

ELECTRONIC SUPPORT MATERIAL 2

Two-round Delphi study – second stage questionnaire

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From Risk Perception to Risk Governance in Nanotechnology: A Multi-Stakeholder Study

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caLIBRAte Survey (Delphi-Exercise, 2nd Stage): Risk Governance and Risk Management of Nanomaterials



Supporting tools for decision making in risk governance and risk management of nanomaterials (and related products)

This questionnaire is the second round of the Delphi Exercise launched by the caLIBRAte Project.

Based on the 1st round results, the 2nd final round intends to collect **in-depth indications** for **the development and use of an integrated risk governance framework (System of systems) for nanotechnologies**.

The aims of the caLIBRAte risk governance System of systems is to make available reliable, tailored and up-to-date tools for evaluation and prioritization of the risks posed by production, use and disposal of nanomaterials.

As in the 1st round, the questionnaire is structured in four sections, and a total of 11 questions:

- **Awareness and Risk Perception** (2 questions)
- **Priorities and Needs for Risk Governance** (2)
- **Best Practices for Risk Management** (6)
- **Insurance coverage for nanomaterials risks** (1)

Most of the questions seek to **reach convergence of opinions amongst you and the other experts**, and provide more detailed views on issues and challenges emerged from the 1st round. To help inform you, each question begins with a very brief summary of relevant results of the 1st round.

We would appreciate your contribution on all topics and questions, but please **feel free to focus on the areas you consider most relevant with respect to your expertise and interest**.

Results of the 2nd round Delphi Exercise will be circulated amongst all participants.

For any information on the survey, write to Elisabetta Borsella (Airi/Nanotec IT): borsella@nanotec.it

You may start the questionnaire, thank you for your valuable contribution!

While answering the survey questions you can go back and forth through your answers at any time using the navigation buttons at the bottom of the page. When you click the [finish>>] button, the survey will be saved and closed. You can access to the questionnaire multiple times after closing, using the link provided in the end page (information will be saved).

1. Awareness and Risk Perception

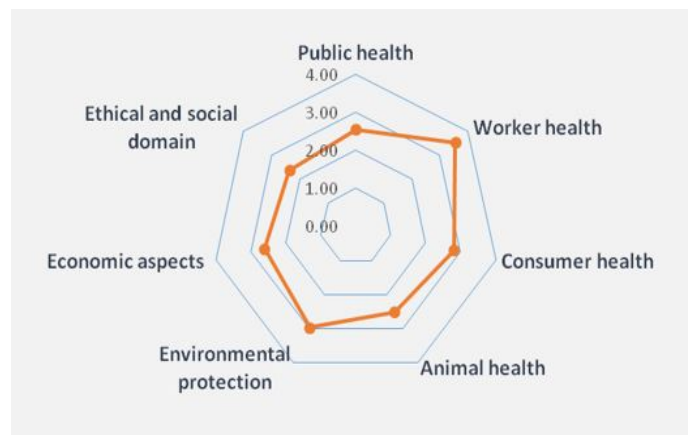
1. Awareness and Risk Perception

This chapter is composed of 2 questions. Feel free to answer only the questions related to your competence/responsibility area(s).

1.

In the first round of this Delphi consultation, the respondents expressed their concern about the potential impact on health and environment deriving from manufacturing/use/disposal of nanomaterials (NMs) and nano-enabled products.

*As shown in the figure below, the highest risks (on a scale of 1 to 5) are perceived for **worker** (3.6) and **consumer** (2.8) **health** and for the **environment** (2.9).*



*A medium-high risk (ranging from 2.1 to 3.7) is perceived in all the existing application domains and market sectors for NMs and nano-enabled products, with the highest level (>3 on a scale of 1 to 5) in **Chemicals and Materials, Agri-food, Cosmetics, Packaging** and the **Environment** sectors.*

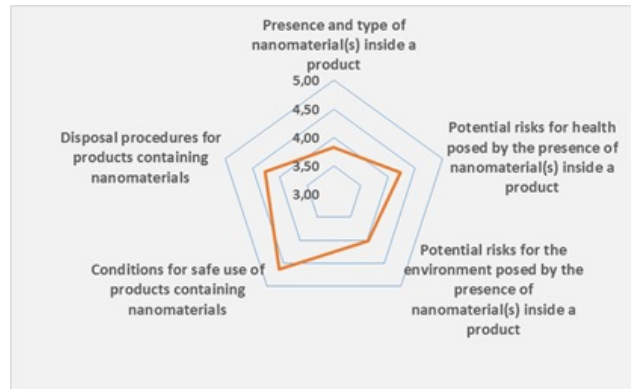
The perceived uncertainty in the safety of nanomaterials and nano-enabled products is considered by the majority of respondents (66%) either a moderate (41%) or a great (25%) limitation to their diffusion on the market and their use. Only very few (3%) think that it does not matter at all.

Q1: In your opinion, which factors contribute most to creating the perceived uncertainty in the safety of nanomaterials and to limit their diffusion on the market and their use?

In your answer please refer to both Business-to-Business (B2B) commercial transactions and Business-to-Consumer (B2C) interactions.

2.

When asked to indicate which information must be available on the nano-products for clear and scientifically based communication to end-users and consumers, the most important aspects were identified by the respondents as the **Conditions for safe use of products containing NMs** (level 4.6 on a scale of 1 to 5) and the **Disposal procedures for products containing NMs** (level 4.3). Other options are shown in the figure below.



It should be noted that there is some reluctance to indicate the Presence and type of NM(s) inside a product (3.8 on a scale of 1 to 5).

Q2: Which specific information on the conditions for safe use of NMs and products containing NMs should be made available along the supply chain for both Business-to-business (B2B) and Business-to-consumer(B2C) interactions?

(Multiple responses are allowed)

- ☐ Known hazard data (B2B)
- ☐ Data on significant exposure scenarios (B2B)
- ☐ Data on potential release of NM at different stages (B2B)
- ☐ Procedures for safe handling/storing of NMs and products containing NMs (B2B)
- ☐ Procedures for safe disposal of NMs and products containing NMs (B2B)
- ☐ Protection measurements for users (e.g. workers) (B2B)
- ☐ Safety Data Sheet related to NMs (B2B)
- ☐ Chemical Safety Assessment related to NMs (B2B)
- ☐ Risk independent labelling of nano-ingredients (for all products) (B2C)
- ☐ Safety Data Sheet related to NMs (B2C)
- ☐ Conditions for safe disposal of NMs and products containing NMs (B2C)
- ☐ Transparent communication on risks and benefits of NMs and related products (B2C)
- ☐ I do not know

Others (Please specify)

2. Priorities and Needs for Risk Governance

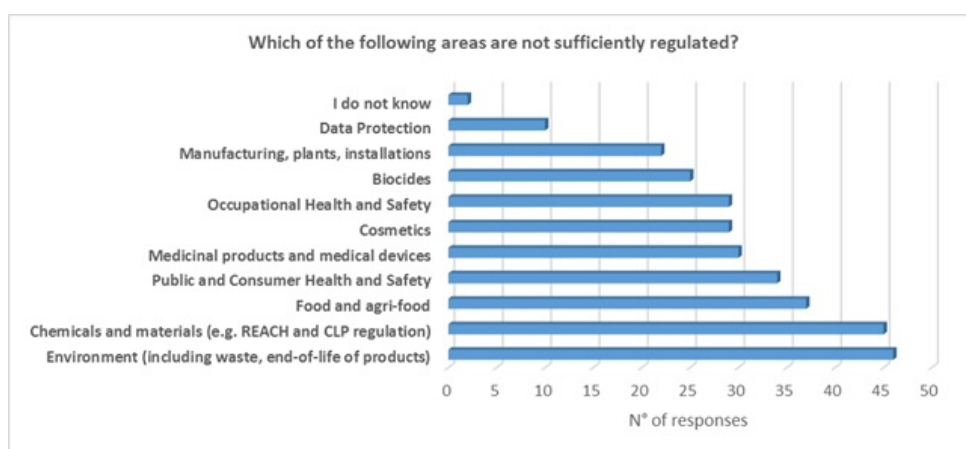
2. Priorities and Needs for Risk Governance

This chapter is composed of 2 questions. Feel free to answer only the questions related to your competence/responsibility area(s).

3.

The wide majority of respondents to the 1st consultation believe that **current guidance and regulation** are partially (54%) or not at all (22%) adequate for effective risk governance.

In their opinion, as shown below, the most critical areas are the **Environmental protection** and **Chemicals & Materials**, followed by **Occupational Health & Safety** and **Food & Agri-food**. However some lack of adequate guidance and regulation is indicated in all areas (except Data Protection).



Q3: Could you please indicate which factors you consider as the main gaps and shortcomings in current guidance and regulation for effective risk governance of NMs and nano-enabled products?

- ☐ Lack of universally accepted definitions for the term nanomaterial
- ☐ Lack of clear nanomaterial labelling/registration procedures
- ☐ Inadequacy of nanomaterial classification
- ☐ Lack of coherence (harmonization) between regulations/normative frameworks in different Member States
- ☐ Unclear technical guidelines for implementation of existing rules
- ☐ I do not know

Others/Comments (optional)

4.

The most voted policy measures (>3.5/5) to be developed for effective risk governance of NMs and nano-enabled products were **Technical guidelines to improve implementation of existing regulation**, **Specific requirements in existing "vertical/product legislation"** and **"Horizontal" regulation**. Also the **Continuous monitoring of risks by public authorities** is considered an important aspect for risk governance (>3 on a scale from 1 to 5).

Industry representatives and Researchers, followed by **Consumer organizations**, are indicated as the most appropriate categories of stakeholders to be involved in the dialogue with regulators and policy makers, to set up a (future) risk-governance framework for NMs and nano-enabled products.

Q4: In your view how should nanotechnology governance evolve to better address nanosafety while maintaining a favourable and stimulating context for innovation?

3. Best Practices for Risk Management

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This chapter is composed of a total of 6 questions, divided into the following sections:

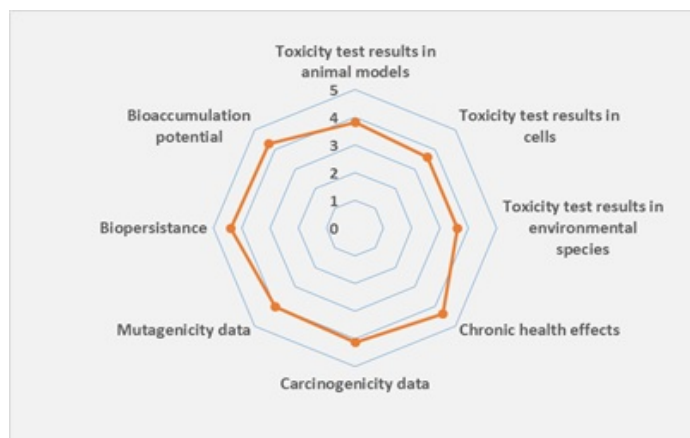
- Environment, Health and Safety issues (4)
- Decision making process (2)

Feel free to answer only the questions related to your competence/responsibility area(s).

5.

A significant fraction (33%) of the respondents gave indications on the best practices currently adopted by their organizations for risk management in the production/use/disposal of nanomaterials and nanoenabled products. The decisions are mostly made in-house (basing on Research activities, Literature review, Internet search of relevant web-sites etc..) but sometimes the advice from Independent experts or Occupational Safety & Health Centers is sought.

There is a strong agreement on the need to know and use a wide range of parameters (morphological & physico-chemical properties, hazard data, toxicological data, biological properties etc.) to assess the level of potential risks related to handling/manufacturing/disposing of nanomaterials. The most critical factors (appraised on a scale of 1 to 5) are indicated in the figure below.



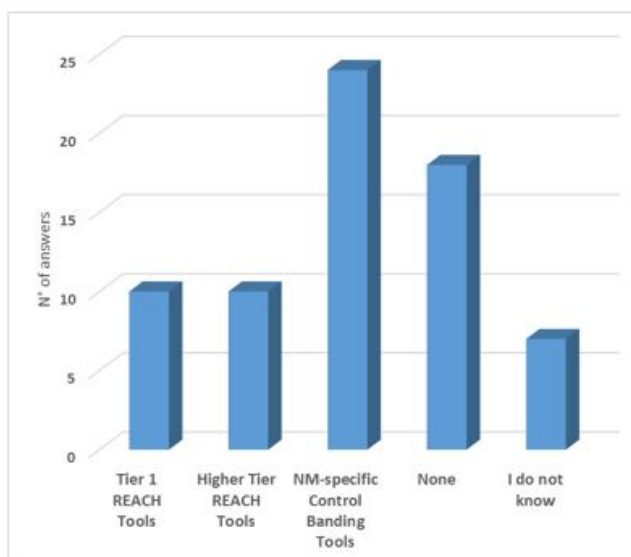
However, the great majority of the respondents (75%) declare that it is either difficult or even very difficult to get this information and consequently it is really important to create reliable and exhaustive databases with state-of-the-art data on NMs properties.

Q5: Please indicate the basic features that databases about properties of NMs (e.g. toxicological, biological, chemical etc.) should possess, in order to feed easily into the risk management process and help effectively to control/mitigate risks.

6.

In the absence of firm and conclusive toxicological data and exposure information, it was pointed out that hazard and risk(s) for the workers are mostly assessed through **Modelling-based concentrations** and **exposure estimates** and/or pragmatic approaches like the **Control Banding**. Though to a lesser extent, also In-house and external laboratories toxicity tests were indicated.

A number of Tools have been developed to assess and manage risks associated with NMs and nano-enabled products. As shown in the graph below, the most popular are those falling under the umbrella of **NM-specific Control Banding Tools**, but the level of knowledge, diffusion and use of these tools appears quite limited.



A very high fraction of repondents (90%) agree that the **risk assessment procedures are important** (36%) **or even very important** (54%) for the identification and management of new risks for workers, consumers and the environment that could derive from the production/use/diposal of nanomaterials and nano-enabled products.

Q6: At what stage of NM/nano-product development would you preferably apply risk assessment procedures? (multiple answers allowed)

- ☐ Idea screening; Early planning stage of R&I
- ☐ Scoping screening; Basic research
- ☐ Go to development; Applied Research/Proof of concept
- ☐ Go to test; Production/Engineering/Testing
- ☐ Go to launch; Go to market
- ☐ Post launch review; On the market
- ☐ In all stages
- ☐ Not applicable

Please explain your choice(s)

7.

Q7: Please provide an approximate indication of the relative cost spent by your organization for typical R&I (Research & Innovation) activities in each of the following R&I stages.

Please give your estimates on a scale of 1 (very low cost) to 10 (very high cost).

	1	2	3	4	5	6	7	8	9	10	I do not know
Idea screening; Early planning stage of R&I	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Scoping screening; Basic research	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Go to development; Applied research/proof of concept	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Go to test; Production/engineering/testing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Go to launch; Go to market	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Post launch review; On the market	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
In all stages	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Others (Please specify)

8.

Q8: Please provide an approximate indication of the relative cost spent by your organization for safety and risk assessment/management activities in each of the following Research & Innovation stages.

Please give your estimates on a scale of 1 (very low cost) to 10 (very high cost).

	1	2	3	4	5	6	7	8	9	10	I do not know
Idea screening; Early planning stage of R&I	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Scoping screening; Basic research	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Go to development; Applied research/proof of concept	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Go to test; Production/engineering/testing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Go to launch; Go to market	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Post launch review; On the market	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
In all stages	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Others (Please specify)

9.

Decision making process

A remarkable number of respondents (69%) declared their interest in **using Decision Support tools (DS)** to take decisions on risk governance in the manufacturing/use/disposal of NMs and nano-enabled products, although only a limited fraction (23%) has presently a direct experience of these tools.

The main barriers to the adoption of the existing DS tools were identified as the complexity in use, insufficient information on the features/capabilities of the tools and the difficulty in determining input data. A negative factor is the current lack of alignment of these tools with national and European legislation.

Q9: Could you appraise (on a scale of 1 to 5) the importance of the following criteria/goals/elements to develop a integrated DS (decision support) tool, and to make it attractive and useful for risk governance of the NMs and nano-enabled products all along their life-cycle?

	1	2	3	4	5
EHS: address occupational Health and Safety aspects	☐	☐	☐	☐	☐
EHS: address Public and Consumer Health aspects	☐	☐	☐	☐	☐
EHS: address Environmental Protection aspects	☐	☐	☐	☐	☐
Planning: Support learning and orientation, guidance, foresight analysis	☐	☐	☐	☐	☐
Planning: Facilitate comparison with conventional (non-nano) materials/products	☐	☐	☐	☐	☐
Planning: Provide scenario analysis to predict possible risks	☐	☐	☐	☐	☐
Planning: facilitate Risk/benefit analysis	☐	☐	☐	☐	☐
Economic: provide guidance to estimate cost of R&D of new NMs/nanoproducts	☐	☐	☐	☐	☐
Economic: provide guidance to estimate cost of EHS risk management	☐	☐	☐	☐	☐
Economic: provide guidance to estimate cost of insurance	☐	☐	☐	☐	☐
Regulatory: provide guidance on safe research and innovation (Safe by Design, Safe Innovation Approach, etc.)	☐	☐	☐	☐	☐
Regulatory: provide guidance for safe production/use of NMs and nano-products all along the supply chain	☐	☐	☐	☐	☐
Regulatory: provide guidance for safe disposal of NMs and nano-products	☐	☐	☐	☐	☐
Regulatory: support compliance with existing regulatory (EU) framework	☐	☐	☐	☐	☐
Not applicable	☐	☐	☐	☐	☐
I do not know	☐	☐	☐	☐	☐



10.

Q10: Are you familiar with the use of horizon scanning / early warning tools for detecting early signs of risks and opportunities in developing NMs and nano-enabled products, when the lack of data poses a challenge to perform specific risk assessment?

- ☐ Yes
- ☐ No

If yes, could you pls express your opinion on the performance and usefulness of these tools

4. Insurance coverage for nanomaterials risks

4. Insurance coverage for nanomaterials risk

This chapter is composed of 1 question.

11.

The majority of respondents (50%) think that **risk coverage for nanomaterials should be considered under traditional products** (that do not exclude them) and the option of exclusion of nanomaterials from risk coverage is left out. However, some respondents (26%) would prefer **a specific risk coverage for nanomaterials**.

A remarkable, but not very high fraction of the respondents (38%) is **interested in a support tool** to make decisions on **risk coverage for NMs**, while others are either not interested (13%) or not aware (44%).

Q11: At what stage(s) would you appreciate receiving guidance and support on issues and costs related to insurance/risk coverage for NMs and nano-products?

- ☐ At the research stage
- ☐ During the manufacturing/engineering phase
- ☐ At the marketing/start-up phase
- ☐ During the deployment phase
- ☐ At the end-of-life stage
- ☐ During the whole life-cycle
- ☐ Never
- ☐ I do not know

Others (Please specify)

5. Demographic information

5. Demographic Information

This chapter is composed of 4 questions.

Note on use of (personal) data collected:

Data collected with the Delphi-Exercise will be managed by Calibrate project partners (Steinbeis Advanced Risk Technologies and Airi-Italian Association for Industrial Research).

The information you provide will be kept confidential and not shared with third parties, confidentiality will be guaranteed.

Analysis of collected data will only be done on anonymized groups of respondents and reports will contain data in aggregate terms.

12. Please indicate to which of the following stakeholder groups does your organization belong to:

- ☐ Industry/Business: Innovation and upscaling company
- ☐ Industry/Business: Manufacturing company
- ☐ Industry/Business: Downstream user
- ☐ Industry/Business: Service provider
- ☐ Research
- ☐ Regulators/Risk Managers/Policy Makers
- ☐ Insurance
- ☐ People/Consumer/Society

Others (Please specify)

13. What is the size of your organization (number of employees)?

- ☐ <10
- ☐ <50
- ☐ <250
- ☐ < 1000
- ☐ >1000

14. In which country is your organization located?



15. ***What is your role/responsibility within the organization?***



16. ***Please include here any further comment you like to add.***

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