

Annex III - Service concession ref. EMA/2016/43/RS

Declaration of honour on exclusion criteria and selection

criteria - where a joint application is proposed, please present a declaration for each member individually and for any subcontractor where more than 10% of the concession contract will be executed by subcontractors.

(only for legal persons) the following legal person:
Full official name:
Official legal form:
Statutory registration number:
Full official address:
VAT registration number:

, representing:

A	> declares whether the above-mentioned person is in one of the following situations or not:		
	SITUATION OF EXCLUSION CONCERNING THE PERSON	YES	NO
a)	it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;		
b)	it has been established by a final judgment or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the concession contract;		
c)	it has been established by a final judgment or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibity where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		
	(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a concession contract;		
	(ii) entering into agreement with other persons with the aim of distorting competition;		



The undersigned

	(iii) violating intellectual property rights;	
	(iv) attempting to influence the decision-making process of the Agency during the award procedure;	
	(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;	
d)	it has been established by a final judgment that the person is guilty of any of the following:	
	(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	
	(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the Agency is located, the country in which the person is established or the country of the performance of the concession contract;	
	(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;	
	(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;	
	(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;	
	(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	
e)	the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;	
f)	it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	
g)	for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to: i.facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; ii.non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics; iii.decisions of the ECB, the EIB, the European Investment Fund or international organisations; iv.decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or v.decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.	

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[Only for legal persons other than Member States and local authorities, otherwise disregard this table]				
declares whether a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares) is in one of the following situations or not:				
SITUATIONS OF EXCLUSION CONCERNING NATURAL PERSONS WITH POWER OF REPRESENTATION, DECISION-MAKING OR CONTROL OVER THE LEGAL PERSON			NO	
Situation (c) above (grave professional misconduct)				
Situation (d) above (fraud, corruption or other criminal offence)				
Situation (e) above (significant deficiencies in performance of a contract)				
Situation (f) above (irregularity)				
declares whether a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations or not:				
SITUATIONS OF EXCLUSION CONCERNING NATURAL OR LEGAL PERSONS ASSUMING UNLIMITED LIABILITY FOR THE DEBTS OF THE LEGAL PERSON	YES	NO	N/A	
Situation (a) above (bankruptcy)				
Situation (b) above (breach in payment of taxes or social security contributions)				
> declares whether the above-mentioned person is in one of the following situate	tions or	not:		
GROUNDS FOR REJECTION FROM THIS PROCEDURE		YES	NO	
h) has not distorted competition by being previously involved in the preparation of documents for this concession procedure;				
 i) has provided accurate, sincere and complete information to the Agency within the context of this concession procedure; 				
acknowledges that the above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.				

REMEDIAL MEASURES

If the person declares one of the situations of exclusion listed above, it should indicate the measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. They may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which appropriately illustrates the remedial measures taken should be provided in annex to this declaration. This does not apply for the situations referred in point (d) of this declaration.

EVIDENCE UPON REQUEST

Upon request and within the time limit set by the contracting authority the person shall provide information on the persons that are members of the administrative, management or supervisory body, as well as the following evidence concerning the person or the natural or legal persons which assume unlimited liability for the debt of the person:

- For situations described in (a), (c), (d) or (f), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.
- For the situation described in point (a) or (b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.
- If the person already submitted such evidence for the purpose of another procedure, its issuing date does not exceed one year and it is still valid, the person shall declare on its honour that the documentary evidence has already been provided and confirm that no changes have occurred in its situation.

>	declares whether the above-mentioned person complies with the selection criteria as provided in the technical specifications:			
	SELECTION CRITERIA	YES	NO	
(a)	It has the legal and regulatory capacity to pursue the professional activity needed for performing the concession contract as required in section 12.1 of the technical specifications;			
(b)	It fulfills the applicable economic and financial criteria indicated in section 12.2 of the technical specifications;			
(c)	It fulfills the applicable technical and professional criteria indicated in section 12.3 of the technical specifications.			
(d)	It is not in one of the situations of professional conflict of interest indicated in section 12.4. of the technical specifications.			
>	declares that the above-mentioned person will be able to provide the necessary supporting documents listed in the relevant sections of the technical specifications and which are not available electronically upon request and without delay.			
Dat	e: Signature of authorised			
	representative:			

(Print name):

Position in company:

Representing (name of applicant):