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nanoSTAIR

D2.1 Snapshot of the needs of the stakeholders and drivers for standardization

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nanoSTAIR - Establishing a process and a platform to support standardization for nanotechnologies implementing the STAIR approach

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Deliverable D2.1 Snapshot of the needs of the stakeholders and drivers for standardization

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More information on the nanoSTAIR project: www.nanoSTAIR.eu-vri.eu

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1 Introduction

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 Programs. This mechanism will be established using existing networks and initiatives and projects such as NanoSafetyCluster or QNano and NanoValid, 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 by producing 2 NWIPs. 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.

The present document presents the results of WP 2 task 2.1 “Identification of the needs from various stakeholders at EU and national level”. It identifies and summarizes the needs and main drivers of various stakeholder groups for new standards to bridge the gap between the research objectives and the standardization needs by facilitating the process of clustering.

2 Method

2.1 Description of work and role of partners

The needs for standardization by various stakeholders (e.g. industry, governments, regulatory agencies, NGO's etc.) has been identified by creating linkages to existing platforms, networks and initiatives with respect to nanotechnology. The IAB members and also other organizations (Attachment 1) have been consulted in a NanoSTAIR workshop in Paris December 19, 2012. In relation with the initiative developed by EU FP 7 nanoSTAIR -project, nanoSTAIR Team executed in addition a survey. Members of the European Technology Platform on Industrial Safety and NanoSafetyCluster were asked to take a part to a survey identifying the needs of the stakeholders and main drivers for standardization.

Respondents' backgrounds as a nanotechnology stakeholder were divided into groups as follows:

- Research and development
- Manufacturer of nanotechnology
- Downstream user or end user of nanotechnology
- Regulator
- Standardization body
- Other stakeholder

Due to the low number of answers (< 3 per group) a new stakeholder group, called "Industry", was formed from the "Manufacturer of nanotechnology" and the "Downstream user or end user of nanotechnology" group. In addition "Regulator" group were integrated to "Other stakeholder" group.

Survey alternatives of different standardization topics were assembled based on

- 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.
- Commission Mandate M/ 409 Standards Needs in Nanotechnology and nanomaterials Report from CEN/TC 352 Nanotechnologies (2008)
- Mandate addressed to CEN, CENELEC and ETSI for standardization activities regarding nanotechnologies and nanomaterials, M/461 (2010)
- Forthcoming standardization opportunities and needs in the field of nanotechnologies Aublant, Jean-Marc (2012)

Survey (Attachment 2) contained 59 possible standardization topics in the area of nanotechnology. The standardization topics were divided in three parts, (1) Metrology and instrumentation, including specifications for reference materials, (2) Science-based health, safety and environmental practices and (3) Nanotechnology products and processes. Respondents rated the level of the relevance of the topic according to their business or work using the scale from 1 (not relevant at all) to 5 (very relevant) of each of the (59) standardization topics. Respondents also indicated if they were as a stakeholder interested to participate standardization process of the topics.

3 Results

3.1 Participants in survey

Total number of participants in survey is 39 and respondent's background as a nanotechnology stakeholder was divided as follows:

Table 1. Proportion of the answers in different stakeholder groups. Answerer could choose several stakeholder groups as their background.

Stakeholder group	Percentage of the answers
Research & development	76 %
Industry	18 %
Standardization body	12 %
Other stakeholder	24 %

Some participants reported several backgrounds. Most of participants have the background of universities or research institutes.

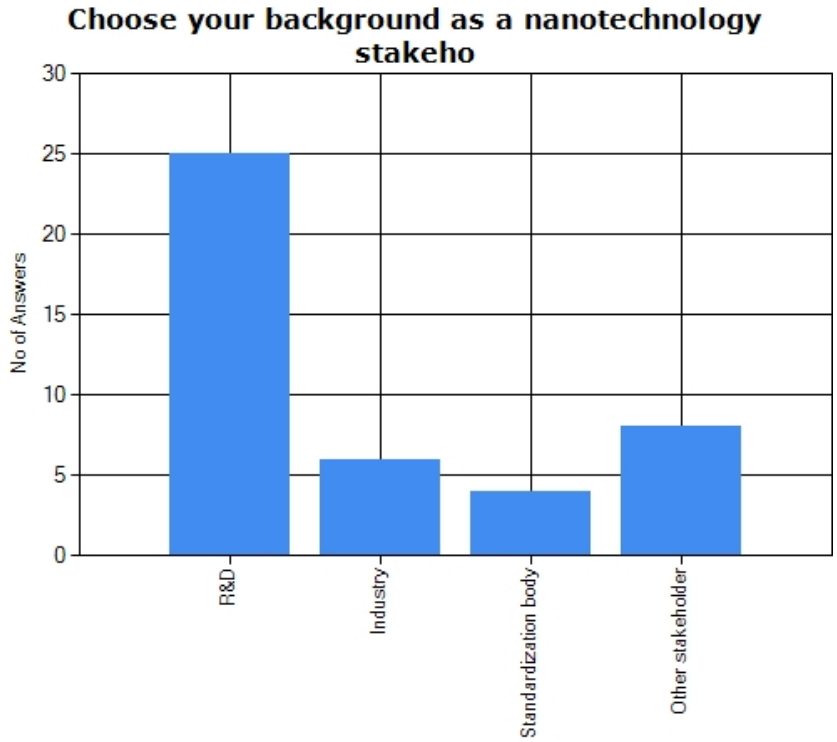
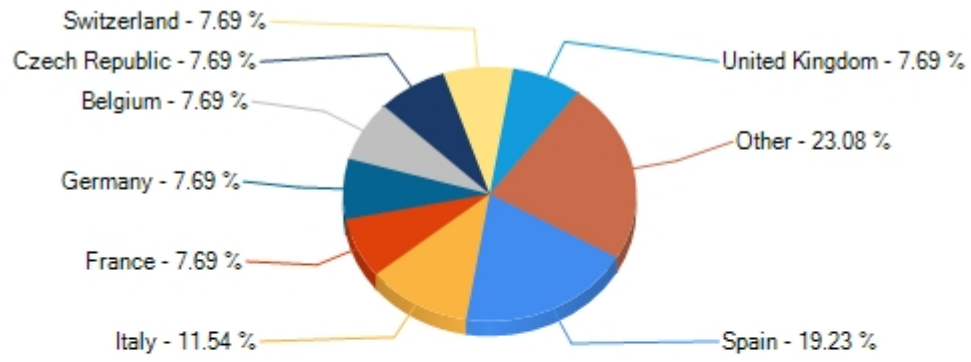


Figure 1. Distribution of the stakeholder background of the participants.

The locations of the respondents are show in the Figure 2. Not all answerers indicated their location.



Color	Name	Value	Percent
	Spain	5	19.23 %
	Italy	3	11.54 %
	France	2	7.69 %
	Germany	2	7.69 %
	Belgium	2	7.69 %

Color	Name	Value	Percent
	Czech Republic	2	7.69 %
	Switzerland	2	7.69 %
	United Kingdom	2	7.69 %
	Other	6	23.08 %

Figure 2. The country of residence of the survey participants.

3.2 Most relevant standardization topics

3.2.1 The whole answering group

As a whole guidance, protocols and related metrology (instrumentation and techniques) for characterisation, measurements and exposure evaluation are needed. The whole answering group highlighted the need for characterization of nanomaterials from aerosols and environmental sources as well as identification and definition of measurands. Also guidance on dosimetry and exposure measurement is needed. In the area of testing methodologies the need for repeatability, reproducibility and intercomparability of test methods were also in the top 15 topics for standardisation. Also the quality control methods and inter-laboratory comparisons were indicated as the high priority topics for standardization. Certified Reference materials for challenging and calibration of instruments are also needed.

In the topic area of safe use of ENM's the whole answering group emphasized the need for guidance on safe handling of ENM's as well as waste management and disposal of nanomaterials.

In the topic area of toxicity and ecotoxicity testing guidance on characterization prior to toxicity testing and guide to performance measurements of materials and devices were also highlighted. Also sample preparation for toxicity studies needs guidance. Guidance for integrated toxicity testing and guidance for short and long term toxicity testing are given high scores in answers.

Of all respondents fifteen most relevant standardization items (top 15) were as follows (average score):

1. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc. (2,95)

2. Repeatability, reproducibility and intercomparability of test methods. (2,92)
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. (2,85)
4. Guidance on nano-material characterization prior to, or in association with toxicity testing. (2,83)
5. Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials. (2,69)
6. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment). (2,59)
7. Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc. (2,58)
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. (2,56)
9. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects. (2,55)
10. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities. (2,55)
11. Guide to the management of waste and the disposal of nanomaterials. (2,44)
12. Guide to performance measurement of nanoscale materials and devices. (2,39)
13. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment. (2,39)
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. (2,35)
15. Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges). (2,35)

3.2.2 R&D group

The answers from the R&D stakeholder group resemble quite well with the answers of the whole answering group. Though, the R&D group was biggest of all the stakeholders answering the survey. Thirteen standardization items were the same as in the top 15 list of the whole answering group. Differences were that R&D stakeholders highlighted need for guidance on detection and identification of and protocols for risk management of ENMs. Also the need for guidance on a common data-format for integrated analysis for risk assessment was scored to the top 15 list.

On the contrary the need for the guide to performance measurement for nanoscale materials and devices does not get as high priority as in the whole answering group. Similarly, the need for protocols for short and long term toxicity testing was not in the top 15 list of the R&D group.

Research and development respondents (76 %) rated fifteen most relevant standardization items as follows (average score):

1. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc. (3,3)

2. Guide to the identification and definition of measurands required for characterizing, evaluating functional properties and performance etc., of materials and devices at the nanoscale. (3,15)

3. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment). (3,05)

4. Repeatability, reproducibility and intercomparability of test methods. (3,02)

5. Guidance on nano-material characterization prior to, or in association with toxicity testing. (3,01)

6. Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc. (2,95)

7. Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials. (2,87)

8. Guide to the management of waste and the disposal of nanomaterials. (2,84)

9. Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges). (2,79)

10. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects. (2,76)

11. Protocols for risk management that specifically refers to potential nanotechnology hazards. (2,71)

12. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities. (2,68)

13. Guidance on a common data-format for an integrated analysis for risk assessment. (2,67)

14. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment. (2,66)

15. 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. (2,64)

3.2.3 Industry group

Due to the low number of answers a new stakeholder group, called “Industry”, was formed from the “Manufacturer of nanotechnology” and the “Downstream user or end user of nanotechnology” group. The standardization need of this industry group differed notably form the needs of the whole answering group. Seven (7) of the most important standardization items (top 15) are the same as in the whole group and eight items are the same as in the R&D group.

The standardization topic area of characterization, identification and detection of nanomaterials was also important to industry stakeholder group. The guidance on nanomaterial characterization for toxicity testing and the identification and definition of measurands for properties and performance evaluations of materials and devices were highlighted the two most important

standardization items. Protocols for the characterization of manufactured nanoparticles from different environmental compartments was ranked as fifth important item for standardization.

The safe use of ENM was another important standardization topic area for industry group. Guidance on waste management and detection and identification of nanoparticles in all media types e.g. waste streams are needed. Also guidance on safe handling of ENM including the selection PPE was also important for downstream user stakeholder 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 this stakeholder group.

Similarly, modeling and simulation standardization topic area seemed to be important for this group. Standardization items such as simulation methods for approximating exposures and guidance for modeling is needed. Risk and life cycle assessment standardization items such protocols for both risk assessment and risk management of potential nanotechnology hazards are important for downstream users.

From the toxicity and ecotoxicity testing topic area the industry emphasizes the development of OECD test guidelines for ENM. From the other test methodologies the repeatability, reproducibility and intercomparability of the methodologies are important.

Industry stakeholder group (18 %) rated fifteen most relevant standardization items as follows (average score):

1. Guide to the identification and definition of measurands required for characterising, evaluating functional properties and performance etc., of materials and devices at the nanoscale. (3,47)

2. Guidance on nano-material characterization prior to, or in association with toxicity testing. (3,42)

3. Guide to the management of waste and the disposal of nanomaterials. (3,3)

4. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc. (3,2)

5. Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges). (3,08)

6. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment). (3,03)

7. Good practice for nano-fabrication and nano-engineering. (3,03)

8. Safety – Pre-competitive research, Design, Manufacture, Use and End-of- life (includes disposal, reuse and recycling). (3)

9. Repeatability, reproducibility and intercomparability of test methods. (2,92)

10. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities. (2,82)

11. OECD test guidelines for manufactured nanomaterials. (2,77)

12. Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities. (2,7)

13. Guide to design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water. (2,62)
14. Guides to purity evaluation of manufactured nanoparticles and other nanoscale entities. (2,6)

15. Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities. (2,58)

The subgroup of answerers resembling downstream users of nanotechnology also highlighted the following standardization items:

- Product specifications for different manufactured nanomaterials.
- Simulation Methods/techniques to approximate exposure.
- Protocols for risk management that specifically refers to potential nanotechnology hazards.
- Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities.
- Guide to modelling (measurement, simulation and visualization) at the nanoscale.

3.2.4 Standardization body

The opinions of the standardization stakeholder group are quite similar to the whole answering group and thus quite similar to that of the R&D group. Twelve of the most important standardization items are the same as the top 15 items of those groups. Differences were found in standardization items such as the need of standard methods for ENM emission assessment methods, protocols for in vitro toxicology evaluation and the need of simulation methods to approximate exposure.

Standardization body (12 %) rated fifteen most relevant standardization items as follows (average score):

1. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc. (4,3)

2. Repeatability, reproducibility and intercomparability of test methods. (4,3)

3. Guidance on nano-material characterization prior to, or in association with toxicity testing. (3,8)

4. Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc. (3,65)

5. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects. (3,65)

6. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities. (3,6)

7. Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials. (3,53)

8. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment). (3,1)

9. Guide to the identification and definition of measurands required for characterizing, evaluating functional properties and performance etc., of materials and devices at the nanoscale. (3,05)

10. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment. (2,95)

11. Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products. (2,95)

12. Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities. (2,85)

13. 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. (2,82)

14. Simulation Methods/techniques to approximate exposure. (2,8)

15. Guide to performance measurement of nanoscale materials and devices. (2,68)

3.2.5 Other stakeholder

The group of other stakeholders consists of e.g. consulting companies, metrology institutes, research funding organizations and research officers as well as regulators. The answers of this group were in good agreement with the whole group answers. Eleven of the top 15 items was the same as in the whole answering group. All of the differences in the most important topics were dealing with the toxicity and ecotoxicity testing standardization items which was the most important standardization topic area for this group. Standardization items such as sample preparation, protocols for evaluation the effects, validated tests methods for in vivo tests, stability assessment of nanoparticles in tests and protocols for in vitro evaluations.

Other stakeholder (24 %) rated fifteen most relevant standardization items as follows (average score):

1. Repeatability, reproducibility and intercomparability of test methods. (3,85)

2. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities. (3,58)

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. (3,54)

4. Guidance on nano-material characterization prior to, or in association with toxicity testing. (3,52)

5. 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. (3,51)

6. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc. (3,29)

7. Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials. (3,28)

8. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects. (3,25)

9. Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities. (3,2)

10. Stability assessment of nanoparticles in vivo and in vitro. (3,19)

11. Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities. (3,19)

12. Guide to the identification and definition of measurands required for characterizing, evaluating functional properties and performance etc., of materials and devices at the nanoscale. (3,14)

13. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment). (3,09)

14. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment. (3,05)
15. Protocols for risk management that specifically refers to potential nanotechnology hazards. (3,02)

3.3 Standardization needs by topic areas

3.3.1 Characterization, identification and detection of nanomaterials

The characterization, identification and detection of nanomaterials are important items for all stakeholder groups.

Table 2. Ranking of the most important standardization items in topic area of "Characterization, identification and detection of nanomaterials" by different stakeholder groups.

Standardization item	Total	R&D	Industry	Standardization	Other
Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.;	1	1	4	1	14
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	3	1	10	12
Guidance on nano-material characterization prior to, or in association with toxicity testing;	4	6	2	4	4
Guide to performance measurement of nanoscale materials and devices;	13	20	22	16	17
Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities;	23	23	12	20	34
Guides to purity evaluation of manufactured nanoparticles and other nanoscale entities.	32	32	14	36	27

Coding

Rank of the importance of the standardization item within the stakeholder group						
1	2	3	…	57	58	59
Most important standardization item				**Least important standardization item**		

3.3.2 Toxicity and ecotoxicity testing

Several standardization items in the topic are of toxicity and ecotoxicity testing was ranked to the most important standardization items. Especially stakeholder group “other” highlighted the need of standardization in this topic area.

Table 3. Ranking of the most important standardization items in topic area of “Toxicity and ecotoxicity testing” by different stakeholder groups.

Standardization item	Total	R&D	Industry	Standardization	Other
Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;	11	13	10	7	2
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	24	21	22	3
Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;	20	28	15	38	9
Stability assessment of nanoparticles in vivo and in vitro;	17	19	24	31	10
Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;	19	21	28	13	11
Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment;	14	15	23	11	15
OECD test guidelines for manufactured nanomaterials;	22	30	11	19	32

Coding:

Rank of the importance of the standardization item within the stakeholder group						
1	2	3	…	57	58	59
Most important standardization item				Least important standardization item		

3.3.3 Safe use of ENM

Especially industry and R&D stakeholders group emphasized the need of standardization in the topic are of safe use of engineered nanomaterials.

Table 4. Ranking of the most important standardization items in topic area of "Safe use of ENM" by different stakeholder groups.

Standardization item	Total	R&D	Industry	Standardization	Other
Guide to the management of waste and the disposal of nanomaterials.	12	9	3	30	24
Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges);	16	10	5	24	23
Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment);	7	4	6	9	13

Coding

Rank of the importance of the standardization item within the stakeholder group						
1	2	3	…	57	58	59
Most important standardization item						Least important standardization item

3.3.4 Nanotechnology processes and devices

Table 5. Ranking of the most important standardization items in topic area of "nanotechnology processes and devices" by different stakeholder groups.

Standardization item	Total	R&D	Industry	Standardization	Other
Good practice for nano-fabrication and nano-engineering;	24	22	7	27	46
Safety – Pre-competitive research, Design, Manufacture, Use and End-of- life (includes disposal, reuse and recycling);	28	29	8	28	31
Guide to design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water;	38	36	13	21	38

Coding

Rank of the importance of the standardization item within the stakeholder group						
1	2	3	…	57	58	59
Most important standardization item						Least important standardization item

3.3.5 Other important standardization topic areas

In other standardization topic areas standardization in the area of exposure evaluation and quality issues of the test methods seem to be important for many stakeholder groups.

Table 6. Ranking of the most important standardization items in other topic areas by different stakeholder groups.

Standardization item	Total	R&D	Industry	Standard-...	Other	Topic group
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	16	41	14	5	Reference materials
Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects;	10	11	25	6	8	Instrumentation and techniques
Repeatability, reproducibility and intercomparability of test methods.	2	5	9	2	1	Test methodologies
Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials;	6	8	17	8	7	Exposure evaluation
Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.	8	7	33	5	28	Other test methods
Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products;	18	17	29	12	26	Other test methods
Simulation Methods/techniques to approximate exposure;	29	31	35	15	18	Modelling and simulation
Protocols for risk management that specifically refers to potential nanotechnology hazards;	21	12	31	25	16	Risk assessment, LCA
Guidance on a common data-format for an integrated analysis for risk assessment;	25	14	39	48	25	Risk assessment, LCA

Coding

Rank of the importance of the standardization item within the stakeholder group						
1	2	3	…	57	58	59
Most important standardization item						Least important standardization item

3.4 Other needs for standardization

Research and development respondents (76 %) identified other specified needs for standardization, which have not been mentioned in the survey. The specific standardization needs are:

- Industrial production of drug nanocarriers
- Behavior and fate in the environment: soil&sediment, water
- Determination of exposure
- The work risks prevention measures using nanoparticles (protection, how to handle them, how to recycle them, etc.)
- To avoid in vivo studies
- Classification of NanoMaterials

4 Conclusions

Different stakeholder groups were asked to rate the relevance of the predefined standardization items according to the relevance to their business or work. The standardization items used in this survey were based on the Mandates form the Commission and future plans of the TC 352.

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 NanoSafetyCulster) 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 our 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.

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

Reliability of the test methods was another important issue and also **the repeatability, reproducibility and intercomparability 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.

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.

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. 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.

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;

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**.

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

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.

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

Similarly, **modeling 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.

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 assessment

5 Attachments

5.1 NanoSTAIR Workshop T1.1 & 2.1

List of participants

Last Name, First Name, Company, Country

1. Aublant, Jean-Marc, Laboratoir National d'Essais, France
2. Martin Segolene, CEN - European Committee for Standardization, Belgium
3. Säämänen Arto, Finnish Institute of Occupational Health, Finland
4. Salvi, Olivier, European Virtual Institute for Integrated Risk Management, Germany
5. Florence, Carré, Ineris, France
6. Ravantti, Elina, Finnish Institute of Occupational Health, Finland

5.2 Questionnaire "Identification of the needs from various stakeholders at EU and national level"

In relation with the initiative developed by EU FP 7 nanoSTAIR -project, You are invited to take part in this survey to provide information to identify the needs of the stakeholders and main drivers for standardization. The objective of the survey is also to chart your interest as a nanotechnology stakeholder to participate the standardization process of different standardization topics.

This survey contains 59 possible standardization topics in the area of nanotechnology. The standardization topics are divided in three parts, (1) Metrology and instrumentation, including specifications for reference materials, (2) Science-based health, safety and environmental practices and (3) Nanotechnology products and processes.

Please rate the level of the relevance of the topic for your business or work using the scale from 1 (not relevant at all) to 5 (very relevant) of each of the (59) standardization topics. Please also indicate if you are as a stakeholder interested to participate standardization process of the topics.

Thank you for your participation.

Best regards,

nanoSTAIR Team

Choose your background as a nanotechnology stakeholder:

□ R&D, please specify name:

□ Manufacturer of nanotechnology, please specify name:

□ Downstream user or end user of nanotechnology, please specify name:

□ Regulator, please specify name:

□ Standardization body, please specify name:

□ Other stakeholder, please specify name:

Part 1. Metrology and instrumentation, including specifications for reference materials (1-26)

Characterization, identification and detection of nanomaterials (Rate each item from 1 to 5)

1. Guide to the identification and definition of measurands required for characterising, evaluating functional properties and performance etc, of materials and devices at the nanoscale
2. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.;
3. Guide to performance measurement of nanoscale materials and devices;
4. Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities
5. Guidance on nano-material characterization prior to, or in association with toxicity testing;

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

Reference materials (Rate each item from 1 to 5)

7. 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;

Instrumentation and techniques (Rate each item from 1 to 5)

8. Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects;
9. Development of In situ/on line non-destructive techniques and contact-less measurements relevant to nanotechnologies;

Test methodologies *(Rate each item from 1 to 5)*

10. Repeatability, reproducibility and intercomparability of test methods

Toxicity and ecotoxicity testing (Rate each item from 1 to 5)

11. OECD test guidelines for manufactured nanomaterials;
12. Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;
13. Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;
14. Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;
15. 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;
16. Stability assessment of nanoparticles in vivo and in vitro;
17. Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment;
18. In vitro evaluation of osseo-genetic behaviour of nanostructured surfaces;

Exposure evaluation(Rate each item from 1 to 5)

19. Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials.
20. Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.

Other test methods (Rate each item from 1 to 5)

21. Methodology to Determine effectiveness of Filtration Media against Nanomaterials
22. Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products
23. Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage)
24. Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.;

Modelling and simulation *(Rate each item from 1 to 5)*

25. Simulation Methods/techniques to approximate exposure;
26. Guide to modelling (measurement, simulation and visualization) at the nanoscale;

Part 2. Health, safety and environmental practices (27-34)

Risk assessment, LCA (Rate each item from 1 to 5)

27. Guidance on a common data-format for an integrated analysis for risk assessment;
28. Protocols for risk management that specifically refers to potential nanotechnology hazards;
29. Protocols for whole life cycle assessment of nanoscale materials, devices and products.
30. Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities;

Safe use of ENM (Rate each item from 1 to 5)

31. Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment)
32. Guidance on containment, trapping and destruction of nanoparticles and other manufactured nanoscale entities
33. Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges)
34. Guide to the management of waste and the disposal of nanomaterials

Part 3. Nanotechnology products and processes (35-59)

Products (Rate each item from 1 to 5)

35. Product specifications for different manufactured nanomaterials
36. Evaluation of new functions specific to manufactured nano-particles and nano-objects;
37. Material specifications for polymer and printable electronics;
38. Release measurement of active materials from nanoporous substrates.

Devices (Rate each item from 1 to 5)

39. Performance measurement of nanoscale materials and devices;
40. Performance assessment – Pre-competitive research, Design, Manufacture and Use
41. Reliability– Pre-competitive research, Design, Manufacture and Use
42. Safety – Pre-competitive research, Design, Manufacture, Use and End-of- life (includes disposal, reuse and recycling)
43. Design, construction and performance criteria for cantilever-arrays used in diagnosis;
44. Design and performance of nanoscale cantilever devices for detection and identification of pathogens in water, food and air;
45. Design, construction and performance criteria for lab-on-a-chip devices;
46. RFID standards to complement ISO/IEC TR 18047-7:2005;

47. Guide to design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water.
48. Quality of nanoscale materials used in the preparation of devices;

Processes (Rate each item from 1 to 5)

49. Good practice for nano-fabrication and nano-engineering;
50. Design criteria for high spatial resolution monitors for environmental monitoring.

Standardization in the area of renewable energy generation and sustainability (=renewable, climate friendly, energy production and for reducing energy consumption) such as (Rate each item from 1 to 5):

51. new lighter, stronger, more robust materials for use in, e.g. wind-power equipment, and vehicle and aircraft construction;
52. new, more efficient and lower cost solar cells for local electricity generation;
53. new catalysts for gasification, for cleaner and more efficient combustion, and for removing atmospheric pollution;
54. new, light weight and high efficiency fuel cells for use in vehicles and consumer electronics;
55. heat-reflecting layers for windows;
56. highly efficient thermal insulators for buildings and vehicles, and new thermal barriers and blade materials to increase the efficiency of gas turbines;
57. highly efficient lighting; very low power-consumption consumer electronics;
58. new lubricants and surface layers to reduce energy loss and increase component life.
59. Other need for standardization, which have not been mentioned, please specify

5.3 The ranking of the standardization items

Ranking of the most important standardization items by different stakeholder group (rank 1 = most important).

Standardization item	Whole group	R&D	Industry	Standardization	Other
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	3	1	10	12
Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.;	1	1	4	1	14
Guide to performance measurement of nanoscale materials and devices;	13	20	22	16	17
Guide to basic morphology and purity of manufactured nanoparticles and other nanoscale entities;	23	23	12	20	34
Guidance on nano-material characterization prior to, or in association with toxicity testing;	4	6	2	4	4
Guides to purity evaluation of manufactured nanoparticles and other nanoscale entities.	32	32	14	36	27
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	16	41	14	5
Related metrology (instrumentation and techniques) for measurement and characterization of nanoparticles and other nano-objects;	10	11	25	6	8
Development of In situ/on line non-destructive techniques and contact-less measurements relevant to nanotechnologies.	34	35	51	23	19
Repeatability, reproducibility and intercomparability of test methods.	2	5	9	2	1
OECD test guidelines for manufactured nanomaterials;	22	30	11	19	32
Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;	11	13	10	7	2
Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;	20	28	15	38	9
Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;	19	21	28	13	11
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	24	21	22	3
Stability assessment of nanoparticles in vivo and in vitro;	17	19	24	31	10
Guidance on integrated (toxicity) testing strategies (ITS) and integrated risk assessment;	14	15	23	11	15
In vitro evaluation of osseo-genetic behaviour of nanostructured surfaces.	58	60	43	54	56
Guidance on dosimetry and exposure determination in occupational settings relevant to manufactured nanomaterials;	6	8	17	8	7
Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc	5	2	26	3	6
Methodology to Determine effectiveness of Filtration Media against Nanomaterials;	27	27	18	29	40

Standardization item	Whole group	R&D	Industry	Standardization	Other
Standard Method to Assess Emissions from Handling, or Machining of Nanomaterial Containing Products;	18	17	29	12	26
Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage);	35	34	37	26	55
Inter-Laboratory Comparisons and validated methods/techniques for measurement/control of quality, process, etc.	8	7	33	5	28
Simulation Methods/techniques to approximate exposure;	29	31	35	15	18
Guide to modelling (measurement, simulation and visualization) at the nanoscale	33	33	44	17	30
Guidance on a common data-format for an integrated analysis for risk assessment;	25	14	39	48	25
Protocols for risk management that specifically refers to potential nanotechnology hazards;	21	12	31	25	16
Protocols for whole life cycle assessment of nanoscale materials, devices and products;	30	25	40	56	20
Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities.	26	18	32	35	21
Guidance on safe handling of manufactured nanoparticles and other manufactured nanoscale entities (including selection of Personal Protective Equipment);	7	4	6	9	13
Guidance on containment, trapping and destruction of nanoparticles and other manufactured nanoscale entities;	31	26	19	37	41
Guidance on detection and identification of nanoparticles and other nanoscale entities (in all media types, including waste streams from manufacturing and manufacturing discharges);	16	10	5	24	23
Guide to the management of waste and the disposal of nanomaterials.	12	9	3	30	24
Product specifications for different manufactured nanomaterials;	36	38	20	46	22
Evaluation of new functions specific to manufactured nano-particles and nano-objects;	53	52	42	58	37
Material specifications for polymer and printable electronics;	57	57	59	59	33
Release measurement of active materials from nanoporous substrates.	46	43	57	57	35
Performance measurement of nanoscale materials and devices;	37	37	49	18	59
Performance assessment – Pre-competitive research, Design, Manufacture and Use;	43	41	48	42	45
Reliability– Pre-competitive research, Design, Manufacture and Use;	39	42	46	34	42
Safety – Pre-competitive research, Design, Manufacture, Use and End-of- life (includes disposal, reuse and recycling);	28	29	8	28	31
Design, construction and performance criteria for cantilever-arrays used in diagnosis;	59	56	55	53	54
Design and performance of nanoscale cantilever devices for detection and identification of pathogens in water, food and air;	56	50	27	49	57
Design, construction and performance criteria for lab-on-a-chip devices;	47	44	56	41	52
RFID standards to complement ISO/IEC TR 18047-7:2005;	54	53	58	51	53
Guide to design, manufacture and performance of low cost, nanoscale filtration devices for point of use purification of water;	38	36	13	21	38

Standardization item	Whole group	R&D	Industry	Standardization	Other
Quality of nanoscale materials used in the preparation of devices.	44	40	36	32	51
Good practice for nano-fabrication and nano-engineering;	24	22	7	27	46
Design criteria for high spatial resolution monitors for environmental monitoring;	40	39	45	39	58
new lighter, stronger, more robust materials for use in, e.g. wind-power equipment, and vehicle and aircraft construction;	48	49	30	50	36
new, more efficient and lower cost solar cells for local electricity generation;	45	47	34	45	39
new catalysts for gasification, for cleaner and more efficient combustion, and for removing atmospheric pollution;	41	46	50	33	48
new, light weight and high efficiency fuel cells for use in vehicles and consumer electronics;	49	48	53	43	43
heat-reflecting layers for windows;	52	51	54	44	50
highly efficient thermal insulators for buildings and vehicles, and new thermal barriers and blade materials to increase the efficiency of gas turbines;	51	54	38	47	47
highly efficient lighting; very low power-consumption consumer electronics;	55	59	47	52	44
new lubricants and surface layers to reduce energy loss and increase component life.	50	55	52	55	49
Other need for standardization, which have not been mentioned	60	58	60	60	60

6 References

[1] 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.

[2] Comission Mandate M/ 409 Standards Needs in Nanotechnology and nanomaterials

[3] Report from CEN/TC 352 Nanotechnologies (2008)

[4] Mandate addressed to CEN, CENELEC and ETSI for standardization activities regarding nanotechnologies and nanomaterials, M/461 (2010)

[5] Forthcoming standardization opportunities and needs in the field of nanotechnologies Aublant, Jean-Marc (2012)