EUROPEAN COMMISSION

DIRECTORATE-GENERAL
ENVIRONMENT
Directorate E – Global & Regional Challenges, LIFE
ENV.E.2 - Global Sustainability, Trade & Multilateral Agreements

CALL FOR TENDERS

ENV.E.2/SER/2015/0016

SERVICE CONTRACT FOR PREPARATION OF GUIDANCE DOCUMENTS ON THE IMPLEMENTATION OF THE EU ABS REGULATION (Regulation (EU) No 511/2014)

TENDER SPECIFICATIONS

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1. INFORMATION ON TENDERING

1.1 Participation

Participation in this tender procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the Multilateral Agreement on Government Procurement[1] concluded within the WTO applies, the participation to the call for tender is also open to nationals of the countries that have ratified this Agreement, on the conditions it lays down.

1.2 Contractual conditions

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

1.3 Joint tenders

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

In case of joint tender, all economic operators in a joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole. Nevertheless, tenderers must designate a single point of contact for the Contracting Authority.

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

1.4 Subcontracting

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

Tenderers must give an indication of the proportion of the contract that they intend to subcontract. See Annex 2, questionnaire for joint bids and subcontracting.

Tenderers are required to identify all subcontractors. In case a tenderer relies on subcontractors to meet the required level under selection criteria, the subcontractor(s) concerned must provide the relevant supporting documents to that effect (see section 2.3).

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

1.5 Content of the tender

The tenders must be presented as follows:

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

Part A: Identification of the tenderer (see section 1.6)

Part B: Evidence for exclusion criteria (see section 2.2)

Part C: Evidence for selection criteria (see section 2.3)

Part D: Technical offer (see section 2.6)

Part E: Financial offer (see section 2.7)

1.6 Identification of the tenderer: legal capacity and status

The tender must include a cover letter presenting the name of the tenderer (including all entities in case of joint offer) and identified subcontractors if applicable, and the name of the single contact person in relation to this tender. Coherence must be ensured between the information in the cover letter and in Annex 1.

If applicable, the cover letter must indicate the proportion of the contract to be subcontracted.

In case of joint tender, the cover letter must be signed by a duly authorised representative for each economic operator, or by one of the economic operators duly authorised by the other economic operators (with power of attorney).

Subcontractors must provide a letter of intent stating their willingness to provide the service foreseen in the offer and in line with the present tender specification.

In order to prove their legal capacity and their status, all tenderers (or the single point of contact / all members of the consortium, see paragraph 1.3) must provide a signed Legal Entity Form with its supporting evidence. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

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

The tenderer (or the single point of contact / all members of the consortium, see paragraph 1.3) must provide a Financial Identification Form and supporting documents. Only one form per offer should be submitted (no form is needed for subcontractors). The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm

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

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

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

2. EVALUATION AND AWARD

2.1 Evaluation steps

The evaluation is based on the information provided in the submitted tender. It takes place in three steps:

(1) Verification of non-exclusion of tenderers on the basis of the exclusion criteria;

(2) Selection of tenderers on the basis of selection criteria;

(3) Evaluation of tenders on the basis of the award criteria.

Only tenders meeting the requirements of one step will pass on to the next step.

2.2 Exclusion criteria

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

The declaration on honour is also required for all subcontractors. The subcontractor must, if and when requested, provide all the supporting documents in relation to exclusion criteria**.**

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex 5 before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender and to identified subcontractors whose capacities will be relied upon to fulfil the selection criteria.

2.3 Selection criteria

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

The evidence requested should be provided by each member of the group in case of joint tender and identified subcontractors whose capacities will be relied upon to fulfil the selection criteria.

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

2.3.1 Economic and financial capacity criteria and evidence

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

- Annual turnover of the last two financial years above **€** 430,000

The following evidence should be provided:

- Copy of the profit & loss account and balance sheet for the last two years for which accounts have been closed,

- Failing that, appropriate statements from banks,

- If applicable, evidence of professional risk indemnity insurance.

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

2.3.2 Technical and professional capacity criteria and evidence

(a) Criteria relating to tenderers

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

- The tenderer must prove experience in preparing guidance documents and studies or impact assessments and in carrying out complex consultation process involving multiple partners representing different sectoral or policy perspectives, with at least two projects delivered in this field in the last three years with a minimum value for each project of € 100,000; experience in projects cutting across different sectors would be an asset.

- The tenderer must prove its capacity to draft reports in English.

- The tenderer must prove experience of working in multiple EU countries with at least 3 projects delivered in the EU in the last three years. Experience of working with EU institutions on EU-wide issues will also fulfil this criterion.

- The tenderer must prove experience in survey techniques, data collection, drafting reports and recommendations

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

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

(b) Criteria relating to the team delivering the service:

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

Project Manager: At least five years of experience in project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in project of a similar size and coverage (geographical scope at least six EU countries), with experience in management of teams of at least four people.

Experts: The team of experts should demonstrate a relevant higher education degree and/or a minimum of three years' of professional experience covering each of the following fields: law and regulatory issues; access and benefit sharing. Experience in carrying out research activities on genetic resources and/ or scientific background of one expert in the team would be considered an asset.

Language quality check: at least 3 members of the team should have native or near-native level language skills in English as guaranteed by a certificate or past relevant experience.

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

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

2.4 Award criteria

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

A maximum of 60 points will be attributed to criterion 1, and a maximum of 20 points each to criteria 2 and 3. In addition a minimum threshold will be set up under this system of points: Technical sufficiency levels: Selected companies will have to score a minimum of 36, 12 and 12 points under criteria 1, 2 and 3 respectively, with a minimum total of 65 points.

Tenders scoring less than 65 in the overall points total or less than the technical sufficiency level in the points awarded for a single criterion will be excluded from the rest of the assessment procedure. Since assessment of the tenders will focus on the quality of the proposed services, 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, will only result in a very low score. In addition, if certain essential points of these specifications are not expressly covered by the tender, the Commission may decide to give a zero mark for the relevant qualitative award criteria.

1 ***Quality of the proposed methodology*** (60 points – minimum threshold 36 points)

The degree to which the methodology shows the capacity to analyse, review and evaluate documents and figures, in accordance with the needs of the contracting authority. Furthermore the tender must demonstrate the capacity to resolve the questions underlying in the tender in a realistic and well-structured way, as well as demonstrate whether the methods proposed are suited to the needs set out by the Commission in the Technical Description.

Sub-criterion 1.1 – The evaluation committee will examine whether or not the requirements of the Nagoya Protocol and Regulation (EU) No 511/2014 (EU ABS Regulation) are understood and fully integrated in the tender's methodology, taking into account horizontal and sector-specific expert discussions which are ongoing at EU and international level (30 points – minimum threshold 50%)

Sub-criterion 1.2 – This sub-criterion will examine if the methodology proposed is suitable for the development of guidance in a transparent and participatory manner and if it demonstrates in detail how the tenderer will communicate with the key stakeholders, with EU Member States authorities and with the Contracting Authority, and how this will inform the development of the guidance documents (10 points – minimum threshold 50%).

Sub-criterion 1.3 – This sub-criterion will examine the suitability of the proposed methodology for drafting and finalising comprehensive sector-specific guidance documents as described in sections 3.2 and 3.3 (Objectives and Tasks) below, taking into account the specificities of different sectors while ensuring overall consistency across the documents (20 points – minimum threshold 50%).

2 ***Organisation of the work*** (20 points – minimum threshold 12 points)

This criterion will assess how the roles and responsibilities of the proposed team and of the economic operators (in case of joint tenders, including subcontractors if applicable) are distributed for each task. It also assesses the global allocation of time and resources to the project and to each task or deliverable, and whether this allocation is adequate for the work. The tender should provide details on the allocation of time and resources and the rationale behind the choice of this allocation. This will be evaluated through the following sub-criteria:

The evaluation committee will examine the general management of the work, organisation of team, allocation of resources, including distribution of the funds, distribution of tasks between team members, supervision by project manager, planning of man-hour allocation and timeline envisaged to perform the various tasks, contact and exchange of information with the Commission services.

3 ***Quality control measures*** (20 points – minimum threshold 12 points)

This criterion will assess the quality control system applied to the service foreseen in this tender specification concerning the quality of the deliverables, the language quality check, and continuity of the service in case of absence of a member of the team. The evaluation committee will examine the proposed approach to the identification of potential risks that could compromise the delivery of a quality final product and approach to the measures necessary to overcome such risks, as well as the proposed approach to ensuring the continuity of service and to ensure the quality of the deliverables, including the necessary language checks. The quality system should be detailed in the tender and specific to the tasks at hand; a generic quality system will result in a low score.

2.5 Ranking and Award

Having examined the tenders from a technical point of view, the evaluation committee will proceed considering which is the economically most advantageous offer taking into account **only those tenders that have obtained at least 65 out of the 100 points that are available for the technical quality of the bid**. The evaluation committee will then proceed with the financial comparison of the tenders retained for further consideration according to the ranking procedure below.

The bid offering the best value for money will be chosen, provided that the minimum number of points cited above is achieved. The ranking of the tenders will be calculated as follows:

(1) All bids that do not reach the stated technical sufficiency levels for each individual award criteria will not be considered for contract award.

(1) All bids that have passed the individual levels and score 65 or higher are deemed to be technically sufficient. Then the price is divided by the total number of points awarded

to obtain the price-quality ratio. The award of the contract will be made in accordance with the lowest ratio.

The Commission reserves the right not to select any tender if the amounts tendered exceed the budget envisaged for this project.

2.6 Compliance of technical offer

The technical offer must cover all aspects and tasks required in the technical specification and provide all the information needed to apply the award criteria. Offers deviating from the requirements or not covering all requirements may be excluded on the basis of non-conformity with the tender specifications and will not be evaluated.

2.7 Financial offer

The price range is fixed between € 190,000 and € 215,000 excluding VAT (including fees, travel and all other costs). Any offers received that do not respect the upper limit will be automatically excluded from the evaluation procedure. The lower limit is indicative. **Travel and subsistence expenses are not refundable separately**. For guidance purposes see Annex 3.

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

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

3. TECHNICAL SPECIFICATIONS

3.1 General background

3.1.1 International level

The access and benefit sharing of genetic resources (ABS) became an issue during the 1980s. In the agricultural arena, countries from the Southern hemisphere began to argue that they provided a large amount of genetic resources for food and agriculture. These resources were used and commercialised with the help of the breeders in the North, but their benefits were not shared. In the trade and intellectual property arena, critics of intellectual property rights – and in particular of patents on biological matter argued that these enabled the appropriation, without compensation or consent, of biological resources and knowledge of indigenous communities and farmers (cases of so-called "bio-piracy"). The emerging discourse on the economic value of genetic resources and the distribution of benefits derived from their use blended with the discourse on nature conservation and resulted in the launch of international negotiations on the Convention on Biological Diversity (CBD) (http://www.cbd.int/).

The ABS is an important element of the CBD. The third objective of the CBD, which entered into force in 1993, is "the fair and equitable sharing of the benefits arising out of the

utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding" (Article 1 CBD).

The entry into force of the CBD did not however create legal certainty. After its entry into force the discussions on implementing the ABS provisions initially focused on the operationalization of access measures. Gradually awareness shifted also to benefit sharing. There was, however, a lack of agreement between the Parties as to the need to transpose the provisions of the Convention into national legal orders.

The situation was unsatisfactory from a legal, but also from an ecological and economic point of view. Even though in 2002 the Conference of the Parties to the CBD adopted the so-called Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization, they remained voluntary. The group of Like-Minded Megadiverse Countries (LMMC) launched an initiative at the World Summit on Sustainable Development in Johannesburg, also in 2002, which resulted in the adoption of the recommendation "to negotiate within the framework of the CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of utilisation of genetic resources". This triggered the process of international negotiations, which led to the adoption of the Nagoya Protocol in October 2010 (http://www.cbd.int/abs/). The Protocol implements and further specifies Article 15 of the CBD, while also expanding its scope to traditional knowledge associated with genetic resources.

The basic rules derived from the Nagoya Protocol are that users may only utilise genetic resources and associated traditional knowledge, if the genetic resources they intend to utilise have been accessed with the prior informed consent (PIC) of the provider country, i.e. a decision by a competent authority to grant such access, and that utilisation is based on mutually agreed terms (MAT), i.e. a contract between the provider and the user which also includes the rules for benefit sharing. If a Party decides not to regulate access to their genetic resources and associated traditional knowledge, genetic resources will remain freely accessible.

The Nagoya Protocol has three pillars: access, benefit-sharing and compliance measures. All Parties to the Protocol are free to establish access measures in the exercise of sovereign rights. Similarly, the EU Member States are free to establish the access measures they deem appropriate. Benefit-sharing is covered by contractual agreements (MAT) between users and the providers. The important added value of the Protocol is the duty on the Parties to establish compliance measures, i.e. checkpoints to monitor utilisation of genetic resources obtained from countries of origin. The role of the checkpoints is to verify whether appropriate permits (PIC) were obtained and contractual agreements, (MAT) were established, where appropriate.

3.1.2 EU implementation of the Nagoya Protocol

The third pillar of the Nagoya Protocol is implemented in the EU by means of the Regulation on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (Regulation (EU) No 511/2014). The Regulation can be found here:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0511.

The Regulation entered into force on 9 June 2014 and applies from 12 October 2014, i.e. the date on which the Nagoya Protocol entered into force for the Union. Some of the provisions of the Regulation however will only become applicable one year after that, because

additional measures need to be put in place before they can be applied. This concerns, in particular, Article 4 on due diligence, Article 7 on checkpoints and Article 9 on checks on user compliance.

The relevant documents leading to the adoption of the EU ABS Regulation, including the impact study and the Commission's impact assessment, can be found here:

http://ec.europa.eu/environment/biodiversity/international/abs/index_en.htm.

The cornerstone of the EU ABS Regulation is due diligence. In line with Article 4 of the Regulation the user (a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources) is under the obligation to ascertain that genetic resources and the associated traditional knowledge which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared on mutually agreed terms. As the impact-assessment study indicated, it is not very often the case that the same entity accesses genetic resources and places the final product developed via utilisation of genetic resources on the market, as the users tend to change along the value chain. To address this, Article 4(3) of the Regulation puts an obligation on the users to seek, keep and transfer to subsequent users either the internationally-recognized certificate of compliance, or equivalent information (details provided for in Article 4(3)(b) of the EU ABS Regulation).

The EU ABS Regulation establishes two checkpoints, i.e. one at the stage of receiving research funding (Article 7(1) of the Regulation) and the other one at the stage of final development of the product (Article 7(2) of the Regulation). In both situations the user is expected to declare either that they exercise due diligence in accordance with Article 4, or that they have fulfilled the obligations under Article 4.

The modalities of the application of Article 7 will be defined in a Commission implementing regulation. The Commission is currently in the process of developing this regulation, with assistance of the newly set up ABS Committee. The Regulation will establish the procedures for implementing the provisions on monitoring user compliance, which include appropriate templates for due diligence declarations required to be filled in based on Article 7(1) (research funding) and based on Article 7(2) (stage of final development of a product) respectively; it will also determine the authorities to whom the declarations need to be submitted as well as the time within which to complete the declarations. The implementing regulation will also establish procedures concerning voluntary tools of compliance, such as the register of collections (Article 5) and best practices (Articles 8). The implementing regulation is expected to be adopted in October 2015.

3.1.3 Underlying issues

A lot of questions are raised concerning the scope of application of the Protocol and of the EU ABS Regulation. There also remains a degree of uncertainty and lack of common understanding of some of the terms used by the Protocol and the EU ABS Regulation among stakeholders. It is thus necessary to provide clear guidance to users on the scope of application of the Regulation and to work out a common understanding of the terms used by the two legal instruments.

Among other questions affecting the scope of application (on which the Commission will undertake to provide clarity, in consultation with Member States), clarification is urgently required on the meaning of the term "utilisation", as referred to in the Protocol and the EU ABS Regulation. The rules under the Nagoya Protocol and the EU ABS Regulation only

apply to the "utilisation" of genetic resources and associated traditional knowledge. The Protocol specifies that "utilisation of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology" (Art. 2(c)). It is clear that the mere trade in commodities is not covered by ABS. However, what precisely does fall within the scope of utilisation under the Protocol and under the EU ABS Regulation remains subject to various debates and is thus at the core of the tasks under this call for tender, as described more specifically in Section 3.3 below.

3.1.4 Different approaches to genetic resources: actors upstream and downstream in the value chain

Genetic resources are utilised in a wide range of sectors and by a wide range of actors in the EU. There are some actors which are involved in what can be described as "*upstream*" activities in the value chain of dealing with genetic resources. These include bio-prospecting and importing genetic resources into the EU, storing of genetic resources in ex-situ collections and handing out/ distribution of genetic resources. Typically, botanic gardens, culture collections, seed banks and other public or private ex-situ collections are the actors here. They also identify and document the genetic resources, which often include taxonomic description of the genetic resources and testing of the resources to define their qualities.

Furthermore, there is academic research (universities and research institutes), which often but not always are linked with the ex-situ collections (the collections may be hosted by the same institutions). The universities and research institutes play an important role in the value chain. Most typically they concentrate on basic and non-commercial research.

Subsequently, a wide range of industries are involved in "*downstream"* uses of genetic resources. The list includes the biotechnology industry[2], the pharmaceutical industry, the plant breeding and seed industry, animal breeding industry, the horticulture industry, the bio-control industry[3], the cosmetic industry and the food and beverage industry. They develop products via utilisation of genetic resources with the aim of commercialising these products.

Different challenges present themselves for the different actors in the value chain. For the first group of actors, dealing with genetic resources upstream, it is important to describe when the utilisation of genetic resources (and traditional knowledge associated with them) starts, since this triggers a due diligence obligation. For the users down the value chain, it is of more importance to know when the utilisation of genetic resources finishes (though a clear identification of the start of process is also of relevance).

3.1.5 The challenges for upstream actors

As indicated already, the precise scope of utilisation under the Protocol and under the EU ABS Regulation is subject to various debates. The Protocol defines utilisation as "conducting research and development on the genetic resources" (Art. 2(c) – emphasis added). The EU ABS Regulation repeats this definition. At the same time, Article 8(a) of the Protocol establishes an obligation for Parties to "create conditions promoting and encouraging

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2 Companies developing, manufacturing and selling using or containing biological material as catalyst or feedstock to make industrial products – for example developing enzymes.

3 Developing techniques for crop protection

research [...] including though simplified measures on access for non-commercial research purposes".

It would seem from the above that a mere description of a biological/genetic phenomenon does not fall under the notion of utilisation. Where does the utilisation start however? Is taxonomy included in the scope of utilisation of genetic resources or not? Does basic research fall under the definition of utilisation or not? Would a description of a phenomenon initiate utilisation under any specific circumstances?

The core obligations of the EU ABS Regulation are addressed to users, i.e. those who utilise genetic resources under the meaning of the Protocol and the EU ABS Regulation. Consequently, having clear answers to those and other questions raised in this context is fundamental, as it will impact on the scope of application of the EU ABS Regulation. With the Regulation being applicable as of October 2014, and with Articles 4, 7 and 9 entering into application in October 2015, describing the concept of utilisation has become a matter of urgency. The Commission is therefore in the process of developing a guidance document which will address the issue of utilisation for the upstream actors. This material should be available in the 2nd half of 2015 and should also be considered in the process of preparation of guidance documents addressed to different sectors.

3.1.6 Sectoral specificities of users downstream

The use of genetic resources varies among different sectors where products are developed via utilisation of the genetic resources (and/or traditional knowledge associated with them). Depending on the sector, utilisation of genetic resources may thus take a different form. The point in time when utilisation is started and finalised may also be different depending on the sector. A common understanding needs to be developed for each of the different sectors as to which activities precisely fall under the definition of utilisation. More information about different sectors can be obtained from Annex 3 to the "Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union" (to be found here:

http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20FINAL%20REPORT%20-%20Annexes.pdf).

In line with Article 7(6) of the EU ABS Regulation, the implementing act aimed at establishing the procedures under Art. 7(1)-(3) of the Regulation "shall determine the stage of final stage of development of a product in order to identify the final stage of utilisation in different sectors" (emphasis added). The draft implementing regulation as proposed by the Commission remains rather general, distinguishing only between different approval procedures, which are applicable to different sectors. It is therefore necessary to provide sector-specific guidance, in addition to the implementing regulation, on the term utilisation, including a specification of when development of a product starts and ends.

It should be noted that various sectors are in the process of developing sector-specific guidance documents on their own initiative. These initiatives should be considered during the process of preparation of the guidance documents. In addition, sectoral guidance developed at international level, such as those prepared under auspices of the Secretariat of Convention on Biological Diversity should be considered.

3.2 Objectives

The objective of this contract is to assist the Commission in developing a common understanding of the term "utilisation" used under the EU ABS Regulation among different

stakeholders utilising genetic resources in different sectors downstream with a view to ensuring a harmonized application of the Regulation across the EU. This objective is to be achieved by completing the following more specific tasks:

3.3 Tasks

In order to achieve the objectives set out above the Contractor will be required to carry out the following tasks.

3.3.1 Task 1

Preparing final guidance documents on the utilisation of genetic resources for the pharmaceutical sector

The final document should take into account feedback received from key actors, including representatives of the sector and relevant Member States' authorities. It should provide the basis for a common interpretation by the users of the notion of "utilisation" within the pharmaceutical sector. While developing the document for the pharmaceutical sector, the work on the guidance document for the biotechnology sector (sub-section on bio-based chemicals) should also be considered, as there is a strong inter-linkage between these sectors.

Sub-steps of Task 1:

a) Preparing draft guidance concerning the utilisation of genetic resources by users in the pharmaceutical sector, as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 4 examples of different forms of utilisation within the sector;
b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users more particularly, as well as relevant authorities of the Member States, with a view to getting their feedback and checking whether the draft addresses key concerns of the users and takes into account practical questions faced by them; such involvement should include in particular:
    - Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);
    - Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;
c) Finalising the draft guidance document taking into account the feedback received.

3.3.2 Task 2

Preparing final guidance documents on the utilisation of genetic resources for the plant-breeding/seeds industry and horticulture sectors

The final document should take into account feedback received from key actors, including representatives of the sectors and relevant Member States' authorities. It should provide the basis for a common interpretation of the notion of "utilisation" within each sector mentioned

above by the users. Plant breeders, seed industry and horticulture have been grouped together as they use similar methods to achieve the final results, however there is a difference in the legal framework applicable to plant and seed sector and to the horticulture sector, which should be taken into account.

Sub-steps of Task 2:

a) Preparing draft guidance concerning the utilisation of genetic resources by users in the plant-breeding/seeds industry and horticulture sectors as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 5 examples of different forms of utilisation for the sectors concerned;
b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users more particularly, as well as relevant authorities of the Member States, with a view to getting their feedback and checking whether the draft addresses key concerns of the users and takes into account practical questions faced by them; such involvement should include in particular:
    - Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);
    - Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;

c) Finalising the draft guidance document taking into account the feedback received.

3.3.3 Task 3

Preparing final guidance documents on the utilisation of genetic resources for the animal breeding sector

The final document should take into account feedback received from key actors, including representatives of the sector and relevant Member States' authorities. It should provide the basis for a common interpretation of the notion of "utilisation" within the animal breeding sector by the users.

Sub-steps of Task 3:

a) Preparing draft guidance concerning utilisation of genetic resources by the users in the animal breeding sector as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 3 examples of different forms of utilisation within the sector;
b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users more particularly, as well as relevant authorities of the Member States, with a view to getting their feedback and checking whether the draft addresses key concerns of the users and takes into account practical questions faced by them; such involvement should include in particular:
    - Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);

- Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;

c) Finalising the draft guidance document taking into account the feedback received.

3.3.4 Task 4

Preparing final guidance documents on the utilisation of genetic resources for the food and beverage industry

The final document should take into account feedback received from key actors, including representatives of the sector and relevant Member States' authorities. It should provide the basis for a common interpretation of the notion of "utilisation" for the food and beverage industry. While developing the document for this sector, the work on the guidance document on the biotechnology industry sub-section bio-based chemicals should also be considered, as there is a strong inter-linkage between these sectors.

Sub-steps of Task 4:

a) Preparing draft guidance concerning utilisation of genetic resources by the users in a given sector as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 5 examples of different forms of utilisation within the sector;
b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users more particularly, as well as relevant authorities of the Member States, with a view to getting their feedback and checking whether the draft addresses key concerns of the users and takes into account practical questions faced by them, such involvement should include in particular:
    - Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);
    - Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;

c) Finalising the draft guidance document taking into account the feedback received.

3.3.5 Task 5

Preparing final guidance documents on the utilisation of genetic resources for the biotechnology industry

The final document should take into account feedback received from key actors, including representatives of the sector (including different sub-sectors) and relevant Member States' authorities. It should provide the basis for a common interpretation of the notion of "utilisation" within the sector. The guidance document should address different sub-sectors of

the biotechnology industry, such as biofuels, bio-based chemicals and bioplastics. While developing the document for the bio-based chemicals, the work on the guidance document on the food and beverage industry, cosmetic industry and pharmaceutical industry should also be considered, as there is a strong inter-linkage between these sectors.

Sub-steps of Task 5:

a) Preparing draft guidance concerning utilisation of genetic resources by the users in the biotechnology industry as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 7 examples of different forms of utilisation within the sector;

b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users more particularly, as well as relevant authorities of the Member States, with a view to getting their feedback and checking whether the draft addresses key concerns of the users and takes into account practical questions faced by them; such involvement should include in particular:

- Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);
- Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;

c) Finalising the draft guidance document taking into account the feedback received.

3.3.6 Task 6

Preparing final guidance documents on the utilisation of genetic resources for the cosmetic sector as well as cosmetic ingredients' suppliers

The final document should take into account feedback received from key actors, including representatives of the sector and relevant Member States' authorities. It should provide the basis for a common interpretation by the users of the notion of "utilisation" for the sector. While developing the document for the cosmetic sector, the work on the guidance document on the biotechnology sector sub-section bio-based chemicals should be considered, as there is a strong inter-linkage between these sectors.

Sub-steps of Task 6:

a) Preparing draft guidance concerning utilisation of genetic resources by the users in the cosmetic sector as well as cosmetic ingredients' suppliers as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 5 examples of different forms of utilisation for the sector;

b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users (including the perspective of cosmetic ingredients' suppliers), as well as relevant authorities of the Member States, with a view to getting their feedback and checking

whether the draft addresses key concerns of the users and takes into account practical questions faced by them; such involvement should include in particular:

- Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);
- Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;

c) Finalising the draft guidance document taking into account the feedback received.

3.3.7 Task 7

Preparing final guidance documents on the utilisation of genetic resources for the bio-control sector

The final document should take into account feedback received from key actors, including representatives of the sector and relevant Member States' authorities. It should provide the basis for a common interpretation of the notion of "utilisation" within the sector by the users.

Sub-steps of Task 7:

a) Preparing draft guidance concerning utilisation of genetic resources by the users in the bio-control sector as a draft for discussion with the relevant actors; the draft guidance document should comprise at least 3 examples of different forms of utilisation for the sector;
b) Involving relevant actors in a debate on the draft document, i.e. representatives of European associations representing the sector in general and representatives of users more particularly, as well as relevant authorities of the Member States, with a view to getting their feedback and checking whether the draft addresses key concerns of the users and takes into account practical questions faced by them; such involvement should include in particular:
    - Submission of the draft guidance documents to key actors (representatives of the sector and relevant Member State authorities) with a request for feedback (after approval of the text by the Commission);
    - Organisation of a sectoral 1-day workshop in Brussels (by default on Commission premises), within 1-2 months after the draft guidance documents have been produced. This involves the preparation of the agenda and of invitations and all the logistics of the workshops on the spot. Catering does not need to be included in the offer. Each workshop should involve 15-60 participants;

c) Finalising the draft guidance document taking into account the feedback received.

3.4 Input by the Contracting Authority

The contracting authority will provide any additional information and documents relevant to the implementation of the contract during the first project meeting with the European

Commission (the kick-off meeting). This meeting will be scheduled within three weeks after signature of the contract.

3.5 Outputs and deliverables

3.5.1 Initial outputs

The Contractor is expected to deliver an **inception report** describing the methodology and detailed breakdown of the timetable for the delivery of outputs. The inception report shall be presented and discussed during the 2nd meeting (a follow up meeting to the kick-off meeting). This meeting will be scheduled within 2 months after contract signature. The final inception report has to be agreed with the Commission and should be submitted no later than 2 weeks after the follow-up meeting.

3.5.2 Intermediate outputs and deliverables

A concise but comprehensive **interim report** describing progress with all tasks, and most importantly presenting draft guidance documents, for Tasks 1-7 should be presented 6 months after the presentation of the inception report. This report should outline progress made towards implementation of the agreed work programme.

3.5.3 Final output and deliverable

A **final report** should be made available to the Commission services in electronic format for commenting 12 months after the signature of the contract. The final report must be supplied in one paper copy and electronically; all specific deliverables agreed should be supplied on a CD-ROM or submitted electronically. A final report should contain information on all activities carried out and final guidance documents for Tasks 1-7.

The Contractor has to provide draft minutes of all the meetings with the Commission within one week after the meeting and send these for approval to the Commission.

3.5.4 Details on deliverables

For each of the 7 individual tasks listed above the Contractor is expected to produce the following deliverables:

Preparation of guidance documents on the utilisation of genetic resources for each of the different sectors downstream in the value chain, as listed above under tasks 1-7:

1. Table of contents, structure of the document and list of relevant literature, identification of stakeholders (to be presented at the second meeting, referred to under 3.5.1);

2. Draft guidance documents for each sector with the selection of case studies (number as specified in section 3.3) containing practical examples per sector (to be submitted to the Commission as part of the interim report referred to under 3.5.2); the process of preparation of the first draft should involve contacts with the representatives of the key actors for each sector in order to reflect the main issues of concern;

3. Reports from the sectoral workshops containing: list of participants, description of problems discussed during the workshop and recommendations for use of the feedback gathered in the final report. The reports have to be provided in English, in electronic form, within 15 working days of the workshop;

4. Submission of draft guidance documents for each sector with consolidated written comments submitted by the consulted key actors and comments gathered during the workshop to relevant Member States authorities for their final feedback and comments (to be submitted to them within 2 months after the organization of the workshop);

5. Final version of the guidance documents (one paper copy + electronic version) with the case studies and any annexes (12 months after signature of contract). The final version shall consider the feedback received from the sector concerned in writing and during the workshops.

   The final guidance documents should be drafted in English.

Timely provision of deliverables under both tasks is crucial due to the tight calendar of the contract.

The tasks should be completed within **12** months of the signature of the contract. The execution of the tasks may not start before the contract has been signed.

3.6 General guidance on methodology

The contractor should take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the contract. In particular, the contractor must indicate in the offer for every member of the team whether he/she is involved in work in the sectors concerned. Those members of the contractor's team which work on substance must declare that all tasks will be carried out in an objective way and that the work is based only on sound science and not on any possible commercial or similar interests.

The contractor undertakes to treat in the strictest confidence and not make use of or divulge to third parties any information or documents which are linked to the performance of the assignment and he/she shall continue to be bound by this undertaking after the completion of these tasks.

The contractor must work in close collaboration with the relevant services of the European Commission.

All deliverables shall be written in English. They have to be drafted in a proper literate manner and must be fully comprehensible in terms of grammatical structure (complete sentences, explanations of abbreviations etc.).

The final sector-specific guidance documents shall include:

(1) an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French.

Furthermore, the sector-specific guidance documents should be consolidated into one document, which should be accompanied by the following standard disclaimer:

> *"The information and views set out in this [report/study/article/publication…] are those of the author(s) and do not necessarily reflect the official opinion of the*

Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

3.7 Performance and quality requirements

The contractor shall ensure timely delivery of required outputs as agreed with the Contracting Authority.

3.8 Place of performance

The place of performance of the tasks shall be the contractor's premises or any other place indicated in the tender, with the exception of the Commission's premises. The workshops will be organized at the Commission's premises.

ANNEX 1 - ADMINISTRATIVE INFORMATION FORM

Organisation or individual:

NAME: …….....
ADDRESS: …….....

Address where contract should be sent to (if different from above):

…….....

PERSON AUTHORISED TO SIGN CONTRACT:

Name and position: .....

PERSON FOR ROUTINE CONTACT:

Name and position: .....
ADDRESS: .....
Telephone and E-mail: .....

Signature of Tenderer .....

ANNEX 2 – QUESTIONNAIRE FOR JOINT BIDS AND SUBCONTRACTING

This questionnaire should only be completed if your tender involves a joint bid or subcontracting.

Joint bid (refer to paragraph 1.3)

1. Does your bid involve more than one tenderer? Yes □ No □

Questions 2 - 4 shall be answered only if you have answered yes to question 1.

2. Please fill in the name of the company having power of attorney for the group of tenderers and acting as a co-ordinator:

   _____

3. Please fill in the names of the other companies taking part in the joint offer:

   _____

   _____

   _____

4. If a consortium or similar entity exists, please fill in the name and the legal status of the entity:

   _____

Subcontracting (refer to paragraph 1.4)

5. Does your bid involve subcontracting? Yes □ No □

If the answer is yes, please complete question 6, and the next page per sub-contractor.

6. List of sub-contractors:

……..……..…

……..……..…

……..…….

Reasons, roles, activities and responsibilities of sub-contractors.

Please complete this page for each sub-contractor (one page per sub-contractor):

Name of the sub-contractor:

……..……..

Official legal form:

……..……..

Country of registration:

……..……..

Statutory registration number:

……..……..

(Internet address, if applicable):

……..……..

Official address in full:

……..……..

……..……..

Contact person:

……..……..

Telephone number:

……..……..

Reasons for subcontracting:

……..……..

Role, activities and responsibilities of the sub-contractor:

……..……..

The volume or the proportion of the sub-contracting:

……..……..

Do you intend to rely on capacities from the sub-contractor in order to fulfil the selection criteria? If yes, specify which selection criterion - financial and economic capacity or technical and professional capacity - and be aware that the tenderer must provide the documents which make it possible to assess the selection criteria.

……..……..

- Tenderer: Date: Signature:

ANNEX 3 – FINANCIAL OFFER TEMPLATE

(for guidance purposes only)

Price and Estimated budget breakdown

Calculation of the costs (incl. travel, overheads, consumables and any other related costs)

Type of service provider	Position within the project team	Number of working days	Allocation of tasks	Proportion of the contract in %	Costs in €
Lead contractor					
	……	…….	……..	……..	……..
	……	…….	……..	……..	……..
	……	…….	……..	……..	……..
	Sub-total	…….		……..	……..
Sub-contractor 1					
	……	…….	……..	……..	……..
	……	…….	……..	……..	……..
	Sub-total	…….		……..	……..
Sub-contractor 2					
	……	…….	……..	……..	……..
	……	…….	……..	……..	……..
	Sub-total	…….		……..	……..
Sub-contractor 3					
	……	…….	……..	……..	……..
	……	…….	……..	……..	……..

	Sub-total	**…….**		**……..**	**……..**
…….					
	Total	**……**		**……**	**……**

Signature of Tenderer **.....**

Date **.....**

ANNEX 4 - LEGAL ENTITY AND FINANCIAL IDENTIFICATION FORMS

These forms can be downloaded from

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm (Legal entity form)

http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm (financial identification form)

ANNEX 5 - DECLARATION OF HONOUR

Declaration of honour with respect to the Exclusion Criteria and absence of conflict of interest

The undersigned *[insert name of the signatory of this form]*:

(1) in his/her own name (for a natural person)

or

(1) representing the following legal person (only if the economic operator is a legal person)

full official name :
official legal form :
full official address :
VAT registration number :

(1) declares that [the above-mentioned legal person][he][she] is not in one of the following situations:

(1) is bankrupt or being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

(1) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;

(1) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;

(2) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;

(3) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the Union's financial interests;

(4) is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the Union's budget.

(1) *(Only for legal persons other than Member States and local authorities, otherwise delete)* declares that the natural persons with power of representation, decision-

making or control[4] over the above-mentioned legal entity are not in the situations referred to in b) and e) above;

(1) declares that [the above-mentioned legal person][he][she]:

g) has no conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;

h) will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;

i) has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to award of the contract;

j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure ;

(1) acknowledges that [the above-mentioned legal person][he][she] may be subject to administrative and financial penalties[5] if any of the declarations or information provided prove to be false.

In case of award of contract, the following evidence shall be provided upon request and within the time limit set by the contracting authority:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

If the tenderer is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

Full name Date Signature

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4 This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

5 As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

ANNEX 6 - ACKNOWLEDGEMENT OF RECEIPT

EUROPEAN COMMISSION

DIRECTORATES-GENERAL
ENVIRONMENT AND CLIMATE ACTION
SRD - Shared Resources Directorate
SRD.2 - Finance

(Please fill in your address)

ACKNOWLEDGEMENT OF YOUR TENDER

Our reference: ENV.E.2/SER/2015/0016

Your reference:

We wish to confirm the receipt and opening of your offer[1]. Your offer will now be evaluated by the Commission and its experts. You will be informed of the result in due course.

We thank you for your interest.

MarketsTeam
SRD.2

[1] Your personal contact data has been recorded in a database used by the Markets Team of unit SRD.2 for the administrative management of offers. The Commission is bound by Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies. For more information, and to exercise your rights to access and eventually correct data concerning you, please don't hesitate to contact us.