European Commission

Tender specifications
Call for tender VT/2015/068

«2ND STUDY TO COLLECT UPDATED INFORMATION FOR A LIMITED NUMBER OF CARCINOGENIC SUBSTANCES WITH A VIEW TO ANALYSE THE HEALTH, SOCIO-ECONOMIC AND ENVIRONMENTAL IMPACTS IN CONNECTION WITH POSSIBLE AMENDMENTS OF DIRECTIVE 2004/37/EC ON THE PROTECTION OF WORKERS FROM THE RISKS RELATED TO EXPOSURE TO CARCINOGENS OR MUTAGENS AT WORK»

Employment, Social Affairs and Inclusion

Table of content

Technical part

1. Title of the contract

Second study to collect updated information for a limited number of carcinogenic substances with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

2. Background

2.1 EaSI Introduction[1]

The European Programme for Employment and Social Innovation "EaSI" 2014-2020[2] is a European-level financing instrument managed directly by the European Commission to contribute to the implementation of the Europe 2020 strategy, by providing financial support for the Union's objectives in terms of promoting a high level of quality and sustainable employment, guaranteeing adequate and decent social protection, combating social exclusion and poverty and improving working conditions.

2.2 Context and information specific to this contract

2.2.1 Policy and legal background

Ensuring a safe and healthy work environment for over 217 million workers in the EU is a strategic goal for the European Commission according to the recent Communication from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020[3]. One of the main challenges identified in the EU OSH Strategy is to improve

1 Regulation (EU) No 1296/2013 of the European Parliament and of the Council of 11 December 2013 on a European Union Programme for Employment and Social Innovation ("EaSI") and amending Decision No 283/2010/EU establishing a European Progress Microfinance Facility for employment and social inclusion, OJ L 347, 20/12/2013, p. 238

2 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0238:0252:EN:PDF http://ec.europa.eu/social/main.jsp?langId=en&catId=1081

3 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN

the prevention of work-related diseases by tackling existing, new and emerging risks.

Despite the fact that according to this Communication considerable progress has been achieved in the area of health and safety protection of workers as the result of the comprehensive legislation and policy action launched and implemented by the Union, Member States and stakeholders, further improvement is still needed.

This concerns for example the necessity to further reduce occupational exposure to hazardous chemicals in general, and to carcinogenic substances in particular when considering the following facts:

In 2008, 2.45 million people were diagnosed with cancer and 1.23 million died because of cancer in the then 27 countries of the EU. The cost of cancer in the EU was estimated to be €126 billion in 2009, with health care accounting for €51.0 billion (40%). Productivity losses because of early death cost €42.6 billion and lost working days €9.43 billion. Informal care was estimated to cost €23.2 billion. Lung cancer had the highest economic cost (€18.8 billion, 15% of overall cancer costs), followed by breast cancer (€15.0 billion, 12%), colorectal cancer (€13.1 billion, 10%), and prostate cancer (€8.43 billion, 7%).[4]

More recently, in the European Union in 2012, it was estimated that cancer caused the death of 1.75 million people, around 980,000 men and 780,000 women. Cancers of the lung (353,000 deaths), colorectal (215,000), breast (131,000) and stomach (107,000) were the most common fatal forms of cancer. In the same year in Europe, approximately 3.45 million number of new cases of cancer (excluding non-melanoma skin cancer) were estimated, respectively 1.8 million in males and 1.6 million in females. The most common cancer sites were cancers of the female breast (464,000 cases), followed by colorectal (447,000), prostate (417,000) and lung (410,000), which all together represent half of the overall burden of cancer in Europe[5].

For occupational cancer, meaning for the fraction of cancers attributable to working conditions, the figures vary between 4[6] and 8-12%[7]. In the UK for example, 5.3% of cancer deaths were attributable to occupation (8.2% in men and 2.3% in women) in 2005, meaning that in that year, overall 8019 people died from occupational cancer, 6362 men and 1657 women. Occupational attributable fractions are over 2% for mesothelioma, sinonasal, lung, nasopharynx, breast, non-melanoma

[4] Economic burden of cancer across the European Union: a population-based cost analysis, *Ramon Luengo-Fernandez, Jose Leal, Alastair Gray, Richard Sullivan,* www.thelancet.com/oncology Published online October 14, 2013 http://dx.doi.org/10.1016/S1470-2045(13)70442-X)

[5] Ferlay, J. et al., Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012, *European Journal of Cancer*, 49 (2013), pp. 1374–1403.

[6] The causes of cancer: quantitative estimates of avoidable risks of cancer in the United States today, R. Doll & R. Peto, J J Natl *Cancer* Inst. *1981* Jun;66(6):1191-308. http://www.ncbi.nlm.nih.gov/pubmed/7017215

[7] http://www.etui.org/content/download/7515/71981/file/Occupational+cancer++the+main+challenge+for+the+new+Community+Strategy.pdf

skin cancer, bladder, oesophagus, soft tissue sarcoma, larynx and stomach cancers. Industries and occupations with high cancer registrations include construction, metal working, personal and household services, mining, land transport, printing/publishing, retail/hotels/restaurants, public administration/defence, farming and several manufacturing sectors. Respectively, 56% of cancer registrations in men are attributable to work in the construction industry (mainly mesotheliomas, lung, stomach, bladder and non-melanoma skin cancers) and 54% of cancer registrations in women are attributable to shift work (breast cancer).[8]

Although the exact magnitude of the occupational cancer burden may vary between countries, it seems likely that the situation in the UK is comparable to the situation in the majority of other EU Member States.

At EU level, Directive 2004/37/EC[9] (the so-called Carcinogens and Mutagens Directive or CMD), requires eliminating or reducing to a minimum the risks arising from the occupational exposure to carcinogenic or mutagenic substances and mixtures.

Whether a substance or mixture is under the scope of the CMD is primarily based on its classification as a carcinogen and / or mutagen (category 1A or 1B) according to the criteria established under the CLP Regulation[10].

However, there is also a possibility to bring a substance / mixture under the scope of the directive by including it in Annex I to the Directive. This Annex covers substances, mixtures or processes (or substances / mixtures released by a process referred to in that Annex) which are not yet classified according to the CLP Regulation as carcinogens or mutagens, but are for example recognised by other international bodies (like the International Agency for Research on Cancer - IARC) as substances, mixtures or processes of equal concern. These substances are often referred to as process-generated substances or PGSs. Currently, this Annex contains 5 entries[11].

In order to reduce the occupational exposure to these substances or mixtures, the CMD provides for a hierarchy of preventive and protective measures, amongst which the obligation of the employer to substitute these chemicals by less or non-hazardous substances, mixtures or processes as far as technically possible has the highest priority. If

[8] Rushton, L. et al. Occupation and cancer in Britain. *Br J Cancer*. 2010 Apr 27;102(9):1428-37

[9] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004L0037-20140325&qid=1430226850048&from=EN

[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures - http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396363361882&uri=CELEX:02008R1272-20110419

[11] 1. Manufacture of auramine. / 2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch. / 3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes. /4. Strong acid process in the manufacture of isopropyl alcohol. / 5. Work involving exposure to hardwood dusts.

substitution is not technically possible, other measure to prevent exposure like working in a closed system or to reduce the number of workers potentially exposed have to be put in place by the employer.

Another obligation of the employers is to ensure that so-called limit values set out in Annex III to the Directive shall not be exceeded.

Limit values are time-weighted upper thresholds for hazardous substances in the air within the breathing zone of a worker established for a reference period (normally 8 hrs). Under the current EU-OSH legal framework, two types of occupational exposure limit values (OELs) are established:

- Indicative Limit Values (IOELVs) and
- Binding Limit Values (BOELVs)

Under certain circumstances, e.g. if considerable uptake of the substance occurs via the skin or the gastrointestinal tract, biological instead of atmospheric monitoring of a substance may be preferable in order to better or more correctly assess its risks to human health.

In such a case, and if suitable methods are available, so called Biological Limit Values (BLVs) are derived. A BLV represents the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect.

The main other legal tool next to the CMD to establish OELs within the EU OSH legal framework is the Chemical Agents Directive (Directive 98/24/EC, CAD[12]).

When establishing OELs, the Commission always takes Recommendations or Opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL) into account. SCOEL recommendations are recommendations for health-based limit values that describe a threshold below which adverse effects to human health are unlikely to occur. The Commission (COM) proposals for OELs follow such SCOEL recommendations by taking the scientific-technical feasibility of monitoring exposure including the availability of suitable measurement techniques into account. On the other hand, COM proposals for BOELVs are in addition also based on socio-economic and further technical feasibility factors. This also means that even under the condition where the occupational exposure of workers is equal or below the BOELV, additional protective and preventive measures need to be in place in order to ensure an effective health and safety protection of workers.

Under the CAD, COM can propose both, IOELVs and BOELVs. Under the CMD, the Commission can only propose BOELVs. This is based on the assumption that at least for the majority of the carcinogenic or

[12] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work as amended / http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:31998L0024&qid=1399304939016&rid=2

mutagenic substances strictly health-based limit values cannot be derived, which was in line with the scientific knowledge at the time the CMD was adopted. Or in other words: It is not possible to derive occupational exposure concentration below which carcinogenic or mutagenic effects will not occur for a majority of carcinogens and mutagens.

For EU IOELVs, Member States are only obliged to establish a national OEL by taking the EU IOELV into account, meaning they can go lower (more protective) or higher (less protective), provided they can justify the deviation to the Commission.

For EU BOELVs, Member States must establish a corresponding national limit value, from which they can only deviate to a lower more protective but not to higher value.

Since the CMD was first adopted in 1990, BOELVs have been set for three substances (benzene, vinyl chloride monomer and hardwood dusts), whereas under the CAD, one BOELV (for inorganic lead and its compounds) and 123 IOELVs have been adopted since 1991.

It has to be recalled that OELs, regardless which type, are only one tool within the preventive and protective measures foreseen under both, the CAD and CMD. Regardless whether a OEL is established for a hazardous substance or mixture, all obligations for employers and Member States' competent authorities alike to protect workers' safety and health remain in force and have to be applied. However, a numerical value, like an OEL, is a useful tool to help employers to determine the suitable risk management measures and also for labour inspectors to check compliance with the legislation. In any case, it is to be noted that the provisions of the CMD obliges to keep the exposure as low as possible regardless of the existence of a limit value.

2.2.2 Work already performed

The Commission started work intended to adapt the existing Directive to reflect changes in "scientific knowledge" and "technical progress" by launching the first and second stage of social partners consultation according to Article 154 of the TFEU in April 2004 and March 2007 respectively.

The main proposals among others as set out in the second stage of Social Partner consultation were:

- The addition of a limited number of process generated substances to Annex I of the Directive, thereby bringing these substances within the scope of the Directive;
- The revision of the BOELVs for the three substances already listed in Annex III of the Directive; and
- The addition of new BOELVs for a limited number of carcinogenic substances to be placed in Annex III.

Thereafter, the Commission put to tender two studies:

- The first one (signed in April 2009) mainly dealt with the socioeconomic, health and environmental impact for amending the CMD by introducing of up to three possible BOELVs for 25 substances in Annex III to the Directive (final report submitted to the Commission in May 2011). This study will be referred to further below as the IOM study.

- The second one (signed in December 2010) evaluated the potential socioeconomic, health and environmental impact of the possible inclusion of substances toxic to reproduction, category 1A and 1B within the scope of the Directive (final report submitted to the Commission in February 2013). This study will be referred to further below as the RPA study.

In June 2011, the Commission started to consult the tri-partite Working Party "Chemicals at the Work Place" (WPC) of the Advisory Committee on Safety and Health at Work (ACSH) on the possible amendment of the CMD to insert new and revise existing BOELVs on the basis of the final report of the IOM study. The discussion focussed mainly on the socioeconomic impact and the technical feasibility of the revision of the BOELVs for the three substances already included in Annex III of the Directive and the inclusion of additional PGSs in Annex I and new BOELVs for these and other substances in Annex III to the Directive.

Another key area of the discussion in the WPC concerned the pros and cons of extending the scope of the Directive to substances toxic to reproduction once the results of the RPA study were available.

Following the discussions in the WPC, the ACSH adopted in December 2012, May 2013 and November 2013 one opinion and two supplementary opinions, in which a common position and – if considered necessary by each interest group – specific comments were provided on

- the inclusion of certain PGSs in Annex I to the Directive; and
- the proposed BOELVs (revised for existing BOELVs / new for substances not yet included in Annex III).

2.2.3 Preparation of the Impact Assessment Report

Each Commission initiative expected to have significant impacts needs to be accompanied by an impact assessment (IA) report in line with the Commission's Better Regulation (BR) Guidelines[13] and its Toolbox[14]. This IA report needs to analyse the economic, social and environmental impacts of the initiative. Specific impacts such as on SMEs and on the competitiveness of the EU need to be given particular attention. Based

[13] http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm
[14] http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

on these requirements, the following problems were encountered when preparing the IA report:

Lack of data

The IOM study concluded that the strength of evidence to support a BOELV for the 25 substances subject to the study had to be divided into three groups:

Substances for which there is

- Evidence to support the introduction of the suggested BOELV;
- Uncertainty in how well the evidence supports the suggested BOELV; and
- Doubt about the appropriateness to introduce the suggested BOELV.

An in-depth analysis by the relevant Commission Services of the IOM study revealed for some substances considerable data gaps regarding the economic impacts presented in the IOM study even in cases where the study concludes that there is sufficient evidence to justify a BOELV.

Nevertheless, the ACSH requested in its opinions, that for all except for two substances (Hexachlorobenzene and Beryllium) BOELVs should be included in Annex III to the CMD. A BOELV for Beryllium was not considered by the ACSH as there was on-going work in SCOEL for this substance.

In addition, the ACSH also proposed for some substances BOELVs which do not correspond to the levels of concentration assessed in the IOM study without providing any socioeconomic justification, which as a consequence would require a complete new evaluation of the costs and benefits derived in the IOM report.

In order to address and close identified data gaps for a first set of carcinogenic substances, the Commission published in July 2015 an open call for tender for an additional study, the procedure of which is currently on-going (Open Call for Tender, VT number VT/2015/031)[15].

On-going Ex-post evaluation of 24 OSH directives and overlap with legal actions concerning certain substances or mixtures already or soon in force under REACH

An ex-post evaluation of the Framework Directive 89/391/EEC[16] and its 23 individual directives including the CAD and the CMD is currently

15 http://ec.europa.eu/social/main.jsp?langId=en&catId=625&callId=454&furtherCalls=yes&path=cms&visible=0&preview=cHJldkVtcGxQb3J0YWwhMjAxMjAyMTVwcmV2aWV3

16 Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, as amended / http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:01989L0391-19890619&qid=1399304370349&rid=5

being performed, and the results of which are not expected before the end of 2015. At this stage, amending certain articles of the CMD previously envisaged could pre-empt the results of the ex-post evaluation.

In addition, certain substances included in the IOM study are either already or will be soon covered by restrictions or authorisations as foreseen in the REACH Regulation, both procedures aiming at minimising the risks from substances of very high concern (SVHC) for human health and the environment. SVHC include amongst others substances classified as carcinogens, mutagens or substances toxic to reproduction category 1A or 1B according to the CLP Regulation, and therefore covering at least also partly substances under the scope of the CMD. In particular substances subject to authorisation cannot be placed any longer on the EU market or used after a certain date unless the applicant can demonstrate in its application for authorisation that either the risks from the use of the substance is adequately controlled or the socio-economic benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies. Taking the long latency period for the majority of cancer causing agents into account, it is far too early to say now whether or not these measures will have the envisaged effect.

3. Subject of the contract

This invitation to tender is intended to attract bids with a view to provide the relevant Commission services with up-to-date input in relation to certain carcinogenic substances so as to prepare an Impact Assessment Report necessary to accompany a draft proposal to amend Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work for a second time. This input will also include preparatory work to conduct a SME panel consultation via the Enterprise Europe Network of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), as well as, a questionnaire for a public consultation in line with the Commission's BR Guidelines (namely Chapter VII) and Minimum Standards on Consultation[17].

The concerned substances and related OELs and/or other aspects requested to be evaluated are the ones mentioned in section 4.1. of this document.

The final outcomes of the project shall be the following:

- A report containing for each substance and the given limit values and/or the other aspects specified in section 4 an impact assessment including a cost-benefit analysis in line with the Commission's IA Guidelines in its latest version containing all the elements mentioned above.

[17] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF

- A proposal on how to conduct the SME panel for these substances and their limit values including the questions to be submitted to stakeholders in line with the Commission's BR Toolbox[18] .
- A proposal on how to perform the public consultation for these substances and their limit values in line with the rules and procedures laid down in the Commission's BR Guidelines and Minimum Standards on Consultation.

4. Tasks to be carried out by the contractor

4.1 Tasks

This invitation to tender involves the following tasks:

4.1.1 Task 1

Assess the impacts including the cost and benefits for establishing the BOELVs proposed by the ACSH for the substances listed below by comparing them with existing national Limit Values:

- Chromium VI compounds (only those chromium VI compounds already included in Annex XIV of the REACH Regulation); BOELV 25 ug/m^3 8 hrs TWA
- Trichloroethylene – CAS number 79-01-6; BOELV 10 ppm 8 hrs TWA
- 1,2-dichloroethane –CAS number 107-06-2; BOELV 8.14 mg/m^3 (2 ppm) 8 hrs TWA
- Beryllium and inorganic beryllium compounds – BOELV 0;02 ug/m^3 8 hrs TWA (measured as inhalable fraction)
- 1,2-dibromoethane –CAS number 106-93-4; BOELV 0,8 mg/m^3 or 0.1 ppm 8 hrs TWA
- 1-chloro-2,3-epoxypropane (epichlorohydrine) – CAS number 106-89-8; BOELV 1,9 mg/m^3 8 hrs TWA
- 4,4'-methylenedianiline (MDA) – CAS number 101-77-9; BOELV 80 ug/m^3 8 hrs TWA

Regarding the overall impact of introducing the above mentioned BOELVs in Annex III to Directive 2004/37/EC, it has to be taken into account that a number of these substances are already subject to authorisation under the REACH Regulation[19]:

[18] See notably Tool #50 of the BR Guidelines Toolbox on stakeholder consultation (http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf)

[19] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive

This concerns in particular the following substances mentioned above:

- Chromium VI compounds
- Trichloroethylene, CAS Number 79-01-6
- 1,2-dichloroethane –CAS number 107-06-2
- 4,4'-methylenedianiline (MDA) – CAS number 101-77-9

The impact, including the costs and benefits, of introducing OELs under the CMD which would occur in addition to the measures already applicable to these substances under REACH needs to be evaluated.

4.1.2 Task 2

Assess the impacts including the cost and benefits for establishing a binding BLV for the following substances by comparing them with existing national Limit Values:

- Beryllium and inorganic beryllium compounds; 0;05 ug beryllium/l urine
- 4,4'-methylenebis(2-chloroaniline) (MOCA) – CAS number 101-14-4; 5 umol total MOCA in urine / mol creatinine; with regard to this substance, it has to be taken into account that this substance is already subject to authorisation under the REACH Regulation.

In addition, potential ethical problems in EU Member States with regard to the introduction of binding BLVs, their use in practice, surveillance and their enforcement need to be evaluated.

4.1.3 Task 3

This task concerns the substance hexachlorobenzene - CAS number 118-74-1.

For this substance, no BOELV is proposed. However, the contractor needs to assess on which scale this substance is still present at the workplace, taking into account that there is the obligation for all EU Member States as parties to the Stockholm Convention on Persistent Organic Pollutant[20] to take measures to eliminate the production and use of the substance.

However, the substance is still formed as a by-product during the manufacture of chlorine containing compounds (e.g. chlorinated solvents like tri- and tetrachloroethylene) and chlorinated pesticides.

Under the assumption that the assessment still reveals a considerable risk for workers, the contractor should also assess the impacts including the costs and benefits for establishing a binding BLV of 150 ug/l in

1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[20] http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx

plasma or serum as currently proposed by SCOEL[21] by comparing this value with existing national limit values.

With regard to tasks 1, 2 and 3, the following assumptions have to be made with regard to the cost-benefit analysis:

- In case where the national OEL is the same as the BOELV / the binding BLV proposed for the substances above, no impact (neither benefits nor costs) will occur and therefore needs to be calculated;
- For all national OELs full compliance of the employers is assumed.

4.1.4 Task 4

This task concerns the following Process Generated Substances (PGSs):

- Diesel Engine Exhaust Emissions
- Mineral oils as used engine oils
- Rubber process dust and fumes

For these PGSs, no BOELV is proposed. However, the contractor needs to assess the impact of bringing these PGSs under the scope of the CMD by introducing an entry for each of them in Annex I to the Directive.

For this purpose, the contractor also has to develop a legally sound definition of what is covered by the relevant entries.

The contractor also has to provide an analysis on the progress made in technology with regard to reduction and / or substitution of carcinogenic substances contained in these PGSs. A comparison of the progress in technology has to be made in particular with regard to the data used in the recent IARC monograph 100F[22], which is mainly based on a systematic review published in 1998 of epidemiological studies on cancer in the rubber-manufacturing industry.

With regard to tasks 1, 2, 3 and 4, the contractor should collect the best available information on actual exposures in workplaces (level, duration, frequency) and on the risk management measures in place, as well as any contextual information relevant for describing the exposures to these substances per sector, per country and per activity/task as appropriate and feasible. Information on the number of cancer cases related to exposure to these substances is of most importance for the assessment of impacts.

For each substance the contractor will collect all the data necessary to assess:

- The likely economic, social and environmental impacts for establishing either a specified BOELV, and/or a binding BLV, or an entry in Annex I to the Directive for each of the above mentioned substances covering

21 http://www.ser.nl/documents/82398.pdf
22 http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-36.pdf

- direct and indirect costs inside and outside the EU as well as administrative burden for Competent Authorities, Enterprises / Industries concerned, and the European Commission
- Direct and indirect Benefits inside and outside the EU

4.1.5 Task 5

Assess the impact of these limit values on SMEs (differentiating between micro, small and medium enterprises) in line with the guidance to assess these impacts[23].

4.1.6 Task 6

Assess the impact of these limit values on sectoral competitiveness in line with the relevant guidance to assess these impacts[24].

4.2 Input by the contracting authority

The lead service and contact point in the European Commission is DG Employment, Social Affairs and Inclusion, Unit EMPL B/3 "Health, Safety and Hygiene at Work".

The European Commission, DG Employment, Social Affairs and Inclusion, Unit EMPL B/3 "Health, Safety and Hygiene at Work" will grant to the contractor access to the following documents:

- The IOM reports related to the substances subject to this contract;
- The SCOEL recommendations related to the substances subject to this contract;
- The opinions of the ACSH related to the substances subject to this contract;
- The existing limit values in EU Member States related to the substances subject to this contract;
- Recent publications published by EU-OSHA related to occupational carcinogens;
- Report "Assessing the Compliance Costs and Benefits of European OSH Directives;
- REACH documents related to the authorisation process of the substances concerned.

[23] See notably Tool #19 of the BR Guidelines Toolbox (http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf) and operational guidance on impacts on micro-enterprises (http://ec.europa.eu/smart-regulation/impact/key_docs/docs/meg_guidelines.pdf)

[24] See notably Tool #17 of the BR Guidelines Toolbox (http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf) and the operational guidance on competitiveness (http://ec.europa.eu/smart-regulation/impact/key_docs/docs/sec_2012_0091_en.pdf)

A steering group composed of representatives from different Commission Services including the above mentioned European Commission Unit, will oversee the implementation of the project.

The contractor will take part in three (3) meetings with the Commission services.

These meetings will be organised by the Commission (Unit EMPL B/3) and held in the Commission premises in Luxembourg.

Any problem that is likely to result in a departure from the agreed project schedule must be notified to the Commission services as soon as possible. In executing the contract, the contractor will be expected to work closely with the Commission.

The contractor will appoint a person to coordinate the project, who will be the Commission's contact point.

4.3 Intermediate outputs and deliverables

The contractor is expected to produce an inception report, an interim report, and a final report. All reports have to be validated by the Commission. Additionally, the contractor must also be available to present the results of the reports at 3 meetings of the Commission department responsible (EMPL B-3) and the steering committee in Luxembourg.

4.4 Final output and deliverable – content, structure and graphic requirements

All studies produced for the European Commission and Executive Agencies shall conform to the corporate visual identity of the European Commission by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo[25].

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on Commission policy on accessibility for information providers, see: http://ec.europa.eu/ipg/standards/accessibility/index_en.htm.

Pdf versions of studies destined for online publication should respect W3C guidelines for accessible pdf documents. See: http://www.w3.org/WAI/.

Content

The final study report shall include:

[25] The Visual Identity Manual of the European Commission is available upon request. Requests should be made to the following e-mail address: comm-visual-identity@ec.europa.eu

- an abstract of no more than 200 words and an executive summary of maximum 6 pages in English.

- the following standard disclaimer:

  "The information and views set out in this [report/study/article/publication…] are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

- specific identifiers which shall be incorporated on the cover page provided by the Contracting Authority.

Publishable executive summary

The publishable executive summary shall be provided both in English and French and shall include:

- the following standard disclaimer:

  "The information and views set out in this [report/study/article/publication…] are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

- specific identifiers which shall be incorporated on the cover page provided by the Contracting Authority.

Graphic requirements

For graphic requirements please refer to the template provided in the annex I. The cover page shall be filled in by the contractor in accordance with the instructions provided in the template. For further details you may also contact comm-visual-identity@ec.europa.eu.

4.5 Details on deliverables

In fulfilling the contract, the contractor shall ensure that:

a) the text of all documents is drafted in English;

b) the final report is delivered both in accessible electronic (Word – or compatible – and PDF) and paper form (10 copies). Key points should be concise, sharp and easily understandable;

c) the final report contains an executive summary (in EN and FR), a glossary of technical terms used, and definitions to assist the understanding.

The methodology and work plan, together with the various reports (inception report, interim report, draft final report and final report) referred to in this document, must be submitted to the European Commission (Unit EMPL B-3) both on paper (in triplicate) and in a widely-used electronic format. The contractor must also supply a copy of the information collected and used in preparing the draft and the final report.

4.6 General guidance on methodology

Tenderers will indicate the methodology they intend to use and explain how it is suitable for carrying out the tasks described above.

Tenderers must clearly indicate the fundamental elements of the methodology allowing the objectives and tasks set out respectively in sections 4.1 of these specifications to be achieved.

The methodology must enable the identification, analysis and assessment of the various elements cited in these specifications and should not be restricted to documentary identification and analysis. It must also show the approach envisaged and its suitability for reflecting correctly the requirements of these specifications as well as the work plan.

The methodology described above and the work plan proposed will be among the factors governing the award of the contract.

4.7 Performance and quality requirements

The information must be comprehensive, up to date, accurate, relevant to the specified topic, and at a level suitable for the specified target audience. All deliverables must be in high quality English in a style suitable for the specified target audience and have a clear, logical and easy to follow structure.

The contractor shall provide references to all sources used during the work. Data that has been collected in the course of the project shall be made accessible, while respecting the principles of data protection.

4.8 General delivery time and progress meetings foreseen with the Commission Authority

The contractor must be available to present the results of the reports at 3 meetings of the Commission department responsible (EMPL B-3) and the steering committee in Luxembourg. These meetings are foreseen to take place in line with the time schedule outlined in section 6.1 of these specifications.

4.9 Monitoring Information

The Commission, with the support of an external contractor, will monitor regularly the EaSI Programme. Therefore, contractors will have to transmit qualitative and quantitative monitoring data on the results of the activities. These will include the extent to which the principles of equality between women and men has been applied, as well as how anti-discrimination considerations, including accessibility issues, have been addressed through the activities. Related templates are attached or will be provided.

In setting up the action, contractors must foresee the necessary funding for monitoring and reporting to the Commission.

5. General requirement on issues to consider for the activities funded under EaSI

The EaSI Programme shall, in all its axes and actions, aim to:

(a) pay particular attention to vulnerable groups, such as young people;

(b) promote equality between women and men,

(c) combat discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation;

(d) promote a high-level of quality and sustainable employment, guarantee adequate and decent social protection, combat long-term unemployment and fight against poverty and social exclusion.

Hence, in designing, implementing and reporting on the activity, contractors must address the issues noted above and will be required to provide detail, in the final activity report on the steps and achievements made towards addressing those aims.

6. Time schedule and reporting

See article I.2. of the contract.

6.1 Time schedule

The **full duration of the contract** will be **6 months**, from the date of the contract signature.

Actions/Deliverables	**Timetable**
Entry into force of the contract	**Signature of the contract**
Inception report	Reference date + 1 month
Inception meeting	Reference date + 6 weeks
Interim report on progress of the work done and first results obtained in relation to the tasks specified in section 4.1, in particular on • the remaining work to be carried out, • problems encountered, • summary of the work accomplished, • a draft proposal on how to run the SME panel, • a draft proposal on how to	Reference date + 3 months

perform the public consultation.	
Interim meeting	Reference date + 14 weeks
Draft final report on the tasks performed as specified in section 4 of this document, containing in particular • for each substance an impact assessment and a cost benefit analysis for either the proposed BOELVs / the proposed binding BLVs, or the inclusion of the substance in Annex I to the Directive, • a final proposal on how to run the SME panel, • a final proposal on how to perform the public consultation.	Reference date + 4 months
Meeting on the draft final report	Reference date + 18 weeks
Definitive version of the final report	Reference date + 6 month(s)

6.2 Reporting

The project is expected to produce one inception report, one interim report, and a final report, on the basis of the following timetable.

a) Inception report – the contractor is expected to provide an inception report, specifying the plan of work, the distribution of tasks and the methodological tools of the examination. The contractor will submit and then present at a meeting with the Commission department responsible (EMPL B-3) and the Monitoring Group in Luxembourg a detailed account of the methodology, work plan and approach which the contractor intends to use, together with the work schedule.

The inception report should be summited **within 1 month of the signature of the contract**.

This inception report should be presented and discussed at a meeting of the Commission department responsible (EMPL B-3) and the steering committee in Luxembourg within the two weeks following the submission of the report.

b) Interim report – to cover the progress of work done and first results obtained. The interim report should explain progress made so far, covering the tasks specified in section 4.1. of this document. The interim report should include sufficient information to permit reorientation, if appropriate and required, and will contain the information:

i. On the remaining work to be carried out;

ii. Any particular problems encountered that would have a notable effect on the tasks to be carried out;

iii. A summary of the work accomplished;

The Interim Report should contain in particular

- a draft proposal on how to conduct the SME panel and
- a draft proposal on how to perform the public consultation.

The interim report should be summited **within 3 months after the signature of the contract**.

This interim report should be presented and discussed at a meeting of the Commission department responsible (EMPL B-3) and the steering committee in Luxembourg within the two weeks following the submission of the interim report.

c) Draft final report – The contractor has the obligation to take into account the conclusions of the steering committee for the preparation of the draft final report. The draft final report will contain a maximum of 100 pages, excluding annexes. The draft final report should cover the tasks specified in section 4 of this document and contain:

- An executive summary (in EN and FR)
- A report containing for each of the substances and their BOELVs, and / or the binding BLVs, or their inclusion in Annex I to the Directive, an impact assessment including a cost-benefit analysis in line with the Commission's IA Guidelines in latest version
- A final proposal on how to conduct the SME panel for these substances and their limit values including the questions to be submitted to stakeholders
- A final proposal on how to perform the public consultation for these substances and their limit values

The draft final report should be summited **within 4 months of the signature of the contract**.

This draft final report should be presented and discussed at a meeting of the Commission department responsible (EMPL B-3) and the steering committee in Luxembourg within the two weeks following the presentation of the report.

The conclusions of the meeting of the steering committee will be taken into account by the contractor in preparing the final report.

d) Final report: the European Commission (Unit EMPL B-3) may transmit objections and comments to the contractor within 1 month of receipt of the draft final report. The contractor will then have 1 month to present the final report, **6 months after signature of the contract**, taking these objections and comments into account or presenting another point of view. The final report will include a PowerPoint Presentation explaining the context and the results of the study.

7. Price

7.1 Protocol and taxes applicable

The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to assume the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

7.2 Details for prices

The maximum amount of the contract is € 400,000

Lump sum

The quoted price must be a fixed amount which includes all charges (including travel and subsistence). Travel and subsistence expenses are not refundable separately.

x Professional fees and other costs expressed as the number of person-days multiplied by the unit price per working day for each expert proposed. The unit price should cover the experts' fees and administrative expenditure.

X Other costs

7.3 Presentation of financial offer

Description	Unit price in EUR	Max. No of units	Unit type	Sub-total per item EUR	Total amounts in EUR
Experts' fees[26] Details	0.00	0	w.d.	0.00	0.00
Other costs [27] Details	0.00	0	Unit	0.00	0.00
Total amount					**0.00**

[26] To be specified for each specific task
[27] To be specified for each particular cost

(art. I.3.1. of the contract°					

8. Payments and contract

In drawing up the bid, the tenderer should take care into account the provisions of the standard contract comprising the "General terms and conditions applicable to service contract"

The price will be paid as follows:

- 50% on approval of the interim report,
- 50% on approval of the final report.

Payments will be made in EUR (€) following acceptance by the European Commission of the reports referred to in these specifications (section 6.1 and 6.2) and following submission of the final invoice.

9. Source of funding

Contractors must acknowledge in writing that the project has been supported by the European Union Programme for Employment and Social Innovation ("EaSI") 2014-2020. In practice, all products (publications, brochures, press releases, videos, CDs, posters and banners, and especially those associated with conferences, seminars and information campaigns) must state the following:

> *This (publication, conference, video, xxx) has received financial support from the European Union Programme for Employment and Social Innovation "EaSI" (2014-2020). For further information please consult: http://ec.europa.eu/social/easi*

The European emblem must appear on every publication or other material produced. Please see:

http://ec.europa.eu/dgs/communication/services/visual_identity/pdf/use-emblem_en.pdf

Every publication must include the following:

> *The information contained in this publication does not necessarily reflect the official position of the European Commission.*

Administrative part

10. Participation

10.1 Participation to the procedure

Participation in this tender procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the Multilateral Agreement on Government Procurement[28] concluded within the WTO applies, the participation to the call for tender is also open to nationals of the countries that have ratified this Agreement, on the conditions it lays down.

10.2 Contractual conditions

The tenderer should bear in mind the provisions of the draft contract which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, and checks and audits.

10.3 Sub-contracting

Subcontracting is permitted in the tender but the contractor will retain full liability towards the Contracting Authority for performance of the contract as a whole.

Tenderers must give an indication of the proportion of the contract that they intend to subcontract.

Tenderers are required to identify subcontractors whose share of the contract is above 10% of the budget.

During contract execution, the change of any subcontractor identified in the tender will be subject to prior written approval of the Contracting Authority.

11. Joint tenders

A joint tender is a situation where a tender is submitted by a group of economic operators (consortium). Joint tenders may include subcontractors in addition to the joint tenderers. In case of joint tender, all economic operators in a joint tender

[28] See http://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm

assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole[29]. Nevertheless, tenderers must designate a single point of contact for the Contracting Authority.

After the award, the Contracting Authority will sign the contract either with all members of the group, or with the member duly authorised by the other members via a power of attorney.

The documents required and listed in the following points (12 and 13) must be supplied by every member of the grouping.

12. Exclusion criteria and supporting documents

1) All tenderers shall provide a declaration on their honour (see Annex 5 of the invitation letter), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in ***Articles 106 and 107 (1) of Financial Regulation***.

   The declaration on honour is also required for identified subcontractors whose intended share of the contract is above 10%.

2) The successful tenderer shall provide the documents mentioned as supporting evidence in the Annex mentioned beforehand, before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender and to identify subcontractors whose intended share of the contract is above 10%.

Article 143 of the Rules of Application – Evidence

3. *The contracting authority shall accept as satisfactory evidence that the candidate or tenderer to whom the contract is to be awarded is not in one of the situations described in points (a), (b) or (e) of Article 106(1) of the Financial Regulation, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. The contracting authority shall accept, as satisfactory evidence that the candidate or tenderer is not in the situation described in point (a) or (d) of Article 106(1) of the Financial Regulation, a recent certificate issued by the competent authority of the State concerned.*

Where the document or certificate referred to in paragraph 1 of this Article is not issued in the country concerned and for the other cases of exclusion referred to in Article 106 of the Financial Regulation, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative

[29] These entities can take the form of an entity with or without legal personality but offering sufficient protection of the Commission's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association). The contract has to be signed by all members of the group, or by one of the members, which has been duly authorised by the other members of the grouping (a power of attorney or sufficient authorisation is to be attached to the contract), when the tenderers have not formed a legal entity.

authority, a notary or a qualified professional body in his country of origin or provenance.

4. *Depending on the national legislation of the country in which the candidate or tenderer is established, the documents referred to in paragraphs 1 and 3 shall relate to legal persons and/or natural persons including, where considered necessary by the contracting authority, company directors or any person with powers of representation, decision-making or control in relation to the candidate or tenderer".*

See Annex 5 of the invitation letter (which may be used as a checklist) for the supporting documents accepted by the European Commission to be provided by applicants, tenderers or tenderers to who the contract will be awarded.

3) The contracting authority may waive the obligation of a candidate or tenderer to submit the documentary evidence referred to in Article 143 of the Rules of Application, if such evidence has already been submitted to it for the purposes of another procurement procedure launched by DG EMPL and provided that the issuing date of the documents does not exceed one year and that they are still valid.

In such a case, the candidate or tenderer shall declare on his honour that the documentary evidence has already been provided in a previous procurement procedure and confirm that no changes in his situation have occurred.

13. Selection criteria

Tenderers must prove their economic, financial, technical and professional capacity to carry out the work subject to this call for tender.

The evidence requested should be provided by each member of the group in case of joint tender and identified subcontractor whose intended share of the contract is above 10%. However a consolidated assessment will be made to verify compliance with the minimum capacity levels.

The tenderer may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to the Contracting Authority that it will have at its disposal the resources necessary for performance of the contract, for example by producing an undertaking on the part of those entities to place those resources at its disposal.

13.1 Economic and financial capacity and evidence

a. Criteria

In order to prove their economic and financial capacity, the tenderer (i.e. in case of joint tender, the combined capacity of all members of the consortium and identified subcontractors) must comply with the following criteria:

x Turnover of the last two financial years of at least € 1,500,000 (statement of overall turnover for the grouping/consortium when applicable)

b. Evidences

The following evidence should be provided:

x Copy of the profit and loss accounts and balance sheets for the last two years for which accounts have been closed

x Failing that, Appropriate statements from banks

x Presentation of balance sheets

x If applicable, evidence of professional risk indemnity insurance

If, for some exceptional reason which the Contracting Authority considers justified, a tenderer is unable to provide one or other of the above documents, he or she may prove his or her economic and financial capacity by any other document which the Contracting Authority considers appropriate. In any case, the Contracting Authority must at least be notified of the exceptional reason and its justification in the tender. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

13.2 Technical and professional capacity criteria and evidence

a. Criteria relating to tenderers

Tenderers (in case of a joint tender the combined capacity of all tenderers and identified subcontractors) must comply with the following criteria:

- The tenderer must prove experience in the field of performing an impact assessment similar to the requirements of the Commission's Better Regulation (BR) Guidelines[30] and its Toolbox[31] with at least 3 projects delivered in this field in the last three years with a minimum value for each project of € 300,000.

- The tenderer must prove experience of working in 4 EU languages with at least 3 projects delivered in the last three years showing the necessary language coverage.

[30] http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm
[31] http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

- The tenderer must prove ability to work with data sources and reports submitted in original EU languages without depending on the Commission translation services with at least 3 projects delivered in this field in the last three years with a minimum value for each project of € 300,000.

- The tenderer must prove capacity to draft high quality reports in English with at least 3 projects delivered in this field in the last three years with a minimum value for each project of € 300,000.

- The tenderer must prove experience of working in 10 EU countries with at least 3 projects delivered in the last three years, the combination of which must show the coverage necessary for the contract

- The tenderer must prove experience in data collection, statistical analyses, impact assessment (economic, social and environmental) and cost-benefit analysis in particular with regard to SMEs, occupational exposure limit values and the related EU legislation, as well as drafting reports and recommendations in these areas with at least 3 projects delivered in this field in the last three years with a minimum value for each project of € 300,000.

b. Criteria relating to the team delivering the service

The team delivering the service should include, as a minimum, the following profiles:

- Project Manager: At least 15 years of experience in project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in project of a similar size (at least € 300,000) and geographical coverage, with experience in management of team of at least 10 people.

- Expert in performing Impact assessments and cost-benefit analyses, in particular with regard to SMEs in line with the requirements of the Commission's Better Regulation (BR) Guidelines[32] and its Toolbox[33] : Relevant higher education degree and / or 5 years' professional experience in this area

- Expert in EU-OSH legislation, in particular with regard to occupational exposure limit values: Relevant higher education degree and / or 5 years' professional experience in this area

- Text and language quality check: the team should include at least one member entirely responsible for reviewing the text and language proofreading of reports. This person should have the highest proficiency level in English equivalent to the level of native speaker as guaranteed by a certificate or past relevant experience. .

c. Evidence

The following evidence should be provided to fulfil the above criteria:

[32] http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm
[33] http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

- List of relevant services provided in the past three years, with sums, dates and recipients, public or private. The most important services shall be accompanied by certificates of satisfactory execution, specifying that they have been carried out in a professional manner and have been fully completed;

- The educational and professional qualifications of the persons who will provide the service for this tender (CVs) including the management staff. Each CV provided should indicate the intended function in the delivery of the service.

14. Award criteria

The tender will be awarded according to the best value for money procedure. The quality of the tender will be evaluated based on the following criteria. The maximum total quality score is 100 points.

The contract will be awarded to the most economically advantageous bid, as explained below, in terms of the following criteria:

x Quality and consistency of the proposed approach 45 points

- Sub-criterion 1.1 – Comprehensiveness of the proposed approach including identified risks (25 points)

- Sub-criterion 1.2 – Technical coherence and quality of the proposed approach (20 points)

x Quality of the work plan proposed 25 points

- Sub-criterion 1.1 – realistic scheduling of deliverables (10 points)

- Sub-criterion 1.2 – realistic milestones (5 points)

x Organisation of the work and management of the project 30 points

- Sub-criterion 1.1 – realistic calculation and allocation of resources (10 points)

- Sub-criterion 1.2 – overall organisation of the project (10 points)

Tenders must score minimum 50% for each criterion and sub-criterion, and minimum 70% in total. Tenders that do not reach the minimum quality thresholds will be rejected and will not be ranked.

After evaluation of the tender, the tenders are ranked using the formula below to determine the tender offering the best value for money. A weighting of respectively 70% / 30% is given to quality and price.

Score for tender X = cheapest price/price of tender X * 100 * price weighting (in %) + total quality score (out of 100) for all award criteria of tender X * quality criteria weighting (in %)

15. Content and presentation of offers

15.1 Content of bids

The Tenders must include:

- A cover letter presenting the name of the tenderer (including all entities in case of joint offer) and identified subcontractors if applicable, and the name of the single contact person in relation to this tender;
  - The name and function of the contractor's legal representative (i.e. the person authorised to act on behalf of the contractor in any legal dealings with third parties);
  - In case of joint tender, the cover letter must be signed by a duly authorised representative for each tenderer, or by a single tenderer duly authorised by other tenderers (with power of attorney).
  - If applicable, the cover letter must indicate the proportion of the contract to be subcontracted.
- Identified subcontractors must provide a letter of intent stating their willingness to provide the service foreseen in the offer and in line with the present tender specification.
- Proof of eligibility: tenderers must indicate the State in which they have their registered office or are established, providing the necessary supporting documents in accordance with their national law;
- The tenderer (or the single point of contact in case of joint tender) must provide a Financial Identification Form and supporting documents. Only one form per offer should be submitted (no form is needed for subcontractors and other joint tenderers). The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm .
- In order to prove their legal capacity and their status, all tenderers must provide a signed Legal Entity Form with its supporting evidence. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

  [Tenderers that are already registered in the Contracting Authority's accounting system (i.e. they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.]

  Tenderers must provide the following information if it has not been included with the Legal Entity Form:

- For legal persons, a legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation which applies to the legal entity concerned requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.

- For natural persons, where applicable, a proof of registration on a professional or trade register or any other official document showing the registration number.

- A technical and financial offer:

  - All information and useful documents in view to give to the Commission the opportunity to assess the offer on the basis of selection and award criteria (see points above);

  - Price;

  - List of experts assigned, their VCs, classified by level of expertise according following criteria:

Level of qualification I
Highly qualified expert having assumed important responsibilities in his/her profession, recruited for his/her management/supervisory, thought and creativity skills as regards professional practise. He/she must have at least 15 years professional experience of which at least 7 must be connected with the professional sector concerned and the type of tasks to be performed.
Level of qualification II
Highly qualified expert having assumed responsibilities in his/her profession, recruited for his/her management/supervisory, thought and creativity skills as regards professional practise. He/she must have at least 10 years professional experience of which at least 4 must be connected with the professional sector concerned and the type of tasks to be performed.
Level of qualification III
Certified expert having received a high-level training in his/her profession recruited for his/her thought and creativity skills as regards professional practise. He/she must have at least 5 years professional experience of which at least 2 must be connected with the professional sector concerned and the type of tasks to be performed

Level of qualification IV
Junior expert, newcomer to the profession but holding a university degree or equivalent training related to the professional sector concerned and the type of tasks to be performed.

15.2 Presentation of bids

They must include all requested information (see tender specifications and draft contract).

They must be clear and concise.

They must be signed by the legal representative of the tenderer.

They must be submitted in accordance with the specific requirements of the invitation to tender letter, within the deadline laid down.