#### Specifications - Open Invitation to tender No VT/2011/039

Study service contract to establish the potential impact of Nanomaterials & Nanotechnology at the Workplace, evaluate the scope and requirements of possible modifications of relevant EU Safety & Health at Work legislation and elaborate a guidance document to accommodate corresponding risks/concerns, with a view to ultimately ensure adequate protection of workers health and safety from risks inherent to exposure to Nanomaterials and/or Nanotechnology use.

# 1. TITLE OF THE CONTRACT

Study service contract to establish the potential impact of Nanomaterials & Nanotechnology in the Workplace, evaluate the need and scope of possible modifications of relevant EU Safety & Health at Work legislation and elaborate a guidance document to accommodate corresponding risks/concerns, with a view to ultimately ensure adequate protection of workers health and safety from risks inherent to exposure to Nanomaterials and/or Nanotechnology use.

# 2. BACKGROUND

#### 2.1. PROGRESS Introduction

PROGRESS<sup>1</sup> is the EU employment and social solidarity programme, set up to provide financial support for the attainment of the European Union's objectives in employment, social affairs and equal opportunities as set out in the Social Agenda<sup>2</sup>, as well as to the objectives of the Europe 2020 Strategy. This new strategy, which has a strong social dimension, aims at turning the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion. The European Union needs coherent and complementary contributions from different policy strands, methods and instruments, including the PROGRESS programme, to support the Member States in delivering on the Europe 2020's goals.

The PROGRESS mission is to strengthen the EU's contribution in support of Member States' commitments and efforts to create more and better jobs and to build a more cohesive society. To this effect, PROGRESS is instrumental in:

- Providing analysis and policy advice on PROGRESS policy areas;
- Monitoring and reporting on the implementation of EU legislation and policies in PROGRESS policy areas;
- Promoting policy transfer, learning and support among Member States on EU objectives and priorities; and
- Relaying the views of the stakeholders and society at large.

More specifically, PROGRESS supports:

- The implementation of the European Employment Strategy (section 1);
- The implementation of the open method of coordination in the field of social protection and inclusion (section 2);
- The improvement of the working environment and conditions including health and safety at work and reconciling work and family life (section 3);
- The effective implementation of the principle of non-discrimination and promotion of its mainstreaming in all EU policies (section 4);

<sup>1</sup> Decision No 1672/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Community Programme for Employment and Social Solidarity — Progress, JO L 315 of 15.11.2006

<sup>2</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Renewed social agenda: Opportunities, access and solidarity in 21st century Europe COM/2008/0412 final of 02.07.2008.

• The effective implementation of the principle of gender equality and promotion of its mainstreaming in all EU policies (section 5).

The present call for tenders is issued in the context of the implementation of the 2011 annual work plan which can be consulted at <u>http://ec.europa.eu/social/main.jsp?catId=658&langId=fr</u>

# 2.2. Background information specific to this contract

# What is nanotechnology, what benefits can it provide and what workplace health and safety problems does it pose?

Nanotechnology is an emerging, cross-disciplinary science that incorporates nanoscale (i.e. one billionth of a metre) particulates into the development of new products and applications.

As this technology matures and thrives, international, *e.g.* OECD, and governmental regulatory agencies throughout the world, have now begun to focus on a perceptual 'risk/benefit' equation as a societal value consideration. In fact, products of nanotechnology have the potential to provide a wide range of benefits to, *inter alia*, consumers (*e.g.* food and cosmetics), workers, agriculture, environment, industry and medical applications, all promising to contributing to a higher standard of living.

Advances in new forms of energy generation (*e.g.* photovoltaics) and storage (*e.g.* fuel cells and batteries), environmental treatment and remediation (*e.g.* soil and groundwater remediation) and health care (*e.g.* targeted drug delivery) are already a reality. Nanomaterials' catalytic, electrical, magnetic, mechanical, optical and/or biological properties and combinations of them can be selectively adjusted at the nanoscale to optimise functionality and properties of almost any material class and finished products. As some of the features can be only obtained via nanotechnologies, their application can become a survival question for the competitiveness of companies, while in some other sectors nanotechnology applications yet only offer technical advantages over the nonnanoapplications, but are not yet necessarily price competitive.

The direct employment generation impact of nanotechnology is estimated to be around 2.3 million jobs worldwide by 2015, of which 0.9 million in USA and 0.4 in Europe. These forecasts have been reflected in funding for research, which at the global level has doubled from around 6.5 billion € in 2004 to around 12.5 billion in 2008. The EU member states perform well in terms of R&D, especially in terms of scientific publication activity in areas such as nanochemistry but also in nanoelectronics and nanomedicine. This is also reflected in patenting activity, although the EU is lagging behind Japan and USA in all the other sectors except aerospace, automotive & transportation and construction.

Currently, despite its leadership in research publications, the EU lags behind the US and Japan in terms of private sector uptake. And as far as research targeting is concerned the focus of nanotechnology based R&D has essentially been at the applications level (*i.e.* designing and constructing nanoparticles with novel properties) with some at the level of environment and health and safety effects, but the bulk of research funds is going for applications research.

Despite this funding disparity, it is now generally recognised that the assessment of human health and ecological implications of exposure to nanoscale materials are necessary prerequisites before the commercial benefits of this technology can be fully realised.

But such benefits and potential may be offset or compromised by some possible human health (both at consumers and workers level) and environmental effects. Given the paucity of meaningful health effects data for nanomaterials (**hereafter denominated NMs**) that has showed up so far, there is growing concern about their potential risks and therefore assumptions have been made regarding their possible human health effects. This is because

the hazard database for virtually all nanoparticle types is largely incomplete. Moreover, the usefulness of the few published toxicity studies is arguably limited, due still in large part to study design limitations, including at the level of justification for dose selection or route of exposure criteria.

In parallel, serious concerns have been expressed in particular relative to possible long term health effects that NMs could present, some of which could have mechanisms of action similar to those of asbestos, where it is well known that the effects on human health do not normally materialise before very long latency periods. A more recent example of a concrete concern is provided by airborne super-small particles of titanium dioxide which the US NIOSH (National Institute for Occupational Safety and Health) has just concluded should be considered a potential occupational carcinogen<sup>3</sup>.

All such considerations should be subordinated to the principle that it is important to relate the information on hazards and exposure with the benefits of the various applications of NMs and nanotechnologies (risk/benefit ratio). There is a difference on whether a NM is used for life saving purposes (*e.g.* cancer drugs) or purely for convenience or fashion related reasons. There is also a difference on whether the adequate assessment of risk is imposed in advance (pre-market authorisation) or the responsibility is only implied. Finally there is a difference between uses in well controlled circumstances with little potential exposure and uses where widespread exposure of human beings or the environment can be expected.

Consequently, it is of the utmost importance to stimulate a thoughtful consideration of pertinent testing aspects for evaluating human health effects in general, and on workers in particular, as well as trying to come up with concrete and particularly practical preventive risk management approaches. The implementation of risk assessment methodologies has to take account of the classical components, *i.e.* hazard assessment and exposure, on the understanding that effects of NMs may be substantially different from those of the same material/chemical in bulk form.

This knowledge gap is a potential obstacle for sustainable growth and innovation in this sector, as public acceptance of goods developed by or using new technologies has tended to depend on reliable and transparently communicated safety information. But the European Union (and the world) is currently still faced with a situation where safety information for most NMs currently on the market is incomplete and hence there is insufficient reassurance that these materials may be used safely.

#### Commission role and activities – past and ongoing

As a response to growing concern about the risks of nanotechnologies, in 2008 the Commission adopted a Communication<sup>4</sup> on how existing legislation covers the safety aspects of NMs. The communication concluded that although NMs are in principle covered by the various regulatory frameworks, there are difficulties at the implementation level due to the lack of available safety information needed for hazard and risk assessments. The Commission concluded that further work at implementation level, as well as more research, are needed and would report on progress by June 2011 to the Council and EP.

The Commission also adopted in 2008 a Recommendation for a Code of Conduct for Responsible Nanotechnologies and Nanosciences Research<sup>5</sup> (endorsed by the Council in 2009)<sup>6</sup> that pays special attention to the health and safety aspects of research undertaken in the field of nanosciences requesting *'students, researchers and research organisations involved in N&N research {...}* (to) take specific health, safety and environmental measures adapted to the particularities of the nano-objects manipulated. Special reference was made to the possibility of developing specific guidelines on the prevention of pathologies induced

<sup>3</sup> http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf

<sup>4</sup> COM(2008) 366 final. Regulatory aspects of nanomaterials, and SEC(2008) 2036 final

<sup>5</sup> http://ec.europa.eu/research/science-society/document\_library/pdf\_06/nanocode-recommendation-pe0894c08424\_en.pdf

<sup>6</sup> http://register.consilium.europa.eu/pdf/en/08/st13/st13672.en08.pdf

by nano-objects in line with the Community Strategy 2007-2012 on Health and Safety at Work.

The overall Commission Policy for Nanotechnology was expressed in the Action Plan 2005-2009<sup>7</sup>. This is expected to be continued by a European Roadmap for Innovating with Nanotechnologies 2011-2015 which should provide an overarching framework presenting coherently the different aspects of research, innovation, safety and environment protection policy.

Thus, as far as protection of workers health and safety from possible risks inherent to exposure to NMs and/or nanotechnology use are concerned, the current EU Occupational Safety and Health (OSH) legal framework covers such risks even if only by default. Such coverage is essentially provided for by Council Directive 89/391/EEC<sup>8</sup> on the introduction of measures to encourage improvements in the safety and health of workers at work and some of its 'daughter' directives. However, should significant new information become available indicating the need to amend OSH legislation then any decisions to revise it should be taken, *inter alia*, on such a basis.

The results of this study should help bridge this information gap in order to widen as much as possible the information base. The EU Commission has also introduced the issue of nanomaterials, in terms of risk assessment and management in EU workplaces, in the framework of the Advisory Committee on Safety and Health at Work's activities' and in particular its Working Party on Chemicals.

Similarly, a role is expected from the EU SCOEL (Scientific Committee on Occupational Exposure Limits). The SCOEL should ensure that its methodology remains appropriate when addressing the evaluation of nanomaterials and consider how information is presented in SCOEL Recommendations particularly where different physical forms of the same substance/compound may exist *e.g.* TiO2. When requested, SCOEL is expected to review existing data on a chemical in the form of nanomaterial, which may produce different effects from those of the bulk material and may also be robust enough to allow for the establishment of an Occupational Exposure Limit (OEL).

#### European Parliament Resolution

In April 2009, the European Parliament adopted a resolution on NMs<sup>9</sup> by a very large majority. The Resolution expressed strong scepticism *vis à vis* the Commission's conclusions, particularly that NMs are in principle covered by the various EU regulatory frameworks, and requested a more solid and in-depth review<sup>10</sup> of legislation. In particular, the EP requested that the June 2011 review should address actual applications of NMs and include a market inventory.

Also, and specifically on workers protection, in point 14 of the Resolution, the EP underlined the importance for the Commission and/or Member States to ensure full compliance with, and enforcement of, the principles of Community legislation on the health and safety of workers when dealing with nanomaterials, including adequate training for health and safety specialists, to prevent potentially harmful exposure to nanomaterials.

COM(2007) 505 final. Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007 8 Official Journal L 183, 29.6.1989 p.1

<sup>7</sup> COM(2007)243 final. Nanosciences and nanotechnologies: An action plan for Europe 2005-2Ü09. O J C 306 E, 15.12.2006, p. 426

<sup>9</sup> P6\_TA(2009)0328. European Parliament Resolution of 24 April 2009 on regulatory aspects of nanomaterials (2005/2208/INI)

<sup>10</sup> The word 'review' is understood here, and that is how it should be interpreted throughout the text of this call for tender, to mean an analysis of whether or not, the current EU-OSH legal framework covers sufficiently and appropriately any potential risks posed by NMS and/or Nanotechnology in the workplace. In this sense it is fundamentally different from the word 'revision', this one implying the very process of change to said legal framework.

And on point 15 of the resolution, the EP called on the Commission to evaluate the need to review worker protection legislation concerning, inter alia:

- the use of nanomaterials only in closed systems or in other ways that exclude exposure of workers as long as it is not possible to reliably detect and control exposure,
- a clear assignment of liability to producers and employers arising from the use of nanomaterials,
- whether all exposure routes (inhalation, dermal and other) are addressed;

Other points of the EP Resolution also impact, albeit indirectly, on the Workers protection legal framework, *e. g.* points 21 and 22, and the contractor is invited to take this information on board. Bidders to this call for tender are strongly advised to duly consider and understand the full text of the Resolution in view of obtaining an insight about an important aspect of the political context in which the Commission is operating regarding NMs.

#### Definition of 'Nanomaterial'

At the time of drafting these technical specifications the European Commission is still discussing internally what exact definition of 'nanomaterial' it will adopt for the purposes of its own internal dealings, possible legislative implications and applications and how it will communicate externally whenever a definition of a nanomaterial may be at stake.

The contractor should try and keep up with developments on the mentioned European Commission definition and duly consider it for the purposes of the elaboration of the report and guidance document. However, because part of the tasks imply referring to activities carried out by different sets of stakeholders, other definitions and associated documents should also be borne in mind namely, but not exclusively, those of the SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) and ISO's as well as other relevant ones that the contractor will deem robust enough for the purposes of the study report to be contracted under this call for tender.

As regards the NMs size range to consider some believe that such a range may practically be set between 1nm and 100nm, but the contractor will rather consider an unspecified size range – the nanoscale range – and accept any values below and particularly above the mentioned upper one; this may be of up to at least 1000nm in principle.

Other parameters conventionally used in NMs definitions, like number size range and specific surface area by volume, as well as a range of concepts normally associated to them such as those of 'particle', 'aggregates' and 'agglomerates' should be also taken into consideration. The 'bottom line' for the contractor however, in order for it to make sense of which exact NMs should be considered for the purposes of elaborating the report and guidance document, is that a wide definition paradigm, *i.e.* one that is as widely encompassing as possible, should be used.

Finally, considerations on whether the focus of the report is on manufactured NMs or naturally occurring ones, or even nanomaterials that are by-products of processes, the contractor will bear in mind that, while the focus of the report should cover essentially the manufactured ones, i.e. NMs that have been specifically manufactured to take advantage of their properties at the nanoscale, by-products of processes and naturally occurring NMs should also be borne in mind and addressed in the report, should their implications at OSH level so justify.

#### The workplace contexts - specific and general

#### Nanomaterials and the construction industry – an example.

The nanotechnology revolution is having a profound impact on diverse science, engineering, and commercial sectors, including the construction industry. This industry sector is used here by way of example with what may be considered likely scenarios that are, in this particular case, information based.

The construction industry is traditionally a sensitive one from a safety angle because of its typical high incidence of accidents and fatalities. Hence, any demonstrable points proving that technological innovation in the industry may be in the process of making the respective workers potentially suffer from additional/new risks do go some away towards demonstrating the need to take preventive and/or corrective action for the benefit of a workforce that is already marred by serious workplace concerns.

In fact, the physical and chemical properties unique to the nanoscale can lead to remarkable efficacy enhancement in (photo)catalysis, (thermal and electrical) conductivity, mechanical strength, and optical sensitivity, enabling applications such as catalysts, electronic and energy storage devices, advanced mechanical materials, and sensors.<sup>11 12 13 14</sup>

Consequently the construction industry recently started seeking ways to improve conventional construction materials using a variety of NMs<sup>15 16 17</sup>. Various NMs can improve vital characteristics of construction materials such as strength, durability, and lightness<sup>13 18 19</sup>, add useful properties (e.g., heat-insulating, self-cleaning, and antifogging)<sup>20 21</sup> and function as key sensing components to monitor construction safety and structural health<sup>22 23</sup>. Despite the current relatively high cost of nano-enabled products, their use in construction materials is likely to increase because of:

1. Highly valuable properties imparted at relatively low additive ratios;

2. Rapid development of new applications harnessing unique nanoscale properties;

3. Decreasing cost of base nanomaterials as they are produced in larger quantities (economies of scale).

But the benefits of incorporating NMs in construction materials could be offset by concerns about their capacity to behave as harmful human health and environmental contaminants after their incidental and/or accidental release – and there is indeed a significant potential for such contamination to come about as will be demonstrated below.

#### Occupational Exposure

The inhalation of NMs during coating, molding, compounding, and incorporation can pose a respiratory health risk to workers. A risk assessment worksheet on nano-TiO2<sup>24</sup> showed that occupational exposure exceeded the acceptable limit in packaging processes. For some

<sup>11</sup> Tans, S. J.; Verschueren, A. R. M.; Dekker, C. Room-Temperature Transistor Based on a Single Carbon Nanotube. Nature 1998, 393, 49–52

<sup>12</sup>Daniel, M. C.; Astruc, D. Gold Nanoparticles: Assembly, Supramolecular Chemistry, Quantum-Size-Related Properties, and Applications toward Biology, Catalysis, and Nanotechnology. Chem. Rev. 2004, 104, 293–346

<sup>13</sup> Chan, W. C. W.; Maxwell, D. J.; Gao, X. H.; Bailey, R. E.; Han, M. Y.; Nie, S. M. Luminescent Quantum Dots for Multiplexed Biological Detection and Imaging. Curr. Opin.Biotechnol. 2002, 13, 40–46

<sup>14</sup> Arico, A. S.; Bruce, P.; Scrosati, B.; Tarascon, J. M.; Van Schalkwijk, W. Nanostructured Materials for Advanced Energy Conversion and Storage Devices. Nat. Mater. 2005, 4, 366–377

<sup>15</sup> Ge, Z.; Gao, Z. Applications of Nanotechnology and Nanomaterials in Construction. First International Conference on Construction in Developing Countries, 2008; pp 235\_240 16 Mann, S. Nanotechnology and Construction. Nanoforum Report May 30, 2006

<sup>17</sup> Zhu, W.; Bartos, P. J. M.; Porro, A. Application of Nanotechnology in ConstructionOSummary of a State-ofthe-Art Report. Mater. Struct. 2004, 37, 649–658

<sup>18</sup> Li, G. Y. Properties of High-Volume Fly Ash Concrete Incorporating Nano-SiO2. Cem. Concr. Res. 2004, 34, 1043–1049

<sup>19</sup> Sobolev, K.; Gutierrez, M. F. How Nanotechnology Can Change the Concrete World. Am. Ceram. Soc. Bull. 2005, 84, 16–20

<sup>20</sup> Irie, H.; Sunada, K.; Hashimoto, K. Recent Developments in TiO2 Photocatalysis: Novel Applications to Interior Ecology Materials and Energy Saving Systems. Electrochemistry 2004, 72, 807–812

<sup>21</sup> Kumar, A.; Vemula, P. K.; Ajayan, P. M.; John, G. Silver-Nanoparticle-Embedded Antimicrobial Paints Based on Vegetable Oil. Nat. Mater. 2008, 7, 236–241

<sup>22</sup> Zhang, W.; Suhr, J.; Koratkar, N. Carbon Nanotube/Polycarbonate Composites as Multifunctional Strain Sensors. J. Nanosci. Nanotechnol. 2006, 6, 960–964

<sup>23</sup> Saafi, M.; Romine, P. Nano- and Microtechnology. Concr.Int. 2005, 27, 28–34

<sup>24</sup> Nanomaterial Risk Assessment Worksheet; DuPont TM Light Stabilizer, June 21, 2007; pp 1\_52.

NMs, worker exposure may also occur during production and processing before incorporation into products.

Aerosolized carbon NMs can also be generated during aqueous dispersion of fullerenes and CNTs *via* sonication, while airborne particles are emitted during weighing<sup>25</sup>. Therefore, air monitoring during the overall manufacturing processes should be periodically conducted over entire operation areas. Manufacturing of NMs in sufficient amounts that can be used for construction purposes requires significant scale up and potentially different controls and backups. The lack of material descriptors (*e.g.*, Material Safety Data Sheets – MSDS - for NMs) further limits the development and enforcement of handling and safety standards.

Also, some NMS may display different material forms during their lifecycles, which impact on the potential for occupational exposure. For example, sepiolite clay (used as a nanofiller for nanocomposite applications) can be found as free powder as received from suppliers, as slurries prior to polymerization, and as pellets encapsulated in the PET poly(ethylene terephthalate) resins in commercialized products<sup>26</sup>. Potential occupational exposure to sepiolite (and the associated health risks) is higher for the earlier processing steps and decreases after incorporation into the polymer resin. A risk analysis for sepiolite reported that clay mines treated the nanoclays as nuisance dust, while full exposure controls were used at the factory.

Given this state of affairs, provision of engineering controls (*e.g.* ventilation systems and dust collectors) and personal protective equipment (*e.g.* masks, coveralls and gloves) may have to be considered for enclosed manufacturing facilities, along with personal monitoring and medical check-up on dermal, respiratory, and optical exposure. Also, and since construction activities predominantly occur in outdoor environments, advocating the use of personal protective devices such as air filter masks, gloves, safety goggles, and visors could equally be considered appropriate. But environmental health and safety controls that may be used within a company are not necessarily and consistently applied across the industry.

Such scenarios underscore the need for proactive risk assessment and guidelines (eventually including some of a regulatory nature) to ensure the safe use and disposal of products containing NMs<sup>27</sup>. But particularly because of the acknowledged paucity if not total absence of validated test methods that could be used to demonstrate, or otherwise, any hazardous properties that NMs can have, together with the wide range of exposure scenarios possible, there is, at the very minimum, a need for a range of precautionary approaches based on the (limited) information available.

For all the above, it can be reasonably assumed that, in other industry sectors/workplaces where the use of NMs is also increasing, comparable scenarios are likely and a corresponding set of concerns is justified. The NMs may be different as may the respective uses and exposure scenarios but the potential for likely health effects cannot be dismissed outright, making the need for practical risk management approaches even more pressing, particularly as there is as yet no clear indication as to when exactly will validated test methods and exposure scenarios be available that concerned professionals, which includes manufacturers, downstream professional users and ultimately regulators, can rely on.

<sup>25</sup> Johnson, D. R.; Methner, M. M.; Kennedy, A. J.; Steevens, J. A. Potential for Occupational Exposure to Engineerd Carbon-Based Nanomaterials in Environmental Laboratory Studies. Environ. Health Perspect. 2010, 118, 49–54.

<sup>26</sup> DuPont TM Crystar 6920 PET Poly(ethylene terephthalate)Resin with Sepiolite Clay, Pangel S-9 as an Encapsulated Nanodispersed Filler; June 23, 2008; pp 1\_35.

<sup>27</sup> Lee, J.; Mahendra, S.; Alvarez, P. J. J. Potential Environmental Impacts of Nanomaterials Used in the Construction Industry. In Nanotechnology in Construction -3; Bittnar, Z., Zeman, J., Nemecek, J., Smilauer, V., Bartos, P. J. M., Eds.; Springer Verlag: Berlin, 2009; pp 1\_14.

#### 2.2.1 Purpose of the study contract

This study contract has three objectives. The first is to provide the European Commission with information on the suitability, or otherwise, of the current EU legal framework on workers health and safety protection (hereafter denominated as OSH, for Occupational Health and Safety) relative to potential or identified hazards and risks posed by Nanomaterials (NMS) and Nanotechnology that workers are likely to come into contact with or use in their daily professional activities.

To do this due consideration shall be given to the current coverage and scope of a number of EU-OSH legal instruments, some of a legally binding nature and some not. This should serve as a springboard for possible future amendments that may bring them 'up to speed' relative to NMs / Nanotechnology specific risks. An indicative list of relevant EU OSH legal instruments is included under section 3 below – the final list will be agreed between Commission and contractor.

**The second objective** is to develop a **range of scenarios**, and identify the pros and cons of each with the ultimate objective of providing a sufficiently robust information base on which the Commission may ensure that workers are effectively protected from risks to their health and safety arising from exposure to nanomaterials at the workplace.

The contractor will have to take account of health, socio-economic and, if relevant, also environmental consequences of all scenarios deserving consideration, related either to possible amendments of existing EU-OSH legal instruments (that the contractor will take great care identifying and justifying), drafting of new ones or of alternative solutions, *e.g.* voluntary agreements, guidance documents, information campaigns or any combinations thereof.

Concurrently, and on the understanding that the current *status quo* is such that no established NMs / technology workplace specific risk management practices exist as yet that might have been validated internationally, **a guidance document shall also be drafted** to help employers and workers alike fulfil their obligations, namely those under the provisions of Framework Directive 89/391/EEC, whenever contact with NMs or use of Nanotechnology in a professional capacity is known or likely to take place; **this is the third objective**.

#### 3. SUBJECT AND SCOPE OF THE STUDY

#### 3.1 SUBJECT OF THE STUDY

The subject of the study is:

- To analyse the suitability of the EU-OSH legal framework in its current form relative to Nano specific workplace risks,
- To elaborate possible scenarios as referred to in point 2.2.1, individually or, possibly for a number of selected ones, combined.
- In parallel, a Guidance document shall be prepared that addresses actual shortcomings in a realistic manner.

Any available evidence supporting the possible inclusion of NMs / Nanotechnology under the scope of any identifiable EU-OSH legal instrument should be considered.

The contractor should provide information as up to date as possible, <u>duly supported by references</u> to <u>published data</u> and <u>relevant ongoing activities</u> to enable the European Commission to initiate policy discussions on any options deemed justified. Such policy discussions will be informed, inter alia, by the result of the analysis of the EU-OSH legal framework and other information deemed relevant and/or necessary, including stakeholders' consultation.

To provide a comprehensive view of the situation that could result from the amendment of the EU-OSH legal framework as described above, the contractor will have to accomplish the different tasks specifically mentioned under point 5.

The full study will address the situation in EU Member States together with the countries ,which are not EU member States but which form part of the European Economic Area.

# 3.2. SCOPE OF THE STUDY

In line with the objectives described under 2.2.1 the scope of the study is <u>threefold:</u> <u>A</u>, <u>B</u> and <u>C</u>:

**A. EU-OSH legal framework review** in order to adequately ensure safety for applications of NMs (and/or use of nanotechnology) with potential health and safety at work consequences over their life cycle, and to ascertain, whether existing legislative provisions and instruments of implementation address the particular features of NMs (manufactured, naturally occurring or by-products of processes) to which workers may be exposed.

In the 1<sup>st</sup> instance the acts listed below should be considered and assessed (the final list of legislation to be included in the review will be agreed between Commission and contractor).

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work *Official Journal L 183, 29/06/1989 P. 0001 0008*
- Council Directive 89/654/EEC of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) Official Journal L 393, 30/12/1989 P. 0001 – 0012
- Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (Text with EEA relevance) *Official Journal L 260, 3.10.2009, p. 5–19*
- Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC)
   Official Journal L 393, 30/12/1989 P. 0018 0028
- Council Directive 92/57/EEC of 24 June 1992 on the implementation of minimum safety and health requirements at temporary or mobile construction sites (eighth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) *Official Journal L* 245, 26.8.1992, p. 6–22
- Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) Official Journal L 348, 28.11.1992, p. 1
- Directive 92/91/CEE du Conseil, du 3 novembre 1992, concernant les prescriptions minimales visant à améliorer la protection en matière de sécurité et de santé des travailleurs des industries extractives par forage (onzième directive particulière au sens de l'article 16 paragraphe 1 de la directive 89/391/CEE)

Official Journal L 348 du 28.11.1992, p. 9–24

- Council Directive 92/104/EEC of 3 December 1992 on the minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries (twelfth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)
   Official Journal L 404, 31/12/1992 P. 0010 – 0025
- 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) *Official Journal L 131, 5.5.1998, p. 11–23*
- Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Text with EEA relevance)
   Official Journal L 142, 16.6.2000, p. 47–50
- Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC (Text with EEA relevance)
   Official Journal L 38, 9.2.2006, p. 36–39
   Official Journal L 330M, 28.11.2006, p. 158–161 (MT)
- 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) (codified version) (Text with EEA relevance) Official Journal L 158, 30.4.2004, p. 50–76
- Commission Decision 95/320/EC of 12 July 1995 setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents Official Journal L 188, 09/08/1995 P. 0014 – 0015
- Commission Recommendation 670/2003/EC, of 19 September 2003 concerning the European schedule of occupational diseases (Text with EEA relevance) (notified under document number C(2003) 3297)
   Official Journal L 238, 25/09/2003 P. 0028 – 0034
- Communication from the Commission on the Guidelines on the assessment of the chemical, physical and biological agents and industrial processes considered hazardous for the safety or health of pregnant workers and workers who have recently given birth or are breastfeeding (Council Directive 92/85/EEC) /\*COM/2000/0466 final\*/
- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions on the practical implementation of the provisions of the Health and Safety at Work Directives 89/391 (Framework Directive), 89/654 (Workplaces), 89/655 (Work Equipment), 89/656 (Personal Protective Equipment), 90/269 (Manual Handling of Loads) and 90/270 (Display Screen Equipment) /\* COM/2004/0062 final \*/
- Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee concerning the Guidelines of a nonbinding nature for implementing certain provisions of Directive 98/24/EC of the

Council on the protection of the health and safety of workers form the risks related to chemical agents at work {SEC(2004) 1594} /\* COM/2004/0819 final \*/

<u>Note:</u> Some of the acts listed above are not, either (i) of a legally binding nature in a strict sense, *e.g.* Commission Recommendation 670/2003/EC, or (ii) of a sufficiently typical subject specific nature, making their inclusion in the list seemingly misplaced, but, for example, Commission Decisions setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents could have taken account of the need to ensure that availability in the committee of an expertise in the Nanos field was sufficiently and explicitly covered. – it is in this sense that they are 'Nano specific', at least potentially.

In the event that relevant EU-OSH legal instruments may be in the process of development, either new or in the form of amendments or adaptations to technical progress of existing ones, *e.g.* in the OSH chemicals field, the contractor will be provided access to the relevant interim deliverables so the results of this ongoing work may be taken into account as much as possible.

Other pieces of EU legislation may be relevant for the effective implementation of OSH legislation and while such legislation is outside of the scope of the review, it may be invoked when NMs or Nanotechnology may be identified within its scope in a way that may be deemed to likely impact on OSH. This may be the case of REACH Regulation 1907/2006 and CLP Regulation 1272/2008 which while not part of the in-depth analysis to be carried out under this contract are definitively relevant in this context.

For this part of the contract the results will be inputted in a background report containing a review and an assessment of the suitability of the current EU-OSH legal framework, or where identified, the revision needs that can be considered by the Commission for the purposes of ascertaining, whether or not an adaptation of the current EU-OSH legal framework, or indeed the drafting of new legal instruments, is in order.

Apart from the analytical aspect of this part of the contract (any act agreed to be included in the list should be the object of an individual assessment as to its suitability and potential candidacy for being amended in the light of the concluded need to take account of the properties of NMs) the contractor is also expected to summarise the conclusions globally, maybe in tabulated form / scoreboard, in a way that clearly provides almost an 'instant snapshot' of the outcome of the analytical exercise in its globality.

#### B. Elaboration of scenarios

Based on the conclusions arrived at under part A, the contractor will elaborate scenarios aimed at highlighting and correcting any shortcomings that the review may make clear relative to the theoretical non-suitability of the current EU-OSH legal framework. The scenarios so indentified shall be duly justified and draw, not only on the conclusions of the EU-OSH legal framework review, but also on consultation of relevant stakeholders *e.g.* social partners, national, regional and local authorities in the Member States, enterprises or non-governmental organisations and concrete business examples (case-studies). Obtaining data from concrete examples is an integral part of the data gathering needed to duly inform this analytical step.

**C. Draft a guidance document** that will help all stakeholders concerned better address potential risks to workers likely to come about from their exposure to NMs and/or use of Nanotechnology. The guidance document will be complemented by **associated materials** for the purposes of **an information campaign** for the benefit of concerned workers.

In gathering the necessary information a workplace NMs exposure and nanotechnology use assessment will have to be carried out including, *inter alia*:

**a)** The types, uses and likely exposures and which workers are more likely to be exposed as well as future exposure trends based on current knowledge.

**b)** The specific information requirements for risk assessment and what are the more significant gaps relative to workplace risk assessment needs (conclusions arrived at under this point may not be immediately 'transferable' but may provide an insight as to which immediately available risk management approaches can compensate for such gaps).

c) Identification of types and effectiveness of risk management measures relevant in this context.

**d)** Based on current knowledge, and to the extent possible, identification of whether the mode of action of NMs is similar or different from traditional work based chemicals, *e.g.* whether or not there is an increased risk from the dermal and inhalation exposure routes.

**e)** State of the art regarding measurement and monitoring approaches and techniques, *e.g.* have national or other Occupational Exposure Limits setting bodies any standards in place and/or whether there are already any associated measurement methodologies.

Conclusions arrived at when addressing this part of the contract may be feeded back and used to review the appropriateness of current EU-OSH legislation to protect workers from potential risks posed by NMs and/or nanotechnology in EU workplaces.

#### 4. PARTICIPATION

Please note that:

The competition is open to any physical person or legal entity coming within the scope of the Treaties and any other physical person or legal entity from a third country which has concluded with the Communities a specific agreement in the area of public contracts, under the conditions provided for in that agreement.

Where the Multilateral Agreement on Public Contracts concluded within the framework of the WTO applies, the contracts are also open to nationals of States that have ratified this Agreement, under the conditions provided for therein. It should be noted that research and development services, which come under category 8 of Annex II A of Directive 2004/18/CE, are not covered by this Agreement.

# 5. STRUCTURE OF THE REPORT AND TASKS TO BE CARRIED OUT BY THE CONTRACTOR

#### 5.1 <u>Possible</u> structure of the study report

The study report should cover all relevant areas and present the information in a clear and structured way, including the following five parts:

- **5.1.1** EU-OSH legal framework review
- **5.1.2** Baseline scenario based on the conclusions of the OSH legal framework review
- **5.1.3** Definition of the problem(s) highlighted under the previous step
- **5.1.4 Elaboration of scenarios** and analysis of the respective implications

#### **5.1.5** Guidance document and associated material

It has to be noted that the tasks to be carried out by the contractor are fit into all the parts of the structure of the study report, as follows: (Tasks are described below in detail for parts **5.1.1**, **5.1.4** and **5.1.5**. For parts **5.1.2** and **5.1.3** a more generic description of the nature of the tasks is indicated).

#### 5.2 Tasks to be carried out by the contractor

The tasks described below are listed on the understanding that they conform to the possible structure of the study report, as indicated above, under 5.1.

#### 5.2.1. EU-OSH legal framework review

#### Task 1 - Elaborate a methodological framework for delivering on part A of the contract

This task shall provide the foundation for the elements described in section 3.2. as part A of this study, but will obviously also impact on the drafting of parts B (scenarios) and C (guidance document). The justification for this task is that there is limited empirical data available today enabling a full review of the adequacy of the EU-OSH legal framework as to its effectiveness relative to potential workplace risks arising from use of nanotechnology and possible exposures to NMs in workplaces. Therefore it is required that a methodological framework and assumptions are established allowing a coherent assessment across the different pieces of EU-OSH specific legislation. This should go beyond a simple textual analysis and pay particular attention to existing implementation set-ups as well as anticipated implementation and enforcement possibilities.

During Task 1 a final list of the legislation to be included in the review will be agreed between the Commission and the contractor (that depicted under scope of the contract is indicative at the call for tender publication stage). Bidders may want to argue the inclusion or otherwise of specific pieces of legislation when submitting their offer.

Consequently, if relevant, the contractor may identify which specific methodological approach is to be applied for specific individual legislative instruments. As some pieces of legislation may be in different phases of the policy cycle, the contractor shall seek from the Commission the information on any potential development to be taken into consideration alongside consideration of the features of the legal acts in force as such.

The tenderer will indicate the methodology it intends to use, the approach envisaged and how suitable it is for carrying out the tasks. The quality and consistency of the proposed approach and its suitability for correctly reflecting the actual situation form part of the elements governing the award of the contract.

The tenderer will also indicate which persons and entities (social partners, national, regional and local authorities in the Member States, enterprises or non-governmental organisations) it intends to contact in the process of the study and how the information to be provided by them will be used in this analysis.

#### Task 2 – Review of acts from agreed list

Applying the methodological framework and building on the assumptions established in Task 1, Task 2 shall review all the acts from the agreed list.

While the scope of the review is the general aspect of NMs / Nanotechnology coverage, differences in coverage/risk between different NMs / Nanotechnologies shall be outlined

where appropriate. Explicit examples of NMs / Nanotechnology coverage are expected to be included.

#### Task 3 - Identification and description of legislative and implementation gaps

Having fulfilled Task 2, the contractor should indicate if there are gaps in reviewed parts of the EU-OSH legislation as regards their coverage of NMS / Nanotechnology exposure. It should be identified whether the gap is due to, *inter alia* NMS / Nanotechnology:

- Not being covered by the general objective of the legislation
- Being covered by the general objectives but explicitly excluded from the scope (*e.g.* not on the list of regulated materials / chemicals)
- Being covered in principle but not effectively addressed (*e.g.* issues of definition, scope, metric or measurement method, monitoring criteria etc.)
- Being ineffectively covered due to implementation gaps or critical dependence on other legislation

Attention should in particular be paid to areas where NMs are covered in principle due to assumptions about their effects being similar to same material in bulk size.

Description of the gaps should be specific, identifying relevant articles, implementing rules, etc. as appropriate, enabling the determination of whether actual legal revision or only additional implementation efforts are required to bridge them.

#### 5.2.2. 'Baseline' scenario

The baseline scenario will include:

**a)** An overview of the problem in both legal and practical terms at EU level, and, where relevant, in individual Member States and EFTA/EEA countries, together with an estimation of likely future trends.

**b)** A thorough description of the current context and challenges, and demonstrate clearly the necessity and added value of EU action on this issue from an OSH perspective.

#### 5.2.3. Definition of problem

The definition of the problem will focus on:

**a)** Identification/characterisation of the need to address risks posed by NMs and Nanotechnology in the workplace

**b)** Extent to which alternative scenarios are likely to impact on the protection of the health and safety of workers at work by employment sector together with an appraisal of likely future trends.

**c)** Identifying the extent to which the requirement on inclusion of NMs / Nanotechnology in the scope of relevant EU-OSH legal instruments or the non inclusion of them, are relevant for the protection of the health and safety of workers at work, together with an appraisal of likely future trends.

**d)** If possible, identify whether Nano specific thresholds of exposure exist for adverse health effects or if these effects are non-threshold based. The contractor should provide specific examples which can be supported by relevant scientific data. This should be illustrated by including examples of exposure to specific NMs.

#### 5.2.4. Elaboration of scenarios and analysis of the respective implications

### Task 4 – Analysis of scenarios

The elements of information obtained and/or used during the previous tasks shall be fed into the analysis of any scenarios that the contractor will identify. Consultation of relevant stakeholders (social partners, national, regional and local authorities in the Member States, enterprises or non-governmental organisations) and obtaining of data from concrete examples is of extreme importance for the analysis; such data gathering will also help understand better the implications of each individual scenario, themselves to be 'articulated' with the findings under tasks 1 to 3.

#### Necessary steps to the analysis of scenarios and respective features

- 1) Identify and assess the foreseeable benefits and disadvantages from a protection of workers health perspective, of a Community binding or combination of binding and non-binding initiatives.
- Assess the possible benefits of any proposed amendments of which legal instruments/acts in terms of preventing or reducing identified or likely adverse health effects.
- 3) Identify particular groups of workers affected by exposure to NMS or Nanotechnology use determined by age, gender and highlight benefits and drawbacks for each of the groups following a possible amendment of any relevant legal instrument/act in relation to exposure to NMS or Nanotechnology use.
- 4) Identify and assess the costs and benefits for employers, workers, Member States and civil society for each of the scenarios.
- 5) Identify and assess the administrative burden and costs for the present situation and alternative scenarios.

The contractor should provide a **socio-economic analysis** corresponding to the questions listed below in relation to extending the scope of relevant legal instruments/acts to exposure to NMs or Nanotechnology use, as well as for keeping the status quo.

The alternative scenarios should be quantified to the extent possible and if this is not possible qualitative examples should be provided.

The contractor should aim to characterise alternative scenarios bearing the following in mind:

- Operating costs and conduct of business
- a) What kind of compliance costs will amendments impose on business?
- b) Will they entail stricter regulation of the conduct of a particular business?
- c) Will they lead to the closing down of businesses?
- d) Would some businesses (for example SMEs) cope better or worse than others in a comparable situation?
- Innovation and research
- a) Would any amendments stimulate or hinder research and development?
- b) Would they facilitate the introduction and dissemination of new production methods, technologies and products?
- Specific sectors
- a) Would the amendments have significant effects on certain sectors?
- b) Would they have specific consequences for SMEs?

#### • The macroeconomic environment

What are the overall consequences of any amendments for economic growth and employment?

- Employment and labour markets
- a) Would the amendments have specific negative/positive consequences for particular professions, specific groups of workers (e.g. pregnant workers) or self-employed persons?
- b) Would they affect access to the labour market?

The contractor shall provide answers to the questions above separately for each scenario. The answers shall be provided at EU-level, if appropriate, significant disparities at national level shall be identified.

#### Specific aspects to be considered in respect to the analysis of implications

In considering different scenarios, the contractor should take the following into account:

**1.** The advantages and disadvantages for each scenario should be examined to support the European Commission in making the most appropriate evidence-based decisions on how best to ensure that workers health and safety is effectively protected from potential risks inherent to exposure to NMS or Nanotechnology use.

**2.** The information should be presented in a way that facilitates the ease of comparison between and within the various scenarios, for example by means of a 'scoreboard' in tabulated form.

**3.** Where possible the study should be supported by examples of actual situations identified in EU Member States or elsewhere.

**4.** Identify whether there are specific challenges for particular Member States and business sectors.

**5.** Assess the transposition and compliance aspects of the described scenarios to determine the feasibility of implementation, management and, if relevant, enforcement. Identify specifically where legislation that is not part of the review plays an important role and may require specific action to ensure the objectives for worker protection are achieved.

**6.** Take account of the content of any documents used by the Commission when discussing and/or consulting the Social Partners at EU level on the protection of workers from risks arising from their exposure to NMS or Nanotechnology use.

#### 5.2.5 Guidance document

#### Task 5 - Preparation of a guidance document and associated material

The guidance document will mainly but most likely not exclusively draw on the findings and conclusions obtained during the previous steps; the organisation of an event (workshop type, the coverage of which may be wider that just checking acceptance of the draft guidance document) during which the draft guidance document will be discussed and its acceptance tested would be welcome.

The stakeholders' consultation part, in particular, will be of the utmost importance in that it will be expected that a representative sample will be resorted to; this will go some way towards providing a 'validation' (which the event alluded to before may help fulfil) of the guidance document. The real

measure of the guidance document usefulness will probably be its practical acceptance and dissemination on the part of interested parties, ultimately employers and workers themselves, and as such the 'crude' validation alluded to here has necessarily limitations, but it has to be understood that no formal endorsement can be given *a priori* to an untested approach / model and that such a validation step of the kind(s) alluded to is a prerequisite.

The contractor should try and identify a range of Good and, if possible, Best practice examples of concrete approaches that specific workplace settings (that can be found in specific industries / enterprises) may have put in place with the aim of protecting workers from exposures to potentially risky NMs or Nanotechnology use, that are typical of such workplaces. In doing so the contractor will argue the case for such an inclusion.

In looking for such cases the contractor should try and identify representative examples of different industry settings / workplace exposure scenarios. In turn, the contractor is expected to elaborate on its findings and try, to the extent possible, extrapolate such practices / risk management approaches to other workplaces / industry settings, the reason being that the usefulness of the Guidance document is expected to be the more significant the more it is 'user friendly' *i.e.* easily applied across different workplace realities (transferability of main principles).

It is difficult to predict the length of such a guidance document. However, an indicative length could be of up to 100 pages, including any description of Good/Best practice examples and supporting information material for information campaign purposes. The potential use of this, and other guidance, is partly linked to the consideration to be given to any scenarios identified by the contractor. It shall, however, be carried out independently of any conclusions arrived at by the contractor when it will check the pros and cons of each scenario, as per the principles it is expected to abide by.

The guidance should be presented in a style that will help employers, who may not have an indepth technical understanding of the issues involved and their associated hazards and risks, with their obligations to ensure that Nano specific risks can be adequately controlled at the workplace.

#### The final report

The final report at the end of the project will collate findings from **5.1.1 to 5.1.4** and include the Guidance document (**5.1.5**), taking into consideration the outcome of any consultations. It shall support the Commission's obligations relative to the EP (see background section) and other relevant stakeholders.

The contractor shall, to the extent appropriate, apply common and consistent terminology and phrasing across the evaluation of different legislative areas.

Throughout the execution of the tasks, the contractor should be prepared to consider new information as it becomes available from related Commission activities. Modalities of inclusion of this information in the execution of individual tasks will be discussed on a case-by-case basis.

#### Details of how the tasks are to be carried out

The tasks described above will be implemented and completed by the contractor **within 15 months**, following the scheduled and approved timeline. The contractor will be working outside (extra muros) the Commission premises.

For Tasks 5.1.1 - 5.1.4 the contractor should also provide supporting evidence contributing to the setting of priorities for policies directed towards the regulation of NMs (see also 'background' and 'subject of the contract' sections).

# 5.3. Requirements on how the tasks shall be carried out

The PROGRESS Programme aims to promote gender mainstreaming in all its five policy sections and commissioned activities. Consequently, the Contractor shall take the necessary steps to ensure that:

- Gender equality issues are taken into account when relevant for the drafting of the technical offer by paying attention to the situation and needs of women and men;
- Implementation of proposed activities includes a perspective informed by a systematic consideration of the gender dimension;
- Performance monitoring includes the collection and gathering of data disaggregated by sex when needed;
- Its proposed team and/or staff respect the gender balance at all levels.

Equally, needs of disabled people shall be duly acknowledged and met while executing the requested service. This will ensure in particular that where the Contractor organises training sessions and conferences, issues publications or develops dedicated websites, people with disabilities will have equal access to the facilities or the services provided.

Finally, the Contracting Authority encourages the Contractor to promote equal employment opportunities for all its staff and team. This entails that the Contractor is encouraged to foster an appropriate mix of people, whatever their ethnic origin, religion, age, and ability.

The Contractor will be required to detail in its final activity report the steps and achievements made towards meeting these contractual requirements.

# 6. SKILLS AND PROFESSIONAL QUALIFICATIONS REQUIRED

See also Annex IV of the draft contract, experts' CVs.

#### Additional requirements:

The contractor should have a proven capability to carry out the tasks related to the evaluation of employment legislation in the field of occupational safety and health at EU level. This should be based on a multi-disciplinary staff and/or access to external experts on a wide range of relevant disciplines and experience, for example, occupational health and safety, occupational hygiene, occupational medicine, toxicology, OSH legislation, epidemiology, chemistry, workplace chemical risk assessment and management, economics and drafting of technical guidance, information and awareness raising material. Specific experience in the domain of Nanotechnology will be particularly valued.

#### 7. TIME SCHEDULE AND REPORTING

See also Article I.2. of the draft contract.

Note: Due to the nature of the study, the contractor should be prepared for extensive interaction with the relevant policy unit of DG EMPL, organised via contacts with the responsible desk officer for the contract and that will follow the project. Given the 'dynamic' nature of policy developments in the area, DG EMPL will try and support the contractor by provision of additional information on ongoing policy developments at the wider European Commission services level; it will also ensure a close scrutiny of the contractual work even between formal deliverables to ensure that deadlines are met effectively. For this purpose, the contractor should consider developing working materials that facilitate effective exchange (*e.g.* documents and tables in a form that allows for inclusion of track change options etc.).

#### 7.1. Specific deadlines for the performance of the tasks

The duration of the contract will be **<u>fifteen (15) months</u>** from the date on which the contract is signed. It will include the following stages:

- 7.1.1 Not later than <u>one (1) month</u> after signature of the contract, the contractor must submit to the European Commission (Unit Health, Safety and Hygiene at Work, named Unit EMPL B/3 hereafter in the document) a detailed document relating to the methodology and approach presented in the bid, together with the work schedule. Subsequently the Commission will organise a **first** (kick off) meeting with the contractor in Luxembourg to further explain what it expects from the study and discuss any practicalities, namely linked to the approach and methodology proposed by the contractor.
- **7.1.2** No more than <u>seven (7) months</u> after signature of the contract, the contractor must submit an interim report in English to the European Commission (Unit EMPL B/3), describing the progress of the work in relation to the envisaged timetable. This report must contain a summary of the results that far and a copy of the draft guidance document as it will stand then.

Following the reception of the interim report the Commission will organise a **second** meeting with the consultant in Luxembourg to discuss the content of the interim report and to provide guidance on the preparation of the final report and the guidelines.

- **7.1.3** <u>Thirteen (13) months</u> after signature of the contract, the contractor must submit a draft final report in English to the European Commission (Unit EMPL B/3). This draft final report will also include the final draft of the guidance document and a brief draft summary in English of the main results obtained. Following the reception of the draft final report and draft summary, the Commission will organise a **third** meeting with the contractor in Luxembourg to discuss their content.
- 7.1.4 A final report including the final guidance document will be submitted to the European Commission (Unit EMPL B/3) before the end of the contract. The European Commission (Unit EMPL B/3) may transmit objections and comments to the contractor within <u>sixty (60)</u> <u>days of receipt</u> of the draft final report. The contractor will then have 30 days to present a revised final report, in English, taking these objections and comments into account or presenting another point of view. When submitting the final report, the contractor may obtain written confirmation of acceptance.

The final report must include a brief summary in English, French and German of the main results obtained. A one-page presentation of the key points of the results must accompany the summary. These key points should be concise, clear and easy to understand. They must also be drafted in English, French and German.

The detailed methodology and work plan, together with the various reports, including model guidance document, and draft reports referred to in this section, must be submitted to the European Commission (Unit EMPL B/3) both on paper (in triplicate) and in a widely-used electronic format (CD-ROM or DVD). The contractor must also supply a copy of the information collected and used in preparing the guidance document and the final report. The pictograms, pictures, graphics and other illustrations must also be presented in a widely-used electronic format.

# 7.2. Publicity and information requirements

In accordance with the General conditions, all contractors are under the obligation to acknowledge that the present service has received funding from the Union in all documents and media produced, in particular final delivered outputs, related reports, brochures, press releases, videos, software, etc, including at conferences or seminars. In the context of the European Union's Programme for Employment and Social Solidarity – PROGRESS, the following formulation shall be used:

This (publication, conference, training session etc) is commissioned by the European Union Programme for Employment and Social Solidarity - PROGRESS (2007-2013).

This programme is implemented by the European Commission. It was established to financially support the implementation of the objectives of the European Union in the employment, social affairs and equal opportunities area, and thereby contribute to the achievement of the Europe 2020 Strategy goals in these fields.

The seven-year Programme targets all stakeholders who can help shape the development of appropriate and effective employment and social legislation and policies, across the EU-27, EFTA-EEA and EU candidate and pre-candidate countries.

For more information see: <u>http://ec.europa.eu/progress</u>

For publications it is also necessary to include the following reference: "The information contained in this publication does not necessarily reflect the position or opinion of the European Commission".

With regard to publication and any communication plan linked to the present activity, the Contractor will insert the European Union logo and mention the European Commission as the Contracting Authority in every publication or related material developed under the present contract.

#### 7.3 Reporting requirements

PROGRESS is implemented through a results-based management (RBM). The Strategic Framework, developed in collaboration with the Member States, social partners and civil society organisations, sets out the intervention logic for PROGRESS-related expenditure and defines PROGRESS' mandate and its long-term and immediate outcomes. It is supplemented by performance measures which serve to determine the extent to which PROGRESS has delivered the expected results. See in Annex the overview of PROGRESS performance measurement framework. For more information on the strategic framework, please visit PROGRESS website <a href="http://ec.europa.eu/social/main.jsp?catId=659&langId=en">http://ec.europa.eu/social/main.jsp?catId=659&langId=en</a> .

The Commission regularly monitors the effect of PROGRESS-supported or commissioned initiatives and considers how they contribute to PROGRESS outcomes as defined in the Strategic Framework. In this context, the Contractor will be asked to dedicatedly work in close cooperation with the Commission and/or persons authorised by it to define the expected contribution and the set of performance measures which this contribution will be assessed against.

The Contractor will be asked to collect and report on its own performance to the Commission and/or persons authorised by it against a template which will be annexed to the contract/service order/. In addition, the Contractor will make available to the Commission and/or persons authorised by it all documents or information that will allow PROGRESS performance measurement to be successfully completed and to give them the necessary rights of access.

### 8. PAYMENTS AND STANDARD CONTRACT

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

### 8.1 Interim payment

The contractor can request an interim payment. To be acceptable, such request must be accompanied by:

- An interim technical report in accordance with the instructions laid down in section 7,
- The relevant invoices
- Statements of reimbursable expenditure in accordance with Article II.7 of the draft contract.

The report must have been approved by the Commission.

The Commission has 60 days from receipt of the report to approve or reject it, and the contractor has 30 days in which to submit additional information or a new report.

Within 30 days of the date on which the report is approved by the Commission, an interim payment corresponding to the relevant invoices, up to a maximum of 50% of the total amount referred to in Article I.3.1 of the draft contract shall be made.

#### 8.2 Payment of the balance

To be acceptable, the contractor's request for payment of the balance must be accompanied by:

- a final technical report in accordance with the instructions laid down in section 7,
- the relevant invoices,
- statements of reimbursable expenditure in accordance with Article II.7 of the draft contract.

The said report must have been approved by the Commission.

After receiving the report, the Commission has 60 days in which to accept or reject it, and the contractor has 30 days in which to submit new documents.

The balance corresponding to the relevant invoices will be paid within 30 days following the date of approval of the report by the Commission.

#### 9. PRICES

Under the terms of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union, the latter are exempt from all charges, taxes and duties, including value added tax; such charges may not therefore be included in the calculation of the price quoted. The amount of VAT is to be indicated separately.

The price must be stated in  $EUR(\in)$ , net of VAT (using, where appropriate, the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued), and broken down according to the model in Annex III included in the attached standard contract.

- Part A: Fees and direct costs
- Fees, expressed in number of person/days and unit price per working day for each expert proposed. The unit price covers the experts' fees and administrative expenditure, but not the reimbursable expenses referred to below.
- Other direct costs (please specify).
- Part B: Reimbursable expenses
- Travel expenses (not including local transport)

- Subsistence expenses of the contractor and his personnel (covering expenditure incurred by experts on short trips away from their normal place of work) — see Annex III to the model contract
- Expenses for the shipment of equipment or unaccompanied luggage, directly connected with performance of the tasks specified in Article I.1 of the draft contract
- Contingencies.

Total price = Part A + Part B with a maximum of € 280,000

#### 10. GROUPINGS OF ECONOMIC OPERATORS OR CONSORTIA

Tenders can be submitted by groupings of service providers/suppliers who will not be required to adopt a particular legal form prior to the contract being awarded, but the consortium selected may be required to assume a given legal form when it has been awarded the contract if this change is necessary for proper performance of the contract28. However, a grouping of economic operators must nominate one party to be responsible for the receipt and processing of payments for members of the grouping, for managing the service administration, and for coordination. The documents required and listed in the following points 11 and 12 must be supplied by every member of the grouping.

#### 11. EXCLUSION CRITERIA AND SUPPORTING DOCUMENTS

**1)** <u>Bidders must provide a declaration on their honour, duly signed and dated, that they are not in one of the situation referred to in Articles 93 and 94 a) of the Financial Regulation</u>.

Those articles are as follows :

#### "<u>Article 93</u> :

Applicants or tenderers shall be excluded if:

- a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- *b) they have been convicted of an offence concerning their professional conduct by a judgement which has the force of res judicata;*
- c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- d) they have not fulfilled their obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;
- e) they have been the subject of a judgement which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- f) they are currently subject to an administrative penalty referred to in Article  $96(1)^{29}$ .

#### Article 94 :

<sup>28</sup> These entities can take the form of an entity with or without legal personality but offering sufficient protection of the Commission's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association).

The contract has to be signed by all members of the group, or by one of the members, which has been duly authorised by the other members of the grouping (a power of attorney or sufficient authorisation is to be attached to the contract), when the tenderers have not formed a legal entity.

<sup>29</sup> Cf .Article 96(1): "The contracting authority may impose administrative or financial penalties on the following:

<sup>(</sup>a) candidates or tenderers in the cases referred to in point (b) of Article 94;

<sup>(</sup>b) contractors who have been declared to be in serious breach of their obligations under contracts covered by the budget.

<sup>(...)&</sup>quot;

Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

- a) are subject to a conflict of interest;
- b) are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the procurement procedure or fail to supply this information (...)"

2) <u>The tenderer to whom the contract is to be awarded shall provide, within a time limit defined by</u> the contracting authority and preceding the signature of the contract, the evidence referred to in <u>Article 134 of the implementing Rules, confirming the declaration referred to in point 1 above.</u>

# Article 134 of the Implementing Rules – Evidence

§3. The contracting authority shall accept as satisfactory evidence that the candidate or tenderer to whom the contract is to be awarded is not in one of the situations described in point (a), (b) or (e) of Article 93(1) of the Financial Regulation, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. The contracting authority shall accept, as satisfactory evidence that the candidate or tenderer is not in the situation described in point (d) of Article 93(1) of the Financial Regulation, a recent certificate issued by the competent authority of the State concerned.

Where the document or certificate 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.

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

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

**3)** The contracting authority may waive the obligation of a candidate or tenderer to submit the documentary evidence referred to in Article 134 of the Implementing Rules, if such evidence has already been submitted to it for the purposes of another procurement procedure launched by DG EMPL and provided that the issuing date of the documents does not exceed one year and that they are still valid.

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

# 12. Selection criteria

All bids must also contain the documents listed below, testifying to the tenderer's financial and economic capacity, technical capability and professional qualifications. In particular, the European Commission will verify the following:

# 12.1 Financial and economic capacity (on the basis of the following documents

• Turnover during the previous financial year (statement of overall turnover – at least twice the value of the contract, i.e. € 560,000)

- Balance sheets and profit and loss accounts for the last three financial years, if the legislation of the country in which the tenderer is established requires them to be published;
- Regular accounts for the quarter preceding that in which the tender notice was published, if the full accounts for the previous financial year are not yet available.

If, for some exceptional reason which the contracting authority considers justified, the tenderer or candidate is unable to provide the references requested by the contracting authority, he may prove his economic and financial capacity by any other means which the contracting authority considers appropriate.

#### 12.2 Tenderer's technical capability

- a description of the tenderer's technical capability and practical experience in the field referred to in section 6 of these specifications. For consortia of companies or groups of service providers, this description must relate specifically to the tasks to be performed by each of their members;
- a list of work and/or publications of last 3 years demonstrating the tenderer's practical experience in the fields referred to in section 6 of these specifications
- the tenderer must provide the names and CVs (maximum of three pages each) of the persons responsible for the specific tasks described in section 5 of these specifications, with a view to demonstrating their practical experience and their capability to prepare practical guidelines.
- a description of the parts of the services to be provided by each consortium of companies or groups of service providers (where applicable).
- •

#### 13. Award criteria

The contract will be awarded to the bid offering the best price/quality ratio, taking into account the following criteria :

-	Understanding of the objectives and tasks: Quality and consistency of the methodological approach	20% 45%
-	Quality of the work plan proposed: Organisation of the work and management of the project:	15% 20%

The contract will *not* be awarded to a tenderer whose bid receives less than (70%) for the award criteria.

The points total will then be divided by the price, with the highest-scoring bid being chosen.

#### 14. Content and presentation of bids

#### 14.1 Content of bids

Bids must include:

- a presentation letter duly signed by the legal representative;
- all the information and documents necessary to enable the Commission to appraise the bid on the basis of the selection and award criteria (see sections 12 and 13 above);
- a bank ID form duly completed and signed by the bank;
- a "legal entity" form duly completed;
- the price;
- the detailed CVs of the proposed experts;
- the name and function of the contractor's legal representative (i.e. the person authorised to act on behalf of the contractor in any legal dealings with third parties);

 proof of eligibility: tenderers must indicate the State in which they have their registered office or are established, providing the necessary supporting documents in accordance with their national law.

#### 14.2 Presentation of bids

- Bids must be submitted in triplicate (i.e. one original and two copies).
- They must include all the information required by the Commission (see points 9,10,11 and 12 above).
- They must be clear and concise.
- They must be signed by the legal representative.
- They must be submitted in accordance with the specific requirements of the invitation to tender, within the deadlines laid down.

# Annex I

Exclusion criteria	Supporting documents to be provided by applicants, tenderers or tenderers to who the contract will be awarded	
(Article 93(1) FR)	Procurement (Article 93(2) FR; Article 134 IR)	
1. Exclusion from a procurement procedure, Article 93(1) FR :		
« Candidates or tenderers shall be excluded from participation in a procurement procedure if:		
1.1. (subparagraph a)	<ul> <li>Recent extract from the judicial record</li> </ul>	
they are bankrupt or being wound up,	or	
are having their affairs administered by the courts,	recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance <b>or</b>	
have entered into an arrangement with creditors have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations <sup>30</sup> ;	- Where no such certificate is issued in the country concerned : 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	
<b>1.2. (subparagraph b)</b> they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata <sup>31</sup> ;	Cf. supporting documents for Article 93(1)(a) FR above	
<b>1.3. (subparagraph c)</b> they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;	Declaration by the candidate or tenderer that he is not in the situation described	
<b>1.4. (subparagraph d)</b> they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed <sup>32</sup> ;	Recent certificate issued by the competent authority of the State concerned confirming that the candidate is not in the situation described <b>or</b> Where no such certificate is issued in the country concerned : 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	
<b>1.5. (subparagraph e)</b> they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests <sup>33</sup> ;	Cf. supporting documents for Article 93(1)(a) FR above	
<b>1.6. (subparagraph f)</b> they are currently subject of an administrative penalty referred to in Article $96(1)^{34}$ . »	Declaration by the candidate or tenderer that he is not in the situation described	

31 Cf. footnote n° 30.

33 Cf. footnote n° 39.

<sup>30</sup> See also Article 134(3) IR : Depending on the national legislation of the country in which the tenderer or candidate is established, the documents referred to in paragraphs 1 and 2 shall relate to legal persons and/or natural persons including, where considered necessary by the contracting authority, company directors or any person with powers of representation, decision-making or control in relation to the candidate or tenderer.

<sup>32</sup> Cf. footnote n°39.

<sup>34</sup> Article 96(1) FR: The contracting authority may impose administrative or financial penalties on the following:

<sup>(</sup>a) candidates or tenderers in the cases referred to in point (b) of Article 94;

<sup>(</sup>b) contractors who have been declared to be in serious breach of their obligations under contracts covered by the budget.

Exclusion criteria	Supporting documents to be provided by applicants, tenderers or tenderers to who the contract will be awarded	
(Article 94 FR)	Procurement	Grants
<b>2. Exclusion from a procurement or grant</b> <b>award procedure Article 94 FR :</b> « Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:		
<b>2.1. (subparagraph a)</b> are subject to a conflict of interest;	statement by the applicant, tenderer or bidder confirming the absence of conflict of interests, to be submitted with the application, bid or proposal	
<b>2.2. (subparagraph b)</b> are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information» <sup>35</sup> .	applicant, tenderer or bidder It is the responsibility of the aut	horising officer, represented by to check that the information

<sup>25</sup> Cf. Article 146(3) of the FR Implementing Rules: « ...the evaluation committee may ask candidates or tenderers to supply additional material or to clarify the supporting documents submitted in connection with the exclusion and selection criteria, within the time limit it specifies. » and Article 178(2) of the FR Implementing Rules: « The evaluation committee may ask an applicant to provide additional information or to clarify the supporting documents submitted in connection with the application, in particular in the case of obvious clerical errors. »

<sup>36</sup> Cf. footnote n°35

# <u>Annex II</u>

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

The undersigned [name of the signatory of this form, to be completed]:

- □ in his/her own name (*if the economic operator is a natural person or in case of own declaration of a director or person with powers of representation, decision making or control over the economic operator*<sup>37</sup>)
  - or
- □ representing (*if the economic operator is a legal person*)

official name in full (only for legal person):

official legal form (only for legal person):

official address in full:

VAT registration number:

declares that the company or organisation that he/she represents / he/she:

- a) is not bankrupt or being wound up, is not having its affairs administered by the courts, has not entered into an arrangement with creditors, has not suspended business activities, is not the subject of proceedings concerning those matters, and is not in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) has not been convicted of an offence concerning professional conduct by a judgment which has the force of *res judicata*;
- c) has not been guilty of grave professional misconduct proven by any means which the contracting authorities can justify;
- d) has fulfilled 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 carried out;
- e) has not been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- f) is not a subject of the administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the procurement procedure or failing to supply an information, or being declared to be in serious breach of his obligation under contract covered by the budget.

In addition, the undersigned declares on their honour:

To be used depending on the national legislation of the country in which the candidate or tenderer is established and where considered necessary by the contracting authority (see art. 134(4) of the Implementing Rules).

- g) they have 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 affinities, family or emotional ties or any other relevant connection or shared interest;
- h) they 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) they have not made and will not make any offer of any type whatsoever from which an advantage can be derived under the contract;
- j) they have not granted and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to award of the contract;
- k) that the information provided to the Commission within the context of this invitation to tender is accurate, sincere and complete;
- I) that in case of award of contract, they shall provide upon request the evidence that they are not in any of the situations described in points a, b, d, e above.

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.]

By signing this form, the undersigned acknowledges that they have been acquainted with the administrative and financial penalties described under art 133 and 134 b of the Implementing Rules (Commission Regulation 2342/2002 of 23/12/02), which may be applied if any of the declarations or information provided prove to be false.

Full name

Date

Signature

# **Overview of PROGRESS Performance Measurement Framework**

PROGRESS Ultimate Outcome Member States implement laws, policies and practices in a manner that contributes to the desired outcomes of the Social Agenda

PROGRESS works towards its ultimate outcome by helping strengthen the EU's support for Member States' efforts to create more and better jobs and to build a more cohesive society. PROGRESS seeks to contribute to (i) an effective legal regime in the EU in relation to the Social Agenda; (ii) shared understanding across the EU with regard to Social Agenda objectives; and (iii) strong partnerships working towards Social Agenda objectives.

In operational terms, support provided by PROGRESS facilitates (i) provision of analysis and policy advice; (ii) monitoring and reporting on the implementation of EU legislation and policies; (iii) policy transfer, learning and support among Member States; and (iv) relaying to decision-makers the views of the stakeholders and society at large.

Legal Regime Outcome: Compliance in Member States with EU law related to PROGRESS areas. Performance Indicators 1. Transposition rate of EU law on matters related to PROGRESS policy areas 2. Effectiveness of application in Member States of EU law on matters related to PROGRESS policy areas. 3. EU policies and legislation are grounded in thorough analysis of situation and responsive to conditions, needs and expectations in Member States in PROGRESS areas 4. Extent to which PROGRESS-supported policy advice feeds into the development and implementation of EU legislation and policies 5. Cross-cutting issues are addressed in PROGRESS policy sections 6. EU policies and legislation display a common underlying logic of intervention in relation to PROGRESS issues 7. Gender mainstreaming is systematically promoted in PROGRESS	Shared Understanding Outcome:           Shared understanding and ownership among policy/decision-makers and stakeholders in Member States, and the Commission, of objectives related to PROGRESS policy areas. Performance Indicators           1. Attitudes of decision-makers, key stakeholders and general public regarding EU objectives in PROGRESS policy areas           2. Extent to which national policy discourses or priorities reflect EU objectives           3. Extent to which principles of good governance (including minimum standards on consultation) are respected in policy debate           4. Extent to which the outcomes of policy debates feed into the development of EU law and policy.           5. Greater awareness of policy-and decision- makers, social partners, NGOs, networks regarding their rights/obligations in relation to PROGRESS policy areas           6. Greater awareness of policy-and decision- makers, social partners, NGOs, networks regarding EU objectives and policies in relation to PROGRESS policy areas	Strong Partnerships Outcome: Effective partnerships with national and pan- European stakeholders in support of outcomes related to PROGRESS policy areas. Performance Indicators 1. Existence of common ground/consensus among policy and decision-makers and stakeholders on EU objectives and policies 2. Identification and involvement by the EU of key actors in a position to exert influence or change at EU and national levels 3. Effectiveness of partnerships in relation to outcomes related to PROGRESS policy areas. 4. Number of individuals served or reached by networks supported by PROGRESS. 5. Extent to which advocacy skills of PROGRESS-supported networks have improved 6. Satisfaction of EU and national authorities with the contribution of networks 7. Extent to which PROGRESS-supported networks take a cross-cutting approach
--	--	--