Feb.20 14

nanoSTAIR

D4.3 nanoSTAIR Practical Guideline





nanoSTAIR is a CSA (Coordination and support actions) funded by the European Commission's Seventh Framework Programme. nanoSTAIR - Establishing a process and a platform to support standardization for nanotechnologies implementing the STAIR approach

The research leading to these results has received funding from the European Union Seventh Framework Programme (FP7 / 2007-2013) under grant agreement n° NMP4-SA-2012-319092

Deliverable D4.3 nanoSTAIR Practical Guideline

Published by FUNDACIÓN Tecnalia RESEARCH & INNOVATION (Tecnalia)



www.tecnalia.com

Authors:

Jesús M. Lopezde Ipiña (Tecnalia), Benoit Hazebrouck (EU-VRi), Bastien Caillard (EU-VRi), Olivier Salvi (EU-VRi)

More information on the nanoSTAIR project: <u>www.nanoSTAIR.eu-vri.eu</u>

Paris, February 28, 2014

Table of Contents

Introdu	on	2
1. Learr k ir	ng about the European contex players in standardization a manotechnology	kt and the nd research 4
1	A brief overview of the Europe context	an research 4
1	A brief overview of the Europe standardization context	ean
1	A snapshot of the European in context	dustrial 11
1	The European regulatory cont	ext in brief 12
1	The most relevant standardiza European stakeholder groups	tion needs for
1	. Main barriers between researc standardization	h and 17
2. Integ p	ting standardization into res jects	earch 20
2	. Why integrate standardization	into research?20
2	. Integration in practice	
2	. Standardization and Intellectua Rights (IPR)	al Property 24
3. nano ir p	AIR - providing information grate standardization into re jects on nanotechnologies	and tools to esearch 26
3	The nanoSTAIR approach	
3	The nanoSTAIR contact point tools	(NSCP) and 28
3	Tool 1: The nanoSTAIR web-b	ased platform 28
3	Tool 2: The nanoSTAIR check	30
3	Tool 3: The nanoSTAIR semin	ars 35
3	nanoSTAIR services as a part standardization process	of the 35
4. Conti re	uting to impulse standardiza earch	tion in 37
4	The nanoSTAIR strategy: orie objectives	ntation and 37
4	The nanoSTAIR strategy: depl implementation, at European levels	oyment and and national 41
Conclus	ns	55
Glossar		57
Referen	S	59

List of Figures

Figure 1: Simple procedure to integrate standardization into the research project22
Figure 2: The nanoSTAIR turbine
Figure 3: The nanoSTAIR platform27
Figure 4: The nanoSTAIR website, as a contact point for the nanoSTAIR services and tools
Figure 5: The nanoSTAIR registration page
Figure 6: Tool 2: How the nanoSTAIR semantic tool works
Figure 7: Preliminary version of the Procedure for nanoSTAIR check (Tool 2)32
Figure 8: Form for applicant at nanoSTAIR website 33
Figure 9: nanoSTAIR services as a part of the standardization process
Figure 10: Distribution of nanoSTAIR strategic actions depending on the type of barrier to overcome.4
Figure 11: Distribution of nanoSTAIR strategic actions depending on the strategic objective concerned

List of Tables

Table 1: Fifteen most relevant standardization items (top15) identified by the nanoSTAIR survey (Partof Deliverable D2.1)15
Table 2: Main standardization items identified by the nanoSTAIR survey, grouped by relevant thematic groups
Table 3: Barriers identified by literature sourcesconsulted by nanoSTAIR, classified in thethree main categories established by projectINTEREST19
Table 4: Proposal for standardization activities, according to the project's TRL25
Table 5: Number of strategic actions to be deployed by nanoSTAIR strategy, classified by typology of barrier and strategic objective concerned 39
Table 6: Strategic actions deploying strategic objective 1(1.1)
Table 7: Strategic actions deploying strategic objective 1(1.2)
Table 8: Strategic actions deploying strategic objective 2(2.1)
Table 9: Strategic actions deploying strategic objective 2(2.2)
Table 10: Strategic actions deploying strategic objective2 (2.3)49
Table 11: Strategic actions deploying strategic objective3 (3.1)50
Table 12: Strategic actions deploying strategic objective4 (4.1)
Table 13: Strategic actions deploying strategic objective4 (4.2)54

Acknowledgment

The project nanoSTAIR wants to express its greatest gratitude to CEN, AENOR and the European project BRIDGIT, for their cooperation in the production of this document.

Introduction

Nanotechnology is considered one of the key technologies of the 21st century within Europe and has been identified as a Key-Enabling Technology (KET) inH2020. It has rapidly promoted the development of a new generation of smart and innovative nano-enabled products and processes, creating an important growth potential for a large number of industry sectors. Nanotechnology offers substantial possibilities for improving the competitive position of the EU and for responding to key societal challenges. But ensuring nanotechnology is developed in a safe and responsible manner is a key objective.

The production of knowledge in nanotechnology is very intensive as a great amount of research projects is launched each year on national and European level. The European Commission has identified the time between the end of a research project and the beginning of the valuable exploitation of these results from the industry — the so called "valley of death" — as one of the main obstacles for economic success. In this context, standardization has been identified in Horizon 2020 as one of the innovation-support measures by bridging the gap between research and the market, and helping the fast and easy transfer of research results to the European and international market, providing interoperability between new and existing products, services and processes.

The development of new and improved standards requires high quality technical information. This creates a fundamental interdependency between the standardization and research communities. Consequently the need of direct "pipelines" to connect research to standardization has been widely recognized and promoted by European Commission, European Standardization System and other interested parties.

Standardization is a voluntary cooperation among industry, consumers, public authorities, researchers and other interested parties for the development of technical specifications based on consensus. Formal standards are proposed, developed and approved by the members of the standardization bodies (CEN-CENELEC, ISO, National Standardization Bodies - NSBs, etc). However, the key players are the NSBs that serve as the main focal points to the concerted regional and international standardization system. They facilitate the national interaction between the research and standardization community and thus the majority of them have appointed a dedicated national contact point for standardization in research.

In this context, the overall objective of project nanoSTAIR is to build a sustainable process, a platform and a set of advanced tools (services) in the field of nanotechnologies, to support the transfer of knowledge gained through research to standards and standardization deliverables, in the framework of the STAIR approach promoted by CEN-CENELEC. In other words, nanoSTAIR is a vehicle to coordinate the efforts related to standardization linked to research projects in the area of nanotechnologies.

The nanoSTAIR services will structure and facilitate the development of new standards and standardization deliverables, and thus enable the European nanotechnology related industry to rapidly operate according to the state of the art and thus increase its competitiveness. In addition, the nanoSTAIR services comply nicely with the normal standardization process by adding tools into the pre-standardization step.

Due to the relevance of NSBs in producing new standards (key players), the nanoSTAIR approach promotes the information and involvement of NSBs, in order to increase their awareness of the possibilities of the nanoSTAIR services to support standardization in projects research. The nanoSTAIR tools and services are available through the nanoSTAIR website (www.nanostair.eu-vri.eu).

In the framework of project nanoSTAIR, the main objective of work package 4 (WP4) is to assemble outcomes of previous WPs to produce practical tools and guidelines, addressed to translate the European nano-research in standards and standardization deliverables. The present document – deliverable D4.3 - introduces the results of task 4.3 aimed to develop a European practical guideline to facilitate the above process. Consequently D4.3 compiles and assembles in a practical and synthetic document, all the results previously produced in work packages WP1 to WP4.

The present guideline provides tools and information for researchers and other interested parties, showing:

- 1. How important standardization is to bridge between research activities and the market (Chapter 1)
- 2. How standardization can be integrated in the research projects and benefit to them (Chapter 2)
- 3. How nanoSTAIR can firmly support standardization in research projects (Chapter 3)
- 4. How other parties (standardization bodies, research funding agencies...) could further help bring researchers to standardization, at European and national level (Chapter 4).

Consequently, this guideline can be useful to prepare the future European and national proposals and calls and to promote standardization in research.

1. Learning about the European context and the key players in standardization and research in nanotechnology

1.1 A brief overview of the European research context

The European Commission selected Nanotechnology in H2020 as one of the six Key-Enabling Technologies (KETs), recommended by the High Level Group (HLG) on KETs and identified as technological priority for Europe.

The HLG – KETs report concluded that the EU leads the way in nanotechnology basic research but others commercialize the ideas. This situation, namely the gap between basic knowledge generation and the subsequent commercialization of this knowledge in marketable products ("Valley of Death"), has been also identified in many competitor countries, including the USA, China and Taiwan. All have established coordinated programmes in strategically important areas that cover the full innovation chain addressing basic and applied research, demonstrators, measures, deployment and market access and standardization all at the same time and, significantly, in a logical joined-up manner.

In Europe, Horizon 2020 will have a strong focus on developing European industrial capabilities in Key Enabling Technologies (KETs). The Leadership in Enabling and Industrial Technologies (LEIT) part of Horizon 2020 will support the development of technologies underpinning innovation across a range of sectors. One of the areas covered by this part is nanotechnologies. In order to bridge the gap between nanotechnology research and markets, several research topics have been identified in H2020 as being crucial, also for contributing to other policy areas in nanotechnology, such as safety of nanoparticles, pre-normative research, or research for health, security energy, information society, and environment, or for supporting less developed countries and socially disadvantaged people.

The HLG – KET also recommended that if the EU is to remain a globally competitive location for the development and commercial exploitation of KETs, and to capture a significant part of the value chain related to these, one of the mechanisms to be impulsed is a better integration of standardisation and research, in order to use standards to drive markets and build consumer confidence.

In this sense, H2020 documents refer standardization as an important element to enhance the competitiveness of European industry by promoting the take-up and trade of novel technologies. Several of the calls issued under the Industrial Leadership pillar refer to the possibility of standards and standardization being included in the work activities or as possible outputs of projects. Integrating standards and standardization in project proposals can amplify the impact of projects, facilitate the dissemination and exploitation of research results, and ensure a better evaluation. For instance, the LEIT 5 work programme 2014-2015¹, contains a significant number of topics referring to nanotechnology standardization, e.g. as follows:

- "Contribution to **standardisation** in the nano metrology field for fast product and process design".
- "Contribution to on-going and future **standardisation** work in the field" (See Mandate M/461 addressed by the European Commission to CEN/CENELEC and ETSI)
- "Identification of gaps in **standards**, paving the way for future pre-normative activities in the field"
- "Contribution to **standardisation** in relation to nanomaterial interaction with the printing process for better product and process design"

¹*http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/main/h2020-wp1415-leitnmp_en.pdf*

- "Safety considerations and contribution to **standardisation** should be an integral part of the projects"
- Coordination of EU and international efforts in support of regulation, in particular within the context of NANOREG and NANOREG II, which is a major undertaking jointly funded by FP7, EU Member States, FP7 Associated States and industry, and of the work carried out by OECD-WPMN and **standardisation** bodies such as ISO or CEN;
- "The project is expected to promote **standardisation** at international level"
- "Enabling safer product design guidance, comprehensive laboratory and field test procedures all along the product chain, including metrology and **standardisation** issues for characterisation, and addressing international harmonisation and regulation"

To support the safe development of nanotechnologies, risk management should become an integral part of the culture of the organisations involved in the supply chain, including regulatory support and risk governance. In 2013, the EU Nanosafety Cluster published the document entitled "Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovation", introducing a strategic vision for future research on the safe use and safe applications of engineered nanomaterials during 2015-2025. This roadmap aims to provide an understanding of where the European nanosafety should be at the end of Horizon 2020. The time horizon has been chosen by NSC based on the timing of the "Horizon 2020" Framework Programme for Innovation and Research.

The document identifies the steps and achievements needed to accomplish objectives within this time frame, describing the current status and the research needs and priorities for the coming 10 years in four main thematic areas: 1) nanomaterial identification and classification; 2) nanomaterial exposure and transformation; 3) hazard mechanisms related to effects on human health and the environment; and 4) tools for the predictive risk assessment and management including databases and ontologies.

Hence, the strategic vision on the future directions of European nanosafety research presented in this document may have a major impact on the future nanosafety research within and outside the European Union, and consequently, on the success of nanotechnologies. The document recognizes that standardization is highly important in promoting the success of engineered nanomaterials and technologies, and when incorporating safety as a vital issue in the standardization process, these activities may become important drivers within European Union, EU Member States and beyond.

Key stakeholders are:

✓ Research projects and organizations. A mapping portal for nanotechnology research FP6/7 Projects and organizations can be found at H2020 website². Moreover European nanosafety research is coordinated by the EU NanoSafety Cluster (NSC). The NSC published the European NanoSafety Cluster Compendium 2013³, which contains information on all running or recently completed projects funded under the Seventh Framework Programme FP7 (Information on older projects can be found in the previous editions). Seventeen of the32research projects inventoried in the compendium have referenced activities in the field of standardization. Additionally, information on research projects - completed, underway or planned - that address environmental, human health and safety issues of manufactured nanomaterials can be also found at OECD database⁴. It allows users to search by a variety of categories such as the nanomaterial being investigated, the test methods used and the scope of the research area. Research is defined in a broad sense, thus, it includes not only experimental studies, but also projects addressing: i) comprehensive risk

²<u>http://ec.europa.eu/research/industrial_technologies/pdf/ec-nanotechnology-research-mapping_en.pdf</u>

³<u>http://www.nanosafetycluster.eu/uploads/files/pdf/2013_NSC_Compendium.pdf</u>

⁴ http://www.oecd.org/env/nanosafety/database

assessments of specific substances; ii) risk mitigation measures; iii) regulatory aspects; iv) international standard setting; and v) reports of public dialogues.

- ✓ Nanosafety cluster: The Nanosafety Cluster⁵, is an initiative from the European Commission, DG Research & Innovation, "Industrial Technologies" Programme, to maximise synergies between research projects on EU or national level addressing all aspects of nanosafety including toxicology, ecotoxicology, exposure assessment, mechanisms of interaction, risk assessment and standardisation. Standardization has been identified as a key element in the field of nanosafety, and included within the scope of Dissemination Working Group. In this context, project nanoSTAIR plays a significant role. It is conducting a process towards standardizing research results, supporting the preparation of new work item proposals by identifying potential candidate items, by making explicit the needs from the main stakeholders and by pooling the resources and expertise to reach the necessary critical mass for submitting and developing an item. nanoSTAIR is leading the subgroup "standardization" of the Nanosafety Cluster working group 7 "Dissemination".
- European Technology Platforms, European Innovation Partnerships and other related EC initiatives. European Technology Platforms (ETPs) are industryled stakeholder fora that develop short to long-term research and innovation agendas and roadmaps for action at EU and national level to be supported by both private and public funding. ETPs span a wide range of technology areas and have to date played an important role by developing joint visions, setting Strategic Research and Innovation Agendas and contributing to the definition of the research priorities including those under the Research Framework Programmes. Horizon 2020 recognises the role of ETPs as part of the external advice and societal engagement needed to implement the Programme. Current picture of ETPs consists in 40 ETPs, 30 individual ETPs and 2 cross ETP initiatives. Several of them are relevant to the nanotechnology research Community: e.g. ENIAC (Nanoelectronics), SusChem (Sustainable Chemistry), Nanomedicine, ETP on innovative medicine, TPIS (Industrial Safety) and Nanofutures.

NANOfutures⁶ initiative is a European Technology Integrating and Innovation Platform (ETIP), multi-sectorial, cross-ETP, integrating platform, with the objective of connecting and establishing cooperation and representation of Technology Platforms that require nanotechnologies in their industrial sector and products. NANOfutures considers standardization as critical to scientific communication and commerce because, in order to build on lessons learned, researchers need to quickly convey scientific discoveries across disciplines. Standardization has been identified as across-sectorial non-technological action for all value chains. Consequently actions concerning standardization will be deployed at short and long term by the TP. In addition, a specific NANOfutures' Working Group will help identifying cross-sectorial gaps and challenges in standardization relevant to nanotechnologies. Examples of key topics of interest are: occupational health and safety protocols, measurement and characterization protocols to support hazard and risk assessment of nanomaterials, performance and sustainability assessment.

<u>European Innovation Partnerships (EIPs)</u> are a new approach to EU research and innovation. EIPs act across the whole research and innovation chain, bringing together all relevant actors at EU, national and regional levels in order to: 1) step up research and development efforts; 2) coordinate investments in demonstration and pilots; 3) anticipate and fast-track any necessary regulation and standards; and 4) mobilize 'demand' in particular through better coordinated public procurement to ensure that any breakthroughs are quickly brought to market. EIPs are launched only in areas, and consist only of activities, in which government intervention is clearly justified and where combining EU, national and regional efforts in R&D and demandside measures will achieve the target quicker and more efficiently: 1) Active and Healthy Ageing, 2) Agricultural Productivity and Sustainability, 3) Smart Cities and

⁵ http://www.nanosafetycluster.eu/

⁶http://www.nanofutures.info/about

Communities, 4) Water and 5) Materials. All of them may involve nanotechnology research.

Research carried out by <u>Public-Private Partnership (PPP)</u>, proposed by the European Commission in 2008 to develop new technologies for the vitally important manufacturing, construction and automotive industries, also include significant research in the field of nanotechnology. In H2020, contractual Public-Private Partnerships (cPPPs) will be used extensively for the implementation and deployment of the KET. They will allow industry to directly participate in the definition and implementation of research and innovation priorities. The three cPPPs connected with the area of nanotechnology (LEIT - Nanotechnology) are : Energy-efficient Buildings (EeB), Factories of the Future (FoF) and Sustainable Process Industries (SPIRE).

- ✓ European, national and regional research funding agencies. Horizon 2020 is the main financial instrument from the EC, for funding research over 7 years (2014 to 2020). H2020 will be complemented by further measures to complete and further develop the European Research Area. Within the Leadership in Enabling and Industrial Technologies part of Horizon 2020 (LEIT), a specific section will cover research on nanosciences and nanotechnologies⁷, including environmental, safety and health issues (EHS). Participant Portal⁸ is the entry point for electronic administration of EU-funded research and innovation projects, and hosts the services for managing your proposals and projects throughout their lifecycle. Links with national and regional research funding agencies in European Union can be found at CORDIS (National R&D information service⁹).
- ✓ ERA-NET on Nanosafety: Safe Implementation of Innovative Nanoscience and Nanotechnology (SIINN). SIINN ERA-NET¹⁰ promotes the safe and rapid transfer of European research results in nanoscience and nanotechnology (N&N) into industrial applications. National and regional resources are virtually pooled to create a transnational programme of research. In order to strengthen the European Research Area and to coordinate N&N-related R&D work, the project has the aim of bringing together a broad network of ministries, funding agencies, academic and industrial institutions to create a sustainable transnational programme of joint R&D in N&N.

R&D activities in the Member and Associated States of the EU in the area of N&N remain largely uncoordinated and fragmented, resulting in the sub-optimal use of available resources, such as human resources, research equipment and funding. Since available data on their toxicological behaviour is often scant, unreliable or contradictory, the SIINN Project will focus on ways of remedying this situation. The SIINN-ERA-NET has also joined the EU NanoSafety Cluster.

SIINN started on August 1, 2011 and has been running for three years. A total EU funding of \in 1.5 mill. It enables 19 partners to coordinate their activities, has prepared two calls for proposals and disseminates the knowledge acquired during the lifetime of the project. SINN established a link to NanoSTAIR project for guidance on standardization.

✓ NMP NCP Network. The NMP Network of National Contact Points (NCPs)¹¹ in operation since the beginning of the 5th Framework Programme which began in 1998, is a valuable resource available to the scientific and industrial community of Europe interested in utilizing the expertise of the nationally appointed experts in order to produce high quality research and technological developments.

The NMPTeAm2 project is funded by the European Commission under the NMP

⁷ http://ec.europa.eu/research/industrial_technologies/nanoscience-and-technologies_en.html

⁸ http://ec.europa.eu/research/participants/portal/desktop/en/home.html

⁹ http://cordis.europa.eu/national_service/home_en.html

¹⁰http://www.siinn.eu/en/

¹¹<u>http://ec.europa.eu/research/participants/portal/page/nationalcontactpoint</u>

Thematic area of the Cooperation Programme of the Seventh Framework Programme. NCP's from 15 countries are involved in the NMPTeAm2 project. All NMPTeAm2 partners are officially nominated NMP National Contact Points (NCPs) in their countries. The NMP TeAm 2 project aims at assisting the NMP NCP Network to provide good quality and high standard services to the proposers and therefore helping simplify access to FP7 calls, lowering the entry barriers for newcomers, and raising the average quality of submitted proposals. A section of the project website (NMPTeAm Headlines) contains examples of projects dealing with NMP and FP7 and presenting relevant information on related areas. The project nanoSTAIR has been linked as a method to guide researchers in the standardisation process.

The NMP TeAm Partner Search Facility¹² has been established by the network on NMP NCPs in order to offer best support to its clients. This web service is strictly focused on the open calls for proposals of the key enabling technologies Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing of H2020and related actions like FET open and ERA-NETs like SIINN and M-ERA.NET.

1.2 A brief overview of the European standardization context

The expert panel that reviewed the European Standardization System (ESS) with a vision to 2020, dedicated a specific chapter to standardization and innovation, concluding that there was a disconnect in the exploitation of R&D results by standards development activities, often due to a lack of awareness of the R&D outputs and missing support and incentives. Many research institutions, companies and policy makers have neglected this channel, especially research funding organisations. Standards bodies have also not consistently addressed development of research friendly and innovation-friendly policies.

In addition to the interface between research and standardization, the document emphasizes that the research about the benefits and needs for standardization should also be further developed. Standardization research has rather stagnated despite its increasing relevance for policy and strategy. However, one important reason for the stagnation is due to the difficulties in accessing data on standardization processes and standards. There is not a lack of data, but deficits in the quality, completeness, homogeneity and transparency of data.

CEN and CENELEC Technical Boards agreed in October 2008 to create a joint strategic Working Group to address STAndardization, Innovation and Research, in short: STAIR. STAIR defined the "Integrated Approach" that provides a mechanism to ensure standardization is integrated in research and innovation projects. Main STAIR objectives are: raising awareness of the benefits of standardization in the research and innovation process; transferring research results and outcomes of innovation activities into standardization; fully exploiting the functions of standards for research and innovation activities in order to increase the competitiveness of the EU.

In 2013, STAIR launched a sectorial 'STAIR Platform' to facilitate dialogue and communication on standardization policy in relation to a specific research subject, between the research and innovation communities and the relevant standardization actors in Europe. The first 'STAIR Platform' addresses Additive Manufacturing (AM).

The European Parliament resolution of 21 October 2010 on the future of European standardization (2010/2051/(INI)) underlined that the European framework programmes for research, competitiveness and innovation could provide an important contribution to the standard-setting process by devoting a chapter to standardisation. Considering that such a measure would increase understanding of the benefits of standards and help to promote a systematic approach further upstream between research, innovation and standardisation, called on the EC to include 'relevance to standardisation' amongst the evaluation criteria of EU-funded R&D projects, to promote projects related to standardisation, and raise awareness about those projects via innovative means.

On June 2011, the Commission adopted a Communication entitled "A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of

¹² https://www.nmp-partnersearch.eu/index.php

the European economy by 2020", that places in focus the important role expected from standardisation in supporting the Europe 2020 Strategy for smart, sustainable and inclusive growth. The document identifies European standards as an important step for bringing research results to the market and for the validation of technologies. This is particularly important for nanotechnologies, because standards in this field can facilitate the introduction of new products and contribute to the public acceptance of these innovations.

Scientific activities make a key contribution to the standardisation process and consequently the document identifies that a systematic approach to research, innovation and standardisation should be adopted at European and national level to improve the exploitation of research results, help best ideas to reach the market and achieve wide market uptake.

A project¹³ carried out during 2013 by the Technopolis Group, on behalf of CEN and CENELEC, estimated of 43% of all FP6 and FP7 projects addressing standardization in some way: 39% of all FP6 and FP7 projects has used standards as an input, 12% had proposed new or revised standards as an output, and 8% had gone on to contribute to the development of new or revised standards. The FP7 priority areas estimated to have the highest share of projects addressing standardization were Security (75%), Transport (including aeronautics) (66%), ICT (62%) and Energy (60%). The study also identified that one in eight FP7 calls made explicit reference to standardization, and that projects funded under these calls were almost three times more likely to make use of standards than projects funded through calls that did not refer to standardization. These results confirm the important role of the Commission in encouraging research teams to address standardization.

In the field of nanotechnology, the European Commission addressed in 2007 to CEN, CENELEC and ETSI the "Mandate M/409 for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials".

Work on toxicology and screening, is performed mainly in the framework of the OECD. Work on risk assessment for chemicals is carried out mainly by the authorities involved in the implementation of REACH, in cooperation with ECHA. However, there is a key role for standardisation as regards measurement and testing tools for the characterisation, behaviour of nanomaterials and exposure, complementing the work being carried out in the framework of the OECD and in the context of the implementation of REACH and CLP. Through M/461 the Commission therefore requests CEN, CENELEC and ETSI to develop a set of standardisation deliverables in these fields.

In 2010, CEN accepted 'Mandate M/461 - Standardization Mandate to CEN, CENELEC and ETSI for standardisation activities regarding nanotechnologies and nanomaterials'. In 2013, CEN/TC 352 'Nanotechnologies' was involved together with CEN/TC 195 'Air filters for general air cleaning' and CEN/TC 137 ' Assessment of workplace exposure to chemical and biological agents' in developing several European deliverables under this Mandate.

CEN and CENELEC are fully committed to supporting Horizon 2020 and helping to tackle barriers to innovation in Europe. CEN-CENELEC produced a position paper in 2012 providing a set of concrete steps to integrate standardisation as a tool in support of Horizon 2020.

CEN-CENELEC have developed a dedicated website for standardization in H2020¹⁴ (Research Helpdesk). Additionally webpages provide tools and information for researchers demonstrating how standardization can benefit to them and how they can participate in the standardization process.

In addition, a consortium consisting of the NSBs: AENOR (Spain), AFNOR (France), ASRO (Romania), BSI (United Kingdom), DIN (Germany), DKE (Germany), DS (Denmark), NEN (Netherlands), SN (Norway), SIS (Sweden) as well as CEN and CENELEC, with DIN acting as project coordinator, is developing, from January 2013 to December 2014, the project BRIDGIT¹⁵, funded by the European Commission and EFTA. BRIDGIT - Bridging the Gap

¹³http://www.cencenelec.eu/standards/Education/JointWorkingGroup/Documents/Study_Contribution_St andardization_Innovation_Final2013.pdf

¹⁴*http://www.cencenelec.eu/research/Horizon2020/Pages/default.aspx*

¹⁵http://www.cencenelec.eu/research/BRIDGIT/Pages/default.aspx

between Research and Standardization -aims to "bridge the gap" between standardization, research and innovation:

- 1. demonstrating the best practices in Europe among the standardization organizations to reach out to the research community
- 2. transferring the idea of the Integrated Approach to all CEN and CENELEC members, to the research communities in Europe and to other actors involved in research
- 3. disseminating the evidence of the correlation between standardization and innovation

CEN and CENELEC cannot become formal partners in European funded research projects, delegating this participation to their national representatives. The NSBs should play a useful role as Partners in European research projects, especially when there is a specific expertise in a NSB or close contacts to the relevant national research community.

Key stakeholders are:

✓ European Standardisation Bodies (ESB): European standards are developed through the platforms provided by one of the three European Standards Organisations, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). ESB have established specific Technical Committees (TCs): CEN TC 352 in the field of nanotechnologies and IEC TC 113 for nanotechnology standardization for electrical and electronic products and systems.

Since 2006, CEN/TC 352 – Nanotechnologies under AFNOR/UNMZ (France/Czech) Secretariats, is engaged in standardization in the field of nanotechnologies. This includes the development of a set of standards addressing the following aspects of nanotechnologies: classification, terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; science-based health, safety and environmental practices; nanotechnology products and processes.

✓ National Standardization Bodies (NSBs). CEN's National Members are the NSBs of the 28 European Union countries, the Former Yugoslav Republic of Macedonia, and Turkey plus three countries of the European Free Trade Association (Iceland, Norway and Switzerland).

The standardization system in Europe is based on the national pillars, which are the National Standardization Bodies or the members of CEN. A National Standards Body is the one stop shop for all stakeholders and is the main focal point of access to the concerted system, which comprises regional (European) and international (ISO) standardization. To facilitate the national interaction between the research and standardization community, a majority of CEN and CENELEC members have appointed a dedicated national contact for Research, Development and Innovation (RDI)¹⁶.

✓ International Standardization Organizations. At the international level, ISO established the TC 229 dealing with nanotech-related issues, (JWG 1 Terminology and nomenclature, JWG 2 Measurement and characterization, TG 2 Consumer and societal dimensions of nanotechnologies, TG 3 Nanotechnologies and sustainability, WG 3 Health, Safety and Environmental Aspects of Nanotechnologies and WG 4 Material specifications). Cooperation between ISO and CEN was ensured through the Vienna Agreement. Under CEN/TC 352 coordination, several CEN and ISO Technical Committees are involved in the execution of Mandate M/461.Furthermore, CEN/TC 352 is working closely with ISO/TC 229 Nanotechnologies and will liaise with other European and international bodies (e.g. OECD), to ensure its standards take due account of related work being undertaken elsewhere. Furthermore, activities also are ongoing within the framework of the OECD, which is supported by the Commission.

¹⁶http://www.cencenelec.eu/research/ResearchHelpdesk/Pages/default.aspx

1.3 A snapshot of the European industrial context

According to the Communication from the European Commission on the Second Regulatory Review on Nanomaterials $(2012)^{17}$, the total annual quantity of nanomaterials on the market at the global level is estimated at around 11 million tonnes, with a market value of roughly 20bn \in . Carbon black anamorphous silica represents by far the largest volume of nanomaterials currently on the market. Together with a few other nanomaterials, they have been on the market for decades and are used in a wide variety of applications.

The group of materials currently attracting most attention are nano-titanium dioxide, nanozinc oxide, fullerenes, carbon nanotubes and nanosilver. Those materials are marketed in clearly smaller quantities than the traditional nanomaterials, but the use of some of these materials is increasing fast.

Products underpinned by nanotechnology are forecast to grow from a volume of 200 bn \in in 2009 to 2 trn \in by 2015. These applications will be essential for the competitiveness of a wide area of EU products in the global market. There are also many newly founded SMEs and spin-off companies in this high technology area. Currently, the direct employment in nanotechnology is estimated at 300.000 to 400.000 jobs in the EU, with an increasing tendency.

The economic sectors with the highest use of nanomaterials are aerospace (e.g. lightweight materials, resistant paints and coatings for aerodynamic surfaces); automotive industry and transport (e.g. scratch-resistant paints and coatings, plastics, lubricants, fluids, tyres); agrifood (e.g. sensors to optimise food production); construction (e.g. insulation, stronger building materials, self-cleaning windows); energy generation (e.g. photovoltaic) and storage (e.g. fuel cells and batteries); environment (e.g. soil and groundwater remediation); cosmetics (e.g. sunscreens, tooth paste, face creams); health, medicine and nanobiotechnology (e.g. targeted drug delivery); information and communication technologies, electronics and photonics (e.g. semiconductor chips, new storage devices and displays); security (e.g. sensors to detect biological threats); and textiles (e.g. protective clothing, stronger, self-cleaning or fire-resistant fibres).

It is difficult to find reliable information on the relative strength of the EU in nanotechnology compared to other regions of the world. The KET HLG report mentions that the EU accounts for 27% of worldwide public funding on nanomaterials, 17% of patents, and 15% of nanobased products.

The Communication from the EC concludes highlighting that, in the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required.

According to Nanotechnology Industries Association (NIA), in the field of nanotechnology, the development of appropriate nomenclature and standards is still in its infancy, and fast progress is urgently required so as to avoid hampering the development and acceptance of nanotechnology-based innovation. So far over one hundred key vocabularies, as well as dozens of technical specifications and reports, have been produced. Nevertheless many more are needed, and active industry participation in the standardisation process is of the utmost importance in ensuring the best possible market conditions for nanotechnologies.

Key stakeholders are:

✓ Industry and industrial associations: Industry is a key player in developing standards. The Nanotechnology Industries Association (NIA)¹⁸ is the sector-independent, responsible voice for the industrial nanotechnologies supply chains. NIA

¹⁷ http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf

¹⁸http://www.nanotechia.org

emphasizes that standards are vitally important to the effective worldwide trade of products and services; they guarantee that what is on offer is of an exact specification and quality. Companies that use standards can expect both lower business costs and risks and higher market presence.

1.4 The European regulatory context in brief

The regulatory uncertainties are considered as one of the main challenges in bringing nanomaterials to market in Europe. The current debate, including on the lack of regulatory clarity and on the uncertainties surrounding the potential risks of nanotechnology and nanomaterials have had a negative effect on their development, uptake and exploitation in Europe and have been clearly identified as a major barrier to innovation based on these technologies.

Standards play a role for regulatory compliance, in particular in areas where regulation requires a risk assessment and risk management approach, compliance with which can be demonstrated by standards. In general, the application of standards, unlike legal texts, is voluntary. Standards can however become part of legislation, when their wording or content is taken up by legal texts. This question relates to the "<u>New Approach</u>"¹⁹ Directives, which rely on standards to provide the technical solution in support to European legislative texts (mostly in directives, further in regulations, recommendations and decisions). The standards developed to support legislation are called <u>Harmonised Standards²⁰</u>.

To ensure that nanotechnology is developed in a safe and responsible manner, the European policy on nanomaterials was developed on the basis of a European Strategy for Nanotechnology and Action Plan for Europe (2005/2009), adopted respectively in 2004 and 2005. The first document brought the discussion on nanosciences and nanotechnologies to an institutional level, proposing an integrated and responsible approach for Europe; the second Communication defined a series of articulated and interconnected actions for the immediate implementation of a safe, integrated and responsible approach for nanosciences and nanotechnologies, based on the priority areas identified in the above-mentioned European Strategy. Two implementation reports were produced until 2009.

In 2008, the Commission adopted a code of conduct for responsible nanosciences and nanotechnologies research and, also the same year, prepared a first regulatory review of EU legislation in relevant sectors.

More recently, in October 2011, the Commission adopted the Recommendation on the definition of a nanomaterial. One year later, in October 2012, the Commission adopted the Communication on the Second Regulatory Review on Nanomaterials that describes the Commission's plans to improve EU law and its application to ensure their safe use. The document is accompanied by a Staff Working Paper on nanomaterial types and uses, including safety aspects, which gives a detailed overview of available information on nanomaterials on the market, including their benefits and risks.

On the basis of the Communication of second Regulatory review on Nanomaterials, the Commission concluded that, Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary.

The Commission envisaged modifications in some of the REACH Annexes and encourages European Chemicals Agency (ECHA) to further develop guidance for registrations after 2013. The Commission will make an impact assessment of relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. If appropriate the Commission will come forward with a draft implementing act by December 2013.

¹⁹ http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/index_en.htm

²⁰ http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/

The main REACH and CLP impacts on products of emerging technologies were considered to be administrative burden and information requirements, as well as negative effect to time-to-market and marginal cost structure. Large variations exist in the registrations costs of substances with nanomaterial forms. The compliance costs are largely taken out of R&D resources in smaller companies. In case companies are not able to transfer them to the product price - typically seen as a problem for SMEs - it may affect the time to market of products.

Nanomaterials that fulfil the criteria for classification as hazardous under Regulation 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures must be classified and labelled.

General requirements in relation to occupational safety and health of workers at workplaces are provided by Directive 89/391/EC (OHS Framework Directive) and additional requirements for the protection of workers from risks of chemical agents at the workplace are listed in Directive 98/24/EC. There is not a specific Directive on occupational nano-risks. The European Strategy for Safety and Health at Work 2007-2012 was evaluated at the end of the period. One of the conclusions for the future was to better focus on emerging risks (e.g. nanotechnology).

In brief, there is a large number of general regulations and recommendations within the European Union and in the EU Member States that in many ways regulate the development and use of engineered nanomaterials and nano-enabled products as well as the development of nano-based innovations. In this sense, the NSC Strategic document (2015-20125) emphasizes the importance of the regulatory framework and standardization as two main drivers, promoting the development of safe engineered nanomaterials and their applications.

Currently, the main research aimed at supporting the development of the future European regulation in the field of nanotechnology, is carried out by NANOREG FP7 project²¹.

Public authorities are **key stakeholders** in regulatory issues. Moreover, they act as drivers for standardisation through the development of standards, prescriptive legislation, the issue of standardisation mandates and public procurement. They provide significant funding to standardisation, both for the ESOs and the NSBs.

- ✓ European Commission. EU Commission plays in Europe a key role in regulatory activities within the European setting. European Commission's Directorates involved in nanotechnology regulation are: DG Enterprise and industry (REACH and nanomaterials), DG Environment (Chemicals legislation, including nanomaterials, environmental risk assessment), DG Environment (REACH, including nanomaterials), DG Employment and Social Affairs (Health and safety at work of nanomaterials), DG Health and Consumer Protection (Health risk assessment and regulation).
- ✓ EC Advisory Committees. Three independent scientific committees provide the European Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment; and also draw the European Commission's attention to the new or emerging problems (e.g. nanotechnology) which may pose an actual or potential threat: 1) the Scientific Committee on Consumer Products (SCCP), 2) the Scientific Committee on Health and Environmental Risks (SCHER) and 3) the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), and all are made up of external experts. In addition, the EC relies on the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).
- ✓ NANOREG project. Nanoreg is not strictly a regulatory project, but a project to support the future European regulation in the nanotechnology field. NANoREG is the first FP7 project, involving the three main stakeholders (Regulation, Industry and Science), to deliver the answers needed by regulators and legislators on EHS by

²¹http://www.nanoreg.eu/

linking them to a scientific evaluation of data and test methods. Based on questions and requirements supplied by regulators and legislators, NANoREG will: 1) provide answers and solutions from existing data, complemented with new knowledge, 2) Provide a tool box of relevant instruments for risk assessment, characterisation, toxicity testing and exposure measurements of MNMs, 3) develop, for the long term, new testing strategies adapted to innovation requirements, 4) Establish a close collaboration among authorities, industry and science leading to efficient and practically applicable risk management approaches for MNMs and products containing MNMs.

1.5 The most relevant standardization needs for European stakeholder groups

The project nanoSTAIR carried out a survey to identify the needs of European stakeholder groups for new standards, to bridge the gap between the research objectives and the standardization needs, by facilitating the process of clustering (Deliverable D2.1).

Different stakeholder groups were asked to rate the relevance of the predefined standardization items according to the relevance to their business or work. Respondents were divided into four groups: Research and development, industry, standardization body and other stakeholder. Survey contained 59 possible standardization topics in the area of nanotechnology. The standardization topics used in this survey were based on the Mandates from the European Commission and future plans of the TC 352 and were divided in three main areas: 1) Metrology and instrumentation, including specifications for reference materials (26 topics); 2) Science-based health, safety and environmental practices (8 topics) and 3) Nanotechnology products and processes (25 topics). Respondents rated the level of the relevance of the topic and also indicated if they were as a stakeholder interested to participate in standardization process of the topics.

Total number of participants in the survey was 39. Research and development stakeholder group was the biggest stakeholder group, representing 76% of the answers. Other stakeholder group represents 24%, industry 18% and standardization body 12% of the answers. Thus, the sampling method (sending questionnaire via European Technology Platform of Industrial Safety and NanoSafety Cluster) might cause bias to the response rates. Anyhow, the response rate indicates that R&D stakeholder group recognizes the need of standardization in the area of health and safety of nanotechnology.

According to the survey, the topic area of "Characterization, identification and detection of nanomaterials" is the most important standardization topic for all stakeholders. The need for guidance and protocols for characterization of manufactured nanoparticles was recognized important issue in all stakeholder groups. R&D, standardization body and industry stakeholder groups ranked these items to the most relevant standardization topics. Guidance for the characterization was needed for the determination from aerosols and from environmental samples, in toxicity tests as well as from materials and devices. Table 1and Table 2 respectively summarize the fifteen most relevant standardization items identified by the survey (Top 15) and the main standardization items grouped by relevant thematic groups.

Reliability of the test methods was another important issue and also the repeatability, reproducibility and inter-comparability of test methods was the most relevant topic for the stakeholder group called "other", which included regulators, but it was also important topic for the standardization body and R&D. Also inter-laboratory comparisons and reference materials were seen as important topics.

The answers from the R&D, the standardization, and other stakeholder groups resemble quite well with the answers of the whole group. R&D group was biggest of all stakeholders answering the survey and it might influence why thirteen standardization items were the same as in the top 15 list of the whole stakeholder group. Twelve of the most important standardization items in the standardization stakeholder group were the same as the top 15 items of whole group (Table 1). In addition eleven of the top 15 items in the whole group were the same as in the group of other stakeholders. On the contrary e.g. the need for certified reference materials and the guide to performance measurement for nanoscale materials and devices does not get as high priority among the R&D group as in the whole group. Similarly, the need for protocols for short and long term toxicity testing was not in the top 15 list of R&D group.

The standardization need of industry group, which included manufacturers and down-users or end users, differed notably form the needs of the whole group. Only seven (7) of the most important standardization items (top 15) were the same as in the whole group and eight items were the same as in the R&D group. On the contrary to other stakeholder groups, industry group give a high importance to standardization to nanotechnology products, processes and devices. Standardization items such as product specifications, good practices for nano fabrication and nano-engineering, and safety of nanotechnology devices are important to industry group.

Safe use on nanomaterials was also very important topic for industry stakeholders and also for R&D group. In addition industry group needed guide to the management of waste and the disposal of nanomaterials.

Similarly, modelling and simulation standardization topic area seemed to be important for this industry group. Standardization group needed standard methods to assess emissions from using nanoparticles. Other stakeholder groups give high relevance to the development of reference materials whereas for industry group this was of minor relevance. Common data-format for risk assessment was important for R&D group.

Table 1: Fifteen most relevant standardization items (top 15) identified by the nanoSTAIR survey (Part of Deliverable D2.1)

- 1. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.
- 2. Repeatability, reproducibility and intercomparability of test methods.
- 3. Guide to the identification and definition of measurands required for characterizing, evaluating functional properties and performance etc., of materials and devices at the nanoscale.
- 4. Guidance on nano-material characterization prior to, or in association with toxicity testing.
- 5. Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials.
- 6. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment).
- 7. Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.
- 8. Development of Reference Materials and Certified Reference Materials dedicated to existing and new techniques, particularly for challenging and checking the functioning/calibration of nanoparticle measurement and analysis equipment.
- 9. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects.
- 10. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities.
- 11. Guide to the management of waste and the disposal of nanomaterials.
- 12. Guide to performance measurement of nanoscale materials and devices.
- 13. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment.
- 14. Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities.
- **15.** Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges).

Table 2: Main standardization items identified by the nanoSTAIR survey, grouped by relevant thematic groups

Thematic group 1: Characterization, identification and detection of nanomaterials

1. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.; 2. Guide to the identification and definition of measurands required for characterising, evaluating functional properties and performance etc, of materials and devices at the nanoscale;

3. Guidance on nano-material characterization prior to, or in association with toxicity testing;

4. Guide to performance measurement of nanoscale materials and devices;

5. Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities;

6. Guides to purity evaluation of manufactured nanoparticles and other nanoscale entities.

7. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects

Thematic group 2: Reliability of test methods

1. Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.

2. Repeatability, reproducibility and intercomparability of test methods.

Thematic group 3: Toxicity and ecotoxicity testing

1. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;

2. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment;

3. Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities;

4. Stability assessment of nanoparticles in vivo and in vitro;

5. Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;

6. Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;

7. OECD test guidelines for manufactured nanomaterials;

Thematic group 4: Nanotechnology products, processes and devices

1. Safety –Pre-competitive research, Design, Manufacture, Use and End-of- life (includes disposal, reuse and recycling)

2. Guide to design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water

3. Good practice for nano-fabrication and nano-engineering

Thematic group 5: Safe use of ENM

1. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities(including selection of Personal Protective Equipment)

2. Guide to the management of waste and the disposal of nanomaterials

3. Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges)

4. Protocols for risk management that specifically refers to potential nanotechnology hazards

Thematic group 6: Other standardization items of high relevance

1. Simulation Methods/techniques to approximate exposure

2. Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials

3. Development of Reference Materials and Certified Reference Materials dedicated to existing and new techniques, particularly for challenging and checking the functioning/calibration of nanoparticle measurement and analysis equipment

4.- Guidance on a common data-format for an integrated analysis for risk management

1.6. Main barriers between research and standardization

According to the project FP6 - INTEREST^{22, 23,24}, the barriers to participation of research in standardization can be divided into three broad categories: 1) Resources required for participation (money, time, personnel, etc.); 2) Standardization process (length, flexibility, IPR rules, integration of input, etc.); 3) Awareness and visibility of standards and standardization (awareness of benefits, links to SSBs, helpdesks, etc).

More specifically, the European project identified the four most important barriers to researchers:

- 1. "My expenses are not covered by my organization or by third parties." (This is the most important barrier by far).
- 2. "The standardization process is not flexible and fast enough."
- 3. "Standardization activities do not have a positive impact on the evaluation of my research."
- 4. "My expertise is not relevant in the standard-setting process."

And, in parallel, the four top motivators that could increase participation of researchers in standardization are:

- 1. If my expenses were covered by my organization or by third parties
- 2. If the standardization process was more flexible and faster
- 3. If standardization activities had positive impact on the evaluation of my research
- 4. If I thought my expertise was relevant in the standard-setting process

A set of barriers that obstruct transfer of research outputs into standardization deliverables, were also detected by the NMP Expert Advisory Group (2012):

- 1. When a project is approved, assessment is not made reliably of the potential contribution it can make towards the development of new standards or to the improvement of existing standards;
- Timescale of research projects often not aligned with standardisation timescale. This is because once the research project is completed, there is usually no financial support available for transferring the results into written standards and securing consensus through participation in the relevant standards committee which may be European or International;
- 3. Not all researchers wish to participate in standards committees which require meticulous attention to details and usually provide little recognition and enhancement of a research career;
- 4. Researchers and standardization experts often operate in different circles and may not be aware of each other's activities;
- 5. Funding for pre- and co-normative research, although relatively small, is extremely difficult to find;
- 6. Within DG RTD, there is not a focus for linking research with standardization. Each Directorate deals with this topic within its own programme remit and interacts directly with DG Enterprise who has the overall policy responsibility for European Standards and the European Standards Organizations (ESOs CEN/CENELEC and

²² http://www.interest-fp6.org/

²³ http://www-i4.informatik.rwth-aachen.de/Interest/Manual_SSB.pdf

²⁴ http://www-i4.informatik.rwth-aachen.de/Interest/Manual_R%26D.pdf

ETSI). DG enterprise provides financial support to ESO and can mandate ESOs for the development of standards and request DG research to support pre-normative R&D. Furthermore, Directorate B has the responsibility for a large Article 185 activity called the European Measurement Research Programme (EMRP) which covers primarily the Metrology infrastructure.

The report of the Technopolis Group, on behalf of CEN and CENELEC (2013), refers that the most widely cited issues and barriers²⁵ when proposing new standards relate to the time and/or uncertainty surrounding the decision-making process within SDOs; a lack of funding to take forward the proposed standards development work; competition from other competing proposals or ideas in similar or related areas; the inherent complexity of the standardization world; and difficulties generating industrial support for new standards. When contributing to the standards development process, some consortia encountered issues with non-alignment between the project and standardization 'timetables'; difficulty in gaining acceptance of the inputs provided; lack of resources to provide inputs to the development process; and difficulties gaining access to Standards Organizations and their technical committees.

Finally, the NSC (2013) identified three commonly observed barriers for conducting standardization activities within a project:

- 1. Lack of awareness among researchers of what is going on in standardization,
- 2. Lack of incentives for researchers to invest time and efforts,
- 3. Lack of resources to invest time for standardization activities.

The Table 3summarizes the barriers identified by literature sources consulted by nanoSTAIR in three main categories, according to the classification established by the INTEREST project.

²⁵ http://www.cencenelec.eu/standards/Education/JointWorkingGroup/Documents/Study_Contribution_Standardization_Innovation_Final2013.pdf

Table 3: Barriers identified by literature sources consulted by nanoSTAIR, classified in the three main categories established by project INTEREST

Main typology of barrier	Project INTEREST (FP6) (2006)	NMP Expert Advisory Group (2012)	EU- Nanosafetycluster Strategy (2013)
Resources required for participation	"My expenses are not covered by my organization or by third parties." (This is the most important barrier by far).	Funding for pre- and co-normative research, although relatively small, is extremely difficult to find;	Lack of resources to invest time for standardization activities.
Standardization Process	"The standardization process is not flexible and fast enough."	Timescale of research projects often not aligned with standardization timescale. This is because once the research project is completed, there is usually no financial support available for transferring the results into written standards and securing consensus through participation in the relevant standards committee which may be European or International;	Lack of awareness among researchers of what is going on in standardization.
		Researchers and standardization experts often operate in different circles and may not be aware of each other's activities;	
Awareness and recognition of standardization	"Standardization activities do not have a positive impact on the evaluation of my research."	When a project is approved, assessment is not made reliably of the potential contribution it can make towards the development of new standards or to the improvement of existing standards;	Lack of incentives for researchers to invest time and
	"My expertise is not relevant in the standard-setting process."	Not all researchers wish to participate in standards committees which require meticulous attention to details and usually provide little recognition and enhancement of a research career; Within DG RTD, there is not a focus for linking research with standardization. Each Directorate deals with this topic within its own programme remit and interacts directly with DG Enterprise who has the overall policy responsibility for European Standards and the European Standards Organizations (ESOs - CEN/CENELEC and ETSI). DG enterprise provides financial support to ESO and can mandate ESOs for the development of standards and request DG research to support pre-normative R&D. Furthermore, Directorate B has the responsibility for a large Article 185 activity called the European Measurement Research Programme (EMRP) which covers primarily the Metrology infrastructure.	efforts.

2. Integrating standardization into research projects

A recent <u>study</u>²⁶ presented by CEN and CENELEC, identified that one in eight FP7 calls made explicit reference to standardization, and that projects funded under these calls were almost three times more likely to make use of standards than projects funded through calls that did not refer to standardization. In brief, 43% of all FP6 and FP7 projects addressing standardization in some way: 39% of projects <u>used</u> standards as an input, 12% <u>proposed</u> new or revised standards as an output, and 8% <u>contributed</u> to the development of new or revised standards.

The same study showed that nearly three-quarters (73%) of FP6 and FP7 project coordinators who included standards in their previous projects said that they would be willing to address <u>standardization again</u>.

Many calls for funding programs of RTD projects refer to standardization as a relevant requirement to be considered by the project. This is due to the advantages that standardization provides to projects on issues such as interoperability, dissemination of results and support to market introduction.

Integrating standards and standardization in project proposals can amplify the impact of the project, facilitate the dissemination and exploitation of research results, and ensure a better evaluation.

2.1. Why integrate standardization into research?

According to CEN-CENELEC²⁷ and AENOR²⁸, there are many arguments as to why using existing standards or even shaping future standards will benefit researchers and research projects. In brief,

- Using standards as a knowledge source (State of the art) in the earliest possible stages of the research avoids **duplication of work** and places the project contribution on a broad and **marketable basis**;
- b. Building upon standards ensures **compliance with market conditions**, ensuring compatibility and interoperability and increasing the transparency for prospective customers, facilitating market entry.
- c. Being involved in standardization and shaping future standards helps to **translate the research findings**, including intellectual property rights, **into marketable solutions**.
- d. Addressing standardization as part of the dissemination strategy can help win funding for the research. In parallel, monitoring or even influencing future standards might **lower the future R&D risks and costs**.
- e. Participating in standardization, increases the **visibility** and research will be part of a recognized and **reputable worldwide platform**, providing extensive and directed dissemination.

In addition, integration of standardization in research provides also additional benefits for the European standardization system, such as:

- a. Promotion of **new topics, standards and standardization deliverables** in **innovative and technologically advanced fields**.
- b. Achieve a **tangible approach to the research community**, traditionally distant from standardization.
- **c. Meet the requirements of the European Commission** on the active support of standardization in research and innovation.

²⁶

http://www.cencenelec.eu/standards/Education/JointWorkingGroup/Documents/Study_Contribution_Standardization_Innovation_Final2013.pdf

²⁷ http://www.cencenelec.eu/research/tools/WhyUseENs/Pages/default.aspx

²⁸ http://www.aenor.es/DescargasWeb/normas/normas_proyectos_IDI.pdf

2.2. Integration in practice

Integration of standardization in research project involves, at least, two basic actions:

- a. Consider existing standards and standardization deliverables as a part of the project's state of the art.
- b. Use standards and standardization deliverables as an effective means to disseminate and exploit the project results and facilitate market access.

To ensure integration of standardization in research projects, nanoSTAIR proposes a simple procedure in five steps (Figure 1):

Step 1.- Identifying needs for standardization.

Several of the calls issued under Horizon 2020 as well as other national programmes, refer to the possibility of standards and standardization deliverables being included in the work activities or as possible outputs of projects (see e.g. chapter 1.1). Therefore, read carefully your call for proposals and specific topics and identify potential standardization requirements to be fulfilled by the proposal. Usually CEN-CENELEC and some NSBs publish in due course an overview of all calls – at least at European level - which make direct reference to standardization activities.

Step 2.- Contacting and involving a European standardization body(CEN-CENELEC, National Standardization Body).

If you decided to integrate standardization in your research project, the next step is to contact a European standardization body from the earliest possible stage of a project proposal. Project coordinators and consortia can directly contact the CEN-CENELEC Research Helpdesk (<u>research@cencenelec.eu</u>; Twitter <u>@Standards4RDI</u>) or their respective National Standardization Bodies (NSBs, see Annex 2).

Note that CEN and CENELEC cannot become formal partner in European funded research projects, delegating this participation to their <u>national representatives (NSBs</u>). Consequently the most effective way to integrate standardization in a research project is to make a NSB a part of the research project. In this sense, to facilitate the national interaction between the research and standardization community, most of CEN and CENELEC members have appointed a dedicated national contact point (DNCP)²⁹. For members without a DNCP, you can use their generic e-mail address.

A NSB can inform, train and also participate in research projects as follows:

- ✓ Advising on how to approach standardization issues
- ✓ Leading and managing all activities related to standardization
- \checkmark Assisting to coordinate exploitation issues and standardization, and finally
- ✓ Giving credibility to standardization in the proposal

In addition, because the NSB can access sensitive information on the future project proposal, the signature of a confidentiality agreement is highly recommended.

Step 3.- Preparing the proposal.

After contacting the NSB, you can work together to elaborate the best solution for the project proposal. Some issues to be discussed are:

²⁹<u>http://www.cencenelec.eu/research/ResearchHelpdesk/Pages/default.aspx</u>



Figure 1: Simple procedure to integrate standardization into the research project.

- Scope of the standardization activities to be covered by the proposal. Depending on the Technology Readiness Level (TRL) considered by the proposal and the degree of maturity of the protocols/methods considered, a different set of standardization activities can be defined. As an example, in Table 4 you can find a proposal, developed by the Spanish standardization body AENOR, to select standardization issues according to the TRL. As can be seen, when the TRL level increases, the complexity of recommended standardization activities are (Table 4):
 - <u>Identification of published or under development standards</u>, applicable for the project. There are a couple of databases which provide a simple entry point into the stock of national, European and international standards: CEN's National Standard Bodies and CENELEC National Committees. CEN is involved in a variety of sectors such as nanotechnologies, energy, bio-based products, security, healthcare, etc. and CENELEC in sectors from the electrotechnical field. The websites provide access to a database of over 20.000 existing standards. Browsing this database, those standards useful for the project can be identified.
 - <u>Identification of new standardization fields</u>. This activity can include mapping of standards, identification of standardization gaps, identification and planning of future standardization needs.
 - 3) <u>Collaboration with existing standardization Technical Committees</u>. To facilitate the collaboration between an existing Technical Committee (TC) and the research project, CEN therefore proposes and facilitates "Liaisons". The liaison applies for the duration of the research project and allows a research project representative to participate in the meetings of the Technical Committee and relevant Working Group meetings as an observer (without decision power).
 - 4) <u>Pre-normative technical activities</u> raising the degree of maturity of the protocols considered for standardization: Harmonization of protocols, Inter-Lab training, Inter Laboratory Comparison (ILC) or Round Robin (RR). This may require some funding of experts and teams external to the project. The results, especially the optimized protocol and the documentation of its validity, can be <u>published</u> as a white paper (quick solution) or a scientific publication (slow solution) bearing the names of the authors (contrarily to the norm), that can be cited as reference by the future standard.
 - 5) <u>Technical proposals for new or revised standardization documents</u>, including e.g. the study of real potential to translate the project results in standardization documents and the best way to do it, proposal for new or revised standards and standardization documents in the fields e.g. terminology, testing methods, characterization, best practices or specifications for products, services, processes.
 - 6) <u>Pool experts and initiatives</u> relevant for the protocols considered, so as to reach a critical mass for obtaining positive votes for the New Work Item Proposal and constituting an official drafting group ("Project group") and actually draft the standard. This may require some funding of experts external to the project.
 - 7) <u>Developing new standards activity</u>, through participation and leadership in the elaboration of new or revised standardization documents. If there are no existing standards that "fits" the project proposal and you think that a standard would add value to your project, you might decide to either develop a new standard, or to contribute to ongoing standardization work. A CEN or CENELEC Workshop Agreement (CWA) can be also a good first step, as it can be delivered within your project timeframe.

- **Mode of participation and role of the NSB within the proposal.** The main function of the NSB will be the management of all project activities related to standardization, from the proposal stage to the end of the project, along the life cycle of the research project (Figure 1). Consequently the NSB will provide everything necessary to identify, coordinate and develop the standardization issues considered by the project. Depending on the scope of standardization activities, the level of involvement of the NSB can be different and thus, several options for cooperation can be considered. From a higher to a lower degree of involvement, the NSB can become:
 - 1) A partner of the consortium
 - 2) A subcontractor of a consortium partner, exclusively for project standardization activities
 - 3) A member of the project International Advisory Board or Steering Committee
 - 4) An organization that supports the project by providing a letter of intent (LOI).
- **Translation of standardization issues in the document of the proposal.** Finally, once the scope of standardization activities to be covered by the project, the mode of participation and the role of the NSB have been properly defined, we will proceed to integrate all these issues in the document of the project proposal, defining objectives, associated tasks & work packages, deliverables, planning, budget, etc..

Step 4.- Negotiating the contract with the European Commission. Once the proposal has been positively evaluated and the European Commission (EC) communicates to the coordinator its intention for funding the proposal, the EC may require, prior to signing the Grant Agreement (GA), a fine adjustment or redefinition of some aspects of the future project in the Description of Work (DoW), which may include the standardization issues. Again the NSB will be your best travel companion to adequately perform these tasks.

Step 5.- Developing the project according to Description of Work (DoW). Finally, at this last step, only the development of standardization activities according to DoW, is pending.

In all stages, the nanoSTAIR contact point (see next chapter, 3) can be a sound ally to help the consortium / NSB in the definition and development of standardization activities considered by the project.

2.3. Standardization and Intellectual Property Rights (IPR)

One of the most important questions raised by researchers when trying to integrate the activities of standardization in research projects, is the relationship of standardization and the Intellectual Property Rights (IPR).

Until recently both concepts could seem contradictory. However, it is a fact that in more and more industrial sectors, the existence of a standard is practically a de facto requirement imposed by the market to the success of a new technology, a new product or service; and that this standard is perfectly compatible with the relevant IPR.

For maximum effectiveness, strategies for protection of IPR and standardization should be carefully coordinated from the initial stage of the project and also during development. The NSB³⁰ can assist in this field, defining in each case the most appropriate standardization activities and thus contributing to reinforce the Plan for Use and Dissemination of Foreground (PUDF).

³⁰http://www.aenor.es/DescargasWeb/normas/normas_proyectos_IDI.pdf

Minimum standardization activities Possible proposed TRL Description standardization documents expected or recommended 1.- Identification of published or under 1. Terminology TRL 1 Basic principles observed and reported development applicable standards. sic & applied research Technology concept and/or application 2. Testing methods TRL 2 formulated 2.- Identification of new standardization Basic & fields. 3. Characterization Analytical and experimental proof of concept 4. TRL 3 established 5. Best practices TRL 4 Demonstration in lab /Simulation/real Laboratory validation of component or process Previous activities and: 6. Specifications for products, services, processes, etc Validation of component or process in simulated 3.- Collaboration with existing TRL 5 environment standardization Technical Committees. Subsystem model or prototype demonstrated in TRL 6 4.- Technical proposals for new or revised relevant environment standardization documents. Integrated pilot system demonstrated in Previous activities and: Implementation, industrialization, commercialization TRL 7 operational environment 5.- Participation and leadership in the Actual system completed and qualified through elaboration of new or revised standardization TRL 8 test and demonstration documents. System ready for full scale deployment, end-use TRL 9 operation

Table 4: Proposal for standardization activities, according to the project's TRL

3. nanoSTAIR - providing information and tools to integrate standardization into research projects on nanotechnologies

3.1 The nanoSTAIR approach

The overall objective of nanoSTAIR project is to build a sustainable process and platform in the field of nanotechnologies to support the transfer of knowledge gained through research to documentary standards in the context of the STAIR approach promoted by CEN-CENELEC.

The project is organized around several activities, in order to speed up the development of new documentary standards. The main result of the project is a mechanism to identify the opportunities for standardization from the results of research projects. It is based on bottom-up approach, i.e. from research community to standardization. This is in accordance with the STAIR approach promoted by CENCENELEC.



Figure 2: The nanoSTAIR turbine

The project nanoSTAIR has basically produced a process, a platform and a set of advanced tools (services) that will play an active role before (upstream) the usual standardization process.

The aim of the nanoSTAIR process is to speed up the preparation of the proposal for standardization items and increase the number of proposals. The nanoSTAIR process can be seen as a turbine that accelerates the preparation of new work item proposals (Figure 2: The nanoSTAIR turbine).

The nanoSTAIR platform is a virtual table where all stakeholders will have the opportunity to share common needs and solutions regarding new documentary standards. It will in particular bridge the research community and the standardization community (Figure 3: The nanoSTAIR **platform**).

The nanoSTAIR website make available the nanoSTAIR platform and a set of advanced tools (services) that will assist in identifying the potential candidates for standardization from the



deliverables / relevant documents of the research projects. It will also help in pooling the resources and expertise to reach the necessary critical mass.

Figure 3: The nanoSTAIR platform

In other words, the nanoSTAIR services will support the preparation of documentary standards in early stages. After identifying the candidates and pooling the necessary resources the emergence of the new work items will go to the normal standardization process. The different standardization options will be the same as in normal standardization process.

The main benefits provided by nanoSTAIR - especially for NSBs - can be listed as follows:

- ✓ Link between NSBs and researchers. The utilization of nanoSTAIR services will help the researchers in the pre-standardization steps. In then, a nanoSTAIR web page containing useful information on the standardization of the research results is provided. Joining to the nanoSTAIR community brings researcher and people interested on standardization together and they all become aware of standardization.
- ✓ Identification of standardization opportunities. As more people become aware of the standardization it will enhance the communication between R&D community and NSB community. This will provide possibilities to reach the experts for various knowledge areas and thus, improve the quality of the documents produced and also enhance the identification of standardization opportunities.
- ✓ Generation of additional work items while saving time and money. The nanoSTAIR services provide tools for systematic screening of research documents for the opportunity of standardization. The nanoSTAIR tools will help the researchers in the identification of suitable technical committee of standardization and finding right contacts for standardization system. The utilization of nanoSTAIR check semantic tool will save time and money in the screening process.
- Stimulation of standardization activities. While being a registered member of the nanoSTAIR web platform, you will get information on ongoing activities; you will receive nanoSTAIR newsletters, get information about latest nanoSTAIR Seminars. It will also offer a single platform where all stakeholders interested in standardization may meet.

3.2 The nanoSTAIR contact point (NSCP) and tools

The nanoSTAIR contact point (NSCP) is the cloud that brings all nanoSTAIR services and tools. It is accessible from the nanoSTAIR website (<u>www.nanostair.eu-vri.eu</u>, Figure 3) and provides three different tools / services:

- 1. Tool 1: The nanoSTAIR web-based platform, as a hotspot for communication between standardization experts and R&D community. In this way a community for all stakeholders interested in nanotechnologies and standardization can be created: researchers, industry, policy makers/European Commission, national authorities and standardization bodies. The nanoSTAIR web site offers a single portal to access/receive targeted information on standardization related to nanotechnologies and strengthen the community. To create the nanoSTAIR platform the various community groups on Nanosafety were identified by the project. For some of these groups a direct connection was made between project nanoSTAIR and the group. For all groups the members of identified community groups were informed about the nanoSTAIR project by presentations, e.g. NanoSafety Cluster meetings , mail or direct contact. The contact persons of research projects, authorities and standardization bodies were brought into contact to each other by the nanoSTAIR platform.
- 2. **Tool 2: The nanoSTAIR check** tool gives support to build a standardization strategy. The nanoSTAIR check is based on the semantic analysis of e.g. a scientific paper or project deliverable and its comparison with the production of Technical Committees (TCs). The use of this semantic tool will also help to: 1) Identify standards relevant for a given research, 2) Get in contact with the standardization committees relevant for the research work and 3) Prepare inputs to standardization and have research results implemented. This support complements the expertise provided by CEN CENELEC and the National Standardization Bodies (NSBs).
- **3. Tool 3: The nanoSTAIR seminar** is organized by nanoSTAIR community. The seminars inform the researchers about the standardization process, committees and the support offered by nanoSTAIR.

The nanoSTAIR services can support the construction of the standardization strategy for a research project. Services can be used in many different occasions (See Figure 1):

- ✓ In the proposal stage and/or during the negotiation of the project grant with the funding agency, nanoSTAIR services could be used, e.g. to identify standards relevant to the research.
- ✓ While preparing the exploitation planning of the project. nanoSTAIR will provide assistance to select the right standardization umbrella for your research results (Technical Committee and Working Group at CEN or ISO level).
- ✓ nanoSTAIR seminars can be arranged e.g. in the national or in the project consortium level. In the seminars information about the role of standardization in capitalizing and disseminating knowledge gained in the research projects. It will also give brief guidance on the technical committees suitable for a given research theme.

3.3 Tool 1: The nanoSTAIR web-based platform

The nanoSTAIR website serves as a platform for communication between the research community, the standardization experts and all other stakeholders interested in nanotechnologies and standardization: researchers, industry, policy makers/European Commission, national authorities and standardization bodies. In this way the nanoSTAIR community will be created.

The website has a clear structure with two types of webpage navigation depending on the type of user i.e. visitor (public), Consortium member or representative of the European

Commission (members area). The aim of the website is on one hand to inform general public about the nanoSTAIR project and its services (Figure 3.3).



Figure 4: The nanoSTAIR website, as a contact point for the nanoSTAIR services and tools.

On the other hand the website constitutes a tool to communicate and to exchange information between the members in the nanoSTAIR community:

- ✓ Good to know section contains links to basic information about standards and standardization, such as standards browsers (ISO and CEN), list of TCs addressing nanotechnology etc. It contains also links to practical guidelines on standardization. This section is mainly intended for researchers.
- ✓ In *Get support* section you will be guided to send your documents to the nanoSTAIR check service. Detailed information on the procedure is found there. This section is mainly intended for researchers.
- ✓ Join today section you can be registered to be a member of the nanoSTAIR community.

In other words, the nanoSTAIR web-based platform provides: 1) Information on on-going activities, 2) Link to relevant community groups, research projects and contacts persons, 3) Partners to contribute to standard preparation and 4) National standardization bodies able to provide the secretariat to develop a new standard.

Persons of research projects, authorities and standardization bodies can be linked to each other by the nanoSTAIR platform through the registration page (Figure 5).

🧃 n	anoSTAIR	<i>tvri</i> 5t
	Login	
Welcome to th	e nanoSTAIR Registration page	
Title:	Unassigned	•
First (Given) Name:		
Last (Family) Name:		_
Gender:	Unassigned	-
Company:		
Job Title:		
Address:		
City:		
Postal Code:		
Country:	Unassigned	-
EMail:		
Phone:		
Fax:		
Web Page:		
User Comments:		4

Figure 5: The nanoSTAIR registration page

3.4 Tool 2: The nanoSTAIR check

The nanoSTAIR check is a service to review if the document of your project has a potential to be the basis to develop new standards in the field of nanotechnologies. The document of your project can be e.g. project deliverable, project proposal, scientific paper, PhD thesis, grey literature report, or benchmark of methods. The documents should be provided as .doc, .pdf or even .txt.

The nanoSTAIR check service is based on a semantic tool, a tool used in so called text mining(Figure 6). The main idea of the semantic analysis is to make award frequency analysis of the project documents and compare them with the corpuses of the different Technical Committees. As a result nanoSTAIR semantic tool will give the user recommendation which Technical Committee would fit best to his/her proposal, so that he/she knows which Committee he/she should address. Finally, the document is checked by a standardization expert in order to give an expert opinion of the standardization potential of the document and the most suitable TC. The expert can also recommend the most suitable contact person for future actions.

This tool has been validated by experts currently involved in ISO or CEN Standardization Committees. The tool has also been tested in terms of: (a) applicability by researchers and standardization experts, (b) repeatability of the results when the tool is run by several people and (c) robustness of the results in regards to heterogeneity of the Standardization Committees.

The outcomes are that (a) the tool is easily applicable; (b) the repeatability of the results clearly depends on the cleaning exercise applied to the text describing the research candidates, (c) the robustness, tested for predicting the potential evolution of Standardization Committees being fed by further extra standards, resulted in maximum 10% of changes in Standardization Committees.



Figure 6: Tool 2: How the nanoSTAIR semantic tool works

The procedure of this service is accurately illustrated in Figure 7and can be summarized in three main steps as follows:

1.-Submit your document by sending the form for applicant at nanoSTAIR@eu-vri.eu. The process starts by sending your documents to the nanoSTAIR check via nanoSTAIR web site. The documents should be provided as .doc, .pdf or even .txt. At the nanoSTAIR web site you locate the get support – tab at the menu ribbon. At the get support page you will find the link to the applicant form (Figure 3.7). Fill in the required information and send it together with documents to nanoSTAIR@eu-vri.eu. At the get support page you will find the link to the applicant form. Go there! Fill in the required information and send it together with documents to nanoSTAIR@euvri.eu.

2.- nanoSTAIR experts will **run the semantic tool and analyze the results**.

3.- Within 3 weeks, you will **receive formatted information** on your standardization opportunities and recommendations.

As a result you will get recommendations for the most suitable TC and the contact person in the NSB or its national TC mirror committee. After identifying the Technical Committee within which the standardization project can be developed, you will need to contact the relevant mirror committee of an appropriate national standardization body (NSB) and convince it to support the proposed standard and to submit a NWIP for it. Submitting a NWIP requires the NSB to commit to making resources available during its development, if approved. Hence, there should be need for such a standard. It might be a good idea if the country (NSB) chosen to submit the proposal had made a major contribution to the particular output or had
a significant involvement in it. It might be fruitful to be in contact with CEN or ISO Technical Committee secretariat, also.

Before the actual standardization project can start it is necessary that a New Work Item Proposal (NWIP) has to be prepared and approved by the members of the relevant committee. Usually, the originators of NWIPs are the national standardization bodies (NSB) that actively participate in the work of the committee. The New Work Item Proposals are formal documents containing information required before a proposal will be assessed by the members of the committee. The official proposal is done by the chair and secretary of the national mirror committee submitting the proposal.



Figure 7: Preliminary version of the Procedure for nanoSTAIR check (Tool 2)

nan nan	oSTA	IR	T/	282TH	
<u>www.nanoSTAIR.eu-vri.eu</u>					
nanoSTAIR application					
Project Title					
Acronym (Optional)					
Start date	-	End	date		
Website		I			
Summary of the project (max. 1000 characters.)					
Main deliverable and expected impact					
Project scheme					
Budget					
Main partners					
Topic / Reference to a call for proposal					
Applicant contact details	Organisation				

Figure 8: Form for applicant at nanoSTAIR website

The operation of nanoSTAIR tool can be described as follows:

Step	Description
	1 Collect and merge the standards. All ISO and CEN Technical Committees are defined by several standards. Standards from different Technical Committees were collected, pre-processed (e.g. noise filtering by removing headers, equations etc.) and merged together. In the field of nanotechnologies and OHS issues, e.g. CEN/SC 352 Nanotechnologies, CEN/SC 137 Assessment of workplace exposure to chemical and biological agents, CEN/SC 195 Air filters for general air cleaning, ISO/SC 229 Nanotechnologies, ISO/SC 24/SC4 Particle characterization, ISO/SC 142 Cleaning equipment for air and other gases, ISO/SC 201 Surface chemical analysis
	2 Calculate the word distribution frequency in standards. The second step, the text analysis, was done by using the TROPES software3, an open source application which aims to extract most frequent words, their category (substantives, verbs, adjectives), but also to analyze relationships between words. TROPES was used for getting the frequency distribution of substantives of the different SCs.
40 30 20 10 10 10 10 10 10 10 10 10 10 10 10 10	3 Select the most frequent (key) words. The third step, the extraction of the most representative words, was done by calculating the intersection point between the frequency distribution curve and its tangency. All words for which the frequency number was higher than the one of the intersection point were extracted. This corpus of words, called afterwards Reference Corpus (RC) served for defining the standard.
Immune 10803 10804 Article WG1 29701 12. 9891 0.00 20 0.66 0.22 0.76 0. 9898 3.0 0.00 0.66 0.22 0.80 0. 1016 2.07 0.00 0.66 0.22 0.30 0. 103 0.07 0.00 0.38 0.00 0.35 0. 1035 0.47 0.50 0.07 0.56 0.70 0.57 0.50 0.70 0.51 0.70 0.51 0.70 0.51 0.70 0.51 0.70 0.51 0.70 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.71 0.51 0.75 0.51 0.75 0.75 0.51 <t< th=""><td>4 Reassign keywords to each TC. This creates the reference corpus for the TC, the list of keywords representing the standards produced in the particular TC. This procedure is done for several TC's and the work is going on in order to get more TC's to the nanoSTAIR check tool.</td></t<>	4 Reassign keywords to each TC. This creates the reference corpus for the TC, the list of keywords representing the standards produced in the particular TC. This procedure is done for several TC's and the work is going on in order to get more TC's to the nanoSTAIR check tool.
Research documents (candidates)	5 Compare with TC's keywords. The next step is the building of the topical matrices of the research documents. The similar method was applied to these scientific documents as for TC documents. As a result is the topical matrix for research documents. After that the calculation of distance between the topical matrices of the research document and the reference corpus of the Technical Committee was performed. The lower the distance, the most similar is the research document topic to a TC.
	6 Checking tool results by experts. However, it is obvious that at the moment the use of the semantic tool alone might lead to wrong results. A manual check of the documents by experts is still needed. This is especially true when dealing with very new research topics which have not yet been dealt with in standardization committees.

Feedback to the applicant:

- ✓ Closest TC(s) to the work described in the document analyzed
- \checkmark Information about the person to contact to interact with the TC
- Recommendation to submit a New Work Item Proposal (NWI) in the right TC SC or WG, or to point out a gap

3.5 Tool 3: The nanoSTAIR seminars

A nanoSTAIR seminar is organized to inform the researchers about the standardization process, committees and the support offered by the nanoSTAIR platform. The main idea of the seminars is to sensitize researcher to the possibilities of standardization as a dissemination channel and a way to implement the results to the industry.

The basic content of a one day – nanoSTAIR seminar may include:

- 1. Overview of standardization
 - ✓ How it is organized?
 - ✓ How it works and who are the main actors and their role?
 - ✓ What are the benefits of standardization for innovative
 - ✓ research?
 - ✓ EU standardization policies?
 - ✓ The STAIR approach?
 - / The standardization procedure in concrete
- 2. <u>Standardization in the field of nanotechnologies</u>
 - ✓ What are the main Technical Committees at CEN and ISO?
 - / Definitions of nanotechnologies, nanomaterials...
 - ✓ Recent standards produced and ongoing work
 - ✓ Needs expressed by industry, policy makers, other stakeholders
- 3. <u>nanoSTAIR Check, how it works?</u>
 - Explanation about the procedure of the nanoSTAIR check through a concrete example
 - What you get in concrete, if you do the check:
 - at the beginning of the project: identification of standards relevant for your research, identification of TCs to interact / liaise with, contacts with experts who can join an advisory panel
 - at the mid-term when some results are already available: orientation to propose or not inputs to some specific TCs, exchange with standardization experts to develop an exploitation strategy
- 4. <u>Question and Answer session to demystify standardization</u>

For each part of the seminar, the nanoSTAIR will have a set of slides that will be updated every year or when necessary.

Additionally, nanoSTAIR can organize **annual nanoSTAIR workshops**. The main idea of the annual conferences is to gather the members of the nanoSTAIR community together. It will give the latest information about what is going on the field of nano-standardization and the activity of the nanoSTAIR community. The conference can promote also synergies between projects in order to generate new work item proposals.

3.6 *nanoSTAIR services as a part of the standardization process*

The nanoSTAIR services can be utilized to enhance the standardization process of the R&D results. The nanoSTAIR services are used to identify new standardization items efficiently. The nanoSTAIR services comply nicely with the normal standardization process by adding tools into the pre-standardization step (Figure 9).

Many stakeholders can benefit from the use of nanoSTAIR services such as end-users, researchers / consortia (academics or from industry), clients (researchers, funding agencies, European Commission), partners (CEN/ISO, to liaise with the TCs and standards; NSB, to promote nanoSTAIR, to provide secretariat; NanoSafety Cluster & NanoFutures, to disseminate among the research community; NCP in NMP (NMPTeam).



Figure 9: nanoSTAIR services as a part of the standardization process

4. Contributing to impulse standardization in research

The nanoSTAIR strategy has been designed as a tool to impulse standardization in research, either at national or European level. Among the strategic actions defined by nanoSTAIR, you can select those that you can deploy and thus contribute positively to strengthen the links between standardization and research, either in your own Member State or at European level.

4.1 The nanoSTAIR strategy: orientation and objectives

Integration of European research and standardization is a recurring topic, at least in the last two European research programs (FP6, FP7). Both agents of European Standardization System (ESS) and European Innovation System (EIS) have been or are being involved in projects related to that topic (e.g. FP6 -INTEREST, FP -7 nanoSTAIR, BRIDGIT).

Summarising of all information sources consulted by nanoSTAIR, it can be suggested that perception of EIS agents on the interest of standardization and its importance in research projects, closely depends on several factors:

- Typology of research agent (e.g. university, research institute, technology centre, RDI unit of a company, other stakeholders).
- Research area concerned (e.g. fundamental research, technology development, demonstration).
- Existence of a previous experience or established relationship between EIS and ESS agents (e.g. agent's participation in technical standardization committees (TC), working with ESS in previous research projects, etc.)
- Technology Readiness Level (TRL) assigned to research project.
- Life cycle stage of project concerned (Call for proposals, preparation of the proposal, evaluation process, negotiation phase, implementation phase, stage of completion and exploitation of results).
- IPR issues involved in the project.
- European country, relationships between research community and NSB.

The nanoSTAIR strategic approach is based on the systematic analysis of the barriers that have been identified (Table 3) and of the possible ways to overcome these barriers, involving all relevant actors and identifying the possible benefits for them(Table 6to Table 13). The nanoSTAIR strategy rests on five pillars:

- 1. Strategic focus on the **research project** throughout its life cycle, as a key element for contacting research (EIS) and standardization (ESS).
- 2. Visualization of standardization as a **need to be satisfied by research projects**.
- 3. **Proximity and accessibility to standardization resources**. The nanoSTAIR strategy pivots on NSBs, due to its proximity and ease of interaction with project partners as well as their ability to provide resources to the project in the field of standardization.
- 4. **Synergistic approach** to standardization and strategic actions aimed at coordinating European and national efforts ESS and NSS to maximize impact.
- 5. Development of a **private platform of services nanoSTAIR -** to facilitate integration between research and standardization.

In addition, the nanoSTAIR consortium has identified and selected a set of four strategic objectives aimed at reducing barriers and facilitating connections between research and standardization:

1.- Ensure that nanotechnology standardization is visualized as a demand to be satisfied by researchers, research organizations and research projects.

This goal is composed of two second-level objectives:

- 1.1 Reinforce visibility of standardization in research projects
- 1.2 Foster a culture of implementation of research results in standardization deliverables

2.- Provide support to research projects, from the European Standardization System (ESS).

This goal is composed of three second-level objectives:

- 2.1 Facilitate contact between research projects and standardization organizations.
- 2.2 Provide practical tools to solve standardization issues in research projects
- 2.3 Develop a networking with a view of exchanging experiences and best practices among members of ESS

3.- Provide support to ESS, from the research community.

This goal is composed of one second-level objective:

3.1. Facilitate contact between standardization and research community

4.- Establish and deploy a sustainable platform of services - nanoSTAIR - to facilitate the interaction between research and standardization.

This goal is composed of three second-level objectives:

- 4.1 Provide research projects, advanced services to properly manage standardization issues.
- 4.2 Ensure sustainability of the nanoSTAIR platform after project completion.

Finally, a set of targeted strategic activities were proposed by project nanoSTAIR to deploy each of the four strategic objectives (Table 6to Table 13). In brief, the Table 6 and **Figure 10** and **Figure 11**summarize the nanoSTAIR strategy. Table 6shows that all types of barriers described in chapter 1 of this guideline have been considered by the nanoSTAIR strategy. The total number of strategic actions considered is 53. The deployment of these actions may take place at European level only, national level or in both areas.

The largest number of actions concerns the Strategic Objective 4 (Deploying the nanoSTAIR platform), followed in short order by objectives 1 and 2. These last two objectives are closely related to the satisfaction of the needs of researchers, research organizations and research projects, and both account for more than half of the strategic actions proposed by nanoSTAIR (57%).

By type of barrier concerned, the largest number of actions (78%) is directed towards the awareness and recognition of standardization, as a strategic pillar to establish direct pipelines between research and standardization. Actions to provide resources and actions to improve the standardization process represent the remaining 22%, equally distributed (11% each).

Table 5: Number of strategic actions to be deployed by nanoSTAIR strategy, classified by typology of barrier and strategic objective concerned

nanoSTAIR ST	RATEGIC ACTIONS		В	arriers		
nanoSTAIR S	trategic Objective	Resources available	Standardization process	Awareness and recognition of standardization	TOTAL	
Resource availableSO 1 Ensure that nanotechnology standardization is visualized as a demand to be satisfied by researchers, research organizations and research projectsSO 1.1 Reinforce visibility of nanotechnology standardization in research projects4SO 2 Provide support to research projectsSO 2.1 Facilitate contact between research projects and standardization organizations0SO 2 Provide support to research projectsSO 2.1 Facilitate contact between research projects and standardization organizations1SO 2 Provide support to research projects from the European Standardization System (ESS).SO 2.2 Provide practical tools to solve 	SO1.1 Reinforce visibility of nanotechnology standardization in research projects	4	0	9	13	16
	0	2	1	3	10	
	SO2.1 Facilitate contact between research projects and standardization organizations	1	2	4	7	
SO2 Provide support to research projects, from the European Standardization System (ESS).	System Solution Solut		2	4	6	15
	SO2.3 Develop a networking with a view of exchanging experiences and best practices among members of ESS	0	0	2	2	
SO3 Provide support to ESS, from the research community	SO3.1Facilitate contact between standardization and research community	0	0	2	2	2
SO4 Establish and deploy a sustainable platform of services - nanoSTAIR - to	SO4.1 Provide research projects, advanced services to properly manage standardization issues	0	0	19	19	20
facilitate the interaction between research and standardization	SO4.2 Ensure sustainability of nanoStair platform after project completion	1	0	0	1	20
r i i i i i i i i i i i i i i i i i i i	OTAL	6	6	41	53	53

nanoSTAIR



4.2 The nanoSTAIR strategy: deployment and implementation, at European and national levels

The next tables show how the strategic objectives are deployed in a set of strategic actions, either at European or national level. Strategic actions are grouped by typology of barrier. For each strategic action, it is also suggested the organization that should take the leadership in its implementation.

As has already mentioned at the beginning of this chapter, you can select among all the strategic actions, those that you can impulse to promote links between standardization and research, either in your own Member State or at European level.

Table 6: Strategic actions deploying strategic objective 1 (1.1)

Strategic Objective 1: Ensure that nanotechnology standardization is visualized as a demand to be satisfied by researchers, research organizations and research projects

<u>2nd Level objective 1.1:</u> **Reinforce visibility of nanotechnology standardization in research projects**

ology of ier	Strategic Action				
Main typ barr	European Level	Who should act?	National Level	Who should act?	
ailable	1 Establish a proactive dialogue with the EC (DG Research, DG Enterprise & Industry) to introduce new elements concerning nanotechnology standardization in the process of RDI projects, such as:	ESS	Transfer European action at national level.	NSBs	
1 Resources av	2 Fund RDI in support of nanotechnology standardization and for standardization <u>after finishing the</u> <u>research project</u> , e.g. including the identification of future fields for nanotechnology standardization, road- mapping, pre- or co-normative works etc; as well as specific projects to continue the development of standards. CEN could participate to the selection of funded works.	ERFA	Transfer European action at national level.	NRFA	

	3 Launch a "Call for tenders" addressed to contract a new service to support H2020's research projects, funded by the EC, in solving standardization issues. Tool to be used will be a Standardization Strategy Seminar (SSS), free of charge for the projects. SSS could be a specific standardization seminar itself or a part of the Exploitation Strategy Seminar (ESS) to prepare the project PUDF. The procedure to request SSS could be the same as currently used for ESS, requiring approval from the EC project officer. The consultant is expected to attend a meeting organized by the project coordinator. The consultant's travel and daily expenses would be covered by the European Commission. Travel and daily expenses of the project participants would be covered by the participants and would be eligible costs of the project.	ERFA	Transfer European action at national level.	NRFA
	4 Support and make eligible the implementation of the "nanoSTAIR check" to scientific papers and other descriptions of (planed or achieved) results from R&D projects	ERFA	Transfer European action at national level.	NRFA
2 Standardization Process	NA		NA	
ion of standardization	1 Coordinate with the EC for inclusion in the agenda of H2020 - Info Days (Call for proposals), a presentation by CEN / CENELEC, emphasizing the importance of standardization in RDI projects of H2020 research program.	ESS, ERFA	Transfer European action at national level. Coordinate the above activities at national level - with the NCP - with the goal to include presentations of NSBs in the agenda of National Info Days.	NSBs, NRFA
ess and recognit	Establish a proactive dialogue with the EC (DG Research, DG Enterprise & Industry) to introduce new elements concerning nanotechnology standardization in the process of RDI projects, such as:	ESS	Transfer European action at national level. Establish proactive dialogue with national funding administrations.	NSBs
3 Awaren	2 Integrate standardization in the conception, phrasing, reporting and evaluation of research programmes and calls.	ERFA	Transfer European action at national level.	NRFA

3 Include standardization expertise in the evaluation of proposals and the negotiation of contract for relevant calls, e.g. through the "nanoSTAIR check".	ERFA	Transfer European action at national level.	NRFA
4 Add in the text of topics ("Call for proposals"), a specific sentence/paragraph identifying standardization requirements to be met by the future proposal. The sentence/paragraph will be formatted according to the TRL required by each topic (See Annex 1).	ERFA	Transfer European action at national level.	NRFA
5 Add in the "Call for proposals", a specific requirement to provide a list of references in the field of standardization, for relevant TRLs.	ERFA	Transfer European action at national level.	NRFA
6 Add in the "Guide for applicants H2020" a specific section on standardization, describing how to meet standardization requirements in line with the TRL of topic addressed (Annex 1).	ERFA	Transfer European action at national level.	NRFA
7 In line with the previous two items, establish "relevance for standardization" as a significant evaluation criterion in H2020's research projects.	ERFA	Transfer European action at national level.	NRFA
8 Amend the terms of the project Consortium Agreements to ensure that participating consortia have a clear and explicit plan to satisfy standardization issues.	ERFA	Transfer European action at national level.	NRFA
9 Provide training on nanotechnology standardization for H2020 evaluators and DG 's officers of the programme.	ERFA	Transfer European action at national level.	NRFA

Table 7: Strategic actions deploying strategic objective 1 (1.2)

<u>Strategic Objective 1</u>: **Ensure that nanotechnology standardization is visualized as a demand to be satisfied by researchers, research organizations and research projects**

<u>2nd Level objective 1.2:</u>Foster a culture of implementation of research results in standardization deliverables

ology of 'ier	Strategic Action			
Main typ barr	European Level	Who should act?	National Level	Who should act?
1 Resources available	NA		NA	
rdization ess	1 Include in standardization documents, references to authors of scientific results on which standards are based.	ESS	Transfer European action at national level (NSBs).	NSBs
2 Standaı Proce	2 Include in standardization documents, a lists of contributors, determined according to reliable and fair rules.	ESS	Transfer European action at national level (NSBs).	NSBs
3 Awareness and recognition of standardization	1 Create (with CEN) a well- funded and well publicized award for involvement and successes of researchers, research organizations and projects in standardization activities.	ESS	Transfer European action at national level.	NSBs

 Table 8: Strategic actions deploying strategic objective 2 (2.1)

<u>Strategic Objective 2:</u> Provide support to research projects, from the European Standardization System (ESS)

<u>2nd Level objective 2.1:</u> Facilitate contact between research projects and standardization organizations

ıy of	Strategic Action				
Main typolog barrier	European Level	Who should act?	National Level	Who should act?	
1Resources available	1 Support and make eligible the implementation of the "nanoSTAIR check" to scientific papers and other descriptions of (planed or achieved) results from R&D projects	ESS	Transfer European action at national level.	NSBs	
ocess	NA		1 Identify modalities of participation of NSBs in research projects and contribution expected in each case, according to standardization requirements (TRL).	NSBs	
2 Standardization Pro	 2 Demystify standardization for researchers: Explain the necessity of some rigidity and slowness in standardization, the possibilities and limits of flexible/quick ways (CWA), need for and place of scientific expertise in the standardization process other aspects of the standardization process, e.g. through nanoSTAIR seminars, for research on nanotechnologies. 	ESS	Transfer European action at national level.	NSBs	
3 Awareness and recognition of standardization	1 Update and optimize the CEN/CENELEC - Helpdesk face the Horizon 2020's research projects.	ESS	2 Create a specific webpage at the NSB website to manage all the above items (e.g. Research and standardization in H2020). Join this webpage with CEN-CENELEC Helpdesk and NCP websites.	NSBs	

NA	3 Designate a contact person at NSB level and establish the most appropriate communication channels and procedures to facilitate interrelation with agents of the EIS.	NSBs
NA	4 Elaborate a plan for dissemination to ensure maximum dissemination of NSB's resources among stakeholders of the EIS.	NSBs

Table 9: Strategic actions deploying strategic objective 2 (2.2)

<u>Strategic Objective 2:</u> Provide support to research projects, from the European Standardization System (ESS)

<u>2nd Level objective 2.2:</u> **Provide practical tools to solve standardization issues in research projects**

	jy of		Strategic /	Action	
	Main typolo <u>o</u> barrier	European Level	Who should act?	National Level	Who should act?
	1 Resources available	NA		NA	
	tion Process	NA		1 Encourage NSB to develop a feasible procedure to facilitate the research community 's access to published standards.	NSBs
	2 Standardiza	2 Promote CWA as a valuable and useful tool to disseminate pre-standardization deliverables during the life of the project (Time scale of research project aligned with standardization time scale).	ESS	Transfer European action at national level.	NSBs
3 Awareness and recognition of	standardization 3 Awareness and recognition of standardization	1 Develop by CEN/CENELEC (project BRIDGIT) a guidance to the research community about practical integration of standardization in H2020's RDI projects. Guideline will include several case studies of projects running / completed, to illustrate how standardization was managed in each case (from proposal stage to exploitation of results), lessons learned and benefits provided in each case for standardization. For the selection of case studies, the guide will take into account the three main types of research: fundamental (TRL 1-2), technological development (TRL 3-5) and demonstration (5-7).	BRIDGIT	2 Translate the mentioned CEN-CENELEC guide into national languages (NSB) and disseminate it as a support tool to deal with standardization aspects of research projects.	NSBs

An added value to the guide should be the integration of good practices collected by the project BRIDGIT.			
NA		3 Organize a set of national events (NSB), aimed at training the research community (universities, technology centres , research institutes , R & D units of companies, other stakeholders), in solving practical standardization issues identified in the research projects. Agenda of national events, should include, at least: 1) Practical management of standardization issues in H2020's projects (from the call to the exploitation of results), 2) Role of the NSB in H2020's - projects (modality of participation, contribution expected, etc), 3) Procedure to contact the NSB (channel, contact person, etc), 4) Examples of successful European projects (e.g. successful projects of H2020's previous calls) to demonstrate, management of standardization developed in each case and results obtained.	NSBs
4 Strengthen coordination between projects BRIDGIT and nanoSTAIR in order to coordinate actions, avoid duplication of efforts and maximize the impact of the results of both projects. Coordination between both projects will be promoted in reviewing nanoSTAIR deliverables: 4.1 Innovative strategies to translate into EU- nano research and 4.3 NanoSTAIR practical guideline, as well as other aspects related to dissemination and exploitation of project results .	BRIDGIT, nanoSTAIR	NA	

Table 10: Strategic actions deploying strategic objective 2 (2.3)

<u>Strategic Objective 2:</u> Provide support to research projects, from the European Standardization System (ESS)

<u>2nd Level objective 2.3:</u> **Develop a networking with a view of exchanging experiences and best practices among members of ESS**

JY Of	Strategic Action			
Main typolog barrier	European Level	Who should act?	National Level	Who should act?
1 Resources available	NA		NA	
2 Standardization Process	NA		NA	
3 Awareness and recognition of standardization	1 Link all NSB - databases with CEN -CENELEC helpdesk to ensure access of research community to full information.	ESS	2 Create and updated a database of good practices, at national level (NSBs), for consultation by agents of research community.	NSBs

Table 11: Strategic actions deploying strategic objective 3 (3.1)

Strategic Objective 3: Provide support to ESS, from the research community

<u>2nd Level objective 3.1:</u> Facilitate contact between standardization and research community

logy er		Strategic A	Action	
Main typo of barric	European Level	Who should act?	National Level	Who should act?
1 Resources available	NA		NA	
2 Standardization Process	NA		NA	
l recognition zation	1 Establish and/or update links with websites of nanotechnology community research (see key stakeholders).	EC, NSC	Transfer European action at national level.	NCPs
3 Awareness and of standardi	NA		2 Establish and update databases of nanotechnology experts in the NSB and coordinate them with CEN- CENELEC helpdesk.	NSBs

Table 12: Strategic actions deploying strategic objective 4 (4.1)

<u>Strategic Objective 4:</u> Establish a sustainable platform of services - nanoSTAIR - to facilitate the interaction between research and standardization

<u>2nd Level objective4.1:</u> **Provide research projects, advanced services to properly manage standardization issues**

JY Of		Strategic A	Action	
Main typolog barrier	European Level	Who should act?	National Level	Who should act?
1 Resources available	NA		NA	
2 Standardization Process	NA		NA	
nition of	1 Identify websites of research community groups on nanosafety and link with them (NanoSafety Cluster, SIIN-ERA, Nanofutures, NMP team,)	nanoSTAIR	Transfer European action at national level, supported by partners of consortium nanoSTAIR.	nanoSTAIR
areness and recog standardization	2 Identify channels and procedures to allow contact between interested parties and nanoSTAIR platform (e.g. direct connection through nanoSTAIR, presentations at events, mail or direct contact,)	nanoSTAIR	Transfer European action at national level, supported by partners of consortium nanoSTAIR.	nanoSTAIR
З Аи	3 Develop a catalogue of services offered by nanoSTAIR, including at least two main services:	nanoSTAIR	NA	

4 The nanoSTAIR check, a support to inform a standardization strategy , based on the semantic analysis of a scientific paper and its comparison with the production of standardization committees in the field of nanotechnology.	nanoSTAIR		
5 The nanoSTAIR seminar, a seminar to inform the researchers about the standardization processes, committees and the support offered by nanoSTAIR platform.	nanoSTAIR	NA	
6 Identify experts to support services provided by nanoSTAIR as well as "Terms of reference" for collaboration.	nanoSTAIR	NA	
7 Develop a coherent communication strategy for promoting overall benefits of nanoSTAIR approach, in collaboration with community research, ESS and other interested parties. Strategy will include presentations of nanoSTAIR to key stakeholders in the field of nanotechnology standardization.	nanoSTAIR	Transfer European action at national level, supported by partners of consortium nanoSTAIR.	nanoSTAIR
8 Promote annual conferences to gather the nanoSTAIR community, review the activity of the year, give information to the research community on what's going on regarding nano standardization and promote synergies for NWIP.	nanoSTAIR	Transfer European action at national level, supported by partners of consortium nanoSTAIR.	nanoSTAIR
9 Develop a nanoSTAIR application form to be filled by candidates & end-users	nanoSTAIR	NA	
Develop a web-based platform for communication with experts and project consortia, in order to create a community for all stakeholders interested in nanotechnologies and standardization. The nanoSTAIR web-based platform will provide, at least:	nanoSTAIR	Link nanoSTAIR platform with NSBs ' websites	nanoSTAIR
10 Information on on-going activities	nanoSTAIR		

11 Link to relevant community groups, research projects and contact persons	nanoSTAIR		
12 Partners to contribute to standard preparation	nanoSTAIR		
13 NSB able to provide the secretariat to develop a new standard	nanoSTAIR		
14 Offer of advanced services provided by nanoSTAIR	nanoSTAIR		
15 Procedure of client- provider interaction to guide them in the standardization processes.	nanoSTAIR		
16 nanoSTAIR guideline available online	nanoSTAIR		
Establish a proactive dialogue with the EC (DG Research, DG Enterprise & Industry) to implement:	nanoSTAIR	NA	
17 nanoSTAIR check at the stage of the proposals, during the negotiation of project grants (with the funding agencies)	ERFA	NA	
18 nanoSTAIR check as part of the preparation of the exploitation strategy (contract with funding agencies or eligible cost, like CFS)	ERFA	NA	
19 nanoSTAIR Seminar to sensitize researchers to standardization (e.g. 1) What is standardization?, 2) Overview of Technical Committees in the field of nanotechnologies, 3) Case study during the seminar with some concrete examples to show how nanoSTAIR facilitate the access to standardization).	ERFA	Transfer European action at national level, supported by partners of consortium nanoSTAIR. Cooperation with NSBs.	NRFA

Table 13: Strategic actions deploying strategic objective 4 (4.2)

 $\label{eq:strategic objective 4:} {\begin{subarray}{c} Strategic Objective 4: \\ facilitate the interaction between research and standardization \\ \end{subarray}}$

<u>2nd Level objective4.2</u>: **Ensure sustainability of nanoSTAIR platform after project completion**

gy of		Strategic A	Action	
Main typolog barrier	European Level	Who should act?	National Level	Who should act?
1 Resources available	1 Develop a feasible exploitation plan with the Consortium to ensure sustainability of activities after project completion.	nanoSTAIR	NA	
2 Standardization Process	NA		NA	
3 Awareness and recognition of standardization	NA		NA	

Conclusions

The present deliverable (D4.3) introduces the results of task 4.3 aimed to develop a European practical guideline addressed to the parties involved in the process of transfer results of nano-research into standards and standardization deliverables.

This guideline compiles and assembles in a practical and synthetic document all the results previously produced in work packages WP1 to WP4.

D4.3 provides information and tools for researchers and other interested parties, showing:

- 1. How important standardization is to bridge between research activities and the market (Chapter 1)
- 2. How standardization can be integrated in the research projects and benefit to them (Chapter 2)
- 3. How nanoSTAIR can firmly support standardization in research projects (Chapter 3), and finally,
- 4. How nanoSTAIR strategic actions could be used effectively by interested parties to promote links between standardization and research, at European and national level(Chapter 4).

Consequently, this practical guideline can be very useful to prepare the future European and national proposals and calls as well as to promote standardization in research using the outcomes of the nanoSTAIR project.

A simplified version of this guideline will be made available on the nanoSTAIR website.

Glossary

[1]	BRIDGIT	Bridging the Gap between Research and Standardization (Research Project)
[2]	CEN	European Committee for Standardization
[3]	CENELEC	European Committee for Electrotechnical Standardization
[4]	CWA	CEN Workshop Agreement
[5]	DCNP	Dedicated National Contact Point
[6]	DoW	Description of Work
[7]	EC	European Commission
[8]	EC – AC	European Commission - Advisory Committees
[9]	EIP(s)	European Innovation Partnership(s)
[10]	EIS	European Innovation System
[11]	ERA	European Research Area
[12]	ERFA(ies)	European Research Funding Agency (ies)
[13]	ESB(s)	European Standardisation Body(ies)
[14]	ESS	European Standardization System
[15]	ETIP(s)	European Technology Integrating and Innovation Platform(s)
[16]	ETP(s)	European Technology Platform(s)
[17]	ETSI	European Telecommunications Standards Institute
[18]	EU	European Union
[19]	H2020	Horizon 2020 Programme
[20]	IAB	International Advisory Board
[21]	IECI	International Electrotechnical Commission
[22]	INTEREST	INTEgrating REsearch and STandardisation – FP6 project
[23]	ISO	International Organization for Standardization
[24]	ITU	International Telecommunication Union
[25]	LEIT	Leadership in enabling and industrial technologies – H2020
		Programme
[26]	LOI	Letter of intent
[27]	nanoSTAIR	Innovative strategies and procedures to translate EU nano-research
		into standards (FP7 Project)
[28]	NCP(s)	National Contact Point(s)
[29]	NIA	Nanotechnology Industries Association
[30]	NMP – EAG	NMP Expert Advisory Group
[31]	NMP – NCPN	NMP Network of NCPs
		NMP-RFCS Industrial Technologies Programme (Nano Sciences and nanotechnologies, Materials, New forms of production- Research Fund for Coal and Steel)
[32]	NRFA(ies)	National Research Funding Agency (ies)
[33]	NSB(s)	National Standardization Body(ies)
[34]	NSCP	nanoSTAIR Contact Point
[35]	NSS	National Standardization System

- [36] STAIR STAndardization Innovation and Research, a joint CEN CENELEC
- strategic Working Group
- [37] TC Standardization Technical Committee
- [38] TRL Technology Readiness Level
- [39] NSC NanoSafety Cluster
- [40] OECD Organisation for Economic Co-operation and Development
- [41] PPP(s) Public-Private Partnership(s)
- [42] PUDF Plan for Use and Dissemination of Foreground
- [43] RDI Research, Development and Innovation
- [44] SIINN Safe Implementation of Innovative Nanoscience and Nanotechnology (ERA-NET on Nanosafety)

References

- [1] CEN Strategy 2011 2013
- [2] EU Expert Panel for the Review of the European Standardization System (EXPRESS) Report : "Standardization for a competitive and innovative Europe: a vision for 2020".
- [3] High Level Group on Key Enabling Technologies (KET). Final report, June 2011. European Commission.
- [4] COM(2004) 338 final. COMMUNICATION FROM THE COMMISSION. Towards a European strategy for nanotechnology. Brussels, 12.5.2004.

http://ec.europa.eu/nanotechnology/pdf/nano_com_en.pdf

[5] COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE. Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. Brussels, 7.6.2005. COM(2005) 243 final.

http://ec.europa.eu/nanotechnology/pdf/nano_action_plan2005_en.pdf

- [6] COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE. Towards an increased contribution from standardisation to innovation in Europe. Brussels, 11.3.2008. COM(2008) 133 final.
- [7] Commission Communication (COM(2009)512): "Preparing for our future: Developing a common strategy for key enabling technologies in the EU".
- [8] Communication of the European Commission "Europe 2020 Flagship Initiative Innovation Union" COM (2010) 546
- [9] COMMUNICATION FROM THE COMMISSION EUROPE 2020. A strategy for smart, sustainable and inclusive growth. Brussels, 3.3.2010.COM(2010) 2020 final.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF

- [10] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Horizon 2020 - The Framework Programme for Research and Innovation (Text with EEA relevance) {SEC(2011) 1427 final} {SEC(2011) 1428 final. Brussels, 30.11.2011. COM(2011) 808 final.
- [11] Communication of the European Commission "Partnering in Research and Innovation" COM (2011) 572.
- [12] Communication of the European Commission "A strategic vision for European Standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020" COM (2011) 311
- [13] COMMUNICATION FROM THE COMMISSION TO THE EUROPEANPARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE. Second Regulatory Review on Nanomaterials. {SWD(2012) 288 final}. Brussels, 3.10.2012 COM(2012) 572 final.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:en:PDF

- [14] Commission Decision of 28 February 2011 amending Decision C(2008) 4617 related to the rules for proposals submission, evaluation, selection and award procedures for indirect actions under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011).
- [15] COMMISSION RECOMMENDATION of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research. Brussels, 07/02/2008, C(2008) 424 final.
- [16] COMMISSION STAFF WORKING PAPER. IMPACT ASSESSMENT. {COM(2011) 808 final} {SEC(2011) 1428 final}. Accompanying the Communication from the Commission 'Horizon 2020 - The Framework Programme for Research and Innovation'; Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020); Proposal for a

Council Decision establishing the Specific Programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020); Proposal for a Council Regulation on the Research and Training Programme of the European Atomic Energy Community (2014-2018) contributing to the Horizon 2020 – The Framework Programme for Research and Innovation. Brussels, 30.11.2011. SEC(2011) 1427 final.

[17] COMMISSION STAFF WORKING PAPER. Types and uses of nanomaterials, including safety aspects Accompanying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials. {COM(2012) 572 final} Brussels, 3.10.2012. SWD(2012) 288 final.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0133:FIN:EN:PDF

[18] Compendium of Projects in the European NanoSafety Cluster 2013. Edition February 2013. Editor: Michael Riediker, PD Dr.Sc.Nat. Institute for Work and Health, Lausanne, Switzerland

http://www.nanosafetycluster.eu/uploads/files/pdf/2013_NSC_Compendium.pdf

[19] Council meeting. On 25 September 2008 the Council adopted the following Conclusions. Council Conclusions on standardisation and innovation. 2891st COMPETITIVE_ESS. (INTERNAL MARKET, INDUSTRY and RESEARCH) Brussels, 25 September 2008.

http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/intm/103020.pd f

- [20] European Parliament resolution of 21 October 2010 on the future of European standardization(2010/2051(INI))
- [21] Evaluation of the European strategy on safety and health at work 2007-2012. Final report. DG Employment, Social Affairs and Inclusion. March 2013.

http://ec.europa.eu/social/main.jsp?langId=pt&catId=89&newsId=1912

[22] General guidelines for the cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association 28 march 2003. (2003/C 91/04).

http://eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2003:091:0007:0011:EN:PDF

- [23] Integrated Research and Industrial Roadmap for European Nanotechnology. NANOfutures, European Technology Integrating and Innovation Platform on Nanotechnology. http://www.nanofutures.info/sites/default/files/NANOfutures_Roadmap%20july%20201 2 0.pdf
- [24] INTEREST. Integrating Research and Standardization. Guide to standardization for R&D organisations and researchers.

http://www-i4.informatik.rwth-aachen.de/Interest/Manual_SSB.pdf

[25] INTEREST. Integrating Research and Standardization. What standard-setting bodies could do.

http://www-i4.informatik.rwth-aachen.de/Interest/Manual_R%26D.pdf

- [26] NANoREG A common European approach to the regulatory testing of nanomaterials http://www.nanoreg.eu/images/NANOREG_PressRelease_final.pdf
- [27] nanoSTAIR D1.1.- Matrix with explicit criteria to identify possible candidates for standardization drafting and procedure to select standardization candidates and decision support tool.
- [28] nanoSTAIR D1.2.- A toolbox to make aware the National Standardization Bodies of nanoSTAIR.
- [29] nanoSTAIR D2.1.- Snapshot of the needs of the stakeholders and drivers for standardization.
- [30] nanoSTAIR D2.2.- Database with projects and contact persons describing in which way they planned to contribute.
- [31] nanoSTAIR D3.1.- Documentation of mapping of work items and Technical Committees.
- [32] nanoSTAIR D3.2.- Initiation of a formal process for a NWIP.

- [33] nanoSTAIR D3.3.- Overview of Work to be initiated not under a TC (including e.g. as annexes first drafts of business planning where appropriate).
- [34] nanoSTAIR D4.1.- Innovative strategies and procedures to translate EU nano-research into standards.
- [35] nanoSTAIR D4.2.- Communication plan and strategy and implementation with the project Website and leaflets.
- [36] nanoSTAIR D4.4.- Business Plan to make the nanoSTAIR platform sustainable.
- [37] On-line database on mandates.

http://ec.europa.eu/enterprise/standards_policy/mandates/database/index.cfm?fuseact ion=refSearch.main&CFID=55185580&CFTOKEN=31d48e7d1eaedce-CAB145EB-B306-BB7F-D3F50AE947FA18AE&jsessionid=1cef20cb8f32ee13ca71353155f2d5678665TR).

[38] REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:
PDF

[39] REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC and their competitiveness in the global market.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:
PDF

- [40] Report of the expert panel for the review of the European standardization system. Standardization for a competitive and innovative Europe: a vision for 2020. February 2010.
- [41] Resolution of the European Parliament "The future of European standardization"
- [42] Strategic objectives for the European standardization system to 2020. CEN, CENELEC, ETSI, 2012.
- [43] Successful European Nanotechnology Research. Outstanding science and technology to match the needs of future society EUROPEAN COMMISSION Directorate-General for Research and Innovation Directorate G Industrial Technologies Unit G.4 –Nano-and converging Sciences and Technologies.

http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

[44] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE. A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020. Brussels, 1.6.2011. COM(2011) 311 final.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0311:FIN:EN:PDF

- [40] Wang, L., Notten, A., Surpatean, A., 2013. Interdisciplinarity of nano research fields: a keyword mining approach. *Scientometrics* 94, 877-892.
- [41] Hatto, P., 2011. Standards and standardization. A practical guide for researchers. European Commission Report, 62 p. Available at: http://ec.europa.eu/research/industrial_technologies/pdf/handbookstandardisation_en.pdf
- [42] Hatto, P., 2013. Standards and standardization handbook European Commission, Report, 62 p. Available at: http://www.kowi.de/Portaldata/2/Resources/fp/guidestandardisation-for-researcher.pdf

- [43] Grobelnik, M., Mladenic, D., Milic-Frayling, N., 2001. "Text Mining as Integration of Several Related Research Areas: Report on KDD'2000 Workshop on Text Mining,"... Proceedings of the 2000 ACM SIGKDD, SIGKDD Explorations (Eds.), vol.2, Issue 2, 1-4. http://pdf.aminer.org/001/063/478/text_mining_as_integration_of_several_related_res earch_areas_report.pdf
- [44] Bassecoulard, E., Lelu, A., Zitt, M., 2007. Mapping nanosciences by citation flows: A preliminary analysis. *Scientometrics* 70, 859-880.
- [45] Huang, C., Notten, A., Raster, N., 2010. Nanoscience and technology publications and patents: a review of social science studies and search strategies. *Journal of Technology Transfer* 36, 145-172.
- [46] Bleeker, E. A.J., de Jong, W. H., Geertsma, R. E, Groenewold, M., . Heugens, E. H.W., Koers-Jacquemijns, M., van de Meent, D., Popma, J. R, Rietveld, A.G., Wijnhoven, S.W.P., Cassee, F. R., . Oomen, A.G,2013. Considerations on the EU definition of a nanomaterial: Science to support policy making. *Regulatory Toxicology and Pharmacology 65*, 119–125.
- [47] Freeland, J., Hulme, J., Kinnison, D., MiSChell, A., VeiSCh, Aitken, R., Hankin, S., Poland, C., Bard, D., Gibson, R., Saunders, J., 2012.Working Safely with Nanomaterials in Research & Development. NanoSafety Partnership Group 2012 Report. 44 p.
- [48] Mandate addressed to CEN, CENELEC and ETSI for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials, European Commission, M/409, 2007.
- [49] Commission Mandate M/ 409 Standards Needs in Nanotechnology and nanomaterials[3] Report from CEN/TC 352 Nanotechnologies (2008).
- [50] Mandate addressed to CEN, CENELEC and ETSI for standardization activities regarding nanotechnologies and nanomaterials, M/461 (2010).
- [51] Forthcoming standardization opportunities and needs in the field of nanotechnologies Aublant, Jean-Marc (2012)
- [52] The European Committee for Standardization (CEN) (2012). Hands on standardization A starter guide to standardization for experts in CEN Technical Bodies. Available at:*ftp://ftp.cen.eu/CEN/Services/Education/Handsonguides/Handsonstandards.pdf*
- [53] CEN BOSS. Business Operations Support System. Webpage. Available at:

http://boss.cen.eu/Pages/default.aspx (accessed 26 February 2014).

- [54] CEN CENELEC. Tools for researchers. Webpage. Available at: http://www.cencenelec.eu/research/tools/Pages/default.aspx (accessed 26February 2014).
- [55] European Commission (2010). Standards and Standardization Handbook.Hatto, P. (Author). Available at: http://www.iec.ch/about/globalreach/academia/pdf/academia_governments/handbookstandardisation_en.pdf
- [56] European Commission (2013). EUR 25470 Standards and Standardisation— A practical guide for researchers. Hatto,P. (Author) Luxembourg.Publications Office of the European Union. 58 pp. Available at:

http://ec.europa.eu/research/industrial_technologies/pdf/handbookstandardisation_en. pdf

[57] European IPR Helpdesk (2012). How to reap the benefit of standardisationin R&D. Fact Sheet. Luxembourg. 9 pp. Available at:

<u>http://www.iprhelpdesk.eu/sites/default/files/newsdocuments/How_to_reap_the_benefi</u> <u>t_of_standardisation_in_R%26D.pdf</u>

- [58] Utrilla, F. (2013) Integración de la Normalización (Estandarización) en los proyectos de I+D+i Integration of standardization in RDI projects. AENOR, documento interno.
- [59] Utrilla, F. (2014) La estandarización en los proyectos del Horizonte 2020 Standardization in projects´s Horizon 2020. AENOR, documento interno.
- [60] AENOR (2014) Considerar la estandarización en los proyectos de I+D+i. http://www.aenor.es/aenor/normas/normas/normas_idi.asp

Annex 1: Basic terminology

CEN-CENELEC's National Member: The members of CEN and CENELEC are the National Standards Bodies and Committees in 33 European countries (the National Standards Bodies (NSBs) of the 28 European Union countries, the Former Yugoslav Republic of Macedonia, and Turkey plus three countries of the European Free Trade Association (Iceland, Norway and Switzerland). It is the responsibility of the CEN-CENELEC's National Members to implement European Standards as national standards. The members distribute and sell the implemented European Standard and have to withdraw any conflicting national standards.

CEN-CENELEC Workshop Agreement (CWA): CWA is a document, developed and approved by a CEN/CENELEC Workshop and owned by CEN/CENELEC reflecting the consensus of identified individuals and organizations responsible for its contents. Workshops are fast-relatively informal- consensus building groups, open to direct participation of any interested party, and the result of their work is a CWA. The average timeframe for the delivery of a CWA is 18 months, which makes a CWA the fastest standardization deliverable available. Workshops are particularly relevant in emerging or rapidly-changing technologies that require quickly-developed specifications or results of research projects. They produce CEN and/or CENELEC Workshop Agreements (CWAs). CEN/CENELEC Workshop Agreements are often used by research projects as a dissemination tool to make their results publicly available.

Draft standard(EU-REGULATION 1025/2012):means a document containing the text of the technical specifications concerning a given subject, which is being considered for adoption in accordance with the relevant standards procedure, as that document stands after the preparatory work and as circulated for public comment or scrutiny.

European standard(EU-REGULATION 1025/2012):means a standard adopted by a European standardization organization (ESO).

European Standard Organization (ESO)(EU-REGULATION 1025/2012): means an organization listed in Annex I, the European Commission: CEN, the European Committee for Standardization; CENELEC, the European Committee for Electrotechnical Standardization and ETSI, the European Telecommunications Standards Institute.

European standardization deliverable(EU-REGULATION 1025/2012):means any other technical specification than a European standard, adopted by a European standardization organization for repeated or continuous application and with which compliance is not compulsory.

Harmonized standard(EU-REGULATION 1025/2012): means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonization legislation.

International standard (EU-REGULATION 1025/2012):means a standard adopted by an international standardization body.

International standardization body(EU-REGULATION 1025/2012):means the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU).

Liaison (with a CEN - TC):A liaison applies for the duration of the research project and allows a project representative to participate in the meetings of the Technical Committee and relevant Working Group meetings as an observer (without decision power). The project will sing an undertaking accepting CEN's exploitation rights policy and agreeing that no information brought to the project's attention will be disseminated or exploited in any form. The project requesting the Liaison is an approved bona fide European research or similar project (European Commission or EUREKA). Some of the benefits for the project that can be provided by a liaison are: 1) The project can demonstrate formal collaboration with the European Standardization System; 2) The project representative can participate in the TC directly (as an observer, without decision power), thus ensuring synergies between the research and standardization work (avoiding duplication of standardization work); 3)The

project representative can propose a new work item (standard) directly to the TC without going through a national delegation (direct impact on the standardization work programme).

National standard(EU-REGULATION 1025/2012):means a standard adopted by a national standardization body.

National Standards Body (NSB)(EU-REGULATION 1025/2012):NSB means a body notified to the Commission by a Member State in accordance with Article 27 of EU-REGULATION 1025/2012. A National Standards Body is the one stop shop for all stakeholders and is the main focal point of access to the concerted system, which comprises regional (European) and international (ISO) standardization.

Product(EU-REGULATION 1025/2012): means any industrially manufactured product and any agricultural product, including fish products.

Service(EU-REGULATION 1025/2012): means any self-employed economic activity normally provided for remuneration, as defined in Article 57 TFEU.

Standard (EU-REGULATION 1025/2012):means a technical specification, adopted by a recognized standardization body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following: a) International standard, b) European standard, c) Harmonized standard and National standard. A standard is an agreed definition or specification of a unit, method, product, process or service. The European Standard (EN) is the flagship of the standardization activity in CEN and CENELEC. The process to deliver an EN takes a maximum of 3 years from the date that the technical work begins. European Standards (ENs) are documents that have been ratified by one of the three European Standardization Organizations (ESOs). Once approved, ENs are implemented at national level as identical national standards and all conflicting national standards are withdrawn. Therefore, a European Standard (EN) automatically becomes a national standard in each of the 33 CEN-CENELEC member countries.

Technical Committee (TC): A Technical Committee is a technical decision making body with a precise title, scope and work programme. A TC essentially manages the preparation of CEN-CENELEC deliverables - in accordance with an agreed business plan. Each TC has its own field of operation (scope) within which a work programme of identified standards is developed and executed³¹. TCs work on the basis of national participation by the CEN Members, where delegates represent their respective national point of view. This principle allows the TCs to take balanced decisions that reflect a wide consensus. A Subcommittee can be established within a TC, in the case of large programs of work. The real standards development is undertaken by Working Groups (WGs) where experts, appointed by the CEN Members but speaking in a personal capacity, come together and develop a draft that will become the future standard. This reflects an embedded principle of 'direct participation' in the standardization activities.

Technical specification: A technical Specification is a type of pre-standard and can be produced when there is no immediate need or not enough consensus for an EN. The average timeframe for the delivery of a TS is 2 years. According to EU-REGULATION 1025/2012, Technical specification means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following:

- a. the characteristics required of a product including levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;
- b. production methods and processes used in respect of agricultural products as defined in Article 38(1) TFEU, products intended for human and animal consumption, and medicinal products, as well as production methods and processes relating to other products, where these have an effect on their characteristics;

³¹ http://standards.cen.eu/dyn/www/f?p=CENWEB:6:::NO

- c. the characteristics required of a service including levels of quality, performance, interoperability, environmental protection, health or safety, and including the requirements applicable to the provider as regards the information to be made available to the recipient, as specified in Article 22(1) to (3) of Directive 2006/123/EC;
- d. the methods and the criteria for assessing the performance of construction products, as defined in point 1 of Article 2 of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products (1), in relation to their essential characteristics;

ICT technical specification(EU-REGULATION 1025/2012): means a technical specification in the field of information and communication technologies.

Technical Subcommittee: See Technical Committee.

Technical Working Group (WG): See Technical Committee.

Annex 2: List of National Standardization Bodies

The National Standardization Bodies (NSBs) pursuant to Article 27 of Regulation (EU) N^o 1025/2012 of the European Parliament and of the Council, on European standardization (2013/C 279/08;Official Journal of the European Union 27.9.2013), are:

1. Belgium: NBN - Bureau de normalisation, Bureau voor Normalisatie

2. Bulgaria: БИС - Българскиинститутзастандартизация

3. **Czech Republic**: ÚNMZ - Úřad pro technickou normalizaci, metrologii a státní zkušebnictví

4. **Denmark**: DS - Fonden Dansk Standard

5. **Germany**: DIN - Deutsches Institut für Normung e.V.; DKE - Deutsche Kommission Elektrotechnik Elektronik Informationstechnik im DIN und VDE

6. Estonia: EVS - Eesti Standardikeskus; TJA - Tehnilise Järelevalve Amet

7. Ireland: NSAI - National Standards Authority of Ireland

8. **Greece**: ΕΣΥΠ/ΕΛΟΤ - Εθνικό Σύστημα Υποδομών Ποιότητας/Αυτοτελής Λειτουργική Μονάδα Τυποποίησης ΕΛΟΤ

9. Spain: AENOR - Asociación Española de Normalización y Certificación

10. France: AFNOR - Association française de normalisation

11. Croatia: HZN - Hrvatski zavod za norme

12. Italy: UNI - Ente nazionale italiano di unificazione; CEI - Comitato elettrotecnico italiano

13. **Cyprus**: CYS – Κυπριακός Οργανισμός Τυποποίησης (Cyprus Organisation for Standardisation)

14. Latvia: LVS - Latvijas standarts

15. Lithuania: LST - Lietuvos standartizacijos departamentas

16. **Luxembourg**: ILNAS - Institut luxembourgeois de normalisation, de l'accréditation, de la sécurité et qualité des produits et services

17. Hungary: MSZT - Magyar Szabványügyi Testület

18. **Malta:**MCCAA - L-Awtorita' ta' Malta għall-Kompetizzjoni u għall-Affarijiet tal-Konsumatur

19. **Netherlands**: NEN - Stichting Nederlands Normalisatie-instituut ; NEC - Stichting Nederlands Elektrotechnisch Comité

20. **Austria**: ASI - Austrian Standards Institute (Österreichisches Normungsinstitut) ; OVE - Österreichischer Verband für Elektrotechnik

21. **Poland**: PKN -Polski Komitet Normalizacyjny

22. **Portugal**: IPQ - Instituto Português da Qualidade

23. Romania: ASRO - Asociația de Standardizare din România

24. **Slovenia**: SIST - Slovenski inštitut za standardizacijo

25. Slovakia. SÚTN - Slovenský ústav technickej normalizácie

26. **Finland**: SFS - Suomen Standardisoimisliitto SFS ry - Finlands Standardiseringsförbund SFS rf; FICORA – Viestintävirasto Kommunikationsverket; SESKO - Suomen Sähköteknillinen Standardisoimisyhdistys SESKO ryFinlands Elektrotekniska Standardiseringsförening SESKO rf

27. Sweden: SIS - Swedish Standards Institute; SEK - Svensk Elstandard; ITS - Informationstekniska standardiseringen

28. United Kingdom: BSI - British Standards Institution EN

Annex 3: the project nanoSTAIR

	stablishing a process a for <u>nano</u> technologie	R Ind a plattes implem	form to suppor ienting the <u>STA</u>	t standardization
Cox We Sta Buc FP7	rdinator: EU-VRI - The European Virtual Institu bsite: <u>www.nanoSTATR.eu-vri.eu</u> Contact: r rt date: September 2012; End date: February lget: 0.5 ME- EC contribution: 0.5 ME -NMP-2012-CSA-6 - Grant Agreement no. NM RTNERS	te for Integrated R anoSTAIR@eu-yri, 2014; Duration: 18 P4-SA-2012-31909	lisk Management (EEIG) eu 8 months 92	
Ma	in Beneficiaries (Partners)		International Adviso	ory Board
1.	European Virtual Institute for Integrated Risk Management, EU- VRi, Germany	ED-1781	Jean-Marc Aublant Michael Stintz	Chair of CEN TC 352 Member of ISO TC 229
2.	Institut National de l'Environnement Industriel et des Risques, INERIS, France	INERUS	Georg Reiners Göran Lindén	Member of CEN TC 352 CEN TC 137 WG
		8	Daniel Bernard	ARKEMA
3.	Finnish Institute of Occupational Health, FIOH, Finland	STORE AND	Hans-Georg Horn	151
3. 4.	Finnish Institute of Occupational Health, FIOH, Finland FUNDACIÓN Tecnalia RESEARCH & INNOVATION, Tecnalia, Spain	"Ruthianet teona a∮	Hans-Georg Horn Jean-Paul Dufour Iseult Lynch	CILAS QNano
3. 4. 5.	Finnish Institute of Occupational Health, FIOH, Finland FUNDACIÓN Tecnalia RESEARCH & INNOVATION, Tecnalia, Spain Netherlands Organisation for Applied Scientific Research, TNO, Netherlands	"tublicat Lecina (a) TNO tetytion	Hans-Georg Horn Jean-Paul Dufour Iseult Lynch Michael Riediker	ISI CILAS QNano NanoImpactNet
3. 4. 5. 6.	Finnish Institute of Occupational Health, FIOH, Finland FUNDACIÓN Tecnalia RESEARCH & INNOVATION, Tecnalia, Spain Netherlands Organisation for Applied Scientific Research, TNO, Netherlands Steinbeis Advanced Risk Technologies GmbH, R-Tech, Germany	THE SECOND	Hans-Georg Horn Jean-Paul Dufour Iseult Lynch Michael Riediker Lang Tran Rudolf Reuther	ISI CILAS QNano NanoImpactNet MARINA NANOVALID
3. 4. 5. 6. 7.	Finnish Institute of Occupational Health, FIOH, Finland FUNDACIÓN Tecnalia RESEARCH & INNOVATION, Tecnalia, Spain Netherlands Organisation for Applied Scientific Research, TNO, Netherlands Steinbeis Advanced Risk Technologies GmbH, R-Tech, Germany Deutsches Institut für Normung, DIN, Germany		Hans-Georg Horn Jean-Paul Dufour Iseult Lynch Michael Riediker Lang Tran Rudolf Reuther Kirsten Rasmussen Christelle Saout	ISI CILAS QNano NanoImpactNet MARINA NANOVALID JRC ISPRA University of Namur

Standardization is one of the most adequate solutions to quickly capitalize and disseminate knowledge in "reference documents", and have it implemented in the industry. It is very important in the field of nanotechnologies since the production of knowledge is very intensive. The overall objective of nanoSTAIR project is to build a sustainable process and platform in the field of nanotechnologies to support the transfer of knowledge gained through research to documentary standards in the context of the STAIR approach promoted by CEN-CENELEC.

The project is organized around several activities that will boost the development of new documentary standards.

A mechanism will be set up to identify, with a bottom-up approach, the opportunities for standardization from the results of research projects, co-funded by the European Commission or by National Research Programmes. This mechanism will be established using existing networks and initiatives such as NanoSafetyCluster or NANOfutures, as well as the network of the national standardization bodies in the various Member States.

Then, the expression of the needs for standards from various stakeholders will be collected and resources from consortia sharing similar standardization opportunities will be pooled together to launch New Work Items Proposals (NWIP). The nanoSTAIR approach will be verified during the project thanks to 2 NWIP initiated. The consortium will provide assistance to select the right standardization umbrella (Technical Committee and Working Group at CEN or ISO level).

As a result, nanoSTAIR will provide a set of procedures, a tool box and a practical guideline that will be useful to bridge the gap between research and standardization in nanotechnologies. nanoSTAIR will structure and ease the development of new documentary standards, and thus enable the European nanotechnology related industry to rapidly operate according to the state of the art and thus increase its competitiveness.

Overall Strategy

The nanoSTAIR process will be described in procedures, checklists and communication channels. The nanoSTAIR process can be seen as a turbine that accelerates the preparation of new work item proposals by identifying the potential candidates, by making explicit the needs from the main stakeholders and by pooling the resources and expertise to reach the necessary critical mass. The project is therefore organized around 4 supporting activities.



SUPPORT FROM INANOSAFETY CLUSTER NANOELITURES.

The knowledge developed during the project will be collated in the form of reports and conclusions of discussion workshops, but also practical tools that will be used and exploited after the end of the project.



The most important outcomes of the project are the nanoSTAIR platform that will bring together the best experts to launch standardization work item proposals and the nanoSTAIR process to develop new work item proposal.

The nanoSTAIR platform will be a place to find information, a place to find and meet potential partners, a place to find support... The nanoSTAIR platform which is a virtual table where all stakeholders will have the opportunity to share common needs and solutions regarding new documentary standards.

The nanoSTAIR platform will in particular bridge the research community and the standardization community.

The nanoSTAIR process will be described in procedures, checklists and communication channels. The nanoSTAIR process can be seen as a turbine that accelerates the preparation of new work item proposals by identifying the potential candidates, by making explicit the needs from the main stakeholders and by pooling the resources and expertise to reach the necessary critical mass.

(Registration link: <u>www.nanostair.eu-vri.eu/registration.aspx</u>)

Acknowledgment:

The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 319092.

Contact Person:

EU-VRi European Virtual Institute for Integrated Risk Management Olivier Salvi & Bastien Caillard, Project Coordination Team Haus der Wirtschaft, Willi-Bleicher-Straße 19, 70174 Stuttgart, Germany Tel: +49 (711) 1839–749, <u>www.eu-vri.eu</u>.- <u>nanoSTAIR@eu-vri.eu</u>