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| --- | --- | --- | --- |
| **Key elements to be included in draft contract, as laid down by Commission Delegated Regulation (EU) 2018/573 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products** | **Provision in Delegated Regulation (EU) 2018/573** | **If yes please tick the box****/****If no please provide explanation.** | **Indication of where corresponding provision is set out in draft contract submitted to Commission for approval (e.g. page number/section)** |
| * Are **Key Services** to be rendered by the provider specified?

If yes, do they include: |  |  |  |
| * Establishment & operation of a primary repository?
 | Art. 3 (1) (1)Delegated Regulation |  |  |
| * Specifications relating to operability, availability and performance of the service of the primary repository?
 | Art. 3 (2)Delegated Regulation |  |  |
| * Establishment & operation of a secondary repository?

  | Art. 3 (1) (2)Delegated Regulation |  |  |
| * Specifications relating to operability, availability and performance of the service of the secondary repository?
 | Art. 3 (2) Delegated Regulation |  |  |
| * **Availability**
 |  |  |  |
| * Is a *monthly uptime* and *availability of 99.5%* of the primary repository guaranteed?
 | Art. 5(1) Delegated Regulation  |  |  |
| * Is a *back-up* mechanism guaranteed?
 | Art. 5(2)Delegated Regulation  |  |  |
| * **Access Rights**
 |  |  |  |
| * Are requirements for granting *physical and virtual access* at server and database (to MS, Commission and external auditors) specified?
 | Art. 6Delegated Regulation  |  |  |
| * **Sub-contracting** (applies only in case the contract specifies it)
 |  |  |  |
| * Does the contract include a provision clarifying that the subcontract does not affect the primary responsibility of the provider?
 | Art. 7 (1)Delegated Regulation |  |  |
| * Does the contract require the provider to ensure that the subcontractor has the necessary *technical* *expertise* and *meets the requirement of independence?*
 | Art. 7 (2) (a) Delegated Regulation |  |  |
| * Does the contract require the provider to submit a copy of the *legal* and *financial declaration*, signed by the subcontractor, to the Commission?
 | Art. 7(2) (b)Delegated Regulation  |  |  |
| * **Data Protection/ Confidentiality** (technical, physical, safety and security control info should be provided)
 |  |  |  |
| * Does the contract specify that the provider will ensure the confidentiality, integrity and availability of all data stored through appropriate measures?
 | Art. 9 (1)Delegated Regulation |  |  |
| * Is it specified that personal data will be processed in accordance with Directive 95/46/EC?
 | Art. 9 (2) Delegated Regulation |  |  |
| * **Information security management**
 |  |  |  |
| * Does the contract include a declaration by the provider that the primary repository will be managed in accordance with internationally recognised information security management standards?
 | Art. 10 Delegated Regulation |  |  |
| * **Costs**
 |  |  |  |
| * Does the contract require the costs to be fair, reasonable and proportionate to:
 | Art. 11 (a) (b)Delegated Regulation  |  |  |
| (a) the service rendered by the provider and  |  |  |  |
| (b) the number of unique identifier requested? |  |  |  |
| * **Participation in the Secondary Repository System**
 |  |  |  |
| * Does the contract require the provider to participate in the establishment of the secondary repository system, as may be required in accordance with the Implementing Regulation?
 | Art. 12 (1)Delegated Regulation |  |  |
| * Does the contract contain a provision allowing providers to recover from manufacturers/importers the cost arising in connection with the establishment, operation and maintenance of the secondary repository?
 | Art. 12 (2)Delegated Regulation  |  |  |
| * **Duration**
 |  |  |  |
| * Is the 5 minimum years fixed (with possibility of renewal)?
 | Art. 13 Delegated Regulation |  |  |
| * **Communication with other parties**
 |  |  |  |
| * Does the contract require cooperation among providers?
 | Art. 14 Delegated Regulation |  |  |
| * Does the contract require cooperation with competent authorities of MS?
 | Art. 14 Delegated Regulation |  |  |
| * **Audits**
 |  |  |  |
| * Does the contract lay down terms enabling external approved auditors to carry out announced and unannounced audits (of primary and, where applicable, secondary repositories)?
 | Art. 15 (1)Delegated Regulation  |  |  |
| * Does the contract specify that external auditors are granted unrestricted physical and virtual access (for the duration of the audits) to the primary repository and, where applicable, to the secondary repository?
 | Art. 15 (2)Delegated Regulation  |  |  |
| * **Liability**
 |  |  |  |
| * Does the contract lay down terms detailing the liability of parties (for direct/indirect damages)?
 | Art. 16 Delegated Regulation  |  |  |
| * Does the contract specify that no limitation of liability exists in case of breach of confidentiality or data protection rules?
 | Art. 16 Delegated Regulation |  |  |
| * **Termination of the Contract**
 |  |  |  |
| * Does the contract lay down terms regarding its termination?
 | Art. 17 (1)Delegated Regulation  |  |  |
| * In case of termination: does the contract require the terminating party to notify the Commission?
 | Art 17 (1)Delegated Regulation  |  |  |
| * Does the contract require parties to provide a minimum notice period of 5 months (prior to termination of the contract)?
 | Art 17 (2)Delegated Regulation   |  |  |
| * Does the contract require manufacturers and importers to terminate the contract immediately:
 | Art 17 (2) (a) & (b) Delegated Regulation  |  |  |
| (a) in the event of a serious breach by the providers of its obligations; |  |  |  |
| (b) where the provider becomes or is in imminent risk of becoming insolvent. |  |  |  |
| * **Suspension of Services**
 |  |  |  |
| * Does the contract specify that in case of late payment by a manufacturer or importer suspension of services by the provider is prohibited (unless it has expired by 30 days or more)?
 | Art. 18Delegated Regulation  |  |  |
| * **Data Portability**
 |  |  |  |
| * Does the contract ensure full data portability in case the manufacturer or importer contracts a new primary storage provider?
 | Art. 19 (1)Delegated Regulation |  |  |
| * Does the contract include an Applicable Exit Plan?
 | Art. 19 (2)Delegated Regulation  |  |  |
| * Does the Exit Plan include a requirement for the current provider to continue providing its services until the new provider is operational?
 | Art. 19 (2)Delegated Regulation  |  |  |
| * Does the contract provide provisions ensuring that the current provider has no right of retention of data, information or other after delivery to new provider?
 | Art. 19 (3)Delegated Regulation  |  |  |
| * **Applicable Law and Jurisdiction**
* Is the contract governed by the law of one of the MS?
 | Art. 20 (1)Delegated Regulation |  |  |