1. TECHNICAL SPECIFICATIONS

1.1. OBJECTIVE OF THE CONTRACT

The service contract concerns support to the European Commission in the preparation of an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight for nanomaterials ("nanomaterials registry").

The subject of the Commission impact assessment is to determine whether, in addition to existing information requirements and those considered for the planned revision of REACH annexes[1], there should be new measures to increase transparency and ensure regulatory oversight on nanomaterials (in the following called "transparency measure(s)"). The impact assessment will cover nanomaterials as defined in Recommendation 2011/696/EU[2] (for possible restrictions as regards the scope of possible measures see below). Possible measures include non-regulatory options and regulatory measures such as European Union wide requirements for companies to register or notify nanomaterials in substances, mixtures or articles they manufacture, import or use. Existing requirements to register nanomaterials include REACH, CLP and the Cosmetics Regulation as well as compulsory national schemes (so far only in France). Existing information includes the Staff Working Paper on Nanomaterial Types and Uses, together with Safety Aspects (SWD(2012) 288 final). The Commission has also announced a web platform to link to available information.

The objective of this contract is in the first place to gather available data with relevance to the impact assessment. The biggest part of the study shall analyse the experiences from existing notification schemes on nanomaterials and products containing nanomaterials on the market, and assess the impact of possible variations to the scope and content of existing schemes. However, part of the contract will also be to support the assessment by gathering data that could be used to estimate the scale and likelihood of potential health and environmental impacts affected by possible transparency measures, and to gather basic market data (e.g. for competitiveness proofing, assessing impacts on SMEs), and as appropriate other relevant issues.

1.2. BACKGROUND

As part of the Communication on the Second Regulatory Review on Nanomaterials (COM(2012) 572 final), the Commission has announced to launch "an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight [on nanomaterials], including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes."

The European Parliament called on the Commission to compile an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly

[1] This project is complementary to the separate initiative on the adapting REACH annexes for nanomaterials which is intended to bring a necessary clarity on the information within registration dossiers covering nanomaterial forms of substances.

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

available. Austria, Belgium, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden and Croatia have asked the Commission to "propose legislation on registration or market surveillance of nanomaterials or products containing nanomaterials". France has already put in place relevant national legislation, requiring producers, importers and distributors of nanomaterials on their own, in mixtures where they are not bound and in materials from which they are intended to be released to submit an annual declaration on the quantities, uses and clients to whom these nanomaterials have been sold. The declaration must be submitted for all nanomaterials produced or placed on the market in quantities exceeding 100 grams. The objective is to create full information and traceability of nanomaterials throughout the supply chain. Belgium and Denmark have announced their intentions to introduce similar legislation. Germany has recently sent implementation proposals for a nanomaterial registry. A "nanomaterial registry" has also been called for by a number of non-governmental organisations.

The background is further explained in the document CA/14/2013 which is available on https://circabc.europa.eu/d/d/workspace/SpacesStore/0b00161d-998b-4990-8f2a-3b26cdce5d68/CA_14_2013 Nano Register.doc

The tenderers are invited to demonstrate their understanding of the objective of the context by further elaborating on the context and how the tender could contribute to achieve the objectives of the contract.

1.3. DESCRIPTION OF TASKS

Task 1: Lessons learned from other schemes

The contractor will be required to gather relevant information on the experience from other nanomaterials register-like schemes, in particular the French nanomaterial declaration system[3], under which the first declarations shall be submitted before 1 May 2013, and the European Cosmetics Regulation, under which nanomaterials in cosmetics need to be notified to the Commission before 11 July 2013. This is intended to cover in particular the following points, differentiating where relevant also between aspects relating to the set-up and operation of schemes:

- Analysis of the number of notifications, substances, quantities and uses concerned
- Analysis of notifiers (small/big companies; research organisms etc.)
- Types of information gathered, differentiated between confidential information and publicly available information
- Assessment of plausibility of information received against other sources such as the Commission Staff Working Paper on Nanomaterial Types and Uses, also via analysis of respective methodologies;

[3] The Commission will discuss ways to assess non-published data with the French authorities while ensuring their confidentiality. Getting access to these data is therefore not part of the tenderers tasks but will be handled by the Commission.

- Assessment of critical issues with respect to the interpretation of terminology (e.g. definition used, scope, calculation of volumes related to volume thresholds) that result in borderline cases whether or not a notification is required.

- Initial information on and, as far as possible, an evaluation of compliance rates and enforcement issues.

- Assessment of effectiveness of communication, information and documentation requirements (e.g. Safety Data Sheet) established by existing EU regulation to support the provision of required information .

- Assessment of the total direct cost for providing requested information by the industry.

- Assessment of the different cost elements, including administrative burden for providing specific pieces of information. Where possible provide as well as a comparison with other accumulated costs (i.e. production and transaction costs, as well as costs of other related regulatory obligations) with a view to enable an assessment of the relative weight of the registration/notification cost

- Description of the distribution of costs of the schemes across various value chain dimensions, sectors and company size classes.

- Assessment of the costs for authorities to administer the notification scheme.

- Presentation of evidence for how gathered information was used by authorities, consumers and workers, as well as assessment of possible future use; this shall inter alia include an assessment of the number of uses of the public and confidential databases and a comparison of detail and user-friendliness of information with other existing information sources, such as the Commission Staff Working Paper on Nanomaterial Types and Uses and the databases mentioned in this Staff Working Paper.

- Model the impact of the availability of the information gathered to the authorities, consumers and workers on long term health and environmental benefits.

- Give an initial assessment of (potential) impacts on competitiveness and innovation in the notifying companies, including an assessment of any issues related to intellectual property and confidential business information arisen in the application of the notification scheme; any known effects, including effects relating to perception of nanomaterials in the public, resulting in a change of the use of concerned nanomaterials (e.g. increased public confidence or stigmatisation resulting in changes in research orientation; substitution of nanomaterials by other materials and vice versa).

- Initial information on possible effects on the internal market.

- Identification of critical elements that would need to be taken into account for extrapolation of results of the FR scheme to the EU level.

The tenderers are invited to provide a detailed work plan based on the above indicative sub-tasks. For this task, the tenders are requested to specify specific modes of implementation, sources of information[4], results assessment, validation techniques, and ensuring acceptability of the results among stakeholders taking note of the planned public consultations and validation workshop (in subsequent tasks). The proposed methodology shall include interviews with authorities and notifying companies where this is necessary to fulfil the above tasks.

Task 2: Background information for building blocks of policy options

To support the Commission in designing the details of the policy options the consultant will provide the following feed information:

- **Profiling Risks and Hazards with a view to assessing potential risks :** an inventory of known hazard properties, known incidents with regard to nanomaterials, and make an assessment of the likelihood and dimension of serious incidents, taking into account DNELs/PNECs/OELs and the associated uncertainties Review those known incidents and develop hypothetical examples, where more information on nanomaterials on the market could prevent them or allow more rapid intervention/action. Characterise what level of information would have been necessary and what would be the likelihood of their (re)occurrence. Compare those elements of information with other past examples of emerging technologies outside nanotechnology, where knowledge on adverse effects developed while technology is already on the market[5].

- **Value chain characterisation**: describe distinctive value chains where nanomaterials are developed, produced, traded or used with specific attention to the competitive position of actors in the value chain:

    - distribution of their sizes and localisations,

    - margins and profits (average and total) and their trends - in absolute values and in comparison to other segments of economy, other 'key enabling technologies' and other segments of chemical industry. To the extent possible, this should also include an assessment of the situation within SMEs

    - direct and indirect employment and growth trends.

- **Growth and Innovation**: give an overview of R&D trends into nanomaterials (in EU and globally), with attention to distribution of R&D funding in specific sectors, patents granted and profiling of companies that invest most in R&D in nanomaterials. Characterise key factors for localisation decisions in the nanomaterials industry for different types of economic activities related to nanomaterials: research, production, distribution, use or consumption. Review, which factors should be of primary regulatory focus to stimulate growth and

[4] The Commission will discuss ways to assess non-published data with the French authorities while ensuring their confidentiality. Getting access to these data is therefore not part of the tenderers tasks but will be handled by the Commission.

[5] This shall take into account the 2013 EEA report "Late lessons from early warnings", see http://www.eea.europa.eu/publications/late-lessons-2.

innovation within EU, including public confidence issues. Evaluate future market trends on nanomaterials. In particular, identify emerging nanomaterials, applications and technologies which could influence the results of an impact assessment in the short, medium and longer term.

- **Indicators on fitness-for-purpose**: what could be principal indicators that would facilitate monitoring of the implementation and impact of transparency measures and support future review, if implemented

The tenderers are invited to provide a detailed work plan based on the above indicative tasks. For this task, the tenderers are requested to specify specific modes of implementation, sources of information, results assessment, validation techniques, and ensuring acceptability of the results among stakeholders taking note of the minimum expectations specified below.

Task 3: Organize and carry out public consultations

A standard practice for all Commission Impact assessment is to organize an on-line public consultation on the policy options being scrutinized (the duration of the consultation will be 3 months).
The Contractor will be responsible for:

- **Identifying information gaps** and information to be validated for the completion of other tasks which would be best addressed through the public consultations taking note of the limits of this tool with regard to lack of sample representativeness. For each item the consultant will propose and justify an exact formulation for the question to be asked in the public consultations. The Commission may add further questions for the public consultation.

- Linguistic advice on formulation of an EN version, and encoding into the public consultation tool (IPM) the questionnaire in all 24 official languages (translation will be provided by the Commission).

- Supporting the Commission in answering questions raised by the participants during the course of the public consultations (depending on the nature of the question, those questions shall be answered by the consultant or the Commission).

- Analyzing the results and consolidating responses provided in a free-text form (attention should be paid to the possibility of the responses being delivered in other EU official languages)

Task 4: Support for the option assessment

This part of the project will closely follow the Impact Assessment Guidelines and will compare the impacts of the main policy options:

- No additional action compared to current instruments and plans (baseline options)

- Structured effort to collect available information from other regulatory registers/databases (such as REACH, CLP, Cosmetics Regulation, French nanomaterial register)

- Single register of nanomaterials at EU level with a sensitivity analysis of impacts of various possible building blocks and their variations (for examples see paper CA/14/2013 section 2.3)).

- Parallel existence of EU transparency measures with (multiple) registers at national level (in particular where the chosen measure is not a single EU register)

- Multiple registers at national level.

- Systems based on market operators reporting or on public authorities gathering the information.

The detailed description of the scenarios will be delivered to the consultant before the start of this phase of the project.

The contribution of the consultant to the option assessment will consist of:

- Modelling potential impacts on health and environment (resulting from specific risk management measures taken by regulators, from different consumer choices and from different risk management for workers) as a result of having the specific information available.

- Assessing administrative and any other costs associated with generating the information for institutions running the scheme and companies participating in the scheme being assessed, differentiated between set-up and operational costs.

- Modelling internal market impacts of the various scenarios.

- Particular aspects and sensitivity analysis will include a number of specific questions:

    - Competitiveness proofing for key sectors with significant external trade exposure

    - Possible impact on jobs and growth

    - Possible impacts on SMEs and micro-enterprises

    - Impact on innovation: IP rights and other CBI, impacts on time to market

    - Possible impacts due to perception issues and possible policy responses

    - Enforcement and compliance

- Verification of impacts on borderline cases relating to the threshold values of the nanomaterial definition (e.g. instance pigments, food powders, food additives, substances used for research in laboratories).

- Proposing possible modifications, where and if appropriate, to the scenarios provided by the Commission which would maximize their cost/benefit performance.

The tenderers are invited to provide for each sub-task, specific modes of implementation, sources of information, results assessment, modelling techniques, validation techniques, and ensuring acceptability of the results among stakeholders taking note of general impact assessment guidelines of the European Commission and more specific ones on measuring impacts on SMEs, competitiveness and administrative burden[6].

Task 5: Validation Workshop

At a suitable stage of the project, in month 7-8 (but before end of the public consultation), the consultant will organize a one day validation workshop to discuss with interested stakeholders preliminary conclusions of the Commission impact assessment.

The consultant will be responsible for:

- Preparing the first draft of the workshop agenda
- Administration of the organization (registration, invitation, secretariat and technical support)
- Contribute to animating the discussion under the overall chairmanship of the Commission
- Drafting a workshop report.

The Commission will provide a room for the workshop.

Task 6: Reserve for unexpected developments.

10% of the resources for the contract shall be reserved for additional issues arising during the contract, to be defined in agreement between the Commission and the contractor. If this is not used, this shall go into more work on the previous tasks.

1.4. PROJECT ORGANISATION

For the purpose of this project the Commission will nominate a specific Steering Group, consisting of representatives from a number of Commission services. Representatives from Commission Agencies and other stakeholders may be invited on a case by case basis. The role of the Steering group is to discuss the progress of the work and the next steps between the Commission and the contractor. The steering group will aim to work on the basis of consensus. The ultimate responsibility for clarifying feedback to the consultant will be with the responsible Commission service for the contract. The steering

6 http://ec.europa.eu/governance/impact/index_en.htm

group will meet with the contractor at least 4 times (kick-off meeting, 2 progress meetings, and a pre-final meeting). The meetings will be in Brussels. By way of exception, out of the four meetings, a maximum of two meetings can be held via telephone or video conference. **The contractor pays for his own travelling costs.**

Appropriate quality control mechanisms need to be put in place and should be described in the tender. The tender should propose technically feasible means to ensure continuous oversight from the side of the contractor and the Commission and proper communication at all stages of the project. Means such as biweekly phone conferences, closed internet forum, etc. should be explored in the tender. The Commission will designate principal project supervisors from DG ENTR and DG ENV to conduct regular oversight over the implementation of the project.

The working language for the execution of all tasks is English.

1.5. REPORTS AND OTHER DOCUMENTS

The Contractor will be requested to provide the required reports and documents in accordance with the conditions of the standard service contract appended in Annex 6.2. All Documents must be provided in electronically editable format and written in English.

- **Meeting minutes** – for each meeting of the steering group the contractor will provide written minutes within a week and address any comments notified to the contractor within the following 7 working days. The steering group will provide its comments within 7 working days.

- **Inception Paper** – will be delivered two weeks before the kick-off meeting, taking place within 6 weeks after the signature. The report will need to include:

    - Refined and more detailed work plan for all tasks.

    - **Task 1:** Refine evaluation program and methodology (to be part (b) of the evaluation report (see next point)

    - **Task 2:** Methodology for the building blocks

- **Evaluation Report** – This report will document the findings established in Task 1. The report should contain: (a) executive summary (maximum 5 pages), (b) description of the evaluation methodology, (c) findings, (d) assessment and recommendations for EU policy directions.

  This report will be developed in the following sequence:

    - by month 3: **first draft** with sections (b) and (c)[7].

    - by month 5: **second draft** with sections (a),(b), (c) and (d) – delivered two weeks before for the first progress meeting.

[7] Subject to the availability of access to the necessary data from French authorities.

- by month 7: **final version**, after incorporating any comments provided by the Commission to the second draft within 30 days of the delivery.

The final version of this report may be subject to further comments by the Commission within two weeks after receipt of the final version of the report. If applicable, those comments shall be integrated by the consultant within five working days. An accepted final version of this report will be required for the request for interim payment.

- **Building Blocks Report** – This report will contain result of the analysis and data gathering activities performed under Task 2. This report will contain an (a) executive summary (maximum 5 pages), (b) methodology for each distinctive area of interest as defined under point 1.3 Task 2 and (c) findings for each area of interest.

  - By month 5: first draft with section (b) – delivered two weeks before the first progress meeting.

  - By month 7: second draft with sections (a), (b) and (c) – delivered two weeks before the second progress meeting.

  - By month 9: final version, after incorporating any comments provided by the steering group to the second draft within 30 days of the delivery.

- **Options Assessment Report** – This report will contain result of the analysis and data gathering activities performed under **Task 3, 4 and 5**. This report will contain (a) an executive summary (maximum 5 pages), (b) options definition (c) options assessment methodology, (d) findings including sub-sections on conclusions from public consultations and a validation workshop, (e) options comparison and conclusions.

  The timing for this report begins with the Commission providing the consultant with the description of policy options (n) – expected in month 7.

  - By month n: first draft with section (c) – delivered two weeks before the second progress meeting.

  - By month n+2: second draft with sections (b), (c) and (d).

  - By month n+4: third draft version with sections (a - e) – provided two weeks before the pre-final meeting.

  - By month n+6: **final version**, after incorporating any comments provided by the steering group to the second draft within 30 days of the delivery.

  The final versions of both the *Building blocks* report and the *Options Assessment* reports may be subject to further comments by the Commission within two weeks after receipt of the final version of the report. If applicable, those comments shall be integrated by the consultant within five working days. An accepted final version of all reports, submitted in PDF format and on paper (3 copies) will be required for the request for final payment.

The accuracy of the data produced and published will be under the full responsibility of the contractor. The sources of the data must always be clearly identified. Assumptions and calculations should be made fully transparent.

1.6. TIME FRAME

The tender must include a description of the proposed team, its composition, its expertise and the work effort planned for each member in terms of man/days for each phase of the project, taking into account this indicative time-framework:

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Contract Signature															
Inception Paper		☑													
Evaluation Report			❶		❷		☑								
Building Blocks Report					❶		❷		☑						
Options Assessment Report							❶		❷		❸		☑		
Public Consultations						●	●	●							
Validation Workshop								◆							
Progress Meetings		①			②			③			④				
Meeting minutes		☑			☑			☑			☑				
Payments	❖						⇘	◆					⇘	◆	