EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

Ecosystems I: Chemicals, Food, Retail
F.1 - REACH

European Commission

Call for tenders - Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation

GROW/2023/OP/0042

Open procedure

TENDER SPECIFICATIONS

TABLE OF CONTENTS

1. SCOPE AND DESCRIPTION OF THE PROCUREMENT 4

1.1. Contracting authority: who is the buyer? 4

1.2. Subject: what is this call for tenders about? 4

1.3. Lots: is this call for tenders divided into lots? 4

1.4. Description: what do we want to buy through this call for tenders? 4

1.5. Place of performance: where will the contract be performed? 23

1.6. Nature of the contract: how will the contract be implemented? 23

1.7. Volume and value of the contract: how much do we plan to buy? 24

1.8. Duration of the contract: how long do we plan to use the contract? 24

1.9. Electronic exchange system: can exchanges under the contract be automated? 24

1.10. Security 25

2. GENERAL INFORMATION ON TENDERING 25

2.1. Legal basis: what are the rules? 25

2.2. Entities subject to restrictive measures and rules on access to procurement: who may submit a tender? 25

2.3. Registration in the Participant Register: why register? 26

2.4. Ways to submit a tender: how can economic operators organise themselves to submit a tender? 26

3. EVALUATION AND AWARD 31

3.1. Exclusion criteria 31

3.2. Selection criteria 32

3.3. Compliance with the conditions for participation and minimum requirements specified in the procurement documents 34

3.4. Award criteria 35

3.5. Award (ranking of tenders) 35

4. FORM AND CONTENT OF THE TENDER 38

4.1. Form of the tender: how to submit the tender? 38

4.2. Content of the tender: what documents to submit with the tender? 38

4.3. Signature policy: how can documents be signed? 39

4.4. Confidentiality of tenders: what information and under what conditions can be disclosed? 40

APPENDIX: LIST OF REFERENCES 41

ANNEXES 42
Annex 1. List of documents to be submitted with the tender or during the procedure 43
Annex 2. Declaration on Honour on exclusion and selection criteria 47
Annex 3. Agreement/Power of attorney 48
Annex 4. List of identified subcontractors and proportion of subcontracting 50
Annex 5.1. Commitment letter by an identified subcontractor 51
Annex 5.2. Commitment letter by an entity on whose capacities is being relied 52
Annex 6. Financial tender form 53

1. SCOPE AND DESCRIPTION OF THE PROCUREMENT

1.1. Contracting authority: who is the buyer?

This call for tenders is launched and managed by the European Commission, DG GROW - Internal Market, Industry, Entrepreneurship and SMEs, referred to as the contracting authority for the purposes of this call for tenders.

1.2. Subject: what is this call for tenders about?

The subject of this call for tenders is "Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation".

1.3. Lots: is this call for tenders divided into lots?

This call for tenders is not divided into lots.

1.4. Description: what do we want to buy through this call for tenders?

The purchases that are the subject of this call for tenders, including any minimum requirements, are described in detail below.

Variants (alternatives to the model solution described in the tender specifications) are not allowed. The contracting authority will disregard any variants described in a tender.

1.4.1. Background and objectives

The **purpose of the study** is to identify and evaluate options to better address complex substitution processes in chemicals legislation, in particular in the context of REACH restrictions and authorisations, or as a complement to chemicals legislation, through co-operative planning approaches such as substitution plans.

The overall objectives of such options shall be fostering substitution of harmful substances to increase the protection of human health and the environment, to reduce societal costs resulting from diseases and remediation, minimise business risks associated with harmful substances contained in products and their substitution, and to promote innovation for safer alternatives in Europe. Regulatory efficiency shall be enhanced by enabling a better interplay between regulation and collaborative industry action, building upon expert and stakeholder driven planning of complex and technical substitution processes as well as front-runner's initiatives, and taking inspiration from the recently published Transition Pathway for the Chemicals Industry[1].

Better communication and collaboration between industry actors and authorities, and more flexibility for taking into account practical constraints and opportunities in a planned process should:

[1] European Commission, Transition Pathway for the Chemical Industry, 2023, https://ec.europa.eu/docsroom/documents/54595.

- limit business disruption and guarantee supply of products needed by society during the transition phase,
- improve predictability for industry, trigger a maximum of innovation and investment into safer, greener and sustainable[2] alternatives in Europe, and
- speed up and increase efficiency of regulatory processes by authorities.

In this way, synergies shall be developed between speeding up the phase-out of hazardous substances to better protect human health and the environment against chemical risks and the promotion of innovation and competitiveness through better predictability of the substitution process for industry.

1.4.1.1. Background

Chemicals Strategy for Sustainability (CSS)[3]

The Chemicals Strategy for Sustainability calls for the transition of the EU chemical industry to chemicals that are safe and sustainable by design which entails minimising and substituting as far as possible substances of concern and phasing out the most harmful ones for non-essential uses, in particular in consumer products. As key measures to achieve this objective, the CSS mentions the support of frontrunner companies that are working on safe and sustainable solutions, advice and assistance in particular for SMEs, concerted effort from authorities, business, investors and researchers and regulatory tools that drive and reward the production of safe and sustainable chemicals. As part of the CSS, EU chemicals legislation is being revised with the aim of better protecting human health and the environment, promoting innovation and competitiveness of the EU chemical industry, while ensuring simplification, consolidation and full implementation of the regulatory framework.

REACH Regulation[4]

The REACH Regulation aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. The latest REACH evaluation concluded that REACH is effective but that there are opportunities for further improvement, simplification and burden reduction. Following the evaluation, a number of non-legislative actions were launched (most have been finalised) to improve the implementation of REACH. However, there are problems that remained unaddressed and which are tackled by the ongoing targeted REACH revision. The Commission proposal is scheduled for adoption in Q4 2023. The revision, besides improving the protection of human health and the environment, aims *inter alia* to streamline processes and reduce the financial and administrative burden both for authorities and for industry, promote innovation towards more sustainable alternatives and create stronger incentives to substitute the most harmful substances.

---

[2] European Commission, Commission Recommendation of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials, C(2022) 8854 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?toc=OJ%3AL%3A2022%3A325%3ATOC&uri=uriserv%3AOJ.L_.2022.325.01.0179.01.ENG.

[3] European Commission, Chemicals Strategy for Sustainability. Towards a Toxic-Free Environment, COM (2020) 667 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN.

[4] 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).

This study cannot be taken into account in the Commission proposal but is intended to inform the further discussions in the European Parliament and the Council.

The challenge of substitution for complex cases

To achieve the goal of minimising and substituting the most harmful substances while safeguarding and promoting the competitiveness of EU companies, the transition to safer and more sustainable alternatives, be they a different substance, or a change of process, material or technology, is crucial.

While industry has all interest to act responsibly and avoid damages to health and the environment from their activities or products, they must be successful on the market, make profits and sell their products. Where substitution requires moving to alternatives which are more expensive or do not achieve exactly the same performance as the substance to be substituted or where there is simply less experience with the use of the alternative, substitution is therefore unlikely to happen in the absence of regulatory measures.

In simple cases (e.g. presence of a substance in textiles, microplastics in sports fields, lead in jewellery), regulatory measures can be limited to banning the use of a substance by a certain date and leaving the necessary action to substitute the substance to industry.

Nevertheless, there are also many cases (often more complex products such PFAS in semiconductors, chrome-plated parts in engines, medical products) where the feasibility to substitute depends on a complex set of considerations:

- A first set of considerations is whether available alternatives are indeed preferable for health and the environment, and whether they perform the necessary function in the product. If this is not the case, regulatory measures may lead to 'regrettable substitution'.

- A second set of considerations is related to variations within broad use categories, and practical constraints for the substitution which may differ from one company to another and between similar products, depending on the context of their uses.

Factors determining the availability of alternatives in complex cases

The technical and economic feasibility of alternatives and their availability often depend on a complex set of company and use specific considerations, which can evolve over time, as technology and production capacities are being developed. Factors that determine the possibility and pace of substitution[5] of hazardous substances are in particular:

- In some cases, differences in technology between different use(r)s mean that the alternative may fit into the technology of one producer but not another. For instance, water-based paints require biocides (preservatives), while solvent-based paints have less or no recourse to biocides.

- It may not be clear from the outset whether the alternative works in a particular product, so testing and building prototypes may be necessary. For instance, replacing PFAS in semiconductor production will require testing whether the necessary quality of chips can be achieved with the alternative, or whether undesired effects of alternatives (e.g. foaming during production) prevent a switch to the alternative.

[5] See also ECHA, Impacts of REACH restriction and authorisation on substitution in the EU, 2020, https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf/7c95222f-5f84-57f7-4cba-65b8463c79d4.

- Depending on where a component produced with a hazardous substance ends up, a different level of loss of performance due to the switch to an alternative may be acceptable. For example, alternatives to Chromium(VI) providing less corrosion protection may be acceptable for aeroplane seats but not necessarily for safety relevant machinery parts on the outside of an aeroplane.

- Companies differ in available space and resources to change production processes. For example, some companies may not have spare surface to build a parallel production line, or need to seek permits to expand the factory, others might not have the financial capabilities to change to another machine or train staff on how to handle an alternative.

- Producers of chemical substances are often specialised in a certain type of chemistry and have made important investments in production lines of certain specific substances. Shifting their production to a different substance threatens the viability of those investments.

- It may take time to build up the necessary production capacities for supplying the entire EU market with an alternative. For example, even if the switch to alternative chrome plating technologies is considered technically feasible for certain uses and the alternative is already applied in certain uses, it may take years to build the necessary production capacities for the alternative technologies to serve the entire EU market.

- Legal requirements (hazard assessment of newly developed alternatives, medicine approvals, airworthiness certification etc.) may take time. For instance, new products introduced to the aeronautic sector need to obtain an aeronautic certification, which proves that the properties of the new product are in line with safety requirements.

- Often it is possible to use a substitute in new products but it is much more difficult to switch to alternatives in products that are already on the market or in existing installations (e.g. industrial production sites), in particular if the use is only a small element of a much bigger production process. For instance, certain industrial cooling systems require the use of chromium (VI), while others do not. Therefore, the only way for such companies to replace chromium(VI) would be to build a new cooling installation, while the old one has the potential to last for decades more. Certain medical devices are used for very specific treatments only a limited number of patients needs. As development of such devices is expensive and requires certification, it may not be economically feasible to redesign such devices, even if, in new devices, another substance or technology could be used.

- In some supply chains, customers' preferences can prevent substitution; there are cases where one supplier provides the same or similar products to many clients who may have different requirements. For example, even if a company producing chromium-plated components for aircrafts understands the benefits associated with moving to an alternative, and can move to tartaric sulphuric acid iodising, they may not be able to switch the (entire) production to that alternative, if their biggest customer insists on chromium plating.

- Similar effects may also occur the other way round, i.e. downstream users may have difficulties influencing their supplier. For example, a paint company might want to use a dispersing agent without a specific hazardous substance, but suppliers do not produce or develop it as the demand is too low.

- More generally, in the absence of regulatory pressure or support from the authorities, industry may be inclined to use well-established solutions rather than alternatives which are linked to uncertainties and risks with respect to their performance and market acceptance.

In summary, for such complex cases, substitution usually takes time[6] and requires testing, building or extending production facilities for alternatives, and potentially legal approval procedures.

Impacts of complex substitution patterns on regulatory approaches

Most current restrictions and many authorisations concern simple cases in terms of substitution patterns, and neither the analysis of alternatives nor substitution have created major problems. Normally substance bans or restrictions have clearly improved health and environmental protection and markets adapted after a transition phase.

There are however cases where banning of substances has led to regrettable substitution (e.g. bisphenol A by bisphenol S, or PFOS by other PFAS substances). In such cases, a more thorough prior analysis, including of potential alternatives could have led to better solutions and a better design of the restriction.

The biggest challenge is however to find appropriate solutions for cases where availability and suitability of alternatives vary significantly between uses, their use context and different users. In such cases, dealing with all scientific, technical and socio-economic considerations through current regulatory approaches is challenging, time and resource consuming.

In REACH, such a complex case has arisen with the authorisation requirement for chromium (VI) substances. The existing approach for applicant-by-applicant authorisation has proven unworkable due to a number of applications exceeding ECHA´s and the Commission's capacity to deal with those applications. This is why a transfer from REACH authorisation to REACH restriction is being considered at the time of drafting these terms of reference. The transfer to restriction may resolve the problem with the number of applications but still a solution needs to be found for a restriction requiring substitution of chromium(VI) where it is feasible, without however imposing it where substitution does not work yet or where alternatives are worse than the original chromium(VI) use. Similar challenges may arise for technical uses of PFAS or lead, once they will be subject to REACH restrictions.

Where could planning approaches help to resolve difficulties for uses with complex substitution patterns?

Where complex substitution patterns occur, taking into account all relevant factors requires very detailed analysis, including company and use specific considerations.[7] However, such detailed analysis may not be feasible from a workload perspective, and might bind authority resources to a degree that other important objectives cannot be achieved. Moreover, such detailed regulation may turn out to be over-prescriptive and to stifle innovation through lack of flexibility.

However, less detailed regulation (e.g. uniform phase-out dates for substances for broad uses) bears the risk of not sufficiently taking into account the complex business reality.

- For some users/uses a particular deadline will be too short. Those users may close down operations before an alternative can be found or developed. Products may be lost, or production lines will move to third countries, where the substance still can be used. There is

[6] A study carried out by ECHA indicates that "36 % of 81 respondents considered that substitution would take more than seven years, while 20 % indicated four to six years as a sufficient time to complete the substitution activities and 44 % of the respondents could switch to an alternative in less than three years", ECHA, *supra* note *5*, p. 24.

[7] As also confirmed in a recent Court Judgement ECJ, Judgment of 20 April 2023, European Parliament vs. European Commission, Case C-144/21.

also the risk of regrettable substitution by alternatives which are available in the short term but neither provide the necessary performance nor are necessarily better from a health and environmental perspective.

- For other cases, the phase-out date will be too late compared to what is feasible. This does not only delay substitution but also creates the risk that those producing alternatives cannot sell their products, as the current use is still cheaper, more performant or companies will prefer established solutions with less risk of quality problems. The result may be that innovative products without the substance, which in the long term will likely become world standard, will be developed elsewhere, and not in Europe.

- In the worst case, complex use patterns and situations where substitution is feasible for some uses but not for others can lead to prolonged discussions about restrictions without decisions, which might cause uncertainties preventing investments while, at the same time, delaying the necessary protection of human health and the environment.

For such complex cases, planning of substitution over time could be more successful than setting uniform phase-out deadlines or trying to regulate up to details which is not feasible for authorities. However, in order to be successful, planning of substitution of the substance over time must be neither discretionary or entirely voluntary (in such cases, the market would opt for the cheaper, more performing, more tested existing solution) nor inflexible or overly prescriptive (ignoring technical and economic specificities or uncertainties that cannot be predicted at the outset of the substitution process). Reconciling a clear direction with flexibility will require co-operation or at least co-ordination between regulatory measures and industry-driven approaches.

Which existing approaches could serve as inspiration for planning approaches to tackle complex substitution processes?

Currently, substitution plans are part of the REACH authorisation system. Nevertheless, they are limited to planning at the level of an individual applicant and can only be used under the authorisation system. As the current applicant-by-applicant authorisation system has been found unworkable for complex cases such as chromium(VI) authorisation, more generic approaches such as REACH restrictions may be favoured for such and similar uses in future. Moreover, it may make sense to extend substitution planning to entire uses, in order to ensure better co-ordination between current users of substances, and to integrate alternative providers into the planning, to ensure a better take-up of alternatives developed by front-runner companies. It may also be useful to involve academia and substitution centres into the planning of substitution, to maximise the use of existing expertise.

A similar approach to bundle forces for innovation has recently been taken in the Transition Pathway for the Chemicals Industry[8]. Based on an analysis of challenges, the Transition Pathway identified the necessary actions to accelerate the EU chemical industry's green and digital transitions in a co-creation approach.

A challenge in setting up such a framework could be to respect both sectoral substitution possibilities and activities and company-specific substitution circumstances. Other issues could be *inter alia* compliance with competition law, the respect of confidential business information, issues of liability, free-riding and capacities of the body responsible for the coordination of activities and monitoring of substitution plans. Attention must be paid to the objective of the REACH revision to streamline procedures and reduce the burden for both authorities and industry.

[8] European Commission, *supra* note 1.

What is the link to the planned revision of the REACH Regulation?

The REACH revision might be a good opportunity to further promote substitution of the most harmful substances and substances of concern, strengthen the role of substitution plans in the authorisation system and consider how different actors can best benefit from a new substitution framework. To complement the forthcoming proposal for the revised REACH Regulation, this study should examine ways of improving the current substitution framework in REACH. Moreover, the study may also provide useful conclusions for other pieces of chemicals legislation and substitution planning approaches outside the legal framework.

Current approach under REACH authorisation

Analysis of alternatives[9]

In many pieces of chemicals regulation, including the current REACH processes, an analysis of alternatives is a regulatory requirement. Moreover, an analysis of alternatives is indispensable for the assessment of one of the two cumulative criteria of the essential use concept, i.e. the absence of alternatives (the second being 'necessity for health and safety or criticality for the functioning of society'). The essential use concept was introduced by the CSS and is envisaged to be incorporated under the revised REACH regulation.

Under the current REACH Regulation, the absence of alternatives is a pre-condition for being granted an authorisation for the use of a substance banned under Annex XIV if the risk to human health or the environment from the use of the substance is not adequately controlled (applicants still have to demonstrate that the benefits outweigh the risks)[10]. Applicants for authorisations are required to submit an analysis of alternatives with the aim to help determine if there are any suitable alternative substances or technologies for the applicant that it could use in case it could no longer use a substance banned under Annex XIV of REACH. The analysis of alternatives is strongly linked with the socio-economic assessment of an application for authorisation as the costs and benefits of an alternative - both in terms of human health and environmental impacts and economic impacts - need to be considered.

Applicants are required to submit a list of possible alternatives for each use applied for, a description of efforts made to identify possible alternatives, research and development as well as data searches and consultations undertaken and an analysis of the identified alternatives in terms of technical and economic feasibility, availability and the reduction in the overall risk.

An alternative can be both another substance or another technology either replacing the Annex XIV substance in the function it performs or making this function unnecessary. It is considered available if it is reasonably accessible without undue delay, available in the required quantity (substances), developed enough to allow implementation (technologies) and fulfil the relevant quality or legal requirements. If the substitution is possible before the date the substance included in Annex XIV can no longer be used ('sunset date'), the alternative is considered available.

[9] ECHA, Guidance on the preparation of an application for authorization, 2021, p. 40 ff, https://www.echa.europa.eu/documents/10162/17235/authorisation_application_en.pdf/8f8fdb30-707b-4b2f-946f-f4405c64cdc7?t=1610458546310; ECHA, Analysis of Alternatives: objectives, approach and content, 2012 https://echa.europa.eu/documents/10162/22816103/05_seminar20121001_session_2_analysis_of_alternatives_mottet_en_en.pdf/b215eeae-3a4e-427b-8e1c-df44e7035ba5.

[10] See Article 60(2) ('adequate control route') and Article 60(4) ('socio-economic route').

Taking into account the analysis of alternatives submitted by the applicant, the Committee for Socio-Economic Analysis (SEAC) makes its own assessment which feeds into its recommendations for the Commission.

Substitution Plans

If suitable alternatives are available in general, but the applicant claims that they are not feasible for its company, it must provide a substitution plan. Substitution plans are "a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable"[11]. They should include a list of actions required to transfer to the identified alternative, the timing for those actions with justifications for the proposed actions and timing, as well as uncertainties in achieving those actions in that timing and possible mitigation measures considered. Where alternatives are not yet available, applicants may prepare a R&D plan in support of their application indicating the actions planned to identify, develop and implement an alternative in the future, as explained in the latest ECHA guidance to prepare an application for authorisation[12].

Substitution plans under the current system are prepared by individual companies or, in the case of joint applications, by several applicants jointly. While exchanges with other companies using the same substance or with possible alternative providers can take place,[13] these exchanges are not legally required and do not take place in a systematic way. Substitution plans are, as part of the application for authorisation, published for public consultation. ECHA and any third party can comment on alternatives to the use applied for. ECHA, in these cases, acts as a third party who can and often does act as an intermediary in the communication between the company applying for authorisation and a company providing input on alternatives.

A substitution plan submitted with an application for authorisation is evaluated by SEAC. SEAC assesses its credibility, and, especially, whether the steps and timelines for substitution are appropriate. The conclusion feeds into SEAC's recommendation of a review period for a granted authorisation.

Commission decision

The Commission, taking into account the SEAC opinion, makes its own assessment of the availability of alternatives and, where relevant, the credibility of the substitution plan and decides whether applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives for the use applied for which is a condition for the granting of an authorisation. If an authorisation is granted, the Commission uses the substitution plan as an indication for an appropriate review period, as well as other aspects like risks to health and the environment.

Monitoring of the implementation of substitution plans

In the authorisation decision, the Commission may set out reporting obligations on the progress towards substitution, in accordance with the substitution plan, for monitoring purposes. However, it is in the discretion of the Member State whether or not to request the applicant to make available the documentation of the substitution steps taken in accordance with the substitution plan. Apart from this, there is no independent monitoring of the implementation of substitution plans after an authorisation has been granted.

---

[11] ECHA, *supra* note 10, p. xiii.

[12] ECHA, *supra* note 10, p. 80.

[13] For example, German companies have joined forces to find alternatives to chromium trioxide electroplating in FuSchiDeC (Funktionale Schichten mit Dekorativem Charakter).

Current approach under REACH restrictions

In the framework of restrictions, the second regulatory measure under REACH which addresses risks from chemical substances or groups of substances with general applicability, substitution plans do not play any role today in the Commission decision. However, in particular for complex cases, it may be useful to consider substitution plans also as a tool for derogations under REACH restrictions.

Assessment of Alternatives and Substitution under other EU chemicals legislation

Other pieces of EU chemicals legislation also aim at the substitution of harmful substances. Most of them link the decisions on exemptions from bans or restrictions to the availability of alternatives, such as the **Cosmetics Regulation** and the **Toys Directive** which require applicants for a derogation to demonstrate that no suitable alternative exists.[14] Legislation on the health and safety at the workplace requires employers to ensure the risk from chemical agents is minimised or eliminated, which shall be achieved through substitution[15]. While some Regulations or Directives make only scant reference to alternatives and substitution, others foresee more elaborated assessments or procedures.

Under the **Restriction of Hazardous Substances Directive[16],** exemptions to the prohibition of the use of certain substances in electrical and electronic equipment shall take into account the availability, practicability and reliability of substitutes and the impacts of substitution on the environment, health and consumer safety as well as socioeconomic impacts and impacts on innovation. Applications for exemptions shall include *inter alia* an analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives as well as proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant.

The **Biocidal Products Regulation**[17] and the **Plant Protection Products Regulation**[18] both foresee the designation of certain substances as "candidates for substitution" if they fulfil certain criteria. The placing on the market or use of such substances may only be approved for a limited number of years, as specified in the Regulations. Before granting the marketing authorisations, competent authorities are required to perform a comparative assessment to evaluate if the product containing the active substance can be substituted by other adequate alternatives. If the assessment

[14] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products; Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys; see also Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles.

[15] 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 (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC); Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC).

[16] Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

[17] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

[18] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/ECC.

shows that alternatives are available, the placing on the market or use of the substances shall be prohibited or restricted. Furthermore, both regulations have established "exclusion criteria" for active substance presenting very high concern (CMR category 1A and 1B, PBT/vPvB, endocrine disruptors category 1) which shall normally not be approved unless certain conditions for derogation are met (which, among others, include the availability of alternatives).

The **Persistent Organic Pollutants Regulation**[19] obliges Member States to develop action plans which shall include measures to promote the development of, and, where it is considered appropriate, shall require the use of substitute or modified substances, mixtures and processes. The Regulation also encourages exchange within the Union and with third countries of information relevant to the phase-out of persistent organic pollutants, incl. on alternative substances and related risks and costs. The Commission, ECHA and the Member States shall promote awareness programmes, *inter alia* on alternatives. As to the ban of PFOS, the Commission is required to review the derogation in place when new information on safer alternative substances and technologies become available. As soon as safer alternatives are technically and economically feasible, PFOS shall be phased out. The derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on.

Substitution Centres

In Europe and beyond, there are initiatives to bring together different actors that are working on substitution or are relevant to it and create synergies between their efforts. For instance, the Swedish NGO ChemSec hosts a free-of-charge platform called **The Marketplace**[20] with the aim to connect companies, allow buyers and sellers of alternatives to hazardous chemicals to interact and forge partnerships. Similarly, but on national level, the **Swedish Centre for Chemical Substitution**[21] supports companies and the public sector with knowledge of hazardous chemical substances and alternatives and promotes substitution. In the US, the **Green Chemistry & Commerce Council**[22] - a project of the Lowell Center for Sustainable Production at the University of Massachusetts Lowel – brings companies, government authorities, scientists and NGOs at one table to discuss pathways towards green chemistry.

1.4.1.2. Objectives of the Study

The study shall review current practice of substitution planning in the context of substitution of hazardous chemicals and assess options for a better approach to substitution planning for complex substitution processes in the context of REACH and other EU chemicals legislation. A new approach to substitution planning shall promote the transition to safer substances, processes or technologies, generate innovation and support the future competitiveness of the European chemicals industry and their downstream users.

More concretely, the study shall draw up and evaluate different options for substitution frameworks to accompany and implement regulatory measures both with and without a basis in the revised REACH Regulation. The options shall provide details on the appropriate tools and actions to support substitution planning, including the format of substitution plans, in case the current

[19] Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

[20] https://marketplace.chemsec.org/.

[21] https://www.ri.se/en/the-swedish-centre-for-chemical-substitution.

[22] https://greenchemistryandcommerce.org/.

approach is not considered suitable, the information required from companies, (collaborative) processes for the preparation of substitution, including the analysis of alternatives and the creation of substitution plans, the best stage in regulatory processes for communicating on the plan and progress of substitution, and the possible role of ECHA or other bodies in supporting the substitution framework, e.g. with regard to evaluation and monitoring.

As discussions on the way to strengthen the role of substitution plans started late in the process of preparing the planned revision of the REACH Regulation, the Commission proposal (still in preparation at the time of drafting these terms of reference) will remain general with respect to the future role of substitution plans. The purpose of the contract is therefore twofold: It shall assess the need for possible amendments setting out more details, once the proposal will be discussed in the European Parliament and the Council, and identify options that can be implemented independently of the text.

1.4.2. Detailed characteristics of the purchase

Seven tasks are required under this contract:

1. Work out and elaborate the study methodology;
2. Identify and review existing information relevant for the study and identify possible information gaps;
3. Identify specific problems and refine the objectives of a new substitution framework;
4. Develop different options for substitution frameworks;
5. Assess the social, economic, health and environmental and administrative impacts of the options for substitution frameworks;
6. Organise two workshops, where the preliminary results will be discussed;
7. Final report.

Task 1: Work out and elaborate the study methodology

Based on the outline developed in the tender, the contractor will further refine the methodology. The methodology should allow the identification of the most efficient and effective ways to plan and prepare the substitution of substances of concern and the most harmful substances, including an assessment of the role that substitution plans could play, while keeping in mind the double objective of speeding up substitution and promoting innovation and competitiveness of the EU chemicals industry and its downstream users at the same time. This should include both individual and collective plans and actions towards substitution covering all or several users of a substance in a particular use, or a combination of collective and individual elements in one concerted substitution framework.

The first methodological step should be the gathering of evidence from the experiences under the current REACH authorisation and restriction system and under other legislation regulating chemicals (e.g. biocides, pesticides, etc), including the way substitution plans are used today, as well as from existing substitution models such as under the Montreal Protocol and from stakeholder initiatives. The list of legislation to be looked at shall be agreed between the Commission and the contractor in the inception report, taking into account the pieces of legislation mentioned in section

1.4.1.1. The findings regarding current approaches as well as the objectives and options for the future framework should be further discussed during workshops with stakeholders. Eventually, this should enable the contractor to develop synthetic and internally coherent options for a new substitution framework.

For each objective, the methodology should be sufficiently elaborated to allow the Commission services to assess the degree of the reliability and constraints of the methodology.

The contractor should describe which type of information will be gathered and how. The methodology should include an overview of the most relevant stakeholders and the tools to interview them. The contractor should ensure that the information is collected in the most efficient way to achieve the study objectives and that the gathered information is relevant to the objectives of the study. The contractor should showcase how they intend to evaluate and use the information.

The contractor should provide an outline of the workshops, roughly indicating the content and the potentially involved stakeholders as well as the estimated timing and an explanation on how the knowledge gained during the workshops will be integrated into the final results.

The completed methodology will be presented to the Commission services in the Methodology Report (part of the inception report) that is subject to approval by the Commission services. Some of the activities in this task may require exchange of information with the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and Commission services. These activities need to be identified in advance. Some of the information exchanged may be confidential and therefore, a system needs to be set to keep the information within the remit of the project.

Some of the activities may also require exchange of information with companies. The contractor should describe how it intends to ensure that the information gathered is representatives for all sectors and sizes of companies. In case, individual companies are consulted, this should be made transparent. In all consultations with companies, the confidentiality of business information must be respected.

Task 2: Identify and review existing information relevant for the study and identify possible information gaps

Task 2 consists in gathering and analysing all relevant information. This information should as a minimum include information of the seven categories described below:

a) *REACH related information*. The REACH framework and case law need to be considered to identify the advantages and shortcomings of the current approach for the assessment of alternatives and the role of substitution plans as well as aspects that could be changed or added to improve these approaches. The developments under the REACH revision need to be taken into account to explore where and how elements of a new substitution framework could fit in. Some examples of REACH related information are:

- REACH Regulation and its amendments and implementing acts
- REACH-related case law of the General Court and European Court of Justice
- REACH reviews[23]

[23] European Commission, Commission General Report on the operation of REACH and review of certain elements, Conclusions and Actions COM(2018) 116 final, 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN; European Commission, Periodic Review of REACH, 2013, https://ec.europa.eu/docsroom/documents/14601/attachments/1/translations/en/renditions/native.

- REACH reports from Member States (e.g. Member State reports provided to the Commission and required by Article 117.1 of REACH)
- ECHA and Commission studies and programmes[24]
- Applications for Authorisations submitted under REACH and their substitution plans.
- Dossiers and documentation for recent restrictions introduced under REACH.

To complement this information, the Contractor shall conduct scoping interviews with the ECHA secretariat as well as with the chair and members of SEAC.

b) *Information related to other legislation addressing chemicals*, including, *mutatis mutandis,* the different types of information mentioned under a) if applicable*,* needs to be considered to allow the development of a substitution framework from which different pieces of EU chemicals legislation can benefit.

c) *Information on substances of concern and the most harmful substances, their hazards, uses and potential alternatives* needs to be gathered for the contractor to better understand the context, objectives and potential pitfalls of substitution.

d) *Information on the substitution activities carried out by companies and factors that impede or disincentivize substitution* need to be considered to find out which substitution framework is best suited to foster substitution. Experiences from industry actors, both those that have successfully substituted and those that have given up or relocated to a third country should be obtained to understand whether they have worked alone, with their suppliers, other companies, academia etc., what has functioned well and what has been problematic and which of these experiences can be generalised.

e) *Information on initiatives taken by ECHA, NGOs, industry and other stakeholders for a more collaborative and/or systematic approach to substitution as well as on substitution processes and initiatives on international level or outside the EU* can serve as inspiration for possible substitution frameworks under EU chemicals legislation, such as substitution centres, as mentioned under Section 1.4.2.[25]

f) *Information on financial and personnel capacities of existing structures, organisations or bodies that could be involved in the implementation of a new substitution framework* need to be taken into account to assess which body could play a role in the substitution framework and which degree of involvement it could handle.

g) *Information on legal constraints to possible elements of substitution frameworks* need to be considered and analysed. For example, such constraints could stem from EU primary law and competition law or international treaties and principles.

In addition, further information sources shall be analysed, where appropriate.

---

[24] Useful sources may be the ECHA, Impacts of REACH restriction and authorization on substitution in the EU, *supra* note 5; VVA, Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction, unpublished.

[25] See for example workshops or online training organized by ECHA, https://echa.europa.eu/substitution-to-safer-chemicals.

Task 3: Identify specific problems and refine the objectives of a new substitution framework

Initial problem analysis

On the basis of the information gathered and reviewed under Task 2, the contractor shall identify positive experiences, challenges and problems with the current system for the assessment of alternatives and substitution in the context of REACH and other legislation addressing chemicals, including with substitution plans. In particular, the contractor shall test the hypothesis that the REACH regulation does not sufficiently encourage efficient and effective substitution of substances, especially those with complex use patterns (i.e. where substitutability depends on details of uses and their contexts, and where the time required for substitution is not uniform).

Initial objectives:

Starting from this problem analysis, the contractor shall verify and refine the proposed objectives of establishing an enhanced framework for substitution of chemicals targeted for substitution as assumed in this call for tenders, in particular:

- to speed up innovation and substitution of targeted substances and uses (allowing different competitive solutions, where possible);
- to promote earlier and higher health and environmental protection from chemical risks;
- to enhance competitiveness of involved EU companies (both companies using the targeted substance and alternative providers), by
    - avoiding economic disruptions and delocalisation of economic activities out of the EU and allowing more appropriate, proportionate and flexible solutions for the continued use of targeted substances during complex substitution processes, where suitable alternatives are not available;
    - promoting new market opportunities and fostering market uptake of alternatives where and when they become available, avoiding undercutting by free-riders;
    - creating more predictability and investment security for European industry;
- to render regulation on substituting substance uses with complex use patterns more efficient, effective and manageable for EU authorities and Member States;

If appropriate, and if confirmed by the outcome of the first workshop, this set of objectives should be refined and complemented.

Task 4: Develop different options for substitution frameworks

On the basis of the information gathered, the contractor will develop several options for substitution frameworks that work in practice for both industry and authorities on the basis of the following baseline scenario:

> Use of individual (per applicant(s)) substitution plans for the purpose of REACH authorisation, e.g. for review periods and as a condition for authorisation, invite industry to provide information on alternatives as part of submissions upon calls for information under restrictions, enforcement lies with the Member States (no change compared to current rules).

On the basis of a combination of the below elements, the contractor shall identify at least three main options (on top of the baseline option), with varying degree of integration into regulation. Further possible variations shall be assessed, where appropriate, through sensitivity analysis. Those options shall be validated with the Commission services.

- Scenarios for the early stages of (collaborative) analysis of alternatives and work on substitution plans, incl. different timing (e.g. from the moment a substance is classified for a certain hazard that is of concern, put on the candidate list for Annex XIV, from the moment a substance is included in Annex XIV…), different actors involved (e.g. companies using the targeted substance, alternative providers, researchers, NGOs…); different degrees of involvement of authorities;
- Degrees of granularity of the analysis of alternatives and substitution plans (sectorial, substance and use-specific, company-specific substitution plans or combinations);
- Formats of analysis of alternatives and substitution plans, incl. different information requirements, degrees of details;
- Scenarios for the timing of submission of information on alternatives and substitution plans or parts thereof (e.g. before the start of preparations for a restriction, before a restriction is adopted or afterwards; or e.g. submission of general parts before and company specific commitments after adoption of the restriction);
- Role and legal status of the analysis of alternatives and substitution plans in the authorisation and, potentially, restriction process (informal information under industry responsibility, incorporated into Commission Regulations or Decisions, ECHA administrative decisions etc.);
- Options to use the information from the analysis of alternatives and substitution plans, e.g. for phase-out dates (e.g. one date for specific actions for the entire sector/use and allowing a more differentiated approach/dates per company) or as condition for the continued use of the substance (e.g. obligation of conduct or of result);
- Procedures for credibility assessment of the analysis of alternatives and substitution plans, incl. responsible structures, bodies, criteria, e.g. industry-internal feedback mechanisms on steps undertaken and possibilities to present best practice, giving a stage to front-runners;
- Mechanisms to deal with the exchange of commercially sensitive information and the prevention of anti-competitive conducts, in order to ensure full compliance with EU competition law[26];
- Procedures for reporting and/or monitoring of substitution efforts, incl. possible sanctions, incl. responsible bodies and different degrees of involvement.

When developing the different options, the contractor shall consider whether and to what extent the different options are implementable taking into account:

- legal constraints
- financial and personnel capacity of companies and authorities.

This assessment shall be in line with the Commission Better Regulation guidelines and toolbox.[27]

[26] Taking into account in particular the revised Horizontal Guidelines that accompany the Horizontal Block Exemption Regulations on Research and Development and Specialisation agreements,: see https://ec.europa.eu/commission/presscorner/detail/en/IP_23_2990. See more in general article 101 of the Treaty of the Functioning of the European Union on agreements restrictive of competition.

[27] European Commission, Better Regulation Guidelines, SWD(2021) 305 final; European Commission, 'Better regulation' toolbox – July 2023, 2023, https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en.

Task 5: Assess the social, economic, health and environmental and administrative impacts of the options for substitution frameworks

The contractor will identify and evaluate in a qualitative and where possible semi-quantitative way the relevant social, economic, health and environmental and administrative impacts of the different options of substitution frameworks.

In terms of economic impacts, the contractor shall pay particular attention to the administrative costs for companies, authorities and/or other bodies involved in the substitution framework.

In terms of health and environmental impacts, the contractor shall pay particular attention to achieving sound solutions to reduce human health and environmental impacts through substitution of substances as early as possible, and avoidance of regrettable substitution.

The contractor will in particular assess in a qualitative and where possible semi-quantitative comparison the potential of the different options for achieving the following parameters, including their potential to achieve several of those objectives and synergies between those objectives at the same time (to be refined during the contract):

- regulatory simplification, efficiency and effectiveness for authorities;
- achieving sufficiently detailed solutions to minimise market disruptions, maximise innovation and investments and maximise health and environmental benefits;
- early substitution of targeted substances;
- limited business disruption and supply security for essential products for society during the transition phase;
- predictability for industry;
- innovation and investment into alternatives in Europe.

In addition, the contractor will evaluate the options in terms of their impact on competition related aspects, in particular avoidance of conducts that distort competition, notably via collusive practices, restriction of competition in innovation and the exchange of commercially sensitive information. Those aspects will be weighed against the legitimate objectives of triggering co-operation to foster innovation and investments into safer and more sustainable alternatives in Europe.

For each of the options, the contractor will identify ways how to avoid undue exchange of commercially sensitive information and in general conducts that could be in violation of competition law, as well as ways to ensure openness to a variety of solutions to substitute the targeted substance.

The contractor will also evaluate the degree that the different options ensure openness to a variety of solutions to substitute the targeted substance, provide predictability for businesses and investment decisions and enabling industry to prepare and plan for substitution in advance of regulatory measures. A solid framework would avoid disputes and Court cases, while allowing legal remedies for justified complaints.

Task 6: Discuss the preliminary results in two workshops

The contractor will support the Commission services in the organisation of two workshops.

Workshop 1: The first workshop shall serve to:

- validate the problem analysis and refine the objectives;
- discuss existing experiences with the analysis of alternatives and the use of substitution plans;
- validate and refine the options to be further assessed;

Workshop 2: The second workshop shall be used to discuss the initial results of the assessment of the different options for substitution frameworks, with a view to validating those results and identifying the necessary steps and additional factors to be taken into account in finalising the results.

The format (online, in person or hybrid) of the workshops will be discussed during the kick-off meeting.

The contractor will contribute to it by:

4.1. *Assisting the Commission services in preparing invitations and organise the registration process*. We expect a maximum of around 80 active workshop participants (live or online, details to be determined during the first phase of the study). There should also be a possibility for additional on-site participants following the opening and feedback sessions, and live streaming of those sessions for additional (passive) remote participants.

4.2. *Preparing the agenda and background documents:* The agenda and background documents shall be sent to the Commission services for validation at least four weeks before the workshops take place. The validated agendas and background documents shall be sent to the participants at least two weeks before the day of the workshop.

4.4. *Assisting the Commission services during the workshops:* The contractor shall provide support to the preparation of badges and the on-site registration, and provide moderators and/or rapporteurs for around half of the break-out groups or world café tables.

4.5. *Preparing minutes of the workshops:* The contractor shall, in co-operation with the rapporteurs, prepare minutes of the workshops documenting the main discussions and conclusions. They shall be prepared and sent to the Commission services for validation within one week of the workshops. Once validated, the minutes shall be sent to the participants within one week.

The workshops will be managed by the Commission services. Therefore, only the costs for the above support activities and the travel expenses and accommodation cost of the contractor to the workshops need to be included in the budget of the bid. All other costs related to the workshop organisation, including travel costs for other participants, shall be excluded.

Task 7: Final report

A final report will be prepared by the contractor containing the relevant information gathered in all previous tasks. A set of conclusions and recommendations on the most promising substitution framework options shall be included.

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to the Directive 2014/24/EU.

1.4.3. Deliverables

For the purpose of this contract, four deliverables, in English, are required. The table at the end of this Section provides further information on timing requirements.

1. Inception report

This report should be prepared after the kick-off meeting and should be concise and clearly reflecting the agreements reached at the inception meeting and include an updated methodology (methodology report, see task 1). The draft inception report should be provided no more than 2 weeks after the kick-off meeting and the Commission services will have 15 days to provide comments.

2. Interim report

The draft interim report is due after 5 months of the start of the contract. It will include the results of tasks 2, 3 and 4, as well as of the first workshop (For those tasks, the interim report may at the same time be a first draft of the final report) and outline the next steps for task 5 and the organisation of the second workshop.

The Commission services shall have 15 working days to approve or reject the interim report and the Contractor shall have 15 working days to submit new documents. The Commission services shall then have 10 working days to approve or reject the revised interim report and the Contractor shall have 10 working days to submit the final interim report.

The interim report will be deemed to have been accepted by the Commission services if it does not expressly inform the contractor in writing of any comments within 15 days of its receipt.

3. Material and presentation(s) for the workshops

The contractor will prepare the materials and slides necessary for presenting its work at the workshops. Concise background papers as well as an outline for the break-out groups/world café tables will be prepared jointly with the Commission services and need to be approved by the Commission services before their distribution.

4. Draft final report

After 9 months the contractor shall deliver a draft final report containing at a minimum:

- an executive summary setting out the conclusions and recommendation of the contractor;.
- the methodology and results of tasks 1 to 6, with clear references on sources of information used and the reliability of the results, including any methodological constraints.

The Commission services shall have 15 working days to approve or reject the draft final report and the Contractor shall have 15 working days to submit new documents. The Commission services shall then have 15 working days to approve or reject the revised final report(s) and the Contractor shall have 15 working days to submit the final report.

The final report will be deemed to have been accepted by the Commission services if it does not expressly inform the contractor in writing of any comments within 15 days of its receipt.

After the final report has been accepted by the Commission services, the Contractor must send to the Commission services, one paper copy of the report (bound) and one copy in electronic version (Word and pdf).

The contractor shall also prepare a standard presentation of the project and its results and shall be available for presenting it to the Commission´s CARACAL expert group.

All the requested electronic documents shall be provided in a format natively supported by Microsoft Office.

Graphic requirements:

The contractor must deliver the study and all publishable deliverables in full compliance with 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. The graphic rules, the Manual and further information are available at:

http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's contractors. No template will be provided to tenderers while preparing their tenders.

Required meetings with contractor

The table at the end of this Section provides further information on tentative timing of the meetings.

1. Kick-off meeting: After the signature of the contract, and in the first month of the contract, a meeting between the Commission services and the contractor should be organised at the Commission premises in Brussels.

2. Two meetings to discuss the state of play and prepare the workshops.

3. Final meeting to clarify the comments from the Commission services on the draft final report, if required.

Ideally, meetings should take place in Brussels but, where more practical, all meetings (excluding the workshops) can be replaced by online calls if agreed by both parties (i.e. contractor and the Commission services).

In addition, to maintain a fluid channel of discussion, at least one online call per month needs to be organised between the contractor and the Commission services.

Summary of the contract milestones

Next table summarises how meetings, reports, approval of reports and the payments will be distributed in the period covered by the contract.

Time-line	Meetings	Reports	Approval of reports	Payments
Contract signature				
1 month	Kick-off meeting	Inception report	Inception report	
2 month				
3 month	2nd meeting			
4 month	1st workshop			
5 month		Interim report		40%
6 month				
7 month	3rd meeting		Interim report	
8 month	2nd workshop			
9 month		Draft final report		
10 month	4th meeting			
11 month		Final report		
12 month			Final report	60%

1.5. Place of performance: where will the contract be performed?

The services will be performed at the following locations:

- the contractor's premises
- any other place indicated in the tender, with the exception of the Commission's premises

1.6. Nature of the contract: how will the contract be implemented?

The procedure will result in the conclusion of a direct contract.

In direct contracts all the terms governing the provision of the services, supplies or works are defined at the outset. Once signed, they can be implemented directly without any further contract procedures.

Tenderers need to take full account of the full set of procurement documents, including the provisions of the draft contract as the latter will define and govern the contractual relationship to be established between the contracting authority and the successful tenderer. Special attention is to be paid to the provisions specifying the rights and obligations of the contractor, in particular those on payments, performance of the contract, confidentiality, and checks and audits.

☝ Please be aware that if a tenderer to whom the contract is awarded (any of the group members in case of a joint tender) has established debt(s) owed to the Union, the European Atomic Energy Community or an executive agency when the latter implements the Union budget, such debt(s) may be offset, in line with Articles 101(1) and 102 of 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 (Financial Regulation)[1] and the conditions set out in the draft contract, against any payment due under the contract. The contracting authority will verify the existence of overdue debts of the successful tenderer (any of the group members in case of a joint tender), and, if any such debt is found, will inform the tenderer (the group leader in case of a joint tender who will then have the obligation to inform all other group members before signing the contract) that the debt(s) may be offset against any payment under due the contract.

1.7. Volume and value of the contract: how much do we plan to buy?

The maximum total amount of all purchases under this call for tenders is indicated under Section II.1.5 of the contract notice. The volumes/values of the purchases over the total duration of the contract are specified in Section 1.4 of these specifications.

1.8. Duration of the contract: how long do we plan to use the contract?

The contract resulting from the award of this call for tenders will be concluded for at most 12 months. The details of the initial contract duration and possible renewals are set out in the draft contract.

1.9. Electronic exchange system: can exchanges under the contract be automated?

For all exchanges with the contractor during the implementation of the contract as well as for future possible subsequent proceedings, including, but not limited to, for the purposes of EDES (European Union's Early Detection and Exclusion System), the contracting authority may use an electronic exchange system meeting the requirements of Article 148 of the Financial Regulation. At the request of the contracting authority, the use of such a system shall become mandatory for the contractor at no additional cost for the contracting authority. Details on specifications, access, terms and conditions of use will be provided in advance.

[1] 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 30.07.2018, p.1).

2. GENERAL INFORMATION ON TENDERING

2.1. Legal basis: what are the rules?

This call for tenders is governed by the provisions of the Financial Regulation.

The contracting authority has chosen to award the contract resulting from this call for tenders through an open procedure pursuant to Article 164(1)(a) of the Financial Regulation.

In this procedure any interested economic operator (any natural or legal person who offers to supply products, provide services or execute works) may submit a tender.

2.2. Entities subject to restrictive measures and rules on access to procurement: who may submit a tender?

Tenderers must ensure that no involved entities (see Section 2.4) nor any subcontractors, including those which do not need to be identified in the tender (see Section 2.4.2), are subject to EU restrictive measures adopted under Article 29 of the Treaty on the European Union (TEU) or Article 215 of the Treaty on the Functioning of the EU (TFEU)[2], consisting of a prohibition to make available or transfer funds or economic resources or to provide financing or financial assistance to them directly or indirectly, or of an asset freeze. The prohibition applies throughout the whole performance of the contract.

Participation in this call for tenders is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations.

It is also open to all natural and legal persons established in a third country provided that it has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement.

The Agreement on Government Procurement[3] concluded within the World Trade Organisation ~~does not apply~~ does apply. Therefore, the participation to this call for tenders ~~is not open to~~ is also open to all natural and legal persons established in the countries that have ratified this Agreement, on the conditions laid down therein.

The rules on access to procurement do not apply to entities on whose capacity tenderers rely to fulfil the selection criteria nor to subcontractors. Subcontracting may not be used with the intent or effect to circumvent the rules on access to procurement.

To enable the contracting authority to verify the access, each tenderer must indicate its country of establishment (in case of a joint tender – the country of establishment of each group member) and must present the supporting evidence normally acceptable under the law of that country. The same document(s) could be used to prove country/-ies of establishment and the delegation(s) of the authorisation to sign, as described in Section 4.3.

---

[2] Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

[3] https://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm

2.3. Registration in the Participant Register: why register?

Any economic operator willing to participate in this call for tenders must be registered in the Participant Register - an online register of organisations and natural persons (participants) participating in calls for tenders or proposals of the European Commission and other EU institutions/bodies.

On registering each participant obtains a Participant Identification Code (PIC, 9-digit number), which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other calls for tenders or calls for proposals of the European Commission and other EU institutions/bodies.

☝ **Each participant needs to ensure that its SME status in the Participant Register is registered and kept up to date.**

At any moment during the procurement procedure, the Research Executive Agency Validation Services (hereafter *the EU Validation Services*) may contact the participant and ask for supporting documents on legal existence and status and financial capacity. The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly. The documents that may be requested by *the EU Validation Services* are listed in the EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment.

☝ **Please note that a request for supporting documents by the *EU Validation Services* in no way implies that the tenderer has been successful.**

2.4. Ways to submit a tender: how can economic operators organise themselves to submit a tender?

Economic operators can submit a tender, either as a sole economic operator (sole tenderer) or as a group of economic operators (joint tender)[4]. In either case subcontracting is permitted.

Tenders must be drawn and submitted in complete independence and autonomously from the other tenders. A declaration in this regard by each tenderer (in case of a joint tender, by the group leader) shall be requested ***(Annex 2)***.

A natural or legal person cannot participate at the same time and within the same procedure either as member of two or more groups of economic operators or as a sole tenderer and member of another group of economic operators. In such case, all tenders in which that person has participated, either as sole tenderer or as member of a group of economic operators, will be rejected.

Economic operators linked by a relationship of control or of association (e.g. belonging to the same economic/corporate group) are allowed to submit different and separate tenders, provided that each tenderer is able to demonstrate that its tender was drawn independently and autonomously.

A natural or legal person may act as subcontractor for several tenderers as long as the tenders are drawn and submitted in complete independence and autonomously from each other. However, cross subcontracting among tenderers is forbidden, more precisely an entity "A" may participate as

[4] Each economic operator participating in the joint tender is referred to as "group member".

tenderer (either as sole tenderer or as member of a group of economic operators) and as subcontractor to another tenderer "B" within the same procurement procedure. However, in this case it is forbidden that tenderer "B" (or any of its participating members in case of a group of economic operators) is at the same time subcontractor for tenderer "A" (or for the group of economic operators in which "A" participates) within the same procurement procedure. In this case, both tenders A and B shall be rejected.

In order to fulfil the selection criteria set out in Section 3.2 the tenderer can rely on the capacities of subcontractors (see Section 2.4.2) or other entities that are not subcontractors (see Section 2.4.3).

An **"involved entity"** is any economic operator involved in the tender. This includes the following four categories of economic operators:

- sole tenderer,
- group members (including group leader),
- identified subcontractors (see Section 2.4.2), and
- other entities (that are not subcontractors) on whose capacity the tenderer relies to fulfil the selection criteria.

The role of each entity involved in a tender must be clearly specified in the eSubmission application: i) sole tenderer, ii) group leader (in case of a joint tender), iii) group member (in case of a joint tender), or iv) subcontractor[5].

For an entity on whose capacities the tenderer relies to fulfil the selection criteria (that is not a subcontractor), this role is defined in the commitment letter (***Annex 5.2***)

2.4.1. Joint tenders

A joint tender is a situation where a tender is submitted by a group (with or without legal form) of economic operators regardless of the link they have between them in the group. The group as a whole is considered a tenderer[6].

All group members assume joint and several liability towards the contracting authority for the performance of the contract as a whole.

Group members must appoint from among themselves a group leader (the group leader) as a single point of contact authorised to act on their behalf in connection with the submission of the tender and all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature. All group members (including the group leader) must sign an Agreement/Power of attorney drawn up in the model attached in **Annex 3**.

The joint tender must clearly indicate the role and tasks of each group member, including those of the group leader who will act as the contracting authority's contact point for the contract's administrative or financial aspects and operational management. The group leader will have full authority to bind the group and each of its members during contract execution.

If the joint tender is successful, the contracting authority shall sign the contract with the group leader, authorised by the other members to sign the contract also on their behalf via the Agreement/Power of attorney drawn up in the model attached in ***Annex 3***.

---

[5] Only identified subcontractors (see Section 2.4.2) must be specified in the eSubmission application.

[6] References to *tenderer* or *tenderers* in this document shall be understood as covering both sole tenderers and groups of economic operators submitting a joint tender.

Changes in the composition of the group during the procurement procedure (after the deadline for submission of tenders and before contract signature) shall lead to rejection of the tender, with the exception of the following case:

- case of a merger or takeover of a group member (universal succession), provided that the following cumulative conditions are fulfilled:

  - the new entity is not subject to restrictive measures, has access to procurement (see Section 2.2) and is not in an exclusion situation (see Section 3.1),
  - all the tasks assigned to the former entity are taken over by the new entity member of the group,
  - the group meets the selection criteria (see Section 3.2),
  - the change must not make the tender non-compliant with the procurement documents,
  - the terms of the originally submitted tender are not altered substantially and the evaluation of award criteria of the originally submitted tender are not modified,
  - the new entity undertakes to replace the former entity for the implementation of the contract, in case of an award.

2.4.2. Subcontracting

Subcontracting is the situation where the contractor enters into legal commitments with other economic operators, which will perform part of the contract on its behalf. The contractor retains full liability towards the contracting authority for performance of the contract as a whole.

The following shall not be considered subcontracting:

a) Use of workers posted to the contractor by another company owned by the same group and established in a Member State ("intra-group posting" as defined by Article 1, 3, (b) of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services).
b) Use of workers hired out to the contractor by a temporary employment undertaking or placement agency established in a Member State ("hiring out of workers" as defined by Article 1, 3, (c) of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services).
c) Use of workers temporarily transferred to the contractor from an undertaking established outside the territory of a Member State and that belongs to the same group ("intra-corporate transfer" as defined by Article 3, (b) of Directive 2014/66/EU on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer).
d) Use of staff without employment contract ("self-employed persons working for the contractor"), without the tasks of the self-employed persons being particular well-defined parts of the contract.
e) Use of suppliers and/or transporters by the contractor, in order to perform the contract at the place of performance, unless the economic activities of the suppliers and/or the transporting services are within the subject of this call for tenders (see Section 1.4).
f) Performance of part of the contract by members of an EEIG (European Economic Interest Grouping), when the EEIG is itself a contractor or a group member.

The persons mentioned in points a), b), c) and d) above will be considered as "personnel" of the contractor as defined in the contract.

All contractual tasks may be subcontracted unless the procurement documents expressly reserve the execution of certain critical tasks to the sole tenderer itself, or in case of a joint tender, to a group member.

By filling in the form available in ***Annex 4*** (List of identified subcontractors), tenderers are required to give an indication of the proportion of the contract that they intend to subcontract, as well as to identify and describe briefly the envisaged contractual roles/tasks of subcontractors meeting any of these conditions (hereafter referred to as *identified subcontractors*):

- subcontractors on whose capacities the tenderer relies upon to fulfil the selection criteria as described under Section 3.2;
- subcontractors whose intended individual share of the contract, known at the time of submission, is above 20 % .

Any such subcontractor must provide the tenderer with a commitment letter drawn up in the model attached in ***Annex 5.1*** and signed by its authorised representative.

☝ Each tenderer shall identify such subcontractors and provide the commitment letters with its tender. The information must be true and correct at the time of submitting the tender. Any changes or additions regarding the envisaged subcontractors after the deadline for submission of tenders must be justified to the contracting authority.

The above rules apply also where the economic operators, which will perform part of the contract on behalf of a successful tenderer, belong to the same economic/corporate group as the sole tenderer or a member of the group submitting the joint tender.

Changes concerning subcontractors identified in the tender (withdrawal/replacement of a subcontractor, additional subcontracting) during the procurement procedure (after the deadline for submission of tenders and before contract signature) require the prior written approval of the contracting authority subject to the following verifications:

- any new subcontractor is not subject to restrictive measures, has access to procurement if the rules on access to procurement apply also to subcontractors (see Section 2.2) and is not in an exclusion situation (see Section 3.1),
- the tenderer still fulfils the selection criteria and the new subcontractor fulfils the selection criteria applicable to it individually, if any;
- the terms of the originally submitted tender are not altered substantially, i.e. all the tasks assigned to the former subcontractor are taken over by another involved entity, the change does not make the tender non-compliant with the tender specifications, and the evaluation of award criteria of the originally submitted tender is not modified.

Subcontracting to subcontractors identified in a tender that was accepted by the contracting authority and resulted in a signed contract, is considered authorised.

2.4.3. Entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria

In order to fulfil the selection criteria a tenderer may also rely on the capacities of other entities (that are not subcontractors), regardless of the legal nature of the links it has with them. It must in that case prove that it will have at its disposal the resources necessary for the performance of the contract by producing a commitment letter in the model attached in ***Annex 5.2***, signed by the authorised representative of such an entity, and the supporting evidence that those other entities have the respective resources[7].

[7] This does not apply to subcontractors on whose capacity the tenderer relies to fulfil the selection criteria – for these the documentation required for subcontractors must be provided.

☝ The above rules apply also where the economic operators on whose capacities the tenderer relies to fulfil the selection criteria (that are not subcontractors) belong to the same economic/corporate group as the sole tenderer or a member of the group submitting the joint tender.

2.4.4. Rules common to subcontractors and entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria

If a successful tenderer intends to rely on another entity to meet the minimum levels of economic and financial capacity, the contracting authority may require the entity to sign the contract or, alternatively, to provide a joint and several first-call financial guarantee for the performance of the contract.

With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required, i.e. the latter will either assume the role of subcontractors or will fall within the exceptions listed in Section 2.4.2 and will then assume the role of entities (not subcontractors) on whose capacities the tenderer relies to fulfil the selection criteria.

☝ Relying on the capacities of other entities is only necessary when the capacity of the tenderer is not sufficient to fulfil the required minimum levels of capacity. Abstract commitments that other entities will put resources at the disposal of the tenderer will be disregarded.

3. EVALUATION AND AWARD

The evaluation of the tenders that comply with the submission conditions will consist of the following elements:

- Check if the tenderer is not subject to restrictive measures and has access to procurement (see Section 2.2);
- Verification of administrative compliance (if the tender is drawn up in one of the official EU languages and the required documents signed by duly authorised representative(s) of the tenderer);
- Verification of non-exclusion of tenderers on the basis of the exclusion criteria;
- Selection of tenderers on the basis of selection criteria;
- Verification of compliance with the minimum requirements specified in the procurement documents;
- Evaluation of tenders on the basis of the award criteria.

The contracting authority will evaluate the above mentioned elements in the order that it considers to be the most appropriate.

If the evaluation of one or more elements demonstrates that there are grounds for rejection, the tender will be rejected and will not be subjected to further full evaluation. The unsuccessful tenderers will be informed of the ground for rejection without being given feedback on the non-assessed content of their tenders. Only the tenderer for whom the verification of all elements did not reveal grounds for rejection can be awarded the contract resulting from this call for tenders.

The evaluation will be based on the information and evidence contained in the tenders and, if applicable, on additional information and evidence provided at the request of the contracting authority during the procedure. If any of the declarations or information provided proves to be false, the contracting authority may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria the contracting authority may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

3.1. Exclusion criteria

The objective of the exclusion criteria is to assess whether the tenderer is in any of the exclusion situations listed in Article 136(1) of the Financial Regulation.

Tenderers found to be in an exclusion situation will be rejected.

As evidence of non-exclusion, each tenderer[8] needs to submit with its tender a Declaration on Honour[9] in the model available in ***Annex 2***.[10] The declaration must be signed by an authorised

[8] See Annex 1 which of the involved entities participating in a tender need to provide the Declaration on Honour.

[9] The European Single Procurement Document (ESPD) may not be used yet in calls for tenders of the European Commission.

[10] Unless the same declaration has already been submitted for the purposes of another award procedure of the European Commission, the situation has not changed, and the time elapsed since the issuing date of the declaration does not

representative of the entity providing the declaration. Where the declaration has been signed by hand, the original does not need to be submitted to the contracting authority, but the latter reserves the right to request it from the tenderer at any time during the record-keeping period specified in Section 4.3.

The initial verification of non-exclusion of tenderers will be done on the basis of the submitted declarations and consultation of the European Union's Early Detection and Exclusion System.

At any time during the procurement procedure[11], the contracting authority may request the documents mentioned in the Declaration on Honour as supporting evidence on non-exclusion (the documentary evidence). It may also request information on natural or legal persons that are members of the administrative, management or supervisory body or that have powers of representation, decision or control, including legal and natural persons within the ownership and control structure and beneficial owners, and appropriate evidence that none of those persons are in one of the exclusion situations referred to in Section A point (1) (c) to (f) of the Declaration on Honour.

Annex 1 specifies which of the involved entities participating in a tender need to provide the Declaration on Honour and, when requested by the contracting authority, the supporting evidence.

Please note that a request for evidence in no way implies that the tenderer has been successful.

3.2. Selection criteria

The objective of the selection criteria is to assess whether the tenderer has the legal, regulatory, economic, financial, technical and professional capacity to perform the contract.

The selection criteria for this call for tenders, including the minimum levels of capacity, the basis for assessment and the evidence required, are specified in the following subsections.

Tenders submitted by tenderers not meeting the minimum levels of capacity will be rejected.

When submitting its tender each tenderer shall declare on honour that it fulfils the selection criteria for this call for tenders. The model Declaration on Honour available in ***Annex 2*** shall be used.

The initial assessment of whether a tenderer fulfils the selection criteria will be done on the basis of the submitted declaration(s).

The subsections below specify which selection criteria evidence must be provided with the tender or may be requested later, at any time during the procurement procedure, within a deadline given by the contracting authority[12].

---

exceed one year.

[11] The obligation to provide the supporting evidence will be waived in the following situations:
- if the same documents have already been provided in a previous award procedure of the European Commission, have been issued no more than one year before the date of their request by the contracting authority and are still valid at that date;
- if such evidence can be accessed by the contracting authority on a national database free of charge, in which case the economic operator shall provide the contracting authority with the internet address of the database and, if needed, the necessary identification data to retrieve the document;
- if there is a material impossibility to provide such evidence.

[12] The obligation to provide the supporting evidence will be waived in the following situations:
- if the same documents have already been provided in a previous award procedure of the European Commission and are still up-to-date;

The evidence must be provided in accordance with the applicable basis for assessment of each criterion: in case of a consolidated assessment – only by the involved entities who contribute to the fulfilment of the criterion, and in case of individual assessment – by each entity to whom the criterion applies individually.

In case not all selection criteria evidence is requested with the tender, all tenderers are **invited to prepare in advance the documentary evidence**, since they may be requested to provide such evidence within a short deadline.

☝ If the tenderer does not provide valid documentary evidence within the deadlines set by the contracting authority, the contracting authority reserves the right to reject the tender.

Please note that a request for evidence in no way implies that the tenderer has been successful.

3.2.1. Legal and regulatory capacity

Tenderers can be natural or legal persons. Tenderers are not obliged to take a specific legal form in order to submit their tenders.

Where tenderers submit a tender through an entity, which lacks legal personality (e.g., a branch), the compliance with the exclusion criteria, selection criteria, the rules on access to procurement as well as the absence of restrictive measures shall be assessed at the level of the tenderers.

Tenderers do not need to prove specific legal and regulatory capacity to perform the contract.

In addition, involved entities (see Section 2.4) and all subcontractors, including those which do not need to be identified in the tender (see Section 2.4.2), must not be subject to EU restrictive measures adopted under Article 29 of the Treaty on the European Union (TEU) or Article 215 of the Treaty on the Functioning of the EU (TFEU)[13] that constitute a legal impediment to perform the contract. This requirement will be assessed by reference to the EU restrictive measures in force. Therefore, the tenderer is not required to submit any evidence of not being subject to EU restrictive measures.

3.2.2. Economic and financial capacity

Tenderers must comply with the following selection criteria in order to prove that they have the necessary economic and financial capacity to perform the contract.

Criterion F1	
Minimum level of capacity	Average yearly turnover of the last two financial years above EUR 250.000.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. a consolidated assessment of the combined capacities of all involved entities will be carried out.

- if such evidence can be accessed by the contracting authority on a national database free of charge, in which case the economic operator shall provide the contracting authority with the internet address of the database and, if needed, the necessary identification data to retrieve the document.

[13] Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

Criterion F1	
Evidence	Copy of the profit and loss accounts for the last two years for which accounts have been closed from each concerned involved entity, or, failing that, appropriate statements from banks. The most recent year must have been closed within the last 18 months.

☝ All of the above-specified evidence of economic and financial capacity must be provided with the tender.

3.2.3. Technical and professional capacity

☝ With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required. The entity on whose capacity the tenderer relies will either assume the role of a subcontractor or fall within the exceptions listed in Section 2.4.2.

Tenderers must comply with the following selection criteria in order to prove that they have the necessary technical and professional capacity to perform the contract:

Criterion T1	
The tenderer must prove experience in the field of health and environmental legislation.	
Minimum level of capacity	At least one similar (in scope and complexity) projects completed in the last three years preceding the deadline for submission of tenders, with a minimum value of € 100.000.
Basis for assessment	This criterion applies to the tenderer as a whole, i.e. the consolidated assessment of combined capacities of all involved entities will be carried out.
Evidence	A list of projects meeting the minimum level of capacity. The list shall include details of their start and end date, total project amount and scope, role and amount invoiced. In case of projects still ongoing, only the portion completed during the reference period will be taken into consideration. As supporting documents for each project reference, the contracting authority may request statements issued by the clients and take contact with them.

☝ All of the above-specified evidence of technical and professional capacity must be provided with the tender.

3.3. Compliance with the conditions for participation and minimum requirements specified in the procurement documents

By submitting a tender a tenderer commits to perform the contract in full compliance with the terms and conditions of the procurement documents for this call for tenders. Particular attention is drawn to the minimum requirements specified in Section 1.4 of these specifications and to the fact that tenders must comply with applicable data protection, environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU.

The minimum requirements shall be observed throughout the entire duration of the contract. Compliance with these requirements is mandatory and cannot be subject to any assumptions, limitations, conditions, or reservations on the part of a tenderer.

Tenderers must declare when submitting their tenders in eSubmission whether their tenders comply with the minimum requirements specified in the procurement documents.

☝ **Tenders that are not compliant with the applicable minimum requirements shall be rejected.**

3.4. Award criteria

The objective of the award criteria is to evaluate the tenders with a view to choosing the most economically advantageous tender.

Tenders will be evaluated on the basis of the following award criteria and their weighting:

1. Price – 30 %

The price considered for evaluation will be the total price of the tender, covering all the requirements set out in the tender specifications.

2. Quality – 70 %

The quality of the tender will be evaluated based on the following criteria:

No	Qualitative award criteria	Weighting (maximum points)
1.	*Quality of the work programme and efficiency of the project management including:* ** Realistic time table based on balanced and consistent method of work* ** Level of involvement of senior experts and related allocation of human resources*	20

2.	*Quality of the proposed methodology and approach to collect, analyse and discuss data and information.* *Innovativeness and creativity of the proposed methodology in particular in relation to Tasks 2 and 3.*	35
3.	*Depth of analysis of the project, its context and the tasks*	35
4.	*Quality control, risk management and reporting*	10
	Total number of points	100

The award criteria cannot be further supplemented during the evaluation procedure.

Tenders scoring

**** less than 60 % in the overall points total or***

**** less than 50% in the points awarded for a single criterion***

will be excluded from the rest of the assessment procedure

Tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, may result in a significantly lower score. Where essential elements of these specifications are not expressively covered by the tender, the Commission may decide to give a zero mark for the relevant qualitative award criteria.

The tender may be rejected as non-compliant, when the minimum requirements set in the specifications are not met.

3.5. Award (ranking of tenders)

Tenders shall be ranked according to the best price-quality ratio in accordance with the formula below:

Score for tender X	=	$\frac{\text{Lowest price*}}{\text{Price of tender X}}$	*	100	*	Price weighting (30%)	+	Total quality score (out of 100) for all award criteria of tender X	*	Quality criteria weighting (70%)

☝ The contract shall be awarded to the tender ranked first, which complies with the minimum requirements specified in the procurement documents and is submitted by a tenderer not subject to restrictive measures, having access to procurement, not in an exclusion situation and fulfilling the selection criteria.

☝ **Detection of abnormally low tenders**

Tenderers must be aware of Point 23 of Annex I to the Financial Regulation on abnormally low tenders and of the possibility for rejection of the tender based on it.

4. FORM AND CONTENT OF THE TENDER

4.1. Form of the tender: how to submit the tender?

Tenders are to be submitted via the eSubmission application according to the instructions laid down in the Invitation letter and the eSubmission Quick Guide available at the link below:

https://wikis.ec.europa.eu/display/FTPortal/Open+procedures_EN

☝ Make sure you prepare and submit your tender in eSubmission early enough to ensure it is received within the deadline for receipt indicated under Section IV.2.2 of the contract notice and/or on TED eTendering.

4.2. Content of the tender: what documents to submit with the tender?

The documents to be submitted with the tender in eSubmission are listed in ***Annex 1***.

The following requirements apply to the technical and financial tender to be uploaded in eSubmission:

- *Technical tender*

The technical tender must provide all the information needed to assess the compliance with Section 1.4 of these specifications the award criteria. Tenders deviating from the minimum requirements or not covering all the requirements may be rejected on the basis of non-compliance and not evaluated further.

Tenderers are free to choose where the personal data will be processed or stored as long as they comply with the contractual obligations on data processing (Art.I.9.2 and Art. II.9) and, in particular, with the requirements for transfer of personal data to third countries and international organisations laid down in Chapter V of Regulation (EU) 2018/1725[14].

Tenderers must specify in their technical tender the location where the personal data will be processed and stored only where this location is outside the territory of the European Union or the European Economic Area. If no location is specified in the tender, the contracting authority will consider that the personal data will be processed and stored only within the territory of the European Union or the European Economic Area.

- *Financial tender.*

A complete financial tender, including the breakdown of the price, needs to be submitted. For this purpose, the Financial Model in **Annex 6** shall be used.

[14] 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

The financial tender shall be:

- expressed in euros. 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 bear the risks or the benefits deriving from any variation.
- quoted free of all duties, taxes and other charges, i.e. also free of VAT.

☝ The European Union Institutions are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 annexed to the Treaty on the Functioning of the European Union. Exemption is granted to the Commission by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption.

In case of doubt about the applicable VAT system, it is the tenderer's responsibility to contact its national authorities to clarify the way in which the European Union is exempt from VAT.

4.3. Signature policy: how can documents be signed?

Where a document needs to be signed, the signature must be either hand-written or, preferably, a qualified electronic signature (QES) as defined in Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market (the *eIDAS Regulation*).

Tenderers are strongly encouraged to sign with a QES[15] all documents requiring a signature and only exceptionally to sign such documents by hand as hand-written signatures lead to an additional administrative burden for both the tenderer and the contracting authority. The originals of any hand-signed documents (other than the contract) do not need to be submitted to the contracting authority but the tenderer must keep them for a period of five years starting from the notification of the outcome of the procedure or, where the tenderer has been awarded a contract resulting from this call for tenders and the contract has been signed, the payment of the balance.

All documents must be signed by the signatories (when they are individuals) or by their duly authorised representatives.

For the following documents, when signed by representatives, tenderers must provide evidence for the delegation of the authorisation to sign:

- The Declaration on Honour of the tenderer (in case of a joint tender – the Declarations on Honour of all group members);
- (in the case of a joint tender) the Agreement/Power(s) of attorney drawn up using the model attached in ***Annex 3***).

The delegation of the authorisation to sign on behalf of the signatories (including, in the case of proxy(-ies), the chain of authorisations) must be evidenced by appropriate written evidence (copy of the notice of appointment of the persons authorised to represent the legal entity in signing contracts (together or alone), or a copy of the publication of such appointment if the legislation which applies to signatory requires such publication or a power of attorney). A document that the contracting authority can access on a national database free of charge does not need to be submitted if the contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

[15] See here how to apply a QES on a document exchanged with a European institution, body or agency.

4.4. Confidentiality of tenders: what information and under what conditions can be disclosed?

Once the contracting authority has opened a tender, it becomes its property and shall be treated confidentially, subject to the following:

- For the purposes of evaluating the tender and, if applicable, implementing the contract, performing audits, benchmarking, etc., the contracting authority is entitled to make available (any part of) the tender to its staff and the staff of other Union institutions, bodies and agencies, as well to other persons and entities working for the contracting authority or cooperating with it, including contractors or subcontractors and their staff, provided that they are bound by an obligation of confidentiality.

- After the signature of the award decision, tenderers, whose tenders were received in accordance with the submission modalities, who are not subject to restrictive measures, have access to procurement, who are not found to be in an exclusion situation referred to in Article 136(1) of the FR, who are not rejected under Article 141 of the FR, whose tenders are not found to be incompliant with the procurement documents, and who make a request in writing, will be notified of the name of the successful tenderer to whom the contract is awarded, the characteristics and relative advantages of the successful tender and its total financial tender amount. The contracting authority may decide to withhold certain information that it assesses as being confidential, in particular where its release would prejudice the legitimate commercial interests of economic operators or might distort fair competition between them. Such information may include, without being limited to, confidential aspects of tenders such as unit prices included in the financial tender, technical or trade secrets[16].

- The contracting authority may disclose the submitted tender in the context of a request for public access to documents, or in other cases where the applicable law requires its disclosure. Unless there is an overriding public interest in disclosure[17], the contracting authority may refuse to provide full access to the submitted tender, redacting the parts (if any) that contain confidential information, the disclosure of which would undermine the protection of commercial interests of the tenderer, including intellectual property.

☝ The contracting authority will disregard general statements that the whole tender or substantial parts of it contain confidential information. Tenderers need to mark clearly the information they consider confidential and explain why it may not be disclosed. The contracting authority reserves the right to make its own assessment of the confidential nature of any information contained in the tender.

[16] For the definition of trade secrets please see Article 2 (1) of Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

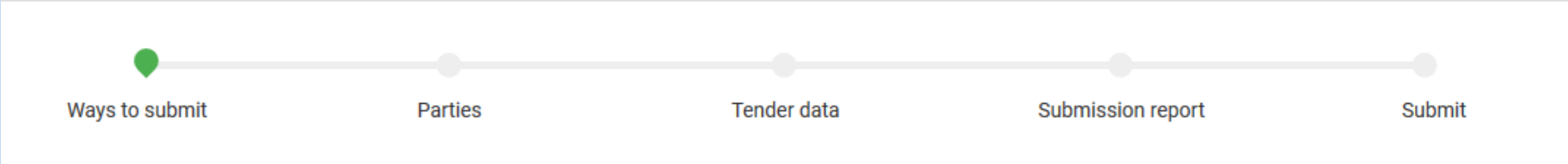
[17] See Article 4 (2) of the Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

APPENDIX: LIST OF REFERENCES

Award criteria	See Section 3.4
Contracting authority	See Section 1.1
Entities on whose capacities the tenderer relies to fulfil the selection criteria	See Section 2.4.3
EU Validation services	See Section 2.3 EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment
Exclusion criteria	See Section 3.1
Financial Regulation	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
Group leader	See Section 2.4.1
Group member	See Section 2.4.1
Identified subcontractors	See Section 2.4.2
Involved entities	See Section 2.4
Joint tender	See Section 2.4.1
Participant Register	See Section 2.3 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register
Selection criteria	See Section 3.2
Sole tenderer	See Section 2.4
Subcontracting/subcontractor	See Section 2.4.2
Treaties	The EU Treaties: https://europa.eu/european-union/law/treaties_en

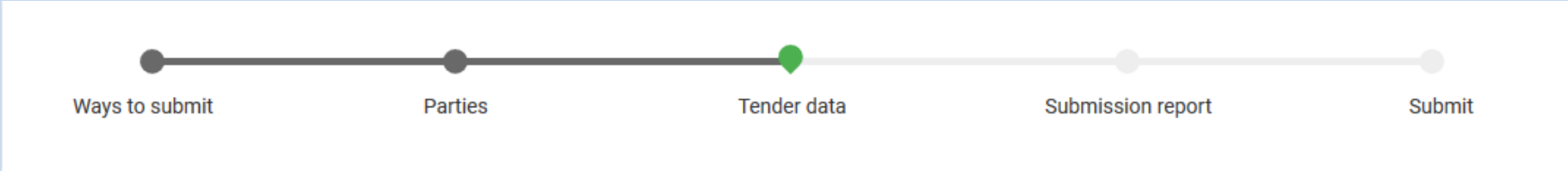
ANNEXES

Annex 1. List of documents to be submitted with the tender or during the procedure

Description	Sole tenderer	Joint tender		Identified Subcontractor	Entity on whose capacity is being relied (that is not subcontractor)	When and where to submit the document?	Instructions for uploading in eSubmission (if applicable)	
		Group leader	Group member				How to name the file?	Where to upload?
1. Identification and information about the tenderer. *eSubmission view* 								
Declaration on Honour on Exclusion and Selection Criteria (see Section 3.1) *model in Annex 2*	☒	☒	☒	☒	☒	With the tender in eSubmission	'Declaration on Honour'	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Declaration on Honour'. For entities that are not subcontractors and on whose capacity the tenderer relies to fulfil the selection criteria, the document must be uploaded in the section of the sole tenderer or group leader: →'Identification of the participant' →'Attachments'→'Other documents'.
Evidence that the person	☒	☒	☒			With the tender	'Authorisation to	With the concerned entity

signing the documents is **an authorised representative** of the entity[18] (see Section 4.3)						in eSubmission	sign documents'	under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Agreement/Power of attorney (see Section 2.4.1) *model in Annex 3*		☒	☒			With the tender in eSubmission	'Agreement Power of attorney'	In the group leader's section under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
List of identified subcontractors (see Section 2.4.2) *model in Annex 4*	☒	☒				With the tender in eSubmission	'List of identified subcontractors'	In the sole tenderer's or the group leader's section under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Commitment letter (see Section 2.4.2 and 2.4.3)				☒ *(model in Annex 5.1)*	☒ *(model in Annex 5.2)*	With the tender in eSubmission	'Commitment letter'	With the concerned entity under 'Parties' →'Identification of the participant' →'Attachments'→'Other documents'.
Evidence of non-exclusion (see Section 3.1)	☒	☒	☒	☒	☒	Only upon request by the contracting authority At any time during the procedure	n.a.	n.a.

[18] A document that the contracting authority can access on a national database free of charge does not need to be submitted if the contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

Evidence of legal existence and status (see Section 2.3)	☒	☒	☒			Only upon request by *the EU Validation services* At any time during the procedure In the Participant Register	n.a.	n.a.
Evidence of economic and financial capacity F1 (see Section 3.2.2)	**The documents must be provided** **only by the involved entities** **which contribute to reaching the minimum capacity level** **for criterion F1**					With the tender in eSubmission	'Balance sheet entity year' 'Profit Loss Account entity year'	With the group leader or the sole tenderer under 'Parties' →'Identification of the participant' →'Attachments'→'Economic and financial capacity'.
Evidence of technical and professional capacity T1 (see Section 3.2.3)	**The documents must be provided** **only by the involved entities** **which contribute to reaching the minimum capacity level** **for criterion T1**					With the tender in eSubmission	'Project reference No.1' 'Project reference No.2' ….	With the group leader or the sole tenderer under 'Parties' →'Identification of the participant' →'Attachments'→'Technical and professional capacity'.
2. Tender data. *eSubmission view*  ***Failure to upload the following documents in eSubmission will lead to rejection of the tender.***								
Technical tender (see Section 4.2)	☒	☒				With the tender in eSubmission	'Technical tender'	Under section 'Tender Data' →'Technical tender'

Financial tender (see Section 4.2) *model in Annex 6*	☒	☒				With the tender in eSubmission	'Financial tender'	Under 'Tender Data' →'Financial tender'

Annex 2. Declaration on Honour on exclusion and selection criteria

Annex 3. Agreement/Power of attorney

Call for tenders – **Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation**

AGREEMENT/POWER OF ATTORNEY

The undersigned:

[- Signatory 1 (Name, Function, Legal entity name, Registered address, VAT Number)]

- Signatory 2 (Name, Function, Legal entity name, Registered address, VAT Number)

- …

- Signatory N (Name, Function, Legal entity name, Registered address, VAT Number)]

having the legal capacity required to act on behalf of the entities they represent,

HEREBY AGREE TO THE FOLLOWING:

1) To submit a joint tender (the tender) as members of a group of tenderers (the group), constituted by ***[Insert names of Legal entity 1, Legal entity 2, ... Legal entity N – the name of the group leader must be included here!]*** (the group members), and led by ***[Insert name of Legal entity 1]*** (the group leader), in accordance with the conditions of the procurement documents and the terms of the tender to which this Agreement/Power of attorney is attached.
2) If the contracting authority awards a contract resulting from this call for tenders (the contract) to the group on the basis of the tender to which this Agreement/Power of attorney is attached, all group members (including the group leader) shall be considered parties to the contract in accordance with the following conditions:
   (a) All group members (including the group leader) shall be jointly and severally liable towards the contracting authority for the performance of the contract.
   (b) All group members (including the group leader) shall comply with the terms and conditions of the contract and ensure the proper delivery of their respective share of the services and/or supplies subject to the contract.
3) Payments by the contracting authority related to the services and/or supplies subject to the contract shall be made through the bank account of the group leader indicated in the contract.
4) The group members grant to the group leader all the necessary powers to act on their behalf in the submission of the tender and the conclusion of the contract, including:
   (a) The group leader shall submit the tender on its own behalf and on behalf of the other group members and indicate in the "Contact Person" section in eSubmission the name and e-mail address of an individual as a single point of contact authorised to communicate officially with the contracting authority in connection with the submitted tender on behalf of all group members, including in connection with all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature.
   (b) The group leader shall sign any contractual documents — including the contract and

amendments thereto — and shall warrant the submission of any invoices related to the performance of the contract on behalf of all group members.

(c) The group leader shall act as a single contact point with the contracting authority in the delivery of the services and/or supplies subject to the contract. It shall coordinate the delivery of the services and/or supplies by the group to the contracting authority, and shall see to a proper administration of the contract.

This Agreement/Power of attorney may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same document.

Any modification to the present Agreement/Power of attorney shall be subject to the contracting authority's express approval. This Agreement/Power of attorney shall expire when all the contractual obligations of the group have ceased to exist. The parties cannot terminate it before that date without the contracting authority's consent.

Name ***Function*** ***Name of the legal entity***	***Name*** ***Function*** ***Name of the legal entity***
signature[s]: _____	***signature[s]:*** _____
Done at ..... on	***Done at ..... on .....***
Name ***Function*** ***Name of the legal entity***	***Name*** ***Function*** ***Name of the legal entity***
signature[s]: _____	***signature[s]:*** _____
Done at ..... on	***Done at ..... on .....***

Annex 4. List of identified subcontractors and proportion of subcontracting

Identification details	Roles/tasks during contract execution	Proportion of subcontracting (% of contract volume)
[Full official name of the identified subcontractor, registered address, statutory registration number, VAT registration number]		
[Full official name of the identified subcontractor, registered address, statutory registration number, VAT registration number]		
[REPEAT AS MANY TIMES AS THE NUMBER OF IDENTIFIED SUBCONTRACTORS]		
Other subcontractors that do not need to be identified under Section 2.4.2[19]		
	TOTAL % of subcontracting	0,00%

[19] For this category of subcontractors, please provide in a general manner their intended roles/tasks during contract execution, as well as the aggregated % of contract volume for all non-identified subcontractors.

Annex 5.1. Commitment letter by an identified subcontractor

[Letterhead, if any]

EUROPEAN COMMISSION

Call for tenders Ref. GROW/2023/0P/0042

Attn:

[Insert date]

Commitment letter by identified subcontractor

I, the undersigned,

Name:

Function:

Legal entity:

Registered address:

VAT Number:

having the legal capacity required to act on behalf of ***[insert name of the entity]***, hereby confirm that the latter agrees to participate as subcontractor in the tender of *[insert name of the tenderer]* for the call for tenders **– Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation**.

In the event that the tender of the aforementioned tenderer is successful, ***[insert name of the subcontractor]*** commits itself to make available the resources necessary for performance of the contract as a subcontractor and to carry out the services that will be subcontracted to it in compliance with the terms of the contract. It further declares that it is not subject to conflicting interests, which may negatively affect the contract performance, and that it accepts the terms of the procurement documents for the above call for tenders, in particular the contractual provisions related to checks and audits.

Done at:

Name:

Position:

Signature:

Annex 5.2. Commitment letter by an entity on whose capacities is being relied

[Letterhead, if any]

EUROPEAN COMMISSION

Call for tenders Ref. GROW/2023/0P/0042

Attn:

[Insert date]

Commitment letter by an entity on whose capacity is being relied

I, the undersigned,

Name:

Function:

Legal entity:

Registered address:

VAT Number:

having the legal capacity required to act on behalf of ***[insert name of the entity]***, hereby confirm that the latter **authorises the *[insert name of the tenderer]* to rely on its [financial and economic capacity] [technical and professional capacity] in order to meet the minimum levels** required for the call for tenders **– Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation**.

In the event that the tender of the aforementioned tenderer is successful, ***[insert name of the entity]*** commits itself to make available the resources necessary for performance of the contract. It further declares that it is not subject to conflicting interests which may negatively affect the contract performance, and that it accepts the terms of the procurement documents for the above call for tenders, in particular the contractual provisions related to checks and audits.

Done at:

Name:

Position:

Signature:

Annex 6. Financial tender form

Staff Category	**Number of days**	**Unit price -** ***(= daily rate for Human Resources)***	**Total**
Role in the project (e.g. project leader, senior expert, junior expert, …)			
Secretariat (administrative and support staff)			
Other (to be specified)			
Subtotal (A)			
Other (to be specified)	**Quantity**	**Unit price**	**Total**
Item X			
Item Y			
…..			
Subtotal (B)			
TOTAL (A+B)			
Overall total (A) +(B)			