completion of the knowledge base);
- a proposal for optimal design of the system for the security feature, including the technical specifications for the security feature and their possible rotation.

3.3. Tasks

WP 0: Inception phase:

The kick off meeting will take place in Luxembourg. During the meeting, the contractor is expected to make a presentation on the offer, notably on:

- the methodology of the three main work packages (i.e. WP1, WP2 and WP3);
- the organisation and management of the project.

The contractor is expected to assure the participation of the core team, e.g. Project Director, Team Leader, Legal Expert, IT architect and three other members with the required experience specified under point 8) in the kick-off meeting.

One week after the kick off meeting the contractor shall present the minutes of the kick off meeting.

The contractor shall prepare the Initiation Report which shall include the offer jointly with the discussions and clarifications made during the kick off meeting.

Note: No further research is needed in this phase. The methodology shall be detailed enough in the offer for final discussions during the kick off meeting, which in principle should be limited to providing clarifications and minor refinements if needed. Thus, the contractor is expected to be ready for the meeting immediately after the signature of the contract, and to start working on the main work packages immediately after the meeting, as the preparation of the Initiation Report is considered as an important but "administrative" task which does not require specific research.

- Deliverables of WP0: Initiation Report;
- Working place: one day onsite in Luxembourg. The preparation of the meeting, drafting of the minutes and preparation of the Initiation Report will be carried out offsite.

Work Package 1: Completion of the technical knowledge base

1. Technical reassessment of the Feasibility Study

To reassess the options proposed in the Feasibility Study on the basis of:

- (a) the comments received in the public consultation of the stakeholders,
- (b) the technical review of the Feasibility Study conducted by the contractor, and
- (c) the opinions received during the expert workshop.

The task requires the check of completeness and coherence of the proposed options, in particular in terms of overall concept, required functionalities, complete allocation of responsibilities and choreography of processes, in particular from the perspective of technological feasibility. The first reassessment should be carried out under sub points (a) and (b). The expert workshop is confined to the review function as described under Specific Task 1.

- The task under sub point (a) above includes the preparation of a non-confidential technical review of the comments from public consultation of the stakeholders, in which the contractor uses its key competences to scrutinise the validity of the received comments.

The stakeholder consultation was open in the period 7 May 2015 to 31 July 2015. It was prepared in the form of the web-based survey. The stakeholders were asked to express their opinions on a number of issues related to the envisaged system for traceability. In reply to the consultation, 109 respondents decided to submit their comments with the help of the EU survey questionnaire. A limited number of submissions were also delivered outside the survey, by means of mail.¹⁰

- The task under sub point (c) above includes the assistance in the organisation of the expert workshop, the provision of experts with necessary information and materials prior to the workshop, the facilitation of discussions during the workshop and the documentation of the workshop. Further requirements as to the assistance in the expert workshops are explained under Specific Task 1.

2. Completion of the technical knowledge base acquired in the Feasibility Study

To complete the technical knowledge base contained in the Feasibility Study with potentially missing elements, in view of the technical reassessment carried out under Task 1 above. A number of the areas in which further analytical effort may be required are outlined in section 13 of the Feasibility Study.

The task includes the preparation of commentaries, analytical notes and if needed, necessary revisions of the options proposed in the Feasibility Study.

Methodology

As a part of its offer, the contractor shall present a **work plan** including key deliverables as to how Tasks 1 and 2 will be carried out. The work plan shall include:

- (a) a description of the methodology proposed for the revision of the opinions received,
- (b) the assistance in the expert workshop (see also Section 4 and Specific Task 1 below),
- (c) a description of the methodology proposed for the contractor's own technical review, and the analytical work required for the completion of the technical knowledge base.

- The results of Work Package 1 should be summarised in the Deliverable 2: *Interim report I "Tracking and tracing of tobacco products and security features in the EU – Technical review of the Feasibility Study"*.

¹⁰ See: http://ec.europa.eu/health/tobacco/consultations/2015_tpd_consultation_en.htm

- As an annex to Interim Report I, the contractor shall prepare a non-confidential technical review¹¹ of the comments collected during the stakeholder consultation of the Feasibility Study.
- Working place: the contractor is expected to work one day onsite in Brussels and one day onsite in Luxembourg. The rest of the work will be carried out offsite.

Work Package 2: High level design of the optimal system

3. General concept of the system for tracking and tracing, including the third party data storage

To propose a concept of the optimal system for tracking and tracing, including the third party data storage, on the basis of the results of Work Package 1. The proposed concept should define all relevant tasks/responsibilities of the various actors involved in the process along the supply chain.

In particular, the following documents need to be prepared/provided:

- a) business case and project charter;
- b) system architecture;
- c) unified modelling language (UML) sequence diagram (business process flow description);
- d) UML data-flow diagram;
- e) business process diagram.

The proposal should be accompanied by an adequate justification, including risks and benefits, and meet the criteria of:

- (a) technical feasibility,
- (b) interoperability,
- (c) ease of operation,
- (d) system integrity,
- (e) potential of reducing illicit trade,
- (f) administrative/financial burden for economic stakeholders and
- (g) administrative/financial burden for public authorities.

It should also set out why other possible alternatives should not be retained.

The proposed concept must meet the requirements indicated in Article 15¹² and should be compatible with Article 8 of the WHO FCTC Protocol.

¹¹ Non-confidential technical review must not disclose any information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components. It must also not disclose any information relating to an identified or identifiable natural person.

¹² All the Articles referred to in the present list of tasks are the TPD Articles unless otherwise stated.

4. General concept of the system for digital (or alternative) security features

To propose a concept of the optimal system for digital (or alternative) security features on the basis of the Tasks accomplished under Work Package 1. The proposed concept should define all relevant tasks/responsibilities of the various actors involved in the process along the supply chain. The proposal should be accompanied by an adequate justification, including risks and benefits, and meet the criteria of:

- (a) technical feasibility,
- (b) interoperability,
- (c) ease of operation,
- (d) system integrity,
- (e) system security,
- (f) potential of reducing illicit trade,
- (g) administrative/financial burden for economic stakeholders and
- (h) administrative/financial burden for public authorities.

It should also set out why other possible alternatives should not be retained.

The proposed concept must meet the requirements indicated in Article 16.

The proposed concept(s) under Tasks 3 and 4 must be also presented and discussed in the workshop meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts. The input received must be reflected in the final version of the proposed concept(s).

Methodology

As a part of its offer, the contractor shall present a work plan including key deliverables as how to carry out Tasks 3 and 4. The work plan shall include a description of the proposed methodology.

The preliminary findings of the contractor under Tasks 3 and 4 should be presented during a round of workshops: one meeting with independent experts and one meeting with stakeholders, and one meeting with representatives of Member States. All three meetings shall take place in Brussels (regarding the organisation of workshops, see also Section 4 and Specific Task 1 to 3 below).

- The results of Work Package 2 should be summarised in the Deliverable 3: *Interim Report II (D3) "Tracking and tracing of tobacco products and security features in the EU – General concept of the system"*.
- Working place: the contractor is expected to work 3 days onsite in Brussels and 1 day onsite in Luxembourg. The rest of the work will be carried out offsite.

Work Package 3: Preparation and specification of technical requirements

5. Technical specifications for the tracking and tracing system

To develop the technical specifications required for the establishment and the operation of the tracking and tracing system on the basis of the proposed concept under Task 3.

If appropriate, the proposed solutions should allow for maintaining a competitive process (e.g. through the use of accreditation system for entities issuing unique identifiers) which does not favour specific technologies and/or providers.

The proposal must be workable in practice and must be comprehensive, including but not limited to the elements listed below. The contractor shall add/complete the list of essential elements as deemed appropriate with a view to making a complete proposal enabling the Commission to prepare the implementing acts envisaged under Article 15(11). The non-exclusive list comprises the following elements:

- a. Definitions of each type of the system users in terms of their responsibilities and rights;
- b. Technical requirements for and specification of a unique identifier, including a format and a serialization method that enables the uninterrupted use over time, ideally even in the global context;
- c. Legal, operational and technical requirements (including relevant specifications) for (an) organisation(s) to operate a system for the issuance of unique identifiers;
- d. Technical requirements for (a) physical data carrier(s) to be used for a unique identifier in view of Article 15(3);
- e. Rules for placement of (a) physical data carrier(s) referred to in point (d) above in view of Articles 8 to 12 and 14, i.e. other mandatory packaging and labelling requirements;
- f. Specification of the coding format for each of the data items referred to in Article 15(2);
- g. Technical requirements regarding local and temporary data storage required for the functioning of the system and in view of Article 15(6);
- h. Definition of messaging "events", including, for each event, a moment in time and a content of the message transmitted to the third party data storage, in particular in view of Article 15(5);
- i. Technical requirements and specifications regarding the messaging format, which must use the XML standard or open equivalent, a protocol for messaging, message types (e.g. create, search);
- j. Rules for aggregation and disaggregation of unique identifiers, including (i) any additional technical requirements for unique identifiers and their physical data carriers intended for the use at aggregated levels and (ii) necessary alternations to messages transmitted to the third party data storage;
- k. Control mechanisms necessary to ensure the overall integrity of the proposed solution (as to the IT architecture and processes, see also Task 8(j) below);
- l. Definition of all procedures (including exception rules) for deactivation of a unique identifier which is applied to a product that will be removed from the supply chain and destroyed (such as a damaged product deemed unsellable);

- m. Contingency plans, e.g. procedures in case of temporary shutdown of the system or its parts;
- n. Consideration should be given to current industry production practices and production line volume and speed requirements for applying and verifying item identification and labelling to minimise disruptions.

The proposed technical specifications must meet the requirements indicated in Article 15 and should be compatible with Article 8 of the WHO FCTC Protocol.

If the proposed solution includes the use of accreditation system, it will have to detail the rules and requirements applicable to the accreditation bodies as well as to the economic operators seeking accreditation and be in line with the security plan (see Task 8(j) below).

6. Technical specifications for the third party data storage

To develop the service description including the technical specifications required for the establishment and the operation of the third party data storage on the basis of the proposed concept under Task 3.

If appropriate, the proposed service description should allow for maintaining a competitive process (e.g. through the use of accreditation system for providers of the third party data storage) which does not favour specific technologies and/or providers.

The proposal must be workable in practice and must be comprehensive, including but not limited to the elements listed below. The contractor shall add/complete the list of essential elements as deemed appropriate with a view to making a complete proposal enabling the Commission to prepare the delegated acts envisaged under Article 15(12). The non-exclusive list comprises the following elements:

- a. Definitions of each type of the system users in terms of their responsibilities and rights (see also Task 5(a) above) in line with the security plan (see Task 8(j) below);
- b. Performance requirements for a data storage facility, including capacity, input and output operations per second, maximum allowed down-times, maintenance and data retention rules and supported interfaces;
- c. Interoperability requirements for a multi-system and multi-facility storage system, including common data dictionary for storing the data and common validation rules for the data (in full compatibility with the coding formats referred to under point 2(f) above, and with the data dictionary document (see Task 8(f) below));
- d. Interoperability requirements in terms of communication with other systems (e.g. EMCS – Excise Movement and Control System, UN/CEFACT);
- e. Security policy, including back-up policy, physical access rights to facilities, logs, encryption and decommissioning of equipment in line with the security plan (see Task 8(j) below);

- f. Data access and confidentiality policy with respect to handling personal and confidential data, in particular the requirements concerning business secrecy, in line with the security plan (see Task 8(j) below);
- g. Interface requirements to enable the proper functioning of query tools to be used by the Commission and the Member States and for the purpose of exchanges via the global information sharing system envisaged under the WHO FCTC Protocol, in line with the security plan (see Task 8(j) below);
- h. Other technical requirements to enable efficient functioning of business intelligence, reporting et alia;
- i. Minimum requirements in terms of the audit procedures in view of Article 15(8);
- j. Definition of exception rules, e.g. procedures for deactivation of a unique identifier (damaged goods);
- k. Contingency plans, e.g. procedures in case of temporary shutdown of the system or its parts (see also Task 5(m) above);

The proposed service description including the technical specifications must meet the requirements indicated in Article 15 and should be compatible with Article 8 of the WHO FCTC Protocol.

If the proposed solution includes the use of accreditation system, it will have to detail the rules and requirements applicable to the accreditation bodies as well as to the economic operators seeking accreditation.

7. Model contract for the third party data storage service

To prepare a model (template) contract for the third party data storage service (to be concluded between manufacturers/importers and provider(s) of data storage services) on the basis of the proposed concept under Task 3 and the proposed technical specifications under Task 6. The model contract must include all the key ICT and legal requirements in the context of smooth functioning of the EU system of tracking and tracing as envisaged in Article 15. In particular, the model contract must be in line with Article 15(8).

8. IT architecture and processes

To prepare an IT system design in line with the proposed concept under Task 3 and the technical specifications proposed under Tasks 5 and 6.

The IT system design must be based on open standards. Interface technology choices (SOAP, REST, Webservices, etc) must be clearly described and reasoned. The interface specification must be defined using a correct modelling language.

The IT system design should follow the Rational Unified Process (RUP) methodology and as a minimum should contain the following sub-documents (to the extent that the documents were already submitted under WP2 the documents should be updated where needed):

- a. Business case and project charter documents;

- b. System architecture document;
- c. Unified Modelling Language (UML) sequence diagram (business process flow description) document;
- d. UML use cases document;
- e. UML activity diagrams document;
- f. Data dictionary document;
- g. UML data-flow diagram document;
- h. UML communication diagrams document;
- i. Business process diagram document;

In addition, the IT system design should be completed with:

- j. System security plan prepared in line with the Information Technology Infrastructure Library (ITIL) security management process including the definitions of each type of the system users in terms of their responsibilities and rights;
- k. Document describing the reasoning, providing the justifications and the risk analysis to support the system security plan.

9. Technical specifications for the digital (or alternative) security features

To develop the technical specifications for the digital (or alternative) security features and their possible rotation on the basis of the proposed concept under Task 4.

If appropriate, the proposed solution should allow for maintaining a competitive process which does not favour specific technologies and/or providers. The proposal must be workable in practice and must be comprehensive, including but not limited to the elements listed below. The contractor shall add/complete the list of essential elements as deemed appropriate with a view to making a complete proposal enabling the Commission to prepare the implementing acts envisaged under Article 16(2). The non-exclusive list comprises the following elements:

- a. Definitions of each type of the system users in terms of their responsibilities and rights (see also Tasks 5(a) and 6(a) above);
- b. Definition of main counterfeit risks along with respective contingency plans in the event of their occurrence;
- c. Definition of and minimum requirements for overt components of the security feature and a list of overt components available on the market; the list shall be ordered according to an indicative unit price of overt components from the cheapest to the most expensive and mark components that are excessively expensive;
- d. Definition of and minimum requirements for semi-covert components of the security feature and a list of semi-covert components available on the market; the list shall be ordered according to an indicative unit price of semi-covert

components from the cheapest to the most expensive and mark components that are excessively expensive;

- e. Definition of and minimum requirements for covert components of the security feature and a list of covert components available on the market; the list shall be ordered according to an indicative unit price of covert components from the cheapest to the most expensive and mark components that are excessively expensive;
- f. If deemed appropriate: Definition of and minimum requirements for forensic components of the security feature and a list of forensic components available on the market; the list shall be ordered according to an indicative unit price of forensic components from the cheapest to the most expensive and mark components that are excessively expensive;
- g. Compatibility table for the components referred to in points (c) to (f) above; the table shall indicate any cross-exclusions among the components, the compatibility with printing and labelling methods and the compatibility with the tax stamps or national identification marks;
- h. Rules for size and placement of a security feature in view of Articles 8 to 12, 14 and 15(1);
- i. Rules as to the rotation of security features and the level of optionality consented to manufactures of tobacco products;
- j. Legal and operational requirements regarding suppliers of the security feature;
- k. Rules as to the comprehensive management of the proposed system maximising its added value in terms of combating illicit trade.

The proposed technical specifications must meet the requirements indicated in Article 16. Technical specifications must not be confused with individual proprietary technology solutions. Minimum requirements must allow for coexistence of multiple solutions and effectiveness of the rotation system.

If the proposed solution includes the use of accreditation system, it will have to detail the rules and requirements applicable to the accreditation bodies as well as to the economic operators seeking accreditation.

The proposed technical specifications under Tasks 5, 6 and 9, the model contract under Task 7 and the IT system design under Task 8, must be also presented and discussed in the workshop meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts. The input received must be reflected in the final version of the proposed technical specifications and the model contract.

Methodology

As a part of its offer, the contractor shall present a work plan including key deliverables as to how Tasks 5 to 9 will be carried out. The work plan shall include a description of the proposed methodology.

The preliminary findings of the contractor under Tasks 5 to 9 should be presented during a round of workshops: one meeting with independent experts, one meeting with

stakeholders and one meeting with representatives of Member States. All meetings shall take place in Brussels (regarding the organisation of workshops, see also Section 4 and Specific Tasks 1 to 3 below).

- The results of Work Package 3 should be summarised in the Deliverable 4: *Interim Report III "Tracking and tracing of tobacco products and security features in the EU – Technical specifications*.
- Working place: the contractor is expected to work 3 days onsite in Brussels and 1 day onsite in Luxembourg. The rest of the work will be carried out offsite.

WP4: Preparation of the Final Report

The contractor shall prepare a Final Report, which will gather the main findings of WP2 and WP3 (for further details on the content of the Final Report please see section 4 on deliverables).

The draft Final Report shall be submitted no later than 15 months after contract signature.

The contractor will assist the Commission in a peer review of the Final Report organised by SANTE (see below for explanations on Specific task 4).

The draft Final Report and the potential amendments following the peer review process will be discussed with Chafea and the Commission during the final meeting under the contract.

- Deliverable 5: *Final Report "Tracking and tracing of tobacco products and security features in the EU – System architecture and technical specifications"*
- Working place: the contractor is expected to work 1 day onsite in Luxembourg. Eventually and if agreed, the contractor might also work 1 day onsite in Luxembourg/Brussels to support the Commission in the peer review process. The rest of the work will be carried out offsite.

Specific tasks:

In order to carry out the tasks described within the three work packages, the contractor shall, as indicated above in the description of each Work Package, assist in "workshop meetings" with independent experts, stakeholders and experts designated by Member States, as well as a peer review of the final report, as follows:

Specific Task 1: Assistance in workshops with independent experts

- To assist in three one-day independent expert workshops as a part of Work Packages 1 to 3.
- Each independent expert workshop will be organised on the basis of the draft report expected under a given Work Package.
- The draft report should be shared with experts at least a week before the workshop.
- The contractor shall: provide experts with all other necessary information and materials prior to the workshop, facilitate expert discussions during the workshop and document the workshop by preparing the minutes of the meeting summarising

the opinions expressed by independent experts. Further comments may be sent to the contractor as a follow-up to the meetings (see also Figure 1).

DG SANTE will organise the workshops in Brussels. Workshops with independent experts are intended as meetings in which the contractor's work will be reviewed with the aim of checking the quality and consistency of the project's deliverables. The comments received from independent experts should be taken into account in the revised draft report.

Specific Task 2: Assistance in workshops with stakeholders

To assist in two one-day stakeholder workshops as a part of Work Packages 2 and 3. Each stakeholder workshop will be organised on the basis of the contractor's preliminary findings expected under a given Work Package.

- The contractor shall assist in completing the list of stakeholders¹³.
- The contractor will make a presentation on the main findings during the workshop and facilitate the discussions.
- The contractor shall prepare the minutes of the meeting summarising the opinions expressed by stakeholders. Further comments may be sent to the contractor as a follow-up to the meetings (see also Figure 1).

DG SANTE will organise the workshops in Brussels. Workshops with stakeholders are intended as meetings in which the contractor's work will be explained to stakeholders who will be given an opportunity to voice their opinions. Reasoned opinions respecting the regulatory requirements should be taken into account in the revised draft report.

Specific Task 3: Workshop meetings with the experts designated by Member States

- During the meetings organised by DG SANTE (two meetings, see also Work Packages 2 and 3), the contractor will be invited to make presentations on the findings. The presentation along with the draft report should be shared with Member States one week before the meeting will take place.
- The contractor will not need to prepare any minutes of the meeting apart from noting the comments expressed by the experts during and after the presentation. Further comments may be sent to the contractor as a follow-up to the meetings (see also Figure 1).

Meetings with the experts designated by Member States are intended as a means of verification of the contractor's work. The comments received from the experts designated by Member States should be taken into account in the revised draft.

¹³ During the stakeholder consultation following the publication of the Feasibility Study, the four groups of stakeholders were specifically targeted: (a) manufacturers of finished tobacco products, (b) wholesalers and distributors of finished tobacco products, (c) providers of solutions for operating traceability and security features systems, and (d) governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade. However, as to the governmental organisations, in the present project, their input is expected to be provided by the experts designated by Member States (see also Specific Task 3).

Specific Task 4: Assistance in a peer review of the Final Report (D5)

- To assist in organising a peer review of the Final Report (D5). The peer review will be carried out by at least 3 independent experts.
- The contractor shall collect comments by the independent experts and subsequently present its response to the collected comments to Chafea and DG SANTE in writing, and if needed, during a face-to-face meeting with Chafea and Commission services.
- The task includes the assistance in the peer review process organised by DG SANTE, the provision of peer reviewers with necessary information and materials, in particular a copy of the draft Final Report, the timely collection of written comments and if needed, the presence during a face-to-face meeting between peer reviewers and Chafea/Commission services.

As a part of its offer, the contractor shall prepare a list of:

- a minimum of 5 independent experts for the expert workshops organised under Work Packages 1 and 2, and for the peer review process and
- a minimum of 7 independent experts for the expert workshop organised under Work Package 3.

The identity of independent experts may differ (although an overlap is not excluded) for each of the workshops and the peer review. The independent experts must meet the following criteria:

- Apart from their independence from the contractor, the independent experts shall meet the same conditions as the contractor with respect to a conflict of interest (see Section 8)
- Independent experts must have at least 5 years of relevant professional experience.
- Proposed selection of independent experts shall provide for a full coverage of the areas of experience required from the contractor.
- Regarding Work Packages 1 and 2, as a group, independent experts have to cover all the five areas of expertise indicated for a team leader in Section 8.
- Regarding Work Package 3 and the peer review process, as a group, independent experts have to cover all the areas of expertise indicated for team members in Section 8.

The offer should clearly indicate the match between the areas of required expertise and the experience of individual independent experts on the basis of their CVs in Europass format.

Candidatures for independent experts will be discussed during the kick-off meeting.

4. Deliverables

The work carried out by the contractor under the contract will be the subject of the following reports, which must be sent to the Executive Agency by the contractor both in three hard copies and in electronic format, except the Project Initiation Report which has to be delivered only in electronic copy.

Deliverable	Title and description	Week/Month
D1	Project Initiation Report	W6
D2	Interim report I <i>"Tracking and tracing of tobacco products and security features in the EU – Technical review of the Feasibility Study"</i>	M4
D3	Interim report II <i>"Tracking and tracing of tobacco products and security features in the EU – General concept of the system"</i> .	M7
D4	Interim Report III <i>"Tracking and tracing of tobacco products and security features in the EU – Technical specifications"</i>	M12
D5	Final Report <i>"Tracking and tracing of tobacco products and security features in the EU – System architecture and technical specifications"</i>	M18

Detailed description of the deliverables D1 to D5:

- **Initiation Report (D1):** in English.

The contractor shall prepare minutes of the kick-off meeting within 1 week after the meeting and send to Chafea/DG SANTE for approval.

The contractor shall present a draft Initiation Report within 3 weeks that will provide Chafea/DG SANTE an opportunity to check whether the work is on track and whether it is focused on the specified needs.

The Final Initiation Report has to be delivered within six weeks after the signature of the contract. It shall include a detailed and fully updated work plan and methodology based on the initial offer and the discussions during the kick-off meeting.

- **Interim Report I (D2):** in English.

Interim Report I will deliver the results of work carried out under Tasks 1 and 2. In particular, it will provide a reassessment of the Feasibility Study based on: (a) the comments received in the public consultation of the stakeholders, (b) the opinions received during the expert workshop and (c) the technical review conducted by the contractor.

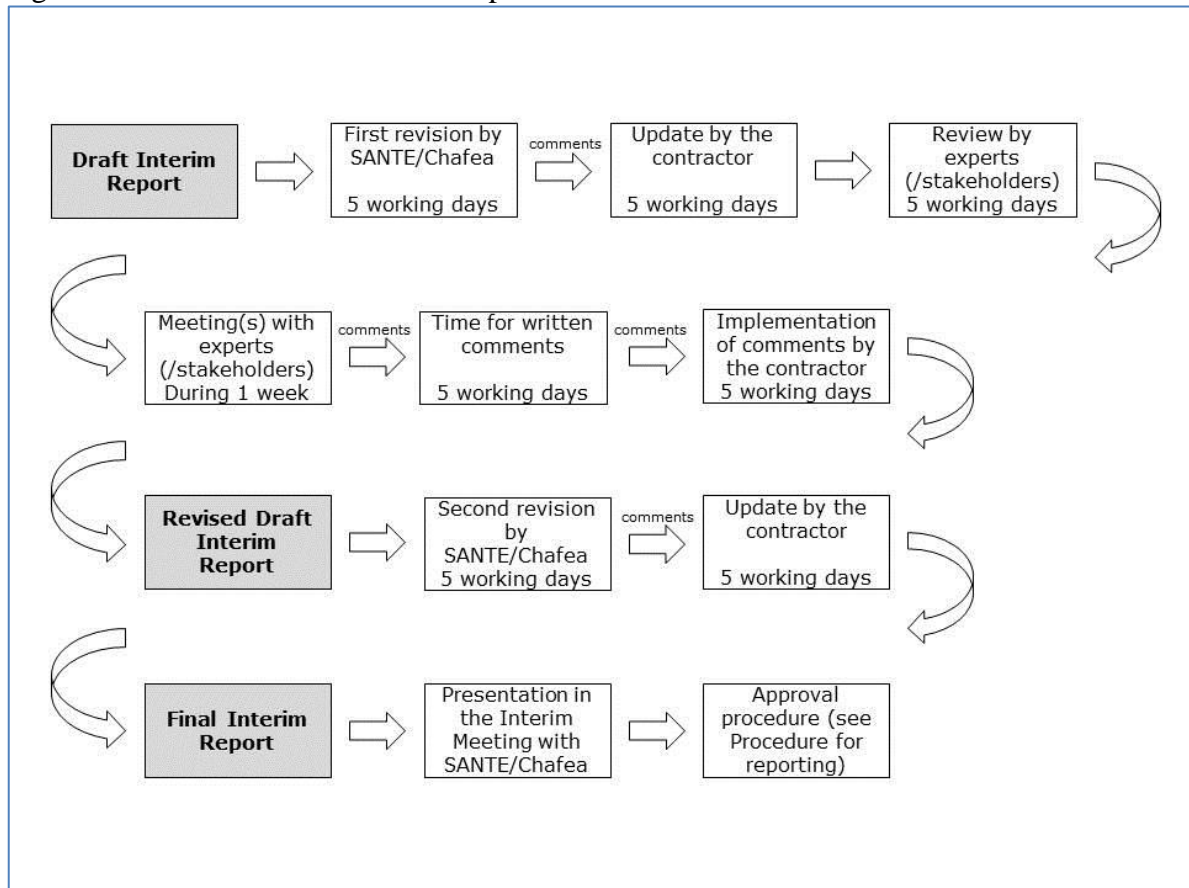
As an annex to Interim Report I, the contractor shall prepare a non-confidential technical review of the comments collected during the stakeholder consultation of the Feasibility Study.

Steps:

- Draft Interim Report I has to be delivered no later than 2 months after contract signature.
- Draft report shall be presented and discussed during the expert workshop.

- Final Interim Report I has to be delivered no later than 4 months after contract signature.
- Intermediary steps between the draft and the final versions of the Interim Report are shown in Figure 1.
- The contractor will present the Final Interim Report I during a meeting in Luxembourg no later than 4 months after contract signature.

Figure 1: Workflow chart – Interim Reports



Sub-deliverables:

1. Minutes of the expert workshop (as specified under Specific Task 2).
2. Update on the implementation of the work plan.

• **Interim Report II (D3):** in English.

Interim Report II will deliver interim results of work carried out under Tasks 3 and 4. It will describe the proposed concepts for the optimal systems for (a) tracking and tracing, including the third party data storage and (b) security features. In particular, the proposed concepts will include the definition of main activities and related responsibilities of the various actors involved in the process along the supply chain.

Steps:

- Draft Interim Report II has to be delivered no later than 5 months after contract signature.

- A draft report shall be presented during the workshops/meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts relating to the concepts for the optimal systems.
- Final Interim Report II has to be delivered no later than 7 months after contract signature.
- Intermediary steps between the draft and the final versions of the Interim Report are shown in Figure 1.
- The contractor will present the Final Interim Report II during a meeting in Luxembourg no later than 7 months after contract signature.

Sub-deliverables:

3. Minutes of the expert workshop (as specified under Specific Task 2).
4. Minutes of the stakeholder workshop (as specified under Specific Task 3).
5. Presentation at the meeting with the experts designated by Member States (as specified under Specific Task 4).
6. Update on the implementation of the work plan.

- **Interim Report III (D4):** in English.

Interim Report III will deliver interim results of work carried out under Tasks 5 to 9. In particular, it will include:

- a. the technical specification document required under Task 5,
- b. the service description document required under Task 6,
- c. the technical specification document required under Task 9.

As separate annexes, Interim Report III will include a draft version of the model (template) contract for the third party data storage (as prepared under Task 7) and a draft version of the IT system design (as prepared under Task 8).

Steps:

- Draft Interim Report III has to be delivered no later than 10 months after contract signature.
- A draft report shall be presented during the workshops/meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts relating to the concepts for the optimal systems.
- Final Interim Report III has to be delivered no later than 12 months after contract signature.
- Intermediary steps between the draft and the final versions of the Interim Report are shown in Figure 1.
- The contractor will present the Final Interim Report III during a meeting in Luxembourg no later than 12 months after contract signature.

Sub-deliverables:

7. Minutes of the expert workshop (as specified under Specific Task 2).
8. Minutes of the stakeholder workshop (as specified under Specific Task 3).

9. Presentation at the meeting with the experts designated by Member States (as specified under Specific Task 4).
10. Update on the implementation of the work plan.

- **Final Report (D5):** in English (except the summary to be provided in both English and French)

Steps:

- A draft Final Report shall be subject to a peer review process no later than 15 months after signature of the contract. The peer review will be conducted over three weeks by at least three independent experts (for the relevant requirements see Specific Tasks 1 and 2). As an outcome of the peer review process, the independent experts will prepare written commentaries as to the extent the draft Final Report meets the requirements of this tender, in particular delivers on each of Tasks 3 to 9 explained in point 3.3 above. DG SANTE will share the written commentaries by the independent experts with the contractor within maximum 5 working days from their receipt.
- The draft Final Report along with potential amendments following the peer review process must be submitted to Chafea no later than 17 months after signature of the contract and will be presented during the final meeting described in point 5 of the present tender specifications. The contractor shall revise the draft Final Report in the light of the comments expressed during the meeting and possible written comments after the meeting.
- The Final Report must be submitted to the Executive Agency no later than 18 months after the contract signature.

Content:

The Final Report will describe all the work carried out and the results obtained under the contract. Subject to necessary refinements and corrections, the main part of the Final Report will be a compilation of the contractor's work contained in the Interim Reports II (D3) and III (D4).

The Final Report shall consist of:

I. The report, in English, consisting of the following section:

- a. Abstract (not exceed 400 words) in English;
- b. Summary (maximum 10 pages) in both English and French;
- c. Introduction (stating the objective of the study);
- d. Background and context;
- e. Main part of the report, consisting of the contractor's work carried out under Tasks 3 to 6 and 9, in particular describing the technical specifications required for the establishment and the operation of the proposed system;
- f. Conclusions;
- g. Annexes with methodology and references.

II. Model contract for the third party data storage (the contractor's work carried out under Task 7)

III. IT system design (the contractor's work carried out under Task 8, including all the sub-documents mentioned under Task 8)

IV. Comprehensive list of data used for the analysis

All copyrights shall belong to the European Union (see Article I.8 of the FW contract). It is the intention of the Commission Services to publish the Final Report at the end of the service contract.

The final version of the Final Report shall be prepared following a template to be provided by Chafea to facilitate its publication at a later stage.

- **Specific Tasks reporting**

For the specific tasks the following reporting will be necessary:

- Minutes from three independent expert workshops, including the shared documents;
- Minutes reports from two workshops with stakeholders, including the shared documents;
- Written response to the comments collected in the peer review process.

Minutes from the workshops have to be delivered within 5 working days following the workshop.

A written response to the comments collected in the peer review process has to be delivered within 10 working days following the receipt of the commentaries by the contractor.

Procedure for reporting:

All main deliverables (D1 to D5) shall be submitted in accordance with the timeframes indicated in point 6. The Executive Agency will then either inform the contractor that it approves the deliverable or will send him its comments within 20 days.

Within 14 days of receiving any such comments, the Contractor will send the Executive Agency his revised report, which will either take account of the comments or put forward alternative points of view.

In the absence of any comments from the Executive Agency within 20 days of its receiving the deliverable, the contractor may request written acceptance of it.

The deliverable will be deemed to have been approved by the Executive Agency if it does not expressly inform the contractor of any comments within 30 days of its request.

Presentation and references:

The Final Report shall be written in a high standard and **checked by a native speaker**.

All reports should have numbered paragraphs and pages and a clear identification, containing:

- the contract number (not the call number),
- the acronym,
- the version (draft, revision or final) and
- the date.

The reports and the deliverables shall be in English. The summary of the Final Report shall be also made available in French.

The contractor shall include in all reports as well as in all written and electronic communication the EU emblem with the following statement besides “*Funded by the European Union in the frame of the EU Health Programme (2014-2020)*”.

In addition to this, the reports shall contain the following disclaimer:

“This report was produced under the EU Health Programme (2014-2020) in the frame of a service contract with the Chafea acting under the mandate from the European Commission. The content of this report represents the views of the contractor and is its sole responsibility; it can in no way be taken to reflect the views of the European Commission and/or Chafea or any other body of the European Union. The European Commission and/or Chafea do not guarantee the accuracy of the data included in this report, nor do they accept responsibility for any use made by third parties thereof.”

Finally, the contractor should note that references to individual brands, products or companies in the Final Report should be made in a way that they cannot be considered to be discriminatory or as a promotion or advertisement of any product or company.

5. Meetings

Whereas most of the coordination of the activities will be possible via audio or videoconference, the contractor will be required to attend four to five face to face meetings with Chafea and the Commission services in Luxembourg, at the Health Unit of Chafea (Luxembourg, Rue Guillaume Kroll 12).

The contractor will be also required to assist in three rounds of workshops/meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts (in total 7 meetings).

The meetings with stakeholders and independent experts will be organised by DG SANTE and will take place in Brussels.

DG SANTE will remunerate independent experts for their participation under (a) separate contract(s) directly concluded with the independent experts by DG SANTE.

The workshop meetings with experts designated by Member States will be organised by DG SANTE, in Brussels, within the framework of the Expert Subgroup on Traceability and

Security¹⁴, and will be attended by the contractor. The workshops/meetings with each group of participants will be separate from each other.

Potentially the contractor will be also required to assist in a meeting with peer reviewers in Luxembourg/Brussels. This meeting may be organised back-to-back with the final meeting between the contractor and Chafea/the Commission services.

Meeting planning and deliverables (expected outputs):

1. Meeting (M1): kick off meeting with Chafea/Commission services(*) in Luxembourg,
2. First round of workshop meetings (M2/M3): Expert workshop in the context of reassessing the options proposed in the Feasibility Study in Brussels.
3. First interim meeting (M4): Interim meeting to discuss a final version of the Interim Report I, with Chafea/Commission services(*), in Luxembourg.
4. Second round of workshop meetings (M5/M6) (in Brussels): Workshop meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts to discuss the proposed concepts of the systems for tracking and tracing and security features.
5. Second interim meeting (M7): Interim meeting to discuss a final version of the Interim Report II, with Chafea/Commission services(*), in Luxembourg
6. Third round of workshop meetings (M10/11) (in Brussels): Workshop meetings with (a) stakeholders, (b) experts designated by Member States and (c) independent experts to discuss the proposed technical specifications, including a model contract for the third party data storage.
7. Third interim meeting (M12): Interim meeting to discuss a final version of the Interim Report III and provide guidance for the final phase, with Chafea/Commission services(*) in Luxembourg.
8. Potential peer review meeting (M17): face to face meeting between peer reviewers and Chafea/Commission services(*), in Luxembourg/Brussels.
9. Final meeting (M17): Final meeting and feedback on a draft version of the Final Report from Chafea/Commission services(*), in Luxembourg/Brussels. If needed, this meeting may be combined with the peer review meeting.

(*) Apart from DG SANTE which is a leading service responsible for this contract, other associated services, in particular OLAF, DG TAXUD and Legal Service, will be invited to participate in the meetings.

6. Timeframe for providing the services

The specific contract period is foreseen from the day after the last party (Chafea) signs the contract. The duration foreseen for the tasks is **19 months**.

¹⁴ The subgroup operates under the Commission Expert Group on Tobacco Policy established by Commission Decision C(2014)3509 of 4 June 2014.

More details are given in the table below:

Time	Milestone	Comments
Month 1 (Week 1)	Kick-off meeting with Chafea and Commission services (*)	In Luxembourg
Month 1 (Week 3)	Draft Initiation Report including draft minutes of the kick-off meeting	To be sent to Chafea
Month 2 (Week 6)	Final Initiation Report (D1) including the minutes of the kick-off meeting as well as the comments thereafter.	To be sent to Chafea
Month 2	Draft Interim Report I	To be sent to Chafea
Month 2/3	First round of workshops/meetings	In Brussels
Month 4	Interim Report I (D2) <i>"Tracking and tracing of tobacco products and security features in the EU – Technical review of the Feasibility Study"</i>	To be sent to Chafea
Month 4	First interim meeting with Chafea and Commission services (*) to discuss a final version of the Interim Report I	In Luxembourg
Month 5	Draft Interim Report II	To be sent to Chafea
Month 5/6	Second round of workshops/meetings	In Brussels
Month 7	Interim Report II (D3) <i>"Tracking and tracing of tobacco products and security features in the EU – General concept of the system"</i>	To be sent to Chafea
Month 7	Second interim meeting with Chafea and Commission services (*) to discuss a final version of the Interim Report II	In Luxembourg
Month 10	Draft Interim Report III	To be sent to Chafea
Month 10/11	Third round of workshop meetings	In Brussels
Month 12	Interim Report III (D4) <i>"Tracking and tracing of tobacco products and security features in the EU – Technical specifications"</i>	To be sent to Chafea
Month 12	Third interim meeting with Chafea and Commission services (*) to discuss a final version of the Interim Report III	In Luxembourg
Month 15	Draft Final Report and Peer review	To be sent to Chafea
Month 17	Final meeting and feedback on draft report from Chafea/Commission services (*) and potential meeting with Peer reviewers	In Luxembourg/Brussels
Month 18	Final Report (D5) <i>"Tracking and tracing of tobacco products and security features in the EU – System architecture and technical specifications"</i>	To be sent to Chafea

(*) Apart from DG SANTE which is a leading service responsible for this contract, other associated services, in particular OLAF, DG TAXUD and Legal Service, will be invited to participate in the meetings.

A detailed timetable respecting the above timeframe should be provided in the offer.

7. Terms of payment

- First interim payment:

The contractor shall submit an invoice for a first interim payment equal to **10 %** of the total amount referred to in Article I.5.2. of the contract.

Invoices for interim payment shall be accompanied by:

the Deliverable 2 "Final Interim Report I" The Executive Agency shall make the payment within 90 days from receipt of the relevant invoice. The contractor shall have 14 days in which to submit additional information or corrections, a new first interim report or other documents if it is required by the contracting authority.

- Second interim payment:

The contractor shall submit an invoice for an interim payment equal to **20 %** of the total amount referred to in Article I.5.2. of the contract.

Invoices for interim payment shall be accompanied by:

- the Deliverable 3 "Final Interim Report II"

The Executive Agency shall make the payment within 90 days from receipt of the relevant invoice. The contractor shall have 14 days in which to submit additional information or corrections, a new second interim report or other documents if it is required by the contracting authority.

- Third interim payment:

The contractor shall submit an invoice for an interim payment equal to **20 %** of the total amount referred to in Article I.5.2.. of the contract.

Invoices for interim payment shall be accompanied by:

- the Deliverable 4 "Final Interim Report III"

The Executive Agency shall make the payment within 90 days from receipt of the relevant invoice. The contractor shall have 14 days in which to submit additional information or corrections, a new third interim report or other documents if it is required by the contracting authority.

- Payment of the balance:

The contractor shall submit a request with the invoice(s) for the payment of the balance.

The invoice shall be accompanied by:

- the Final Report (D5) in accordance with the instructions laid down in the tender specifications;

The Executive Agency shall make the payment within 90 days from receipt of the invoice. The Contractor shall have 14 days in which to submit additional information or corrections, a new Final Report or other documents if it is required by the contracting authority

As a general rule, travel costs to the normal location of delivery mentioned in the specific contract are not reimbursed.

Brussels and Luxembourg are considered as the same location of delivery (e.g. when the location of delivery is either Brussels or Luxembourg), no travel expenses are reimbursed between Brussels and Luxembourg.

8. Requirement as to the contractor

- i. The contractor must have the capacity to put together a **team** which comprises members as indicated in the table below:

TEAM MEMBER	DETAILS OF THE CRITERIA	EXPERIENCE AND EXPERTISE NEEDED	INDICATIVE AVERAGE WORKLOAD (Full Time Equivalent)
Project Director	To have experience in project management and team coordination	University degree (Master's degree) and at least 5 years' experience	0.4 FTE
Team Leader	To have expertise and experience in designing and implementing complex traceability (tracking and tracing) concepts and solutions and in anti-counterfeit measures, including security features	Relevant university degree (Master's degree) and at least 3 years (but preferably more) of professional experience in at least four of the following areas: 1- International standards related to the subject matter (ISO, CEN, UN/CEFACT etc.) 2- Industry supply chain standards 3- Serialization concepts and solutions 4- Traceability concepts and solutions	1 FTE

		5- Interoperability standards and solutions 6- Real-time visibility and event management 7- Anti-counterfeit technologies for high quantity goods 8- Specific knowledge of illicit trade in tobacco products 9- Functioning of market surveillance authorities and law enforcement in the EU	
At least 3 team members	To have expertise and experience in designing and implementing complex traceability (tracking and tracing) concepts and solutions and in anti-counterfeit measures, including security features	As a team, they shall have at least 3 years of experience in all of the following areas: 1- International standards related to the subject matter (ISO, CEN, etc.) 2- Industry supply chain standards 3- Serialization concepts and solutions 4- Traceability concepts and solutions 5- Interoperability standards and solutions 6- Real-time visibility and event management 7- Anti-counterfeit technologies for high quantity goods 8- Specific knowledge of illicit trade in tobacco products 9- Functioning of market surveillance authorities and law enforcement in the EU 10- Audit procedures 11- Cost / benefit assessment	2 FTE
Legal expert: at least 1 team member	To have legal expertise and experience in advising service providers in the IT sector	An expert with at least 5 years of professional experience in Legal advice on IT-related service agreements and data protection	0.2 FTE
IT Architect: at least 1 team member as a leading architect supported by at least 2	To have IT architecture and design expertise and experience, preferably including traceability	At least 3 years of professional experience in: 1- Business modelling, IT service oriented architecture (SOA) and IT procedures 2- Real-time supply chain visibility concepts	2.3 FTE

other team members	(tracking and tracing) concepts and solutions, service oriented architecture (SOA), and real-time event management systems and concepts		
Quality manager: 1 team member	Quality assurance experience	At least 3 years' experience in Quality management of projects,	0.2 FTE

For each of the team members, including the Project Director and the Team Leader, the contractor shall define a minimum level of involvement in terms of either work days or a percentage of the overall work under the project. Note that the only member that has to work on a daily basis is the Team Leader, to ensure the smooth running of the contract. The other members shall be involved in an adequate way, taking into account their concrete tasks.

The estimated duration is 18 months or 360 working days¹⁵.

The work has to be performed mostly at the contractor's premises. On-site presence should not exceed 5% of the global workload.

In general a summary table of main expertise and experience of the persons responsible for providing the services is requested, with for each team member:

- Areas of expertise (as indicated in the above table)

- CV in Europass format¹⁶, including the qualifications and all the work experience of the team members. Summaries will not be accepted.

In addition to the information given in the above table, the ABC III minimum requirements apply for the proposed profiles:

- **Senior Consultant**

It corresponds to **at least 12 years' experience in ICT including 6 years in consultancy among which 3 years in the requested domain(s)**

A relevant education degree (typically a master degree or equivalent) is needed.

¹⁵ Please note, that Month 19 is only included as a contingency measure, in case the Contractor might need more time to close the Final report. Thus, in principle, no man days should be foreseen for Month 19, as the tasks should be accomplished by month 18.

¹⁶ Only Europass format CVs will be taken into account.

- **Consultant**

It corresponds to **at least 6 years' experience in ICT including 3 years in consultancy among which 2 years in the requested domain(s)**

A relevant education degree (typically a master degree or equivalent) is needed.

- **Expert**

It corresponds to **at least 9 years' experience in consultancy including 5 years in the requested policy or field** A relevant education degree (typically a master degree or equivalent) is needed.

Subcontracting:

Subcontracting is allowed, as per the framework contract subcontracting rules. Subcontracting will be accepted for:

- the subcontractors that were proposed in the response to the call for tenders;
- One-person companies (or freelancers) proposed by the contractor in response to this request for offer and during the implementation of the contract;
- Non-profit organisations such as public research centres or universities proposed by the contractor in response to this request for offer and during the implementation of the contract;
- In case of the second round of a cascade (when the first round has not yield any result);
- For very specialised technical expertise if required for the provision of the services.
- Multiple-level subcontracting (e.g. subcontracting of subcontracting) is not authorized.

However, the contracting authority must be informed by the contractor on any part of the contract that the contractor may intend to subcontract to third parties and on the identity of any subcontractor.

In the case of subcontracting, a statement specifying the function, the qualifications and the experience of each member of subcontractor shall be added, identified the concrete person and his/her "profile" following what it is stated in FWC ABC III. Moreover, the contractor has to indicate clearly which are the roles and the contribution of each one.

Evidence:

The offer should clearly indicate the match between the composition of the contractor's team and the expertise required under the contract (**in tabular form**). See the suggested template below:

Function in the team	Experience required	Designated team member	Profile following the FWC requirements ¹⁷	Reference to the relevant passages in the designated team member's Europass format CV
Project Director	5 years experience	Mr/Ms		
Team leader	3-year experience in ...	Mr/Ms		
		...		
Team member	3-year experience in: ...	Mr/Ms		
		Mr/Ms		
		Mr/Ms		
		...		
Team member	5-year legal advice on	Mr/Ms		
		...		
Team member	3-year experience in business modelling, IT ...	Mr/Ms		
		...		

Also in tabular form, the offer should indicate the expected days spent by each team member by work package **or** activityCh.

Suggested template for the expected days spent by each team member by work package or activity:

Name	WP0	WP1	WP2	WP3	WP4	Total man-days
Team member 1	A	B	C	D	E	A+B+C+D+E
...						

- ii. The contractor shall have the technical capacity to develop the tasks explained in Section 3.3: it shall have at least 2 similar services of policy analysis, expert advice on the technical requirements for IT and logistic systems, and cost/benefit analysis in the areas of health and/or economics, provided in the last 5 years.

As evidence the contractor shall enclose a reference list of the principal services and works carried out in the last five years by the contractor, indicating the amount, the date, the place and the recipients (public or private) of each one of these services. The list of the most important works can be accompanied by certificates of satisfactory execution,

¹⁷ As stated in the FWC ABIII under the Service level Requirement "4. Profiles": the three categories are "Senior consultant, Consultant, Experts".

specifying whether they have been carried out in a professional manner and have been fully completed.

Professional conflict of interest criteria:

Article II.3 of the Framework Contract applies. In addition, the following will be added and apply for any specific contract resulting from this offer.

The verification of professional conflict of interest refers both to contractors (including all consortium members) and subcontractors (as legal entities) including their staff members and additional experts (hereafter jointly referred to as contractors and subcontractors in this section) to be engaged in the provision of the service covered by the present request for service.

A conflict of interest will be assumed:

- if the contractor and/or the subcontractor is a stakeholder directly active in the tobacco sector (e.g. manufacturing or distribution);
- if the contractor and/or subcontractor is a stakeholder with vested interests in the area of the tender (in particular because they are a provider of tracking and tracing solutions or of security features);
- if the contractor and/or the subcontractor provide (or used to provide during the last two years) goods (e.g. equipment) or services (e.g. consultancy) to a stakeholder active in the tobacco sector (e.g. manufacturing or distribution) and achieved the cumulated net income of more than EUR 10 million in the financial years 2010 to 2014 in the area of combating illicit trade, including tracking and tracing or security features. In addition, a conflict of interest will be assumed, if the contractor and/or the subcontractor provide (or used to provide during the last two years) goods (e.g. equipment) or services (e.g. consultancy) outside the area of combating illicit trade to a stakeholder active in the tobacco sector (e.g. manufacturing or distribution), when the contractor or subcontractor is not independent from the stakeholder;
- if the contractor and/or subcontractor provide (or used to provide during the last two years) goods (e.g. equipment) or services (e.g. consultancy) to a stakeholder with vested interests in the area of the tender (in particular because they are a provider of tracking and tracing solutions or of security features), when the contractor or subcontractor is not independent from the stakeholder.
- If the contractor and/or subcontractor fail to present their CV with a signed declaration of absence of conflicts of interest (Annexe C).

The criterion "independent from stakeholders" refers in particular to two requirements, which have to be met by the contractor and the subcontractor:

- Legal independence:

Two legal entities shall be regarded as independent of each other where neither of them is under the direct or indirect control of the other nor under the same direct or indirect control of a third entity as the other.

Control may in particular take either of the following forms:

(a) The direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;

(b) The direct or indirect holding of decision-making powers, in fact or in law, in the legal entity concerned.

For the purpose of the verification of a conflict of interest, the contractor and/or subcontractor may also be required to provide additional information, including its shareholding structure and the composition of management board.

- Financial independence:

A contractor or subcontractor will be considered to be financially dependent on a stakeholder, if the turnover generated by the contractor or subcontractor with this stakeholder is equal to or higher than 20% of the annual overall turnover of the contractor or subcontractor (taking the financial years 2010 to 2014 as reference – this information has to be certified by an independent auditor).

If the turnover generated with a stakeholder by the contractor or subcontractor is less than 20% of the annual overall turnover of the contractor or subcontractor (taking the same reference as above), the financial dependence will not be assumed. However, the contractor or subcontractor shall present safety measures, e.g. Chinese walls, which have been undertaken to isolate the project team involved in the contract from any other staff members who are (or used to be during the last two years) involved in the work carried out for the stakeholder in question.

- Measures with regard to the tender's or subcontractor's conflicted staff members:

For avoidance of doubt, any staff members who are (or used to be during the last two years) involved in the work carried out for a stakeholder cannot be a part of the project team and should be subject to safety measures, e.g. Chinese walls, preventing them from accessing the project team as well as the information and data passed on to the project team under the present contract and any preparatory, intermediate and final effects of the project team's work, unless the latter are made public by the Commission.

Evidence:

Any natural person who is proposed in the offer will provide a signed declaration of absence of conflicts of personal and professional interest using the template in Annex C.

The assessment of the above criteria will be carried out based on all the documents and information provided in the offer, in particular the evidence for the selection criteria. If necessary (e.g. in case of doubt), the Executive Agency will ask for clarifications regarding the issue.

The contractors shall note that if it is found that the contractor itself, and/or one or more consortium member(s), and/or one or more subcontractor(s) are in conflict of interest, the offer will not be further evaluated and will be rejected.

The contractors and/or the subcontractor are obliged to report to the contracting authority any change in their situation related to the absence of conflict of interest throughout the implementation of the contract.

9. Requirements of the technical part

The technical part shall describe in detail how the services described in point 3" Subject of the contract" will be provided by the contractor. Since the offer will be judged on the content of their written offer, they must make it clear that how could they meet the requirements of the tender specifications.

The offer must be clear and concise, with continuous page numbering, and assembled in a coherent fashion (e.g. bound or stapled, etc.).

A Technical evaluation will take place, taking into account the following criteria in their order of importance as weighted by percentage:

N°	Qualitative criteria	Details of each criterion (the contractor will)	Weighting (max. points)
1.	Understanding of contract, general approach and quality of the offer	<ul style="list-style-type: none"> – Understanding of the nature, the scope and objectives of the tasks to be performed and of the means needed to be deployed for its development and conduct; – Level of the expertise of the team proposed by the contractor. 	25
2.	Methodology	Quality and the relevance of the proposed approach to: <ul style="list-style-type: none"> – WP0: Inception phase – WP1 Reassessment of the Feasibility Study – WP2 Preparation of the concepts for the optimal system – WP3 Design of the technical specifications – WP4: Preparation of the Final Report 	2 5 18 22 3
3.	Organisation and management	Quality and the relevance of the proposed management of the contract, including <ul style="list-style-type: none"> – the organisation of the work (work plan) and the resources to complete the contractual tasks; – risk management: assessment of potential risks for timely performing of tasks, and the quality of the presented related contingency plans; – the internal monitoring system to control the regular development of planned activities; – quality control measures in addition to the peer review process; – confidentiality and privacy safeguards: 	25

		description of the measures to protect confidentiality and privacy of the information received from stakeholders.	
	<i>Total points</i>		100

1. This criterion serves to assess whether the contractor has understood all of the issues involved, as well as the nature of the work to be undertaken and the content of the final deliverables. The contractor is requested to demonstrate that it is familiar with the context and the subject of the call for tender and has a clear understanding of the service to be provided. In addition, the conformity of the offer to the tender specification will also be assessed.

The contractor must note that a statement alone, confirming that it understands the objectives of the contract and the work to be carried out and a mere repetition of the tender specifications will not be considered as sufficient and will lead to negative assessment and a major reduction of the maximum points under this criterion.

The level of expertise of the team proposed by the contractor will be assessed in detail. It is essential that the level of expertise offered matches with the requirements of the tender specifications.

Going beyond what is specified in this terms of reference regarding tasks and expertise requires thorough justification and will be possible only if the contractor can demonstrate in the offer that additional tasks and expertise are indispensable in achieving the overall objectives of the project, otherwise this will have negative effect on the scoring of the offer.

2. The offer will be assessed with reference to the quality and relevance of the proposed methods, how it reflects objectives of the call for tender and the justification for the methodology of choice, to fulfil the tasks as laid down in the tender specifications. The offer should give indications on the methodology to be used in the provision of the service and on its appropriateness for the purpose.

In particular, the well justified methodology choices, appropriately comprehensive and detailed description of the work process and methods will be evaluated, work package by work package.

3. The offer will be assessed as regards the planning for the completion of the contractual tasks, which should be clearly outlined in the tender. A clear division of the tasks, a feasible and logically structured work plan, the decision-making structure and a realistic timetable shall be included in the offer.

An assessment of the potential risks for ensuring the timely performance of the tasks and a contingency plan has to be detailed in the offer. As the contractor will not be the one implementing the final product, sufficient hand-over information and tools must be foreseen to enable the European Commission to take over and use the knowledge acquired and developed during the implementation of this project. A quality control system, and an internal monitoring system has also to be set up to ensure the good development and results of the

contract. The quality control system should go above and beyond the peer review process required with respect to the Final Report under point 4 above.

The offer shall include detailed confidentiality and privacy safeguard measures needed to protect the confidentiality and privacy of the information received from third parties.

Since assessment of the offer will be based on the quality of the proposed services, the offer should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, will result in a very low score. In addition, if certain essential points of these specifications are not expressly covered by the tender, Chafea may decide to give a zero mark for the relevant qualitative award criteria.

For each criterion above, a 50 % threshold is required. Should the offer fall below these thresholds it will be eliminated.

Moreover, an offer that has not obtained in total of at least 70 out of the 100 points will be excluded.

10. Requirements for the financial part

The contractor should submit a financial offer in accordance with Annex B – Contractor's Financial Offer and a Work Breakdown Structure.

The prices shall respect the Unit Prices of the Framework Contract.

When preparing the financial offer, the contractor shall estimate the number of onsite and offsite man days allocated on the basis of the tasks described in this terms of reference. The unjustified addition of any other task might be considered as a misunderstanding of the specifications, and in consequence, be evaluated in a negative way. In addition, for the preparation of the financial offer the contractor shall take into account the descriptions of profiles requested in this specifications. The allocation of the resource has to be fair and balanced.

ANNEXES

- Annex B – Contractor's Financial Offer and Work Breakdown Structure Template
- Annex C – Declaration of absence of conflict of interests template
- Annex D – Declaration of Confidentiality Template