

8. ANNEX B: DETAILED MODEL CONTRACT FOR THE THIRD PARTY DATA STORAGE

8.1. General Terms and Services

Agreement

between

This Agreement is signed between

the company
with VAT number
, based in

(hereinafter the: "Contractor") in the person of its legal representative *pro tempore* undertakes to perform with respect to

the company
with VAT number
based in (hereinafter referred to as "Manufacturer/Importer") who make a request according to the terms and modalities described herein.

The Contractor and the Manufacturer/Importer will hereinafter be referred to jointly as the "Parties" or individually as a "Party".

1.5. This Agreement sets General Terms of Service (hereinafter: "the Agreement/GTS"), which includes:

- Annex 1: the Technical Requirements (hereinafter: "TR", Annex 1 to the GTS) together with the Special Terms of Service (hereinafter: "STS"), which include the Service Level Agreement (hereinafter: "SLA", Annex A to the STS) and
- Annex 2: the Price Conditions (hereinafter: "PC", Annex B to the GTS);
- Annex 3: Definitions. Annex 3: Definitions govern the provision of Service that the company
VAT number
based in
(hereinafter the: "Contractor")

- in the person of its legal representative *pro tempore*, and
- the company
VAT number
based in
(hereinafter referred to as "Manufacturer/Importer").
- The Contractor and the Manufacturer/Importer will hereinafter be referred to jointly as the "Parties" or individually as a "Party". The GTS, the STS and the Annexes will be jointly referred to below as the "Agreement".

WHEREAS

1. Introduction and definitions

- Directive 2014/40/EU on tobacco products (hereinafter "Directive") aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The Directive entered into force on 19 May 2014 and became applicable in the EU Member States on 20 May 2016.
- Article 15 of the Directive requires that all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession.
- For the purpose of hosting the data storage facility for all relevant data generated by the abovementioned obligation, the Directive requires that Member States ensure that manufacturers and importers of tobacco products conclude data storage contracts

Commented : Clauses to be added : IP ; Business Continuity Plan ; Liability exemption for the Contractor in case of illicit data ; Access to Data (with corresponding duties for persons accessing to Data).

Commented : Please add a table of content

Commented : The structure of the Contract should be reviewed. I do not see any added value to the distinction between GTC (+ annex) and STSs (also with annexes) except if the provisions and the rules are different (depending on the object of the STS). There is also a risk of inconsistency between the contractual documents, with a higher level of complexity.
Recommended structure :
- Work Order (with limited derogation to GTC – on duration ; liability CAP, etc.).
- GTC
- Annex 1 (technical + SLA)
- Annex 2 (price)

Commented [LM4]: Wouldn't it be possible to have a more simple model SLA, rather than General Terms of Service (hereinafter: "GTS"), which include the Technical Requirements (hereinafter: "TR", Annex 1 to the GTS) together with the Special Terms of Service (hereinafter: "STS"), which include the Service Level Agreement (hereinafter: "SLA", Annex A to the STS) and the Price Conditions (hereinafter: "PC", Annex B to the STS)?

Commented [ET5R4]: We have reviewed this matter with our external legal advisors and this is the most common and accepted standard for cloud storing agreements. In comparison with other model contracts of this nature, this is the most simple that it can already get.

We suggest to keep this structure and discuss it with the external expert(s) during the review.

Commented : It should start with this part.

Formatted: Justified

Commented : To be defined

Commented : 1.1 to 1.4. should be included in the "whereas" of the Agreement, together with a short presentation of the Parties.

with an independent third party. The data storage facility shall be physically located on the territory of the European Union.

4. The resulting data storage of the Tracking and Tracing System is based on:

i) a group of independent Primary Data Storage solutions, where each Primary Data Storage solution hosts data exclusively related to a specific manufacturer/importer or a group of distinct manufacturer(s)/importer(s);

ii) a central Surveillance Data Storage solution which hosts a global copy of the distributed data. On this basis, the Surveillance Data Storage solution is able to offer a comprehensive logical view of all relevant data based on its local data, which could be further exploited for the enforcement required by the Directive. Also, the Surveillance Data Storage solution provides a secure Repository Router component (as defined in Annex 1 "Technical Requirements") to facilitate that the distributors and wholesalers transmitting their reports seamlessly through a single point.

Agreement

between

~~1.5. These General Terms of Service (hereinafter: "GTS"), which include the Technical Requirements (hereinafter: "TR", Annex 1 to the GTS) together with the Special Terms of Service (hereinafter: "STS"), which include the Service Level Agreement (hereinafter: "SLA", Annex A to the STS) and the Price Conditions (hereinafter: "PC", Annex B to the STS), govern the provision of Service that the company~~

~~VAT number~~
~~based in~~

~~(hereinafter the: "Contractor") in the person of its legal representative pro tempore,~~

and

~~the company~~
~~VAT number~~
~~based in~~

~~(hereinafter referred to as "Manufacturer/Importer").~~

~~The Contractor and the Manufacturer/Importer will hereinafter be referred to jointly as the "Parties" or individually as a "Party". The GTS, the STS and the Annexes will be jointly referred to below as the "Agreement".~~

56. Pursuant to Article 15(8) of the Directive, the European Commission approves the suitability of the Agreement as a model contract to comply with the Directive and to assure the Contractor's independence and technical capacities.

67. The present Agreement regulates the relationship between the Parties and also enables the European Commission and the competent authorities to effectively exercise their rights pursuant to Article 15 of the Directive.

78. ~~Unless specifically provided in the Agreement, all terms shall have the same meaning as defined in Article 2 of the Directive.~~

The Parties have agreed as follows:

1. General Scope and structure of the Agreement
General Terms of Service (GTS) and Special Terms of Service (STS)

1.1. The GTS describes the general content of the commitments that the Parties assume with regard to the supply of Service ~~identified in the relative STS provided by the Contractor and further details the specific content of the commitments that the Parties respectively assume.~~

2.2. ~~The STS describes the service provided by the Contractor and further details the specific content of the commitments that the Parties respectively assume.~~

1.2. The GTS together with the relative STS and Annexes govern the relationship between the Parties.

2.4. ~~In case of conflict, the provisions of the STS prevail over the provisions of the GTS.~~

Commented [REDACTED]: The relationship (and the difference) between Primary Data Storage solutions and Surveillance Data Storage Solution remains unclear. I also understand that both kinds of services could be provided by distinct providers. Should it be the case, the duties of each of them must be very clear (as well as the liability in case of breach).

Commented [everis10R9]: Indeed, both kinds of services could be provided by distinct providers. However, we are putting focus now on developing the contract between the manufacturers/importers and the provider(s) of primary data storages.

Commented [REDACTED]: To be defined

Commented [REDACTED]: To be included in the whereas.

Commented [REDACTED]: For clarity purposes, I recommend to include such definitions in the Agreement and to define also the other terms (in annex or in the first provision).

Commented [everis17R16]: To be included as an Annex

Commented [REDACTED]: Article 1 and 2 (or 3) should be reviewed in order to ensure that there are no redundancies, and that the scope and main duties are clearly explained and presented.

Commented [LM11]: Wouldn't it be possible to have a more simple model SLA, rather than General Terms of Service (hereinafter: "GTS"), which include the Technical Requirements (hereinafter: "TR", Annex 1 to the GTS) together with the Special Terms of Service (hereinafter: "STS"), which include the Service Level Agreement (hereinafter: "SLA", Annex A to the STS) and the Price Conditions (hereinafter: "PC", Annex B to the STS)?

Commented [ET12R11]: We have reviewed this matter with our external legal advisors and this is the most common and accepted standard for cloud storing agreements. In comparison with other model contracts of this nature, this is the most simple that it can already get.

We suggest to keep this structure and discuss it with the external expert(s) during the review.

Commented [REDACTED]: Please explain also the structure of the Agreement here:
-The GTS
-The Annexes to the GTS
-WO?

Commented [REDACTED]: It should start with this part.

Commented [REDACTED]: Structure to be reviewed

Commented [REDACTED]: Please explain what is covered by the "Services" (data storage, access, maintenance and support).

Commented [REDACTED]: And in case of conflict between the STS or between terms of STS and Annex? Structure: to be moved in the final provisions of the agreement.

1.3 The Service provided by the Contractor to the Manufacturer/Importer is described in detail in the related Technical Requirements STS (hereinafter: "Service").

Unless specifically provided in the Agreement, all capitalised terms or expressions shall have the same meaning as defined indicated in Annex 3 article 2 of the Directive.

2. Subject matter for this Agreement Main duties and warranties of the Contractor

2.1. The Contractor will provide the Services as described in Annex 1 "Technical Requirements". The Contractor and Manufacturer/Importer may also agree on Contractor providing additional services and new services.

2.2. The Contractor shall develop a business continuity plan prior to the commencement date.

3. Obligations of Contractor, procedures for the implementation, maintenance and support of the Service.

3.1. The Contractor warrants that the Service shall be offered provided in compliance with the present Agreement and the relevant annexes, in particular the technical specifications (as defined in Annex 1 "Technical Requirements"). It also warrants that it will be implemented at latest by the date specified in the STS this Agreement, subject to acceptance tests if so provided therein.

3.2. The Contractor warrants that, when providing the Service, it shall undertake to comply comply with the applicable law and the Implementing and Delegated Acts adopted by the European Commission pursuant to the Directive.

3.3. The Contractor assures warrants its independence from the tobacco industry and its technical capacities with respect to the performance of the Service. Independence and technical capacities of the Contractor is to shall be assessed by the European Commission, and maintained during the whole duration of

the Agreement. The Manufacturer/Importer may terminate the contract, under approval of the European Commission, if those conditions are no longer maintained fulfilled.

3.4. The expertise and independence required to the Contractor are set in the Delegated Acts adopted by the European Commission in accordance with article 15.12 of the Directive.

3.5. 4. The Contractor undertakes agrees to provide the Manufacturer/Importer with information on updates (as defined in Annex 1 "Technical Requirements") and to implement updates during the execution of the Agreement pursuant to Annex 1 "Technical Requirements".

3.6. 5. The Contractor makes available to the Manufacturer/Importer support telephone and/or e-mail hotline services for providing support, pursuant to the specifications set forth in Annex A-1 "SLA" to the STS.

4. Availability and performance of Service

3.7. 4.1. The Contractor maintains the operability, availability and performance of the Service for the duration of this Agreement in accordance with the requirements set forth in Annex 1 "Technical Requirements" and Annex A "SLA" to the STS.

3.8. 4.2. The Contractor informs the Manufacturer/Importer about the service maintenance.

4.3. 2.9. The Service may be interrupted for the performance updates and "Ordinary Maintenance" (the scheduled maintenance by the Contractor) or "Extraordinary Maintenance" (unplanned maintenance of the Contractor due to events beyond the reasonable control of the Contractor), as described in Annex 1 'SLA'. The Contractor will have has the obligation (and obligation when required) to carry out updates, patches, fix bugs, or perform other maintenance on the Service in compliance with the Annex 1 "Technical Requirements" and Annex A "SLA" to the STS. It is understood that the Contractor

Commented [REDACTED]: To be defined. Object and scope of the service should also be detailed (in a provision of the agreement) :
- Primary Data Storage
- Surveillance Data Storage
- And for both : (i) access to Data (by whom and under which requirements) ; (ii) Support and maintenance.

Commented [REDACTED]: For clarity purposes, I recommend to include such definitions in the Agreement and to define also the other terms (in annex or in the first provision).

Commented [everis24R23]: To be included as an Annex

Commented [everis26R25]: The full description of the technicalities of both Data Storages is to be included in the Technical Requirements (currently under preparation)

Commented [REDACTED]: Add provision on duty referred to in Article 15 (9)

Commented [REDACTED]: Updates = maintenance?

Commented [REDACTED]: To be defined

Commented [everis38R37]: To be defined in the Technical Requirements document, currently under preparation.

Commented [REDACTED]: Support is not only hotline. Must be much more detailed in the SLA.

Commented [REDACTED]: To be moved to a specific provision named "Business continuity plan". Main duties should be included in the agreement.

Commented [REDACTED]: Articles 3 and 4 should be put together. The Contractor should warrant that the contractual and legal rules are respected. A difference could also be made, when applicable, between obligations of result and obligations of means.

Commented [REDACTED]: Structure : should be included under 3 (Obligations)

Commented [LM30]: The first thing to do is to define the service covered by this contract

Commented [ET31R30]: We rather prefer to describe it in the Special Terms of Service, mainly because the service to be provided in the surveillance data storage is not the same service to be provided in the primary data storage. The scope and responsibilities of the service are different, and therefore specified in the STS.

Commented [LM41]: Isn't this a repetition of par. 3.17

Commented [ET42R41]: No, this paragraph specifies that that contractor shall not only provide the service, but also ensure its operability, availability and performance of the Service.

Commented [REDACTED]: Does it mean that there should be an acceptance procedure? If so, the criterions of acceptance must be ...

Commented [REDACTED]: Additional rules must be prescribed with regard to maintenance (corrective maintenance? Evolutive ...

Commented [everis44R43]: Developed in the SLA annex.

Commented [REDACTED]: The maintenance must be a duty (otherwise, for security reasons, the risks will be unacceptable).

Commented [LM46]: Will the contractor have the right or the obligation to carry on the maintenance?

Commented [ET47R46]: Updated

Commented [REDACTED]: To be defined. This point is very important. It means indeed that the Contractor is like a trust ser ...

Commented [everis34R33]: The expertise and independence requirements are to be defined by the EC in the delegated acts to ...

Commented [REDACTED]: It should be a warranty. What will occur, shouldn't it be the case in the future? What are the criterions ta ...

will promptly notify the Manufacturer/Importer of scheduled Ordinary Maintenance. The Contractor will take all reasonable efforts to forewarn the Manufacturer/Importer of Extraordinary Maintenance and to minimise the inconvenience resulting from such interventions.

4. Improvement of the Service Change control procedure

4.1. The Manufacturer/Importer may, at any time, suggest or request changes, modifications, or additions to the scope of the Service. The Contractor may also propose changes. Such requests shall be conducted in accordance with the Change Control procedures set forth in this article 34. The Contractor shall not take any action or implement any decision which may have a material effect on the Manufacturer/Importer or which adversely affects the function or performance of, or decreases the resource efficiency below the agreed SLA, without first obtaining Manufacturer/Importer's approval, which the Manufacturer/Importer may withhold at its sole discretion.

4.2. No purported amendment or variation of this Agreement, or any provision of this Agreement, shall be effective unless it is in writing in a form specified by the Manufacturer/Importer as set out in Exhibit XXX (Request for Change Form) and duly executed by or on behalf of each of the Parties (a "Change Order"). A Change Order can never result in a non-compliance with the Technical Requirements of Annex 1.

4.3. The scope of the Service may be subject to additions, deletions or revisions agreed upon by the Parties. Additions, deletions or revisions that may impact the price or timeline for completion of the Service must be approved in advance and in writing by the Manufacturer/Importer. If and to the extent that any change does not materially increase the costs or resources requirements of the Contractor, such change will not increase the price or timeline for completions of the affected Service. If a change will materially increase the price or timeline for completion of the affected Service, the

Contractor will document such change using the Change Request Form attached in Exhibit XX (Change Request Form) that sets for the a description of the change, the rational for the change and the impact the change will have on the price and timeline for completion of the affected Service. The Manufacturer/Importer shall not be obliged to pay for any change that has not been approved in writing and in advance in accordance with this Agreement. In no event will changes be requested that require manufacturer/importer to bear the cost of delays, failures or rework attributable to the Contractor's failure to perform in accordance with this Agreement or that arise from the Contractor's delivery of defective or unacceptable Services.

have the right to request the improvement of the Service through the submission to the Contractor of a new STS, that has to be agreed and accepted upon the Parties.

5. Duration of the Service

5.1. The Service is provided for the period determined in the STS.

6.2. The duration and validity of the GTS and STS are decided by the European Commission pursuant to Section 20 "Amendments to GTS and STS". This Agreement shall take effect on the effective date and shall continue and remain in full force for a period of five (5) years (the "Term") unless and until earlier terminated in accordance with this Agreement.

5.2. Manufacturer/Importer shall have the right to extend the Term for up to 2 renewal periods of 1 year each by giving the Contractor written notice of its intention to do so at least six (6) months before the end of the Term of extended term (as the case may be). All extensions to the Term shall be on the same terms and conditions (including charges) as set out in this Agreement.

6. Confidentiality and announcements

Commented [REDACTED]: Perhaps are there too many details. How is it articulated with the duty to submit to the Commission for approval?

Commented [LM49]: Should the STS be signed by both Parties as part of the contract? In that case it can't be unilaterally modified.

Commented [ET50R49]: Updated

Commented [REDACTED]: A change request procedure must be included, in case of modification of the service, at the request of the M/I or following the suggestion of the Contractor.

Commented [everis52R51]: Change Control procedure included

Commented [REDACTED]: Indefinite or definite duration? If indefinite, it is normally possible to terminated it with a reasonable notice period. In the present case, definite duration is probably better, in order to ensure that a minimal duration will be respected.

Commented [REDACTED]: As it is a "model contract", I suggest to mention a minimal duration (and parties are free to agree on a longer period).

Commented [REDACTED]: Why is it limited?

6.1. The Recipient Party shall hold all confidential information in strict confidence, and specifically, shall:

(i) Use confidential information only for the purposes of the performance of its obligations under this Agreement;

(ii) Restrict disclosure of or access to confidential information to its representatives, advisors, auditors, members and users who need to know such for the purposes of the performance of the Agreement, and not divulge confidential information to any other third parties or give any other third party access to confidential Information without the Disclosing Party's prior written consent;

(iii) Subject any person having access to confidential information for the purpose of performing this Agreement to confidentiality and non-use obligations at least as restrictive as the ones set out in this Agreement, and make such person is aware, prior to any disclosure or access, of the confidential nature of this information. Upon request, the Recipient Party shall provide the Disclosing Party with the names of the persons having access to confidential information;

(iv) Only make such copies of confidential information as are strictly necessary for the performance of its obligations under the Agreement, and not alter, modify, dissemble, reverse engineer or decompile any Confidential Information;

(v) Notify the Disclosing Party immediately upon suspecting or becoming aware if any unauthorised disclosure, access or use of confidential information and take all measures necessary to prevent any (further) unauthorised disclosed, access or use thereof;

(vi) Upon the Disclosing Party's request at any time and in any event upon expiration or termination of the Agreement, at the Disclosing Party's option, promptly destroy or return the disclosing Party its confidential information, including any copies, notes, recordings, memoranda and other documents and supports

pertaining to such and provide an affidavit to such effect.

6.2. Unless expressly agreed otherwise, all rights, title and interest to and in confidential information shall vest and remain in the Disclosing Party;

6.3. Should the Recipient Party be required to disclose confidential information pursuant to a statute, a regulation or the order of a court of competent jurisdiction or a public authority, the Recipient Party shall (a) immediately after gaining knowledge or receiving notice of such legislative, administrative or judicial action, notify the Disclosing Party thereof in writing and give the Disclosing Party the opportunity to seek any legal remedies so as to maintain such confidential information in confidence, (b) only supply confidential information that it is legally required to disclose, and (c) take all possible measure to maintain the confidentiality of confidential information.

6.4. Neither Party shall issue any media release, public announcement or other disclosure relating to the existence, the purpose and the content of the Agreement or use the name, trademark or logo of the other Party without the prior written agreement of the other Party including, without limitation, in promotional or marketing material, provided that nothing in this article shall restrict any disclosure to the extent required by a legislative, administrative or judicial action as mentioned under article above.

6.5. Confidential information shall not include information that the Recipient Party can prove:

(i) is at the time of disclosure, or thereafter becomes, in the public domain without violation of this Agreement,

(ii) is lawfully obtained from a third party that has lawfully obtained such information; or

(iii) was already known by and on record at the Recipient Party prior to disclosure by the Disclosing Party or prior to access by the Recipient Party; or

Commented [REDACTED]: Check consistency with rules applicable to access to data.

Commented [REDACTED]: Please check conformity with prohibition to modify or delete recorded data.

(iv) is developed by the Recipient Party completely independently of any disclosure by the Disclosing Party or of any access by the Recipient Party.

6.6. The obligations and restrictions set forth in this article shall be in force for the term of the Agreement and shall remain in effect twenty (20) years after expiration or termination or termination of the Agreement for any reason whatsoever.

7. Data protection and access rights

7.1. In this article, "process", "data processor", "data subject" and "personal data" shall have the meaning given in the EU Data Protection Directive 95/46/EC and, from 25 May 2018 in compliance with Regulation UE 679/2016; and implementing national laws in EU Member States, and all applicable data protection and privacy laws and regulations (hereinafter, "Data Protection Laws").

7.2. The Contractor agrees to perform all Services under this Agreement, including, without limitation, the collection, use, processing, storage, and maintenance of personal data, in accordance with the Data Protection Laws and the terms of this article.

7.3. To the extent that any personal data is processed under the Agreement, or if the Contractor receives or has access to any personal data under or in relation to this Agreement, then the provisions of this article shall apply. To the extent the Contractor receives and/or processes personal data under or in relation to this Agreement on behalf of the Manufacturer/Importer, as data processor, the Contractor shall in respect of such personal data:

(i) act only on instructions and directions from Manufacturer/Importer, which is the data controller, and comply promptly with all such instructions and directions received from the Manufacturer/Importer, and ensure that any person acting under its authority having access to personal data may only process them upon

Manufacturer/Importer's instructions, except for an obligation imposed by law.

(ii) unless otherwise requested by Manufacturer/Importer, process personal data only to the extent and in such manner, as is necessary for the provision of the Services; and for no other purpose;

(iii) ensure that all necessary or appropriate technical and organisational measures shall be taken and implemented to (a) protect the security and confidentiality of personal data processed by it in providing the Services, and (b) protect personal data against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data; and notably implement the security measures imposed under applicable law or adopted by competent regulatory from time to time;

(iv) not disclose personal data to any employee, director, agent or affiliate of the Contractor or any third party except as necessary for the performance of the Service.

(v) take reasonable steps to ensure the reliability and integrity of any Staff who have access to the personal data and, if sensitive personal data are processed, draft a list of the categories of persons having access to such data with a description of their function, ensure that they are kept by a statutory or contractual obligation to maintain the confidentiality of such data, and keep a list of such persons at Manufacturer/Importer's or competent regulators' disposal;

(vi) not cause or permit personal data to be transferred outside the European Economic Area without Manufacturer/Importer's prior written consent;

(vii) provide at no charge such assistance as Manufacturer/Importer may reasonably require in order to the Manufacturer/Importer to deal with any request for data subject access under the applicable Data protection Laws, or any request, inquiry or investigation initiated

Commented [REDACTED]: Are there any personal data in the meaning of GDPR?

Commented [REDACTED]: Clear distinction shall be made between confidentiality and data protection.

Commented [REDACTED]: Not yet compliant with Article 28 of the GDPR.

Commented [REDACTED]: This could be an issue with regard to the obligation to locate data within the UE Territory. It should not be allowed, including with prior written consent.

by any relevant regulatory authority in respect of personal data;

(viii) comply with all relevant provisions of applicable Data Protection Laws.

7.4. The Contractor keeps in strict confidence and does not disclose to any third party any data which it receives or which comes to its knowledge as a result of the performance of its obligations under this Agreement. Only the European Commission, the competent authorities and the approved external auditor (pursuant to Section 11 "Right of audit") have full access to the Contractor's facilities and data stored in the performance of the Service. In duly justified cases the European Commission or the Member States may grant the Manufacturer/Importer access to the data stored in the performance of the Service, provided that commercially sensitive information remains adequately protected in conformity with the relevant European Union and national law.

7.2 The Contractor strictly observes any specific confidentiality and/or security obligations (as defined in Annex 1 "Technical Requirements"). The Contractor warrants that its technical and organisational security measures are appropriate to protect data received or which comes to its knowledge under this Agreement from accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where such data is transmitted over a network.

7.3 To ensure that confidentiality and security is observed at all times, the Contractor similarly binds each of its employees and any other person it retains for the performance of its obligations under this Agreement to observe the confidentiality and security obligations laid down in this Agreement. The Contractor shall impose on such persons conditions at least as stringent as those laid down in this Agreement. When deemed necessary by the Manufacturer/Importer (and the European Commission and/or the competent authorities, the Contractor provides evidence that its personnel and the personnel of any subcontractors have

had such conditions imposed. The Contractor regularly monitors that such obligations are not breached by its personnel or other persons it retains for the performance of activities under this Agreement.

7.4. If personal data are handled under the present Agreement, the Contractor undertakes to process them only to the extent strictly necessary to provide the Service and in compliance with Directive 95/46/EC as implemented in the relevant national law and, from 25 May 2018 in compliance with Regulation UE 679/2016,

7.5. The Manufacturer/Importer retains the exclusive responsibility for damages caused by failure of the preservation of the confidentiality of authentication credentials, including the password needed to use the Service. The Contractor is not responsible for any damage that the Customer may incur for the use of passwords, authentication credentials and accounts by third parties, of which the Manufacturer/Importer is or is not aware, nor for misuse, unauthorised or illegal use of the account, password and credentials attributable to the Manufacturer/Importer or others.

8. Price, billing and payments

8.1. In consideration for Contractor carrying out the Services, Manufacturer/Importer shall pay to the Contractor the Charges as set out in Annex 2 and on receipt of a valid invoice in respect of such charges.

8.2. Payment for Services will be dependent on the acceptance by Manufacturer/Importer of the services.

8.3. Except for VAT, the Contractor shall be responsible for all tax liabilities in respect of any amounts payable hereunder and hereby agrees to indemnify manufacturer/importer in respect of any claims with ay be made against Manufacturer/Importer by the relevant authorities in respect of tax or similar charges, and any costs, interest and penalties which may be found due in respect of such amounts.

Commented [LM71]: This is a repetition of section 7.1, I would suggest to delete it.

Commented [ET72R71]: This sections binds the employees and any other person related to the Contractor, we believe it is important to keep it due to the criticality of the data managed by the data storage(s).

Commented [REDACTED]: Provision on "Confidentiality" must be completed (what is confidential information? Are there exceptions? Who can access? Penalty in case of infringement, etc.).

Commented [REDACTED]: How and when?

Commented [REDACTED]: Not sufficient to comply with GDPR (Contractor is acting as a processor and therefore the requirements of Article 26 must be respected). Who is the controller? The processor? Purpose of processing? International transfer...

Commented [LM64]: I would suggest to have a paragraph on access rights, keeping in mind that the entities that will have access to the data storage won't be party of the contract.

Commented [ET65R64]: Adapted

Commented [REDACTED]: To be defined.

Commented [everis67R66]: By the EC in its delegated acts

Commented [LM68]: This is already defined in the TPD, no need to repeat it. Please consider that this is a contract between industry and data storage provider, therefore you should always keep in mind that it binds only the contracting parties.

Commented [ET69R68]: Even if it is already defined in the TPD, we believe it is important to keep it here in order to provide the full picture of the access rights and the use of data.

We are aware that the agreement binds only the contracting parties (manufacturers/importers and providers of data storage(s) services), but it is also true that the TPD provides a strong legal frameworks which needs to be referenced in the Agreement.

Commented [REDACTED]: Access right should be much more detailed. "Parties agree that access to [please mention DATA] shall be given to the EU Commission and [please mention recipient] in accordance with [please mention legal provision], for the purpose of [please mention purpose]". In case of personal data, it must be compliant with the controller/processor relationship. It could serve as model, for consistency reasons, for the access to data that are not personal data. It is recommended to add a specific provision on access. Access is requested to Contractor or to the M/I?

Commented [LM74]: How could the manufacture responsible for the credential and the authentication if under the Directive they shall not access the data storage?

Commented [ET75R74]: Article 15.8 TPD: "n duly justified cases the Commission or the Member States may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and national law."

Commented [REDACTED]: Not applicable here (except at the beginning of the provision of the service, but I understand that the acceptance procedure was deleted).

8.4. All sums due to the Contractor under this Agreement shall be payable by Manufacturer/Importer by electronic bank transfer after receipt of a correct, undisputed and properly due invoice which shall state, as a minimum:

(i) a short description of the relevant Services;

(ii) the period to which the invoice relates;

(iii) Contractor's bank account for payment; and

(iv) all charges and applicable taxes.

8.5. If Manufacturer/Importer has a bona fide dispute in relation to the whole or any parts of an invoice submitted by the Contractor, Manufacturer/Importer may withhold payment of the amount in dispute.

8.6. Contractor shall continue to perform its obligations under this Agreement and shall not suspend the provision of any Service or other obligations under this Agreement.

8.7. If any amount, in the absence of a dispute, is not paid on the due date, and remains unpaid for a period of 15 days after receipt by Manufacturer/Importer of a written reminder from the Contractor sent by registered mail, Manufacturer/Importer shall pay interest at a rate of 3% per annum calculated on a daily basis as from the due date.

8.8. Contractor acknowledges that payment by Manufacturer/Importer of any invoice due will not be deemed to constitute acceptance of the Services and is without prejudice to any representations or warranties made by the Contractor. The prices, the procedures for billing and payment with respect to the Service are indicated in Annex B to the STS "PC".

9. Location and subcontracting

9.1. The Contractor's facilities providing the Service are located on the territory of the European Union. In the case that the borders of the European Union change during the execution of the Service, the

Contractor ensures that the facilities providing the Service remain on or are relocated to the territory of the European Union.

9.2. Changes in the physical location of the Contractor's facilities during the term of the Agreement may take place only after the written approval of the Manufacturer/Importer.

9.3. The Contractor may not subcontract part of the Service to third parties.

~~9.3. In case of breach of the contract the Manufacturer/Importer may terminate the Agreement.~~

10. Ownership of data

10.1. The Contractor processes data supplied by the Manufacturer/Importer only for the purposes of this Agreement pursuant to the Directive and the Implementing and Delegated Acts adopted by the European Commission to determine the technical standards for the recording, transmitting, processing and storing of data and access to stored data.

10.2. The Manufacturer/Importer has the ownership of provided data and the results of any processing of that data. The Manufacturer/Importer shall not be entitled to modify or delete the recorded data.

10.3. The Contractor- does not retain in any way any data or copies of provided data longer than necessary for the performance of the Agreement. Upon request by the Manufacturer/Importer, the European Commission, or the competent authorities, the Contractor shall deliver a certificate executed by one of its duly authorised officers, confirming compliance with the destruction obligations.

10.4. The above provisions apply without prejudice to any of the Contractor's obligations in connection with termination following Section 16 "Data portability".

11. Intellectual Property Rights

Commented [REDACTED]: Why not? Also under its responsibility, and with prior written agreement of the M/I. Are there providers on the market that do not have any subcontractor?

Commented [everis85R84]: Requested by DG SANTE

Commented [LM86]: I don't think it is beneficial to allow for a subcontract of any of the activities which are part of the service. In addition the Directive doesn't allow the Commission to approve the subcontractor.

Commented [ET87R86]: Updated.

Commented [REDACTED]: To be included in Article 17 : Termination

Commented [REDACTED]: Ownership of data is a very complex and controversial question and this model contract is not the place to solve it. Actually, it depends upon the legal framework used to protect data (IP rules with data base or data protection rules). In this case, data shall not be modified or deleted by the M/I so that it is paradoxical to state that it is the owner of data. I recommend not to refer to the ownership of data and only regulate the access and the prohibition to modify or delete them. It could be included in the provision on confidentiality and data protection.

Commented [everis90R89]: Support to draft this regulation on access an prohibition to modify data would be much appreciated.

Commented [REDACTED]: In which case ? related to 8.5.7

Commented [LM91]: This is more related to the access rights, I would move it to the section where this issue is addressed.

Commented [ET92R91]: See comment above.

Commented [CG78]: An article about suspension of the contract (not termination) is to be added.

Commented [REDACTED]: Please refer to the penalties of directive 2011/07 on late payments. Suspension of services should also be limited.

Commented [REDACTED]: Not necessary here.

Commented [REDACTED]: General rule should be included here, including payment term, possible penalty in case of late payment (cf. directive 2011/7). Is it allowed to suspend the service in case of late payment (this point should be regulated) ?

Commented [REDACTED]: Location in the EU territory should be mentioned. Should it also be a UE provider?

Commented [REDACTED]: Please add, for clarity purposes, that data storage facilities are also included and must be located on the UE territory.

11.1. Unless otherwise expressly agreed elsewhere in this Agreement:

(i) no Intellectual Property Rights are intended to be transferred as a result of this Agreement and nothing in this Agreement will result in Manufacturer/Importer having any right, title, licence to or interest in any Pre-existing IPR of the Contractor in respect of which all rights are hereby expressly reserved, and

(ii) all right, title and interest in relation to the Newly Developed IPR shall automatically be assigned to Manufacturer/Importer on payment of the applicable charges in respect of the same with the Contractor executing such documents as are necessary to give effect to such assignment. The assignment will be valid for the whole duration of the protection and for the territory of [country of Manufacturer/Importer].

11.2. Licence of Pre-existing IPR: Manufacturer/Importer grants to the Contractor, as of the effective date, a non-exclusive, royalty-free, sub-licensable, non-transferrable and worldwide licence to use the Pre-existing IPR of Manufacturer/Importer for the duration and exclusive purpose of its performance under this Agreement. Contractor may use the Pre-existing IPR of Manufacturer/Importer as provided herein, but has no obligation to do so. If Contractor uses Pre-existing IPR of Manufacturer/Importer, the Contractor shall be responsible for verifying and ensuring that:

(i) such Pre-existing IPR is fit for purpose, and

(ii) none of the license types or terms applicable to such Pre-existing IPR (if any), as provided to Contractor, restrict Contractor's ability to transfer ownership and/or grant the licenses to Pre-existing IPR and Newly Developed IPR (as the case may be) as provided in this Agreement.

11.3. Contractor hereby grants to Manufacturer/Importer, as of the effective date, a non-exclusive, royalty-free, sub licensable, transferrable, for the

entire duration of protection of the IPR, irrevocable and worldwide license to use the Pre-existing IPR of Contractor, if and to the extent necessary or useful to benefit from the Service provided and to use the system, for any purpose; for the avoidance of doubt, this shall include in particular, without being limited to, the right to execute, display, install, test, reproduce, distribute, sub-licence, modify, maintain, enhance, commercially exploit and create derivative works of, to grant sublicenses to third parties and to further develop the Pre-existing IPR (and any third party IPR incorporated or delivered by Contractor:

- contained in the system;

- otherwise delivered to Manufacturer/Importer by the Contractor or required to use, maintain or develop the system; and

- to permit such use by Manufacturer/Importer.

12. Auditing

12.1. The Contractor shall grant to the European Commission, the competent authorities of the Member States and any external auditor appointed by the Commission access to the Contractor facilities and all locations that are otherwise relevant to this Agreement and will provide reasonable support as required during the Term of this Agreement in order to undertake the following actions in relation to the Services and Contractor's obligations under this Agreement:

(i) access to the build and test environments of the Contractor to verify compliance with Contractor's obligations under this Agreement;

(ii) verification of Contractor compliance with legal and regulatory requirements;

(iii) verification of the accuracy of the charges in connection with the Services, and any other amounts payable or receivable by manufacturer/importer under this Agreement;

(iv) verification that the Contractor's systems protect the integrity, operational

Commented [REDACTED]: Is it going to occur?

Commented [REDACTED]: To be completed : When? Who? Object of the audit? What will occur in the case of non-compliance? Could it be asked by the Commission?

availability and security of data and Confidential Information; and

(v) verification that the Services are being provided, and Contractor's obligations are being met, in accordance with this Agreement.

12.2. If a material non-compliance is found in relation to any of the matters which were audited in accordance with this article, the Contractor shall bear the full costs incurred by Manufacturer/Importer for the audit, inspecting and/or monitoring where the error or non-compliance was found.

The compliance of the Service with this Agreement and the Directive is monitored by an external auditor proposed and paid by the Manufacturer/Importer and approved by the European Commission.

11.2. The external auditor submits an annual report to the competent authorities and to the European Commission, assessing in particular any irregularities in relation to access to data stored in the performance of the Service.

13. Obligations of the Manufacturer/Importer

13.1. The Manufacturer/Importer provides all the contributions regarding the provision, implementation and testing of the Service as expressly defined in the Annex 1 "Technical Requirements".

13. Delays and penalties

13.1. The Contractor shall notify the Manufacturer/Importer any delays in the provision of the service.

14. Liability

14.1. Direct damages: the Contractor shall be liable for and shall hold harmless, defend and indemnify Manufacturer/Importer from and against any direct damages arising out of or relating to its performance under this Agreement whether based on an action or claim, in contract, equity, negligence, tort, or otherwise, for all events, acts or omissions.

14.2. Indirect damages: without prejudice to the article of this Agreement, neither Party shall be liable for all claims, proceedings, damages, expenses, costs and losses that are indirect or consequential, including without limitation loss of profit, loss of opportunity, loss of business, loss of reputations, loss of savings, loss of clientele, loss of data relating to the Contractor, and loss of goodwill, as well as third parties' claims ("Indirect Damages"), whether based on a contractual breach, tort (include negligence), breach of statutory duty, hidden or latent defect, or otherwise, regardless of whether the damages were foreseeable, arising out of, in connection with its participation in the Services and/or performance of its obligations under this Agreement.

It is expressly agreed that the limitation of liability for Indirect Damages stipulated under this article does not cover a loss of, damage to, or any third party claims arising out of, or relating to, manufacturer/importer data.

14.3. Liability cap: Contractor's liability arising out of, in connection with its participation in the Services and/or performance of its obligations under this Agreement shall be limited to an amount equal to one hundred and twenty five per cent (125%) of the total charges that are due to the Contractor in one calendar year under this Agreement.

Without prejudice to Manufacturer/Importer's obligation to pay charges properly due, the total aggregate liability of Manufacturer/Importer arising out of or in connection with this Agreement, whether in contract, tort (including negligence) or breach of statutory duty or otherwise, howsoever arising, shall be limited to one hundred thousand Euros (100.000 EUR).

The Contractor is liable to compensate the Manufacturer/Importer for all damage or expenses it incurs as a result of a culpable breach of the Agreement by the Contractor.

14.2. Save Section 13 "Delays and penalties", the amount due by the

Commented [REDACTED] : No limitation of liability in case of wilful misconduct or gross negligence.

Commented [REDACTED] : Check conformity with 15(8), al.2, stating that external auditor is paid by the tobacco manufacturers.

Commented [REDACTED] : Too broad. Will never be accepted by the market. Reference could be made to article 6 or 7 for instance.

Commented [REDACTED] : To be completed. Data to be provided? When? Etc. + Structure : just after the provision related to the obligation of the Contractor

Commented [REDACTED] : Not clear. To be completed or deleted.

Commented [REDACTED] : To be included in main duties

Commented [REDACTED] : To be reviewed and completed. What are the limitations of liability (indirect damages? CAP?). Some damages could be excluded from the limitation (breach of confidentiality or data protection rules, for instance).

Commented [REDACTED] : Cap must be determined on a case by case basis. Realistic to include it in a model contract?

Commented [REDACTED] : What does it mean? Recommended to refer to material breach.

Contractor for default of the Agreement is defined in the relevant STS.

~~14.3. The Contractor is not responsible for loss of profits, loss of earnings or for any other form of loss of profit or damage, delays or malfunctions however derived from the provision of the Service which depend on events beyond the reasonable control of the Contractor such as, for example:~~

~~a) force majeure events;~~

~~b) events dependent on the acts of third parties such as, but not limited to, the interruption or malfunction of telecommunication lines and/or electric power networks;~~

~~c) malfunction of the terminals or other communications systems used by the Manufacturer/Importer or improper use of the same and/or the procedures for access to the service by the Manufacturer/Importer or third parties.~~

15. Force Majeure

15.1. "Force Majeure Event" means an occurrence or circumstance, other than financial, beyond a Party's control, which was unforeseeable on the effective date and which such Party cannot avoid, including but not limited to an act of God, fire, flood, storm, revolution, act of terrorism, riot, war or civil commotion (but excluding strikes and industrial disputes of the affected Party), any failures of power or other utilities, surplus or shortage of, or any delay in or inability to procure or remove, any labour, materials, equipment or supplies.

15.2. Any failure or delay by the Manufacturer/Importer or the Contractor in the performance of their obligations pursuant to this Agreement due to a Force Majeure Event shall not be deemed a breach of this Agreement of a ground for termination hereunder (except as provided hereunder) provided that such failure or delay could not have been possibly prevented and cannot possible be circumvented by the non-performing Party through the use of alternate sources, workaround plans, or other means. Upon the occurrence of a Force

Majeure Event, the non-performing Party shall be excused from the performance of its obligations pursuant to this Agreement affected by the Force Majeure Event for as long as (1) such Force Majeure Event continues and (2) such Party continues to use its best efforts to recommence performance whenever and to whatever extent possible without delay.

15.3. The Party delayed by a Force Majeure Event shall immediately notify the other Party by telephone or any other pre-agreed warning (to be confirmed in a notice within 1 day of the inception of such delay) of the occurrence of a Force Majeure Event and describe in reasonable detail the nature of the Force Majeure Event.

15.4. Manufacturer/Importer will be entitled to cease payment of the price and/or to recover from the Contractor any of the charges already paid in connection with the defaulting services until the recovery of from such Force Majeure Event has been completed and in so doing may perform any act that Manufacturer/Importer deems reasonably necessary in order to restore the Services or procure the Services from an alternate source.

15.5. If such Force Majeure Event causes delay in performance for more than thirty (30) days, then the Party not suffering the Force Majeure Event may terminate this Agreement, without cost, compensation or indemnity, effective upon written notice to the other Party.

15.6. The occurrence of a Force Majeure Event does not limit or otherwise affect Contractor's obligation to provide either normal business continuation procedures and/or to ensure full compliance with the Business Continuity Plan for the continuation of business.

15.7. Forthwith upon the Force Majeure Event ceasing to exist, the Party relying upon the Force Majeure Event shall give written advice to the other Party of this fact and resume performance of the affected obligations.

16. Insurance and guarantee

Commented [REDACTED]: To be defined.

Commented [REDACTED]: Probably too many details.

Commented [REDACTED]: I suggest not to define the concept but refer, in this model contract, to the meaning in accordance with the applicable law.

Commented [REDACTED]: Not clear

Commented [REDACTED]: I suggest to delete because issues could occur when articulating this rule with the definition.

16.1. The Contractor provides evidence of an insurance to Manufacturer/Importer against all insurable risks of damage, loss or injury caused by the Contractor in the execution of the Agreement including any act by its personnel or by any person acting on the Contractor's behalf for the performance of the Agreement.

16.2 The insurance is the type customary for the industry sector in which the Contractor operates and shall include insurance cover for professional and corporate liability, providing cover for at least the amount defined in the STS. In any case, the minimum amounts stipulated shall not prevent the Contractor from complying with the obligation to insure itself for higher amounts, where such would be the case, as provided in statutory provisions. Furthermore, the amounts of insurance stipulated shall in no way limit or diminish the obligation of the Contractor to compensate the Manufacturer/Importer for damage incurred.

15.3. The Contractor provides at his own expense, as security for due performance of the Agreement, including the obligation to pay a contractual penalty, a guarantee for the amount to be secured, issued by an established credit institute of good standing registered the European Union. The guarantee must in all cases be directly enforceable, unconditional, irrevocable and issued for the duration of obligations set forth in the Agreement and according to the applicable law.

16.4. At the Contractor's request, the Manufacturer/Importer returns to the former or the guarantor any guarantee deeds provided to it as soon as it is established that the Manufacturer/Importer can no longer invoke any of the rights secured by the guarantee.

165. Data portability

~~165.1. The Contractor delivers to the next Contractor with an up to date backup of the data stored in the performance of the Service. Any updates to data after this delivery and any additional data received or created shall be migrated to the next Contractor without undue delay.~~

~~165.2. The Contractor shall have no right of retention with respect to any data, information and/or other necessary material to be delivered to the next Contractor and allow full data portability in accordance with this Section 16 "Data portability".~~

17. Termination

17.1. Termination for cause by the Manufacturer/Importer: without prejudice to any right or remedy Manufacturer/Importer may have against the Contractor for breach or non-performance of this Agreement. Manufacturer/Importer may terminate this Agreement for cause, without prior intervention of a court or arbitral body and without any financial liability to the Contractor at any time on notice in writing to the Contractor immediately or forthwith following such notice period as described below if:

(i) Contractor commits a material breach of any of its obligations or the terms and conditions set out in this Agreement, provided that where such breach is capable of remedy, Contractor has been notified in writing of the breach and has not remedied it within thirty (30) days of receipt of such notice;

(ii) any of the representations, warranties and undertakings given by the Contractor have become materially inaccurate during the term of the Agreement;

(iii) following an independent review by a qualified external party that Contractor is not, or will not be, able to complete the Services within the timescale contemplated in this Agreement.

(iv) Contractor is in material breach and fails to remedy the material breach within thirty (30) days.

(v) Contractor is in breach of its obligations relating to confidentiality, security and/or Data Protection

(vi) Contractor or any staff are in breach of any anti-corruption laws;

(vii) Manufacturer/Importer exercises its right to terminate all or part of the

Commented [REDACTED]: Not clear. Distinction must be made between termination for cause and termination for convenience (and we recommend not to allow termination for convenience in the present case). Reference should be made to material breach (and not to serious cause). Insolvency should also be mentioned, being agreed that it is not a breach as such. Duties after termination must be mentioned (ref. to exit plan).

Commented [REDACTED]: What about termination for cause by the Contractor? Suggestion to add another clause or to apply this provision to both Parties.

Commented [REDACTED]: To be reviewed and completed. An "exit" plan must be established (information duties before to terminate ; format ; price, collaboration duty, timeline, choice of the next Contractor, etc.).

Agreement under article X ("Price, billing and payments"); and/or;

(viii) as a result of a fault or negligence on behalf of Contractor, Contractor is refused or has revoked any official or regulatory licence, authorisation or permission necessary for the performance of its obligations hereunder and such breach is not cured within one (1) month notice.

17.2. Termination by Contractor: if Manufacturer/Importer fails to pay any undisputed charges exceeding three (3) months of all charges under the Agreement within the time provided for by this Agreement, Contractor may give Manufacturer/Importer notice of its intention to terminate this Agreement if payment is not received within thirty (30) days of that notice.

The Parties may terminate the Agreement following the instructions provided in the relevant STS.

17.2. If the Manufacturer/Importer has serious cause, it may terminate the Agreement in writing without advance notice. There is serious cause, in particular, where:

(a) the Contractor's financial circumstances deteriorate to such an extent that due performance of the Agreement can no longer be expected;

(b) the Contractor becomes, or is at risk of becoming, insolvent or is over-indebted;

(c) the opening of insolvency proceedings or comparable statutory proceedings with respect to the Contractor's assets is refused owing to lack of funds or the Contractor finds himself in a comparable situation under the laws of the country in which he is domiciled;

17.3. The Manufacturer/Importer shall immediately terminate the Agreement if notified by the European Commission that the Contractor no longer meets the necessary requirements with respect to independency and technical capacities set forth in the Directive.

18. Termination Assistance, Data and knowledge transfer

18.1. Following notice of termination of this Agreement for any reason, the Contractor shall provide termination assistance as is reasonably required for such period of time as is reasonable in order to provide for an orderly disengagement and (where applicable) seamless transition to the next Contractor.

18.2. Contractor shall perform the termination assistance services described in this Agreement. In particular, the Contractor shall:

(i) transfer the services, the system and/or work products to the next Contractor in a reasonable time frame;

(ii) assist with the handover of operational responsibility to the next Contractor.

18.3. The Contractor will provide an interim and a final Termination Assistance Plan following the guidelines of this Agreement. Within sixty (60) days of the notice of termination of the Agreement, the Contractor will deliver an initial Termination Assistance Plan to the European Commission for its review and feedback.

18.4. Providing data: on written request during the Termination Assistance Period, the Contractor will provide data regarding:

(i) Consumption and utilisation of resources

(ii) Business process procedures and work flow

(iii) Business process volumes and statistics

(iv) Business process training modules

(v) Performance histories

(vi) Then current and projected work volumes

(vii) Any other data reasonably requested by the European Commission about the

Commented [CG112]: Not aligned with Art. 7 Pricing: there is no longer a reason for terminating the contract due to non-payment. I would remove this paragraph.

Commented [REDACTED]: Is it applicable here?

Commented [REDACTED]: To be regulated in the GTC.

Commented [REDACTED]: Not clear. Distinction must be made between termination for cause and termination for convenience (and we recommend not to allow termination for convenience in the present case). Reference should be made to material breach (and not to serious cause). Insolvency should also be mentioned, being agreed that it is not a breach as such. Duties after termination must be mentioned (ref. to exit plan).

Commented [LM116]: This provision is too unclear, allowing for the possibility to terminate the contract in case of "serious causes" is too vague.

Commented [ET117R116]: The cases of "serious causes" are described hereinafter.

Commented [LM118]: For the purpose of the tracking and tracing system, I don't think it is beneficial to allow an immediate termination of the agreement

Commented [ET119R118]: Please pay attention following sentence. Immediate termination of the agreement by the manufacturer/importer is allowed only "if notified by the European Commission that the Contractor no longer meets the necessary requirements with respect to independency and technical capacities set forth in the Directive".

In this situation, the Agreement would need to be terminated immediately. As the European Commission is not a party to the Agreement, it has to be terminated by the manufacturer/importer.

services as necessary for the next Contractor to assume responsibility for continued performance of the services.

18.5. Contractor will provide for a transfer of knowledge about the services and related topics (which may be specified in the Termination Assistance Plan) to facilitate the provision of replacement services by the next Contractor. This will include:

(i) participate in workshops, meetings, and "hands-on" activities where requested by the European Commission;

(ii) Provide the next Contractor with information about the services that are necessary to implement the Termination Assistance Plan; and,

(iii) Provide the next Contractor with information about the services as necessary for the next Contractor to assume responsibility for continued performance of the services in an orderly manner so as to minimize disruption to the operations;

18.6. The Contractor will deliver to the next Contractor with an up to date backup of the data stored in the performance of the Service. Any updates to data after this delivery and any additional data received or created shall be migrated to the next Contractor without undue delay.

18.7. The Contractor shall have no right of retention with respect to any data, information and/or other necessary material to be delivered to the next Contractor and allow full data portability in accordance with this Agreement.

18. Structure of the Agreement

18.1 The present Agreement consists of:

—General Terms of Service (GTS)

—Annex 1 to the GTS "Technical Requirements"

—Special Terms of Service (STS)

—Annex A to the STS "SLA"

—Annex B to the STS "PC"

19. Amendments to GTS and STS Agreement

19.1 Pursuant to Article 15(8) and (10) of the Directive, Parties do not have the right to amend the GTS and STS Agreement. The European Commission reserves the right to regularly monitoring and evaluating modifications to the GTS and STS Agreement by means of delegated acts in accordance with Article 27 of the Directive.

20. Applicable law and disputes

20.1. The Agreement is governed by the law of _____.

20.1. In the event of Any dispute arising out of, or in connection with, this Agreement, each Party agrees, without prejudice to the right of each Party to immediately seek any interim or final remedy before the court as set forth in 20.4, to attempt in good faith to resolve the dispute amicable and speedily by referring such dispute by written notice:

i) first to the Service Delivery Committee, who shall meet and endeavour to resolve the dispute between them within fifteen (15) business days of such notice,

ii) failing resolution of the dispute, to the Management Committee, who shall meet and endeavour to resolve the dispute between them within ten (10) business days of such notice. The joint written decision of the Management Committee shall be binding on the Parties, and;

iii) failing resolution of dispute, to the Executive Steering Committee who shall meet and endeavour to resolve the dispute between them within fifteen (15) business days of such notice. The joint written decision of the Executive Steering Committee shall be binding on the Parties.

20.2. If the Service Delivery Committee, the Management Committee and the Executive Steering Committee are unable to resolve the dispute, the dispute resolution shall be considered at an end as regards the dispute at stake, unless the Parties agree to refer the matters in

Commented [REDACTED]: It should be the Law and the Jurisdiction of a Member State. The Agreement could also include an out-of-court resolution process (arbitration or mediation) and an escalation process (first refer to project managers and then higher and then higher, with compulsory timeline).

Commented [everis123R122]: Modified. Dispute resolution procedure included SUBJECT TO the approval of the Governance Model by the EC.

Commented [LM120]: This is too complicated. For the purpose of drafting a model contract you should simply the structure, ideally to one single document

Commented [ET121R120]: We have reviewed this matter with our external legal advisors and this is the most common and accepted standard for cloud storing agreements. In comparison with other model contracts of this nature, this is the most simple that it can already get.

We suggest to keep this structure and discuss it with the external expert(s) during the review.

Commented [REDACTED]: Parties should be able to amend this process in accordance with their own practice.

dispute to a non-binding arbitration, expert's assessment, or mediation, in which case, the dispute resolution procedure shall be considered at an end should the findings or recommendations resulting from such additional non-binding procedure are not acceptable to both Parties.

20.3. In either party does not agree with any dispute being referred for determination in accordance with sub-article 20.1, then the dispute shall be determined by the [UE country of Manufacturer/Importer] courts in accordance with the following sub-article.

20.4. The construction, validity an performance of this Agreement and all non-contractual obligations arising from or connected with this Agreement shall be governed by, and construed in accordance with, the Laws of [UE country of Manufacturer/Importer] and any dispute arising out of this Agreement shall be subject to the exclusive jurisdiction of the courts of [courts of the seat of the Manufacturer/Importer] to which both Parties hereby agree to submit irrevocably for these purposes.

~~between the Parties resulting from the interpretation or application of the Agreement which cannot be settled amicably shall be brought before the courts of _____.~~

21. Miscellaneous

21.1 The Agreement constitutes the entire agreement between the Parties. There are no oral agreements or understandings. Any amendment or addition to the Agreement, where possible, must be in writing. Any waiver of the requirement of written form must likewise be in writing.

21.2 Should a clause of the Agreement be or become invalid, the remainder of the Agreement remains in force. The invalid clause must be replaced by a valid clause coming closest to achieving the object and purpose of the invalid clause.

21.3 If the Agreement contains any gaps or ambiguities, it is to be interpreted

in the light of its object and purpose of the Directive.

On behalf of the Contractor:

Name (written in full):

Position:

Address:

Signature.....
(stamp of organisation)

On behalf of the Manufacturer/Importer:

Name (written in full):

Position:

Address:

Signature.....
(stamp of organisation)

Commented [REDACTED]: Add a clause for consistency issues between the documents.

2017

17

Consumers, Health, Agriculture and Food Executive Agency
Health Programme

8.2. Special Terms of Services—Primary Data Storage

Special Terms of Service (“STS”) —Primary Data Storage— Reference Number —[...]—	
Service	Primary Data Storage means the independent Primary Data Storage solution, hosting data exclusively related to a specific Manufacturer/Importer or a group of distinct Manufacturer(s)/Importer(s). The Service shall include making available to the Manufacturer/Importer a development and a test environment for the Service in accordance with the requirements and for the purposes described in the Annex 1 to GTS “Technical Requirements”.
Terms, renewal and termination	The Service shall be provided for a period of X (X) years from the signature of the contract. The Initial Contract Period may be extended, at the exclusive option of the Manufacturer/Importer, by X (X) further periods of X (X) year each (“ Extension Period ”), upon the Manufacturer/Importer giving written notice to the Contractor at least X (X) months before the end of the Initial Contract Period or the subsequent Extension Period. Option: The Manufacturer/Importer may terminate at any time the Agreement, without the need to state reasons, by serving a 90 (ninety) day written notice to the Contractor.
Liability	The Contractor’s liability according to Section 14 “Liability” of the GTS shall be limited to an amount of EUR XXXX (in words: XXXX Euros) per event, whereby a single event shall be considered present in the case of a sequence of connected events (occurrences), and to an amount of EUR XXXX (in words: XXXX Euros) per calendar year in the case of multiple events.
Insurance	The insurance according to Section 15 “Insurance and guarantee” of the GTS shall include insurance cover for professional and corporate liability and will provide cover for at least EUR XXXX (in words: XXXX Euros) per event, with the maximum annual cover of at least XXX% (XXXX) of this amount.
Contractual penalty	Where performance of the Service is delayed, the Contractor is liable to pay a contractual penalty at a rate of 0.2% per working day of such delay but subject to a maximum of 5% of the net price of the delayed part of the Service.

Commented [REDACTED]: To be included in the GTC or in a specific work order.

Commented [LM127]: This is really not clear. Please define better what the contractor should do

Commented [ET128R127]: The specific tasks and technical specifications are to be defined in the Technical Annex for each of the services (primary DS and surveillance DS). This is a common practice in cloud storing agreements. The technicalities and specifications of this kind of storages are too complex to be included in the body of the Agreement itself.

As WP3 (“Technical Specifications”) has not been finalised yet, the Annex 1 to GTS “Technical Requirements” has not been drafted yet.

Commented [REDACTED]: What does it mean? In the case of data storage, it is not really a delay issue.

ANNEX A-1 – SERVICE LEVEL AGREEMENT (“SLA”)

Commented [REDACTED]: To be completed.

1. Availability and performance of the Service

1.1 The Service must be operational and fully functional at all times.

In the event that the Service does not meet the requirement referred to in the previous sentence, the Contractor shall compensate the Manufacturer/Importer.

1.2 Should the Contractor claim that the non-availability of the Service is caused by circumstances beyond the Contractor’s control, the Contractor shall not be liable to pay liquidated damages, provided that the Contractor provides evidence of such circumstances.

1.3 The Contractor shall cooperate with any reasonable request by the Manufacturer/Importer to improve its performance on a structural basis such as, but not limited to, the Contractor applying more resources and/or revising its procedures and/or involving the Manufacturer/Importer more closely in problem solving operations, where it has been established that the Contractor does not meet on a regular basis the requirements and/or Service Levels set out in this Agreement. In this respect, the Contractor shall also cooperate with any analysis of the causes of non-compliance requested by the Manufacturer/Importer and shall allow the Manufacturer/Importer to perform such analyses.

2. Support

2.1 The Contractor makes available to the Manufacturer/Importer a telephone and/or e-mail hotline service for providing support, which is available on all working days (from ____ day ____ to day ____) in the following working hours (from ____ h to ____ h).

3. Data portability

3.1 During the latest 60 (sixty) days before the expiry/termination of this Agreement (according to Section 3 of the STS), at no additional costs to the Manufacturer/Importer, the Contractor shall deliver to the next contractor indicated by the Manufacturer/Importer a complete and up-to-date version of the data stored. Any updates to these data after this delivery and any additional data received or created shall be migrated to the next contractor without undue delay.