



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## General Conditions of the Contract

These general conditions are applicable to *contracts* for the supply of goods, services, and works, ordered by the European Medicines Agency (hereinafter "EMA" or "Agency") via purchase orders. If there is any conflict between different provisions in the purchase order, the general conditions and any annexes to the purchase order, the following rules must be applied:

- (a) The provisions set out in the purchase order take precedence over those set out in the general conditions;
- (b) The provisions set out in the general conditions take precedence over those set out in the technical specifications, provided they are annexed to the purchase order;
- (c) Provided they are annexed to the purchase order, the provisions set out in the technical specifications take precedence over those set out in the *Contractor's* tender;
- (d) All documents issued by the *Contractor* (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable.

### I.1. DEFINITIONS

For the purpose of this *contract*, the following definitions (indicated in *italics* in the text) apply:

**'Breach of obligations'**: failure by the *Contractor* to fulfil one or more of its contractual obligations.

**'Confidential information or document'**: any information or document received by either party from the other or accessed by either party in the context of the *performance of the contract*, that any of the parties has identified in writing as confidential. It may not include information that is publicly available;

**'Conflict of interest'**: a situation where the impartial and objective *performance of the contract* by the *Contractor* is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with EMA or any third party related to the subject matter of the *contract*;

**'Contract'**: means the *contract* concluded through the acceptance of the purchase order (including its annexes such as the technical specifications, the *Contractor's* tender and these general conditions therein referenced) by the *Contractor*. EMA must receive the purchase order duly countersigned by the *Contractor* for the conclusion of the *contract*. The *contract* constitutes the entire agreement between EMA and the *Contractor*.

**'Contractor'**: means the economic operator entering into *contract* with EMA; where the *contract* is being entered into between EMA and a group of two or more economic operators, the *Contractor* means all the economic operators of the group.

**'Force majeure'**: any unforeseeable, exceptional situation or event beyond the control of the parties that prevents either of them from fulfilling any of their obligations under the *contract*. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of the subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes

and financial difficulties may not be invoked as *force majeure*, unless they stem directly from a relevant case of *force majeure*;

**'Formal notification' (or 'formally notify')**: form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

**'Fraud'**: an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests;

**'Grave professional misconduct'**: a violation of applicable laws or regulations or ethical standards of the profession to which a *Contractor* or a *related person* belongs, including any conduct leading to sexual or other exploitation or abuse, or any wrongful conduct of the *Contractor* or a *related person* which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence.

**'Irregularity'**: any infringement of a provision of Union law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the Union's budget.

**'Performance of the contract'**: the execution of tasks and delivery of the purchased services by the *Contractor* to EMA;

**'Personnel'**: persons employed directly or indirectly or contracted by the *Contractor* to perform the *contract*

**'Pre-existing material'**: any material, document, technology or know-how which exists prior to the *Contractor* using it for the production of a *result* in the *performance of the contract*;

**'Pre-existing right'**: any industrial and intellectual property right on *pre-existing material*; it may consist in a right of ownership, a licence right and/or right of use belonging to the *Contractor*, the creator, EMA as well as to any other third parties;

**'Professional conflicting interest'**: a situation in which the *Contractor's* previous or ongoing professional activities affect its capacity to perform the *contract* to an appropriate quality standard.

**'Related person'**: any natural or legal person who is a member of the administrative, management or supervisory body of the *Contractor*, or who has powers of representation, decision or control with regard to the *Contractor*;

**'Result'**: any intended outcome of the *performance of the contract*, whatever its form or nature. A *result* may be further defined in this *contract* as a deliverable. A *result* may, in addition to newly created materials produced specifically for EMA by the *Contractor* or at its request, also include *pre-existing materials*.

## **I.2. ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER**

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

## **I.3. SEVERABILITY**

Each provision of this *contract* is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the *contract*.

This does not affect the legality, validity or enforceability of any other provisions of the *contract*, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in accordance with Article 11. The *contract* must be interpreted as if it had contained the substitute provision as from its entry into force.

#### **I.4. PERFORMANCE OF THE CONTRACT**

**I.4.1.** The *Contractor* must provide services of high-quality standards, in accordance with the state of the art in the industry and the provisions of this *contract*, in particular the technical specifications and the terms of its tender. Where the Agency has the right to make modifications to the *results*, they must be delivered in a format and with the necessary information which effectively allow such modifications to be made in a convenient manner.

**I.4.2.** The *Contractor* must comply with the minimum requirements provided for in the technical specifications. This includes compliance with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU<sup>1</sup>, compliance with data protection obligations resulting from Regulation (EU) 2016/679<sup>2</sup> and Regulation (EU) 2018/1725<sup>3</sup>.

**I.4.3.** The *Contractor* must obtain any permit or licence required in the State where the services are to be provided.

**I.4.4.** All periods specified in the *contract* are calculated in calendar days, unless otherwise specified.

**I.4.5.** The *Contractor* must not present itself as a representative of EMA and must inform third parties that it is not part of the European public service.

**I.4.6.** The *Contractor* is responsible for the *personnel* who carry out the services and exercises its authority over its *personnel* without interference by EMA. The *Contractor* must inform its *personnel* that:

- (a) they may not accept any direct instructions from EMA; and
- (b) their participation in providing the services does not *result* in any employment or contractual relationship with EMA.

**I.4.7.** The *Contractor* must ensure that the *personnel* performing the *contract* and any future replacement *personnel* possess the professional qualifications and experience required to provide the services, as the case may be on the basis of the selection criteria set out in the technical specifications.

**I.4.8.** At EMA's reasoned request, the *Contractor* must replace any member of *personnel* who:

- (a) does not have the expertise required to provide the services; or
- (b) has caused disruption at the premises of EMA.

The *Contractor* bears the cost of replacing its *personnel* and is responsible for any delay in providing the services resulting from the replacement of *personnel*.

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<sup>1</sup> OJ L 94 of 28.03.2014, p. 65

<sup>2</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119, 4.5.2016, p. 1, [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.119.01.0001.01.ENG](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG)

<sup>3</sup> Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39, 21.11.2018, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>

**I.4.9.** The *Contractor* must record and report to EMA any problem that affects its ability to provide the services. The report must describe the problem, state when it started and what action the *Contractor* is taking to resolve it.

**I.4.10.** The *Contractor* must immediately inform the Agency of any changes in the exclusion situations as declared, according to Article 137(1) of Regulation (EU, Euratom) 2018/1046.

## **I.5. COMMUNICATION BETWEEN THE PARTIES**

### **I.5.1. Form and means of communication**

Any communication of information, notices or documents under the purchase order must:

- (a) be made in writing in paper or electronic format in the language of the purchase order;
- (b) bear the purchase order number;
- (c) be made using the relevant communication details set out in the purchase order; and
- (d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

### **I.5.2. Date of communications by mail and email**

Any communication is deemed to have been made when the receiving party receives it, unless this purchase order refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in the purchase order. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to EMA is deemed to have been received by EMA on the date on which the department responsible referred to in the purchase order registers it.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

## **I.6. LIABILITY**

**I.6.1.** EMA is not liable for any damage or loss caused by the *Contractor*, including any damage or loss to third parties during or as a consequence of *performance of the contract*.

**I.6.2.** If required by the relevant applicable legislation, the *Contractor* must take out an insurance policy against risks and damage or loss relating to the *performance of the contract*. It must also take out supplementary insurance as reasonably required by standard practice in the industry. Upon request, the *Contractor* must provide evidence of insurance coverage to EMA.

**I.6.3.** The *Contractor* is liable for any loss or damage caused to EMA during or as a consequence of *performance of the contract*, including in the event of subcontracting, but only to an amount not exceeding two times the total amount of the *contract*. However, if the damage or loss is caused by the gross negligence or wilful misconduct of the *Contractor* or of its *personnel* or subcontractors, as well as in the case of an action brought against EMA by a third party for

breach of its intellectual property rights, the *Contractor* is liable for the whole amount of the damage or loss.

- I.6.4.** If a third party brings any action against EMA in connection with the *performance of the contract*, including any action for alleged breach of intellectual property rights, the *Contractor* must assist EMA in the legal proceedings, including by intervening in support of EMA upon request.

If EMA's liability towards the third party is established and that such liability is caused by the *Contractor* during or as a consequence of the *performance of the contract*, Article 6.3 applies.

- I.6.5.** If the *Contractor* is composed of two or more economic operators (i.e. who submitted a joint tender), they are all jointly and severally liable to EMA for the *performance of the contract*.
- I.6.6.** EMA is not liable for any loss or damage caused to the *Contractor* during or as a consequence of *performance of the contract*, unless the loss or damage was caused by wilful misconduct or gross negligence of EMA.

## **I.7. CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS**

- I.7.1.** The *Contractor* must take all the necessary measures to prevent any situation of *conflict of interest* or *professional conflicting interest*.
- I.7.2.** The *Contractor* must notify EMA in writing without delay of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the *performance of the contract*. The *Contractor* must immediately take action to rectify the situation.

EMA may do any of the following:

- (a) verify that the *Contractor's* action is appropriate;
- (b) require the *Contractor* to take further action within a specified deadline;

- I.7.3.** The *Contractor* must pass on all the relevant obligations in writing to:

- (a) its *personnel*;
- (b) any natural person with the power to represent it or take decisions on its behalf;
- (c) third parties involved in the *performance of the contract*, including subcontractors.

The *Contractor* must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

## **I.8. CONFIDENTIALITY**

- I.8.1** EMA and the *Contractor* must treat with confidentiality any information or documents, in any format, disclosed in writing or orally relating to the *performance of the contract* and identified in writing as confidential.

- I.8.2** Each party must:

- (a) not use *confidential information or documents* for any purpose other than to perform its obligations under the *contract* without the prior written agreement of the other party;
- (b) ensure the protection of such *confidential information or documents* with the same level of protection as its own *confidential information or documents* and in any case with due diligence.
- (c) not disclose directly or indirectly, *confidential information or documents* to third parties without the prior written agreement of the other party.

- I.8.3** The confidentiality obligations set out in this Article are binding on EMA and the *Contractor* during the *performance of the contract* and for as long as the information or documents remain confidential unless:

- (a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
- (b) the *confidential information or documents* become public through other means than a breach of the confidentiality obligation;
- (c) the applicable law requires the disclosure of the *confidential information or documents*.

**I.8.4** The *Contractor* must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the *performance of the contract*, a commitment that they will comply with this Article. At the request of EMA, the *Contractor* must provide a document providing evidence of this commitment.

## **I.9. PROCESSING OF PERSONAL DATA**

### **I.9.1. Processing of personal data by EMA**

Any personal data included in or relating to the *contract*, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the *contract* by the data controller.

The *Contractor* or any other person whose personal data is processed by the data controller in relation to this *contract* has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the *Contractor* or any other person whose personal data is processed in relation to this *contract* have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

For the purpose of this article,

- (a) the data controller is the relevant Head of Division of EMA indicated in the 'Invitation to tender' letter;
- (b) the data protection notice is available at [https://www.ema.europa.eu/documents/other/privacy-statement-processing-personal-data-context-public-procurement-procedures\\_en.pdf](https://www.ema.europa.eu/documents/other/privacy-statement-processing-personal-data-context-public-procurement-procedures_en.pdf)

### **I.9.2. Processing of personal data by the Contractor**

The processing of personal data by the *Contractor* shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller. For the purpose of this article, the subject matter and purpose of the processing of personal data by the *Contractor* are strictly linked to the implementation of the *contract*.

The *Contractor* shall assist the controller for the fulfilment of the controller's obligation to respond to requests for exercising rights of person whose personal data is processed in relation to this *contract* as laid down in Chapter III (Articles 14-25) of Regulation (EU) 2018/1725. The *Contractor* shall inform without delay the controller about such requests.

The *Contractor* may act only on documented written instructions and under the supervision of the controller, in particular with regard to the purposes of the processing, the categories of data that may be processed, the recipients of the data and the means by which the data subject may exercise its rights.

The *Contractor* shall grant *personnel* access to the data to the extent strictly necessary for the implementation, management and monitoring of the *contract*. The *Contractor* must ensure that *personnel* authorised to process personal data has committed itself to confidentiality or is under appropriate statutory obligation of confidentiality in accordance with the provisions of Article 8.

The *Contractor* shall adopt appropriate technical and organisational security measures, giving due regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing, in order to ensure, in particular, as appropriate:

- (a) the pseudonymisation and encryption of personal data;
- (b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
- (c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
- (d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;
- (e) measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

The *Contractor* shall notify relevant personal data breaches to the controller without undue delay and at the latest within 48 hours after the *Contractor* becomes aware of the breach. In such cases, the *Contractor* shall provide the controller with at least the following information:

- (a) nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;
- (b) likely consequences of the breach;
- (c) measures taken or proposed to be taken to address the breach, including, where appropriate, measures to mitigate its possible adverse effects.

The *Contractor* shall immediately inform the data controller if, in its opinion, an instruction infringes Regulation (EU) 2018/1725, Regulation (EU) 2016/679, or other Union or Member State data protection provisions as referred to in the technical specifications.

The *Contractor* shall assist the controller for the fulfilment of its obligations pursuant to Article 33 to 41 under Regulation (EU) 2018/1725 to:

- (a) ensure compliance with its data protection obligations regarding the security of the processing, and the confidentiality of electronic communications and directories of users;
  - (b) notify a personal data breach to the European Data Protection Supervisor;
  - (c) communicate a personal data breach without undue delay to the data subject, where applicable;
  - (d) carry out data protection impact assessments and prior consultations as necessary.
- The *Contractor* shall maintain a record of all data processing operations carried on behalf of the controller, transfers of personal data, security breaches, responses to requests for exercising rights of people whose personal data is processed and requests for access to personal data by third parties.

EMA is subject to Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union, particularly as regards the inviolability of archives and data security, which includes personal data held on behalf of EMA in the premises of the *Contractor* or subcontractor.

For the purpose of this article, the localisation of and access to the personal data processed by the *Contractor* shall comply with the following:

- i. the personal data shall only be processed within the territory of the European Union and the European Economic Area and will not leave that territory;
- ii. the data shall only be held in data centres located with the territory of the European Union and the European Economic Area;
- iii. the *Contractor* may not change the location of data processing without the prior written authorisation of EMA;
- iv. any transfer of personal data under the *contract* to third countries or international organisations shall fully comply with the requirements laid down in Chapter V of Regulation (EU)2018/1725.

The *Contractor* shall notify EMA without delay of any legally binding request for disclosure of the personal data processed on behalf of EMA made by any national public authority, including an authority from a third country. The *Contractor* may not give such access without the prior written authorisation of EMA.

The duration of processing of personal data by the *Contractor* will not exceed the period referred to in Article 22.2. Upon expiry of this period, the *Contractor* shall, at the choice of the controller, return, without any undue delay in a commonly agreed format, all personal data processed on behalf of the controller and the copies thereof or shall effectively delete all personal data unless Union or national law requires a longer storage of personal data.

For the purpose of Article 10, if part or all of the processing of personal data is subcontracted to a third party, the *Contractor* shall pass on the obligations referred to in Articles 9.1 and 9.2 in writing to those parties, including subcontractors. At the request of the Agency, the *Contractor* shall provide a document providing evidence of this commitment.

## **I.10. SUBCONTRACTING**

**I.10.1** The *Contractor* must not subcontract and have the *contract* performed by third parties beyond the third parties already mentioned in its tender without prior written authorisation from EMA.

**I.10.2** Even if EMA authorises subcontracting, the *Contractor* remains bound by its contractual obligations and is solely responsible for the performance of this *contract*.

**I.10.3** The *Contractor* must ensure that the subcontract does not affect the rights of EMA under this *contract*, particularly those under Articles 8, 13 and 22.

**I.10.4** EMA may request the *Contractor* to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article 18.1.

## **I.11. AMENDMENTS**

**I.11.1** Any amendment to the *contract* must be made in writing before all contractual obligations have been fulfilled.

**I.11.2** Any amendment must not make changes to the *contract* that might alter the initial conditions of the procurement procedure or *result* in unequal treatment of tenderers.

## **I.12. ASSIGNMENT**

**I.12.1** The *Contractor* must not assign any of the rights and obligations arising from the *contract*, including claims for payments or factoring, without prior written authorisation from EMA. In such cases, the *Contractor* must provide EMA with the identity of the intended assignee.

**I.12.2** Any right or obligation assigned by the *Contractor* without authorisation is not enforceable against EMA.

## **I.13. INTELLECTUAL PROPERTY RIGHTS**

### **I.13.1. Ownership of the rights in the *results***

EMA acquires irrevocably worldwide ownership of the *results* and of all intellectual property rights on the newly created materials produced specifically for EMA under the *contract* and incorporated in the *results*, without prejudice however to the rules applying to *pre-existing rights* on *pre-existing materials*, as per Article 13.2.

The intellectual property rights so acquired include any rights, such as copyright and other intellectual or industrial property rights, to any of the *results* and in all technological solutions and information created or produced by the *Contractor* or by its subcontractor in *performance of the contract*. EMA may exploit and use the acquired rights as stipulated in this *contract*. EMA acquires all the rights as from the moment the *Contractor* has created the *results*.

The payment of the price includes any fees payable to the *Contractor* about the acquisition of ownership of rights by EMA including for all modes of exploitation and of use of the *results*.



### **I.13.2. Licensing rights on *pre-existing materials***

EMA does not acquire ownership of *pre-existing rights* under this *contract*.

The *Contractor* licenses the *pre-existing rights* on a royalty-free, non-exclusive and irrevocable basis to EMA, which may use the *pre-existing materials* for all the modes of exploitation set out in this *contract*. Unless otherwise agreed, the licence is non-transferable and cannot be sub-licensed, except as provided hereafter:

- (a) the *pre-existing rights* can be sub-licensed by EMA to persons and entities working for it or cooperating with it, including contractors and subcontractors, whether legal or natural persons, but only for the purpose of their mission for EMA;
- (b) if the *result* is a "document" such as a report or a study, and it is meant to be published, the existence of *pre-existing materials* in the *result* may not prevent the publication of the document, its translation or its "reuse", it being understood however that the "reuse" may only be made of the *result* as a whole and not of the *pre-existing materials* taken separately from the *result*; for the sake of this provision, "reuse" and "document" have the meaning given by the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU).

All *pre-existing rights* are licensed to EMA from the moment the *results* are delivered and approved by EMA.

The licensing of *pre-existing rights* to EMA under this *contract* covers all territories worldwide and is valid for the duration of intellectual property rights protection. The payment of the price as set out in the *contract* is deemed to also include any fees payable to the *Contractor* in relation to the licensing of *pre-existing rights* to EMA, including for all forms of exploitation and of use of the *results*.

Where the *performance of the contract* requires that the *Contractor* uses *pre-existing materials* belonging to EMA, EMA may request that the *Contractor* signs an adequate licence agreement. Such use by the *Contractor* will not entail any transfer of rights to the *Contractor* and is limited to the needs of this *contract*.

### **I.13.3. Exclusive rights**

EMA acquires the following exclusive rights:

- (a) reproduction: the right to authorise or prohibit direct or indirect, temporary or permanent reproduction of the *results* by any means (mechanical, digital or other) and in any form, in whole or in part;
- (b) communication to the public: the exclusive right to authorise or prohibit any display, performance or communication to the public, by wire or wireless means, including the making available to the public of the *results* in such a way that members of the public may access them from a place and at a time individually chosen by them; this also includes the communication on the Internet and broadcasting by cable or by satellite;
- (c) distribution: the exclusive right to authorise or prohibit any form of distribution of *results* or copies of the *results* to the public, by sale or otherwise;
- (d) rental: the exclusive right to authorise or prohibit rental or lending of the *results* or of copies of the *results*;
- (e) adaptation: the exclusive right to authorise or prohibit any modification of the *results*;
- (f) translation: the exclusive right to authorise or prohibit any translation, adaptation, arrangement, creation of derivative works based on the *results*, and any other alteration of the *results*, subject to the respect of moral rights of authors, where applicable;
- (g) where the *results* are or include a database: the exclusive right to authorise or prohibit the extraction of all or a substantial part of the contents of the database to another medium by any means or in any form; and the exclusive right to authorise or prohibit the re-utilization of all or a substantial part of the contents of the database by the distribution of copies, by renting, by on-line or other forms of transmission;
- (h) where the *results* are or include a patentable subject-matter: the right to register them as a patent and to further exploit such patent to the fullest extent;
- (i) where the *results* are or include logos or subject-matter which could be registered as a trademark: the right to register such logo or subject-matter as a trademark and to further exploit and use it;

- (j) where the *results* are or include know-how: the right to use such know-how as is necessary to make use of the *results* to the full extent provided for by this *contract*, and the right to make it available to contractors or subcontractors acting on behalf of EMA, subject to their signing of adequate confidentiality undertakings where necessary;
- (k) where the *results* are documents:
  - i. the right to authorise the reuse of the documents in conformity with the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU), to the extent it is applicable and the documents fall within its scope and are not excluded by any of its provisions; for the sake of this provision, "reuse" and "document" have the meaning given to them by this Decision;
  - ii. the right to store and archive the *results* in line with the document management rules applicable to EMA, including digitisation or converting the format for preservation or new use purposes;
- (l) where the *results* are or incorporate software, including source code, object code and, where relevant, documentation, preparatory materials and manuals, in addition to the other rights mentioned in this Article:
  - i. end-user rights, for all uses by EMA or by subcontractors which *result* from this *contract* and from the intention of the parties;
  - ii. the rights to receive both the source code and the object code;
- (m) the right to license to third parties any of the exclusive rights or of the modes of exploitation set out in this *contract*; however, for *pre-existing materials* which are only licensed to EMA, the right to sub-license does not apply, except in the two cases foreseen by Article 13.2;
- (n) to the extent that the *Contractor* may invoke moral rights, the right for EMA, except where otherwise provided in this *contract*, to publish the *results* with or without mentioning the creator(s)' name(s), and the right to decide when and whether the *results* may be disclosed and published.

The *Contractor* warrants that the exclusive rights and the modes of exploitation may be exercised by EMA on all parts of the *results*, be it via a transfer of ownership of the rights, on those parts which were specifically created by the *Contractor*, or via a licence of the *pre-existing rights*, on those parts consisting of *pre-existing materials*.

Where *pre-existing materials* are inserted in the *results*, EMA may accept reasonable restrictions impacting on the above list, provided that the said materials are easily identifiable and separable from the rest, that they do not correspond to substantial elements of the *results*, and that, should the need arise, satisfactory replacement solutions exist, at no additional costs to EMA. In such case, the *Contractor* will have to clearly inform EMA before making such choice and EMA has the right to refuse it.

#### **I.13.4. Identification of *pre-existing rights***

When delivering the *results*, the *Contractor* must warrant that, for any use that EMA may envisage within the limits set in this *contract*, the new created parts and the pre-existing material incorporated in the *results* are free of claims from creators or from any third parties and all the necessary *pre-existing rights* have been obtained or licensed.

To that effect, the *Contractor* must establish a list of all *pre-existing rights* to the *results* of this *contract* or parts thereof, including identification of the rights' owners. If there are no pre-existing rights to the *results*, the *Contractor* must provide a declaration to that effect. The *Contractor* must provide this list or declaration to EMA together with the invoice for payment of the balance at the latest.

#### **I.13.5. Evidence of granting of *pre-existing rights***

Upon request by EMA, the *Contractor* must, in addition to the list mentioned under Article 13.4, provide evidence that it has the ownership or the right to use all the listed *pre-existing rights*, except for the rights owned or licensed by EMA. The Agency may request this evidence even after the end of this *contract*.

This provision also applies to image rights and sound recordings.

This evidence may refer, for example, to rights to: parts of other documents, images, graphs, sounds, music, tables, data, software, technical inventions, know-how, IT development tools, routines, subroutines or other programs ('background technology'), concepts, designs, installations or pieces of art, data, source or background materials or any other parts of external origin.

This evidence must include, as appropriate:

- (a) the name and version number of a software product;
- (b) the full identification of the work and its author, developer, creator, translator, data entry person, graphic designer, publisher, editor, photographer, producer;
- (c) a copy of the licence to use the product or of the agreement granting the relevant rights to the *Contractor* or a reference to this licence;
- (d) a copy of the agreement or extract from the employment *contract* granting the relevant rights to the *Contractor* where parts of the *results* were created by its *personnel*;
- (e) the text of the disclaimer notice if any.

Provision of evidence does not release the *Contractor* from its responsibilities if it is found that it does not hold the necessary rights, regardless of when and by whom this fact is revealed.

The *Contractor* also warrants that it possesses the relevant rights or powers to execute the transfer and that it has paid or has verified payment of all due fees including fees due to collecting societies, related to the final *results*.

#### **I.13.6. Quotation of works in the *result***

In the *result*, the *Contractor* must clearly point out all quotations of existing works. The complete reference should include as appropriate, the following: name of the author, title of the work, date and place of publication, date of creation, address of publication on the internet, number, volume and other information that allows the origin to be easily identified.

#### **I.13.7. Moral rights of creators**

By delivering the *results*, the *Contractor* warrants that the creators will not object to the following on the basis of their moral rights under copyright:

- (a) that their names be mentioned or not mentioned when the *results* are presented to the public;
- (b) that the *results* be divulged or not after they have been delivered in their final version to EMA;
- (c) that the *results* be adapted, provided that this is done in a manner which is not prejudicial to the creator's honour or reputation.

If moral rights on parts of the *results* protected by copyright may exist, the *Contractor* must obtain the consent of creators regarding the granting or waiver of the relevant moral rights in accordance with the applicable legal provisions and be ready to provide documentary evidence upon request.

#### **I.13.8. Image rights and sound recordings**

If natural persons appear in a *result* or their voice or any other private element is recorded in a recognisable manner, the *Contractor* must obtain a statement by these persons (or, in the case of minors, by the persons exercising parental authority) giving their permission for the described use of their image, voice or private element and, on request, submit a copy of the permission to EMA. The *Contractor* must take the necessary measures to obtain such consent in accordance with the applicable legal provisions.

#### **I.13.9. Copyright notice for *pre-existing rights***

When the *Contractor* retains *pre-existing rights* on parts of the *results*, reference must be inserted to that effect when the *result* is used as set out in Article 13.3, with the following disclaimer: '(c) - year - European Union. All rights reserved. Certain parts are licensed under conditions to the EU', or with any other equivalent disclaimer as EMA may consider best appropriate, or as the parties may agree on a

case-by-case basis. This does not apply where inserting such reference would be impossible, notably for practical reasons.

#### **I.13.10. Visibility of EMA funding and disclaimer**

When making use of the *results*, the *Contractor* must declare that they have been produced under a *contract* with EMA and that the opinions expressed are those of the *Contractor* only and do not represent EMA's official position. EMA may waive this obligation in writing or provide the text of the disclaimer.

### **I.14. FORCE MAJEURE**

**I.14.1** If a party is affected by *force majeure*, it must immediately notify the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

**I.14.2** A party is not liable for any delay or failure to perform its obligations under the *contract* if that delay or failure is a *result* of *force majeure*. If the *Contractor* is unable to fulfil its contractual obligations owing to *force majeure*, it has the right to remuneration only for the services actually provided.

**I.14.3** The parties must take all necessary measures to limit any damage due to *force majeure*.

### **I.15. LIQUIDATED DAMAGES**

#### **I.15.1. Delay in delivery**

If the *Contractor* fails to perform its contractual obligations within the applicable time limits set out in this *contract*, EMA may claim liquidated damages for each day of delay using the following formula:

$$0.3 \times (V/d)$$

where

V is the price of the relevant purchase or deliverable or *result* or, failing that, the amount specified in the purchase order;

d is the duration specified in the *contract* for delivery of the relevant purchase or deliverable or *result* or, failing that, the duration of *performance of the contract* specified in the purchase order, expressed in days.

Liquidated damages may be imposed together with a reduction in price under the conditions laid down in Article 16.

#### **I.15.2. Procedure**

EMA must formally notify the *Contractor* of its intention to apply liquidated damages and the corresponding calculated amount.

The *Contractor* has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the *Contractor* submits observations, EMA, taking into account the relevant observations, must notify the *Contractor*:

(a) of the withdrawal of its intention to apply liquidated damages; or

(b) of its final decision to apply liquidated damages and the corresponding amount.

### **I.15.3. Nature of liquidated damages**

The parties expressly acknowledge and agree that any amount payable under this Article is not a penalty and represents a reasonable estimate of fair compensation for the damage incurred due to failure to provide the services within the applicable time limits set out in this *contract*.

### **I.15.4. Claims and liability**

Any claim for liquidated damages does not affect the *Contractor's* actual or potential liability or EMA's rights under Article 18.

## **I.16. REDUCTION IN PRICE**

### **I.16.1. Quality standards**

If the *Contractor* fails to provide the service in accordance with the *contract* ('unperformed obligations') or if it fails to provide the service in accordance with the expected quality levels specified in the technical specifications ('low quality delivery'), EMA may reduce or recover payments proportionally to the seriousness of the unperformed obligations or low quality delivery. This includes in particular cases where EMA cannot approve a *result*, report or deliverable as defined in the purchase order after the *Contractor* has submitted the required additional information, correction or new version.

A reduction in price may be imposed together with liquidated damages under the conditions of Article 15.

### **I.16.2. Procedure**

EMA must formally notify the *Contractor* of its intention to reduce payment and the corresponding calculated amount.

The *Contractor* has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the *Contractor* submits observations, EMA, taking into account the relevant observations, must notify the *Contractor*:

- (a) of the withdrawal of its intention to reduce payment; or
- (b) of its final decision to reduce payment and the corresponding amount.

### **I.16.3. Claims and liability**

Any reduction in price does not affect the *Contractor's* actual or potential liability or EMA's rights under Article 18.

## **I.17. SUSPENSION OF THE PERFORMANCE OF THE CONTRACT**

### **I.17.1. Suspension by the *Contractor***

If the *Contractor* is affected by *force majeure*, it may suspend the *performance of the contract*.

The *Contractor* must immediately notify EMA of the suspension. The notification must include a description of the *force majeure* and state when the *Contractor* expects to resume the *performance of the contract*.

The *Contractor* must notify EMA as soon as it is able to resume *performance of the contract*, unless EMA has already terminated the *contract*.

### **I.17.2. Suspension by EMA**

EMA may suspend the *performance of the contract* or any part of it:

- (a) if the procedure for awarding the *contract* or the *performance of the contract* proves to have been subject to *irregularities, fraud or breach of obligations*;
- (b) in order to verify whether the presumed *irregularities, fraud or breach of obligations* have actually occurred.

EMA must formally notify the *Contractor* of the suspension and the reasons for it. Suspension takes effect on the date of *formal notification*, or at a later date if the *formal notification* so provides.

EMA must notify the *Contractor* as soon as the verification is completed whether:

- (a) it is lifting the suspension; or
- (b) it intends to terminate the *contract* under Article.18.1(f) or (j).

The *Contractor* is not entitled to compensation for suspension of any part of the *contract*.

EMA may in addition suspend the time allowed for payments in accordance with Article 20.5.

## **I.18. TERMINATION OF THE CONTRACT**

### **I.18.1. Grounds for termination by EMA**

EMA may terminate the *contract* in the following circumstances:

- (a) if provision of the services under an on-going *contract* has not actually started within 15 days of the scheduled date and EMA considers that the new date proposed, if any, is unacceptable, taking into account Article 11.2;
- (b) if the *Contractor* is unable, through its own fault, to obtain any permit or licence required for *performance of the contract*;
- (c) if the *Contractor* does not perform the *contract* in accordance with the technical specifications or is in breach of another substantial contractual obligation.
- (d) if the *Contractor* or any person that assumes unlimited liability for the debts of the *Contractor* is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation<sup>4</sup>;
- (e) if the *Contractor* or any *related person* is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation.
- (f) if the procedure for awarding the *contract* or the *performance of the contract* prove to have been subject to *irregularities, fraud or breach of obligations*;
- (g) if the *Contractor* does not comply with applicable obligations under environmental, social and labour law established by Union law, national law, collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU;
- (h) if the *Contractor* is in a situation that could constitute a *conflict of interest* or a *professional conflicting interest* as referred to in Article 7;
- (i) if a change to the *Contractor's* legal, financial, technical, organisational or ownership situation is likely to substantially affect the *performance of the contract* or substantially modify the conditions under which the *contract* was initially awarded or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the *contract*;
- (j) in the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the *contract* would mean that the technical specifications are no longer fulfilled or *result* in unequal treatment of tenderers;
- (k) if the *Contractor* is in breach of the data protection obligations resulting from Article 9.2;
- (l) if the *Contractor* does not comply with the applicable data protection obligations resulting from Regulation (EU) 2016/679.

<sup>4</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046>

### **I.18.2. Grounds for termination by the *Contractor***

The *Contractor* may terminate the *contract* if EMA fails to comply with its obligations, in particular the obligation to provide the information needed for the *Contractor* to perform the *contract* as provided for in the technical specifications.

### **I.18.3. Procedure for termination**

A party must formally notify the other party of its intention to terminate the *contract* and the grounds for termination.

The other party has 30 days following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed.

If the other party submits observations, the party intending to terminate must formally notify it either of the withdrawal of its intention to terminate or of its final decision to terminate.

In the cases referred to in points (a) to (d), (g) to (i), (k) to (n) of Article 18.1 and in Article 18.2, the date on which the termination takes effect must be specified in the *formal notification*.

In the cases referred to in points (e), (f) and (j) of Article 18.1, the termination takes effect on the day following the date on which the *Contractor* receives notification of termination.

In addition, at the request of EMA and regardless of the grounds for termination, the *Contractor* must provide all necessary assistance, including information, documents and files, to allow EMA to complete, continue or transfer the services to a new *Contractor* or internally, without interruption or adverse effect on the quality or continuity of the services. The parties may agree to draw up a transition plan detailing the *Contractor's* assistance unless such plan is already detailed in other contractual documents or in the technical specifications. The *Contractor* must provide such assistance at no additional cost, except if it can demonstrate that it requires substantial additional resources or means, in which case it must provide an estimate of the costs involved and the parties will negotiate an arrangement in good faith.

### **I.18.4. Effects of termination**

The *Contractor* is liable for damage incurred by EMA as a *result* of the termination of the *contract* including the additional cost of appointing and contracting another *Contractor* to provide or complete the services, except if the damage is the *result* of a termination in accordance with Article 18.1 (j) or in Article 18.2. EMA may claim compensation for such damage.

The *Contractor* is not entitled to compensation for any loss resulting from the termination of the *contract*, including loss of anticipated profits, unless the loss was caused by the situation specified in Article 18.2.

The *Contractor* must take all appropriate measures to minimise costs, prevent damage and cancel or reduce its commitments.

Within 60 days of the date of termination, the *Contractor* must submit any report, deliverable or *result* and any invoice required for services that were provided before the date of termination.

In the case of joint tenders, EMA may terminate the *contract* with each member of the group separately on the basis of points (d), (e), (g), (k) or (l) of Article 18.1, under the conditions set out in Article 11.2.

## **I.19. INVOICES, VALUE ADDED TAX AND E-INVOICING**

### **I.19.1. Invoices and value added tax**

Invoices must contain the *Contractor's* identification data, the amount, the currency and the date, as well as the *contract* reference.

Invoices must indicate the place of taxation of the *Contractor* for value added tax (VAT) purposes and must specify separately the taxable amount per rate or exemption, the VAT rate applied and the VAT amount payable.

EMA is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union.

The *Contractor* must complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for *performance of the contract* are exempt from taxes and duties, including VAT. EMA cannot advise the *Contractor* in any way with respect to this obligations.

In case of joint tenders from a group of economic operators without separate legal personality, in order to allow the members of the group to complete the formalities with the relevant authorities to ensure the tax exemption, EMA shall issue a VAT exemption certificate for each respective group member of the joint tender, if the transaction is taxable for VAT purposes as a local or an intra-community purchase. For that purpose, the leader of the joint tender shall:

- (a) ensure that the amount invoiced by each member of the joint tender corresponds to the respective member's share/part of the service
- (b) collect the invoices issued by the members of the joint tender and submit them to EMA
- (c) ensure that the sum of the amounts invoiced by each member of the joint tender corresponds to the amount for payment under the *contract*
- (d) submit to EMA and to each member of the joint tender the duly filled-in and signed Annex, should it be required by the relevant authorities
- (e) distribute to each member of the joint tender its respective VAT exemption certificate issued by EMA, if applicable

EMA shall:

- (a) take into account for the issuance of the VAT exemption certificates the information in the Annex, only if the leader of the joint tender submits said Annex at the latest together with the submission of the invoices; in case the Annex is not submitted by that time, EMA shall issue the VAT exemption certificate for each respective group member of the joint tender solely on the basis of the amount invoiced by each member
- (b) pay the amounts corresponding to the individual invoices to the leader of the joint tender on its bank account; payments to the leader will discharge EMA from its payment obligation vis-à-vis the other members of the group

For the group members (including leaders), if the transaction is taxable for VAT purposes as a local purchase in another Member State, local exemption rules apply.

## **I.20. PAYMENTS**

### **I.20.1. Date of payment**

Payments are deemed to be effected on the date when they are debited to the Agency's account.

### **I.20.2. Currency**

Payments are made in euros, unless another currency is provided for in the purchase order.



### **I.20.3. Conversion**

EMA makes any conversion between the euro and another currency at the daily euro exchange rate published in the Official Journal of the European Union, or failing that, at the monthly accounting exchange rate, as established by the European Commission and published on the website indicated below, applicable on the day when it issues the payment order.

The *Contractor* makes any conversion between the euro and another currency at the monthly accounting exchange rate, established by the Commission and published on the website indicated below, applicable on the date of the invoice.

[http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/inforeuro/inforeuro\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm)

### **I.20.4. Costs of transfer**

The costs of the transfer are borne as follows:

- (a) EMA bears the costs of dispatch charged by its bank;
- (b) the *Contractor* bears the costs of receipt charged by its bank,
- (c) the party causing repetition of the transfer bears the costs for repeated transfer.

### **I.20.5. Payment of the balance**

The *Contractor* (or leader in the case of a joint tender) must send the invoice(s) for payment of the balance within 60 days of the end of the period of provision of the services, as provided for in Article I.19.1, the purchase order or in the technical specifications.

Payment of the invoice(s) and approval of documents does not imply recognition of the regularity, authenticity, completeness and correctness of the declarations and information they contain. Payment of the balance may take the form of recovery.

### **I.20.6. Suspension of the time allowed for payment**

EMA may suspend the payment periods specified in the purchase order at any time by notifying the *Contractor* (or leader in the case of joint tender) that the invoice(s) cannot be processed. The reasons EMA may cite for not being able to process an invoice are:

- (a) because it does not comply with the *contract*;
- (b) because the *Contractor* has not produced the appropriate documents or deliverables; or
- (c) because EMA has observations on the documents or deliverables submitted with the invoice.

EMA must notify the *Contractor* (or leader in the case of joint tender) as soon as possible of any such suspension, giving the reasons for it. In cases b) and c) referred above, EMA shall notify the *Contractor* (or leader in case of a joint tender) the time limits to submit additional information or corrections or a new version of the documents or deliverables if EMA requires it.

Suspension takes effect on the date EMA sends the notification. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the *Contractor* (or leader in the case of a joint tender) may request EMA to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph of this Article and the new document produced is also rejected, EMA reserves the right to terminate the *contract* in accordance with Article 18.1(c).

### **I.20.7. Interest on late payment**

On expiry of the payment periods specified in the purchase order, the *Contractor* (or leader in the case of a joint tender) is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus eight points. The reference

rate is the rate in force, as published in the C series of the Official Journal of the European Union, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article 20.6 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article 20.1.

However, when the calculated interest is EUR 200 or less, it must be paid to the *Contractor* (or leader in the case of a joint tender) only if it requests it within two months of receiving late payment.

## **I.21. RECOVERY**

**I.21.1** If an amount is to be recovered under the terms of the *contract*, the *Contractor* must repay EMA the amount in question.

### **I.21.2. Recovery procedure**

Before recovery, EMA must formally notify the *Contractor* of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the *Contractor* to make any observations within 30 days of receipt.

If no observations have been submitted or if, despite the observations submitted, EMA decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the *Contractor*, specifying the date of payment. The *Contractor* must pay in accordance with the provisions specified in the debit note.

If the *Contractor* does not pay by the due date, EMA may, after informing the *Contractor* in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the *Contractor* by the Union or by the European Atomic Energy Community or by an executive agency when it implements the Union budget;
- (b) by calling in a financial guarantee if the *Contractor* has submitted one to EMA;
- (c) by taking legal action.

### **I.21.3. Interest on late payment**

If the *Contractor* does not honour the obligation to pay the amount due by the date set by EMA in the debit note, the amount due bears interest at the rate indicated in Article 20.7. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when EMA receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

### **I.21.4. Recovery rules in the case of joint tender**

If the *contract* is signed by a group (joint tender), the group is jointly and severally liable under the conditions set out in Article 6 (liability). EMA shall send the debit note first to the leader of the group.

If the leader does not pay by the due date the whole amount, and if the amount due cannot be offset or can only be offset partially in accordance with Article 21.2 (a), then EMA may claim the amount still due to any other member or members of the group by respectively notifying them with a debit note in conformity with the provisions laid down in Article 21.2.

## **I.22. CHECKS AND AUDITS**

**I.22.1** EMA and the European Anti-Fraud Office may check or require an audit on the *performance of the contract*. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf.

Such checks and audits may be initiated at any moment during *performance of the contract* and up to five years starting from the payment of the balance.

The audit procedure is initiated on the date of receipt of the relevant letter sent by EMA. Audits are carried out on a confidential basis.

**I.22.2** The *Contractor* must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance.

**I.22.3** The *Contractor* must grant EMA's staff and outside *personnel* authorised by EMA the appropriate right of access to sites and premises where the *contract* is performed and to all the information, including information in electronic format, needed to conduct such checks and audits. The *Contractor* must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format.

**I.22.4** On the basis of the findings made during the audit, a provisional report is drawn up. EMA or its authorised representative must send it to the *Contractor*, who has 30 days following the date of receipt to submit observations. The *Contractor* must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, EMA may recover all or part of the payments made in accordance with Article 21 and may take any other measures which it considers necessary.

**I.22.5** In accordance with Council Regulation (Euratom, EC) No. 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against *fraud* and other *irregularities* and Regulation (EU, Euratom) No. 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on-the-spot checks and inspections, to establish whether there has been *fraud*, corruption or any other illegal activity under the *contract* affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the services and up to five years starting from the payment of the balance.

**I.22.6** The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939<sup>5</sup> ('the EPPO') have the same rights as EMA, particularly right of access, for the purpose of checks, audits and investigations.

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<sup>5</sup> Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

## ANNEX

Group members' shares in total *Contract* value for VAT purposes

Purchase Order No. *[insert reference of the purchase order]*

<b>Contractor (Member of the group)</b>	<b>Description of the supplies/services provided by the member</b>	<b>Total value of the supplies/services provided by the member</b>

**Signature of the Leader of the Group**

*[Name of Leader]*  
Done on *[date]*