Supplementary materials

– I – List of Stakeholders – Workshop Venice 2017

The names and complete affiliation of the representatives are not provided for personal data protection and privacy reasons.

Table S1. List of Workshop participants, Venice March 2017.

| Delegate | Affiliation | Country |
|----------|-------------|---------|
| Rep. 1   | Risk consultant | GERMANY |
| Rep. 2   | Risk consultant-Regulator | GERMANY |
| Rep. 3   | Academy       | ITALY   |
| Rep. 4   | Manufacturer  | ITALY   |
| Rep. 5   | Academy       | ITALY   |
| Rep. 6   | Research      | GERMANY |
| Rep. 7   | Research      | GERMANY |
| Rep. 8   | Civil society organization | ITALY |
| Rep. 9   | Risk consultant-Research | FRANCE |
| Rep. 10  | Academia      | ITALY   |
| Rep. 11  | Research      | ITALY   |
| Rep. 12  | Academia      | FRANCE  |
| Rep. 13  | Academia      | ITALY   |
| Rep. 14  | Civil society organization | SWITZERLAND |
| Rep. 15  | Research      | GERMANY |
| Rep. 16  | Manufacturer  | GERMANY |
| Rep. 17  | Academia      | ITALY   |
| Rep. 18  | Research      | IRELAND |
| Rep. 19  | Academy-Regulator | ITALY |
| Rep. 20  | Academia      | ITALY   |
| Rep. 21  | Research      | DENMARK |
| Rep. 22  | Risk consultant | GERMANY |
| Rep. 23  | Regulator     | BELGIUM |
| Rep. 24  | Manufacturer  | BELGIUM |
| Rep. 25  | Research      | DENMARK |
| Rep. 26  | Manufacturer  | GERMANY |
| Rep. 27  | Regulator     | GERMANY |
| Rep. 28  | Research      | NETHERLANDS |
| Rep. 29  | Research      | ITALY   |
| Rep. 30  | Research      | GERMANY |
| Rep. 31  | Research      | FRANCE  |
| Rep. 32  | Manufacturer  | GERMANY |
| Rep. 33  | Academia      | IRELAND |
| Rep. 34  | Research      | GERMANY |
| Rep. 35  | Academia      | ITALY   |
| Rep. 36  | Research      | ITALY   |
| Rep. 37  | Research      | BELGIUM |
| Rep. 38  | Risk consultant | GERMANY |
| Rep. 39  | Research      | ITALY   |
| Rep. 40  | Insurance     | SWITZERLAND |
| Rep. 41  | Academia      | ITALY   |
| Rep. 42  | Regulator     | BELGIUM |
- II – Evaluation Criteria

Table S2. The complete list of criteria relevant to risk communication for the evaluation of risk governance tools.

| Criterion | Description/Justification | Selected references |
|-----------|---------------------------|---------------------|
| C1: Uncertainty analysis | Clearly communicating the uncertainty and variability in modeling results through sound uncertainty analysis greatly helps decision-making. It could be otherwise easily misled by overconfident communication of uncertain risk governance results. If uncertainties are large and deeply embedded, more communication will be needed. | [1-5] |
| C2: Structured decision-making | The participation exercise should use/provide appropriate mechanisms for structuring and displaying the decision-making process. | [6] |
| C3: Fair and knowledgeable communication process | Accordingly, the scope of risk communication should be broadened to internalize conflicting issues of concern and decision-makers should deepen their analysis to address the embedding of risk issues in value and lifestyle structures. | [3] |
| C4: Easy to use/understand, user-friendliness | Tools that are easy to use and provide outputs that are easy to analyze, do not require specific expertise for their application. Information should be provided clearly to avoid arising misinterpretation. User-friendly tools are particularly relevant for Small and Medium Enterprises (SME) as those companies often do not have staff with experience or specific training suited to apply sophisticated protocols or models and understand the outcome. | [1,2,7] |
| C5: Quantitative information | Quantitative tools estimate numerical values for consequences and their probabilities, in specific units defined when developing the context. However, this requires quantitative input information to function and they cannot be easily applied in data-poor situations, which reduces their overall applicability and thus the available risk information that could be communicated to stakeholders. | [1,2,7-9] |
| C6: Documented applications – Trustworthingness | Documented applications are the best way to test a tool, confirm its functionality and understand its strengths and limitations. Trustworthiness of input or output sources is important. | [1,2,8,9] |
| C7: Transparency of application/process | To make it easy it is for stakeholders to quickly comprehend how specific data points and decision criteria influence decision-making. The process should be transparent so that the stakeholders can see what is going on and how decisions are being made. | [1,6,7,10] |
| C8: Comprehension | Does the audience understand the content of the communication? | [11] |
| C9: Influence on final policy | The output of the procedure should have a genuine impact on policy. | [6] |
| Effectiveness and efficiency | Effectiveness and efficiency of risk governance processes is desired, especially for a better coordination of dialogues. The information exchange is typical for advanced phases of an inclusive risk debate where in the first phase of risk governance the focus lies on the establishment of a working dialogue and on the recruitment of relevant stakeholders. On the second phase, the call for more effectiveness and efficiency arises due to the different levels of knowledge and expertise of different stakeholders. | [12-14] |
| Flexible for variety of nanomaterials | Framework or tools should be appropriate for various MNs and variations, to be as comprehensive, robust, and practical as possible. | [8,15-17] |
| Assessment tier | The assessment tier criterion distinguishes the “screening-level” from the “high-tier” tools. | [1,4,9] |
| Lifecycle thinking | It is important to assess the risks of MNs from a lifecycle perspective since the characteristics of some MNs are likely to change significantly during their lifetime, which would affect their hazard, exposure, and risk. | [1,4,9] |
| Agreement | Does the audience agree with the recommendation or interpretation contained in the message? | [11] |
| Dose-response consistency | Do people facing a higher dose of a hazard perceive the risk as greater and/or show a greater readiness to act than people exposed to a lower dose of this hazard? | [11] |
| Hazard-response consistency | Do people facing a hazard that is higher in risk perceive the risk as greater and/or show a greater readiness to act than people exposed to a hazard that is lower in risk? | [11] |
| Uniformity | Do audience members exposed to the same level of risk tend to have the same responses to this risk? | [11] |
| Audience evaluation | Does the audience judge the message to have been helpful, accurate, clear, etc.? | [11] |
| Types of communication failures | When different types of failures are possible, are the failures that occur generally of the more acceptable variety? | [11] |
| Representativeness of participants | The public participants should comprise a broadly representative sample of the population of the affected public. | [6] |
| Independence of true participants | The participation process should be conducted in an independent, unbiased way. | [6] |
| Early involvement | The public should be involved as early as possible in the process as soon as value judgments become salient. | [6] |
| Resource accessibility | Public participants should have access to the appropriate resources to enable them to successfully fulfill their brief. | [6] |
| Task definition | The nature and scope of the participation task should be clearly defined. | [6] |
| Cost-effectiveness | The procedure should in some sense be cost-effective. | [6] |
| Persistence for being effective | Risk communication activities need to be more sustained over time, better funded, and more ambitious in the goals adopted and the outcomes sought. | [3] |
| Enhancing trust and creating new principles for a democratic outcome | In situations where high social distrust prevails, and this is increasingly common, a thorough revamping of the goals, structure, and conduct of risk communication will be needed. | [3] |
| Extent of damage | Tools include adverse effects in natural units, such as fatalities, injuries, production losses, etc. | [18] |
Table S3. Criteria for risk evaluation, mitigation, and communication relevant for the different phases of the risk governance paradigm.

| x | Criteria | Risk Governance phases |
|---|----------|------------------------|
|   |          | Risk pre-Assessment | Risk Concern Assessment | Risk Evaluation | Risk Management | Monitoring and Communication |
|  1 | Easy to use / understand, user-friendliness | x | x | x | x |
|  2 | Quantitative information |            | x | x | x | x |
|  3 | Uncertainty analysis | x | x | x | x | x |
|  4 | Documented applications / Trustworthiness | x | x | x | x | x |
|  5 | Transparency of application / process | x | x | x | x | x |
|  6 | Comprehension | x | x | x | x | x |
|  7 | Influence on final policy | x | x | x | x | x |
|  8 | Structured decision-making | x | x | x | x | x |
|  9 | Fair and knowledgeable communication process | x | x | x | x | x |
| 10 | Effectiveness and efficiency | x | x | x | x | x |
| 11 | Flexible for variety of nanomaterials | x | x | x | x | x |
| 12 | Assessment tier | x | x | x | x | x |
| 13 | Lifecycle thinking | x | x | x | x | x |
| 14 | Agreement |            |            |            |            |
| 15 | Dose-response consistency | x | x | x | x | x |
| 16 | Hazard-response consistency | x | x | x | x | x |
| 17 | Uniformity | x | x | x | x | x |
| 18 | Audience evaluation | x | x | x | x | x |
| 19 | Types of communication failures | x | x | x | x | x |
| 20 | Representativeness of participants | x | x | x | x | x |
| 21 | Independence of true participants | x | x | x | x | x |
| 22 | Early involvement | x | x | x | x | x |
| 23 | Resource accessibility | x | x | x | x | x |
| 24 | Task definition | x | x | x | x | x |
| 25 | Cost-effectiveness | x | x | x | x | x |
| 26 | Persistence for being effective |            |            |            |            |
| 27 | Enhancing trust and creating new principles for a democratic outcome | x | x | x | x | x |
| 28 | Extent of damage | x | x | x | x | x |
| 29 | Probability of occurrence | x | x | x | x | x |
| 30 | Uncertainty | x | x | x | x | x |
| 31 | Ubiquity | x | x | x | x | x |
| 32 | Persistency | x | x | x | x | x |
| 33 | Accountability | x | x | x | x | x |
| 34 | Shared strategic focus | x | x | x | x | x |
| 35 | Sustainability | x | x | x | x | x |
Table S4. Methods and techniques useful to implement the identified criteria in decision-support tools and systems.

| #  | Typology / Sector                  | Criteria                                                                 | Method-Technique-Action and Description                                                                 | How the approach can help to fulfil the identified criteria through implementation in decision-support tools |
|----|-----------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| 1  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Multi-Attribute Value Theory (MAVT) MDCA methodology that uses Value (Utility) functions to identify the most preferred alternative or to rank order the alternatives | C1, C2, C3, C4, C5, C6, C7, C8, C9 MDCA methodologies could be used for: 1) examining trade-offs between criteria 2) including user values as preferences for criteria in the decision-making 3) characterizing parameter uncertainty by applying appropriate uncertainty estimation techniques. The choice of methodologies depends on the nature of the desired results and the preferences of the decision maker; therefore it has to be evaluated on a case by case procedure. Overall, the methodologies can be combined and used to support many different tasks simultaneously. They can be applicable to the complete set of criteria or smaller clusters of them |
| 2  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Outranking methods: They are based on the concept that an alternative may be dominant, with a certain degree, over another one | C1, C2, C3, C4, C5, C6, C7, C8, C9 Outranking methods can be used to prioritize alternatives or to assess their dominance |
| 3  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Multi-objective optimization: An area of MDCA concerned with mathematical optimization problems involving more than one objective function to be optimized simultaneously | C1, C2, C3, C4, C5, C6, C7, C8, C9 Multi-objective optimization methods can be used to handle problems with multiple conflicting objectives |
| 4  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Analytic hierarchy process (AHP): MDCA methodology that uses decomposition of the decision problem into a hierarchy of subproblems and evaluation of the relative importance of its various elements by pairwise comparisons | C1, C2, C3, C4, C5, C6, C7, C8, C9 AHP can be used to prioritize alternatives or to assess their dominance |
| 5  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Fuzzy logic: Introduces a formalization of vagueness and the notion of a degree of satisfaction of an object instead of an absolute evaluation | C1, C2, C3, C4, C5, C6, C7, C8, C9 Fuzzy logic can be used to handle problems with uncertain or imprecise information |
| 6  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Decision trees (decision analysis): A tool to model decisions, outcomes chances, and their possible consequences | C1, C2, C3, C4, C5, C6, C7, C8, C9 Decision trees can be used to model decisions, outcomes chances, and their possible consequences |
| 7  | Decision Analysis / MCDA methodologies | C1, C2, C3, C4, C5, C6, C7, C8, C9                                     | Value of Information (Vol): A methodology that can be used in tiers to explore uncertainty in risk assessment and decision-making | C1, C2, C3, C4, C5, C6, C7, C8, C9 Value of Information can be used to explore uncertainty in risk assessment and decision-making |
| 8  | Decision Analysis / Mental modeling | C9                                                                      | Stakeholder profiling/address identification: The process of collecting and reviewing the opinions of relevant stakeholders with respect to the features, capabilities, usability of a decision-support tool | C9 Stakeholder profiling can be used to increase the influence on final policy of decision-support tools by providing in advance specific guidance on the development of decision-support tools. In addition, it supports fulfilling the group of criteria related to audience/participants evaluation and characteristics |
| 9  | Decision Analysis / Mental modeling | C9                                                                      | Interviews / Focus Groups / Influence diagrams: Different techniques to perform mental modeling methodologies and present results | C9 Interviews / Focus Groups / Influence diagrams: Different techniques to perform mental modeling methodologies and present results |
| 10 | Decision Analysis / Software development | C2, C5                                                                 | Decision-Support Systems: Building dedicating software for supporting decision-making | C2, C5 Decision-Support Systems: Building dedicating software for supporting decision-making |
| 11 | Risk Assessment / Management of Models | C3, C5                                                                  | Link-integration of models: Link or integration of various types of models (e.g., ERA-HH-exposure read-across grouping) in a decision-support tool | C3, C5 Link-integration of models: Link or integration of various types of models (e.g., ERA-HH-exposure read-across grouping) in a decision-support tool |
| 12 | Risk Assessment / Management of Models | C3, C5                                                                  | Full life cycle / Cooper Stage Gate: Models and tools to cover the full life cycle (ERA, HH, LCIA, Social, EA, Risk Control) and connected to Cooper Stage Gate model. Provide multiple options for the user | C3, C5 Full life cycle / Cooper Stage Gate: Models and tools to cover the full life cycle (ERA, HH, LCIA, Social, EA, Risk Control) and connected to Cooper Stage Gate model. Provide multiple options for the user |
|   | Risk Assessment-Management / Risk management Measures | C2, C3, C6 | Types of Risk Management measures: Link-Integration of RMMs (e.g., Inventory of Technological Alternatives and Risk Management Measures (TARMMs), personalized risk management measures defined by the user or connection to the Exposure Control Efficacy Library (ECEL) database) | The use of alternatives for integrating risk management measures within a decision-support tool supports the fulfillment of several criteria mainly for the risk management phase of RG by enhancing the risk mitigation and management options (documented applications trustworthiness/structured decision-making/fair and knowledgeable process/feasibility for variety of nanomaterials) |
|---|---|---|---|---|
| 14 | Risk Assessment-Management / Usability | C1, C2, C3, C4, C5, C7, C8 | Automatic conversion system: Introduction of an automatic conversion system, to improve usability of the system | The use of an automated conversion system increases drastically the ease of use/user-friendliness of a tool and supports multiple criteria through all the RG stages (quantitative information/trustworthiness/transparency/comprehension/knowledgeable communication process/effectiveness) |
| 15 | Risk Assessment-Management / Usability | C1, C2, C3, C4, C5, C7, C8 | Quantal data: Support for quantal data in Human Health Hazard Assessment | Support of quantal data in HH hazard assessment increases the satisfaction of the quantitative information criterion and enhances the capacity to handle various nanomaterials in the risk assessment phase |
| 16 | Risk Assessment-Management / Usability | C1, C2, C3, C4, C5, C7, C8 | Nano-specific ontologies: A formal way to describe taxonomies and classification networks, essentially defining the structure of knowledge for various domains, they can be represented and shared through the recognized standard Web Ontology Language (OWL) | Knowledge about nanomaterials, hazard endpoints, compartments etc. needs to be structured in a computer usable way. To this end web ontologies can be used and foster decision analysis as well as application of cascade of tools. |
| 17 | Risk Assessment-Management / Usability | C1, C2, C3, C4, C5, C7, C8 | Assessment tree interface: Visual flow of sections (tiered approach / connected lifecycle models) | Assessment trees are an excellent way to fulfill the criteria ease of use/comprehension/structured decision-making/transparency of application. They guide the user to a clear visualization of the decision-making process and the process that lies beneath the interface of a decision-support tool |
| 18 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Multiple interfaces: Web application accessible from any web browser, which can also be downloaded and installed in an intranet server. Also supports solutions to the confidentiality issue | Ease of use is satisfied as different users expect different functionalities based on their needs. An important issue from stakeholder profiling is “confidentiality” that can be handled through the use of multiple interfaces |
| 19 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Graphical User Interfaces (GUIs): Minimum requirement for modern software-tools | GUIs increase ease of use and comprehension of a system, for all the RG stages |
| 20 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Bugs tracking system: Dedicated system, for efficiently improving Decision-Support Tools | A specialized tool that enables higher Trustworthiness / Effectiveness and efficiency of a tool for all the RG stages. It enables the possibility to constantly improve an application through testing |
| 21 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Feature request system: Dedicated system, for efficiently improving Decision-Support Tools | A specialized tool that in addition to enabling higher Trustworthiness / Effectiveness and efficiency of a tool for all the RG stages, it supports the fulfillment of criteria structured decision-making/fair and knowledgeable communication process/feasibility for various nanomaterials/assessment tiers/lifecycle thinking by allowing the improvement of an application through user requests |
| 22 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Hosting environment: A crucial component for embedding models in a decision-support tool and allowing smooth operations for the user | Fundamental software development feature that fulfills ease of use / trustworthiness / effectiveness and efficiency of a decision-support tool for all the RG stages |
| 23 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Appearance and usability of the web-application: Smartly designed applications allow increased user-friendliness and improve risk/uncertainty communication | An often-neglected characteristic of applications which needs to be taken care of equally during the design and development process and should be considered equally important to theoretical developments of a decision-support tool. It increases user-friendliness and ease of use, as well as lowers the uncertainty on how to use the system and how to communicate results |
| 24 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Public pages: System users can select information for public viewing, allowing communication and partnerships with other stakeholders | Enhances the risk communication stage through sharing of information and fulfillment of criteria such as fair and knowledgeable communication process, documented applications, user-friendliness, and resource accessibility. It also allows the creation of synergies and cooperation between stakeholders |
| 25 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Data extraction/migration/interoperability features: Various import, migration, and export features increase user-friendliness of the systems and interoperability | Effective data handling within a decision-support tool is essential for all the RG stages. A system should allow the user to import-migrate-export data in the easiest and fastest way possible, to improve not only risk assessment and management results but to allow efficient risk communication. Criteria that are fulfilled include ease of use-user-friendliness, documented applications trustworthiness, transparency of application, comprehension, fair and knowledgeable communication process as well as effectiveness and efficiency |
| 26 | Software development / Features | C1, C2, C3, C4, C5, C7, C8, C9 | Easy registration / Multiple login methods: Improved usability of a system through multiple ways of identifying users and allowing them to register to the system | Ease of use is satisfied as different users expect different functionalities |
| Page | Software development / Features | Manual / Wiki: User guides in the form of a manual document or documented wiki pages can be used as technical communication documents | Breaking down the complexity of a decision-support tool with the use of manuals or wikis, to increase ease of use/user-friendliness, transparency of application, comprehension, and general risk communication. Such functionalities are important for all the RG stages |
|------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 27   | Software development / Features | Guidance: Interactive guidance of the user to the functionalities of a system | Similarly, to the use of manuals, interactive techniques such as video tutorials provide useful guidance to the user and support similar criteria |
| 28   | Software development / Features | User communication: Systems can use different types of communication protocols for informing users | Communication to the users is an essential component of the risk communication stage within RG paradigms. It can be enhanced with the use of multiple ways to present data to users/stakeholders and allow easy comparisons between scenarios, materials, or assessments |
| 29   | Software development / Features | Case study examples: Documented applications available to the user for experimentation and information sharing | Supports the documented applications criterion and the trustworthiness of a tool by providing public access to information to the users |
| 30   | Software development / Features | Pairing of functionalities with stakeholder profiling: Driving software developments by implementing identified features through the mental modeling processes | Stakeholder profiling can be used to increase the influence on final policy decision-support tools by providing in advance specific guidance on the development of decision-support tools. In addition, it supports fulfilling the group of criteria related to audience/participants evaluation and characteristics |
| 31   | Software development / Features | Expandable system (modular): System designed to handle multiple material and needs in the future | Modular decision-support tools are common in risk decision-making as they support structured decision-making by providing flexibility for tailoring the tools to the needs of users. They improve effectiveness, can allow flexibility for variety of nanomaterials and support tiered assessments for all the RG stages |
| 32   | Software development / Features | Data gaps: Cover lack of data with modeling techniques | Data gaps are an important issue in modern RG paradigms. The use of modeling techniques to cover data gaps is a solution to the problem to improve quantitative information and effectiveness of a tool and can mainly be applied to risk appraisal, characterization and management |
| 33   | Software development / Features | API communication: Software to software communication | API communication allows software to software communication and is highly important in integrating or linking models to a decision-support tool. Its use can support all the RG stages |
| 34   | Software development / Features | Type of portal: HUB vs Integrated software | Both solutions present peculiar advantages, a HUB-based decision-support tool linking all the important information sources and models within a single location makes the acquisition of knowledge faster while the application of models needs more resources. On the opposite side an integrated solution within a single web application requires more initial efforts to grasp the logic in the tool but speeds up models’ application by supplying a homogeneous integrated user interface. Holistically, both solutions support the fulfillment of all the criteria for all the RG stages |
| 35   | Software development / Features | Models: Basic characteristics of models for decision support: Multiple, Fast, Tailored, Embedded, Peer-reviewed, Integrated, Well-known | Flexibility, assessment tier, and lifecycle thinking are fulfilled by the use of models with the basic characteristics, throughout the RG paradigm |
| 36   | Software development / Features | Public projects: Availability of results to communities | Enhances the risk communication stage through sharing of information and fulfillment of criteria such as fair and knowledgeable communication process, documented applications, user-friendliness, and resource accessibility |
| 37   | Statistical methods / Methodology | Prediction Trees (machine learning): A method that uses a tree-like model of decisions and their possible consequences for identifying a strategy most likely to reach a goal | Decision trees used in the machine learning field (as opposed to the decision analysis field) are useful tools for classification based on learning sets. They are useful in uncertainty analysis, grouping, and the increase of effectiveness and efficiency of decision-support tools |
| 38   | Statistical methods / Methodology | Random forests: An ensemble learning method for classification, regression, and other tasks that operate by constructing a multitude of decision trees | Random forests are useful tools for classification based on learning sets. They support uncertainty analysis, grouping, and the increase of the effectiveness and efficiency of decision-support tools |
| 39   | Statistical methods / Methodology | Sensitivity analysis: Evaluates the effect of changes in input values or assumptions on a model’s results | Sensitivity analysis allows inspection of the stability of results on changes in different inputs and is therefore useful in decisional settings to understand which alternatives are likely to be the most effective |
| 40   | Statistical methods / Methodology | Uncertainty analysis: Investigates the effects of lack of knowledge and other potential sources of error in the model | Uncertainty analysis related methods can give an overview of reliability of results and are therefore useful to understand uncertainty itself and its quantification |
| 41   | Statistical methods / Methodology | Uncertainty analysis: The methods can be used to understanding reliability of results and are therefore useful to understand uncertainty itself and its quantification | Uncertainty analysis related methods can give an overview of reliability of results and are therefore useful to understand uncertainty itself and its quantification |
– III – Description of Identified Tools

Table S5. Risk pre-assessment tools descriptions and references.

| Tool Name                      | Description                                                                 | References        | Sector       |
|-------------------------------|-----------------------------------------------------------------------------|-------------------|--------------|
| NanoRiskRadar                 | Automatic identification of new risks previously developed for the insurance sector to assess internet-based sources measuring singularity and ubiquity of new information. The tool will also include NM-specific methods to consider cognitive factors (interdependencies between context, objectives and biases) for risk perception. | Under development/caLIBRAté | Scanning     |
| Causal diagram assessment     | The causal diagram has been developed as a method to handle the complexity of issues on NP safety, from their exposure to the effects on the environment and health. It gives an overview of available scientific information starting with common sources of NPs and their interactions with various environmental processes that may pose threats to both human health and the environment. | [23] | Scanning     |
| Risk Radar                    | The RiskRadar uses the social media and widely used internet search streams to predict the trends. The output can be viewed in different visual displays and charts. | [24] | Scanning     |
| IKnow                         | Identification of Wild Cards (WI) and Weak Signals (WE) in the field of Science, Technology and Innovation (STI). | [25] | Scanning     |
| FORCE                         | FORCE EU project provides a mapping of past foresight and horizon scanning activities and development of an Intelligent Decision-Support System (IDSS). | [26] | Scanning     |
| Horizon Scanning Centre       | The Horizon Scanning Centre is linked to the UK’s foresight program and further linked to the government top officials and relevant Ministers. There are two main scans consisting of Delta and Sigma Scans. It is oriented mainly towards public policy. | [27] | Scanning     |
| RAHS                          | The Risk Assessment and Horizon Scanning (RAHS), as part of National Security Coordination Secretariat (NSCS) explores methods and tools that complement strategic planning in anticipating strategic issues with significant possible impact on Singapore. | [27] | Scanning     |
| Horizon Scanning Cranfield    | The Cranfield University has developed a horizon scanning approach, mainly using four types of methods and covers largely 13 key areas that potentially have an impact on the UK. | [28] | Scanning     |
| SONAR                         | The Swiss Re’s SONAR is an internal tool for Swiss Re to scan for early signals related to the emerging risks and trends and inform the Swiss Re’s employees about them. Certain information is also shared with external stakeholders. | [29] | Scanning     |
| Risk Barometer                | The Allianz’s Risk Barometer collate the insights from field experts dispersed in various countries. The top risks are categorized across different regions, countries, industry sectors, and sizes. | [30] | Scanning     |
| Futurescaper’s HS platform    | The Futurescaper provides software to clients engaged in foresight, scenario planning and other complex strategic issues, especially those involving multiple stakeholders and geographies. | [31] | Scanning     |
| MCDA procedure for prioritization of Occupational Risks from NMs | A quantitative weight of evidence (WOE) framework that uses multicriteria decision analysis methodology for integrating individual studies on nanomaterial hazard resulting from physicochemical and toxicological properties of nanomaterials. The WOE approach explicitly integrates expert evaluation of data quality of available information. Application of the framework is illustrated for titanium dioxide nanoparticles (nano-TiO₂), but the approach is designed to compare the relative hazard of several nanomaterials as well as emerging stressors in general. | [4] | Ranking / prioritization |
| MCDA procedure for hazard screening of ENMs | Neural networks can be used to predict outcomes of complex nonlinear processes and is therefore useful in decision analysis for grouping or examination of possible alternatives outcomes. | [32] | Ranking / prioritization |
| **MCDA procedure for prioritization of Occupational exposure scenarios of NMs** |
| An approach for relative exposure screening of ENMs. An exposure model explicitly implementing quantitative WOE methods and uses expert judgment for filling data gaps in the available evidence-base. Application of the framework is illustrated for screening of exposure scenarios for nano-scale titanium dioxide, carbon nanotubes, and fullerenes, but it is applicable to other nanomaterials as well. | [33] | Ranking / prioritization |

| **Tool for ENM-Application Pair Risk Ranking (TEARR)** |
| This study examines the use of one risk ranking tool that incorporates both quantitative and qualitative information regarding the potential human health risks of ENMs, focused primarily on worker and soldier health. Using a case study involving Army materiel (i.e., equipment), a relative risk ranking algorithm is proposed that accounts for not only the physicochemical characteristics of the ENMs, but also the characteristics of the Army materiel. In this way, the resulting risk potential for soldiers and workers is not solely based on the inherent characteristics of the ENMs but is also influenced within the context of the technology being developed. | [34] | Ranking / prioritization |

| **Stochastic multicriteria acceptability analysis (SMAA-TRI)** |
| A decision-support system for classifying nanomaterials into different risk categories. The classification system is based on a set of performance metrics that measure both the toxicity and physicochemical characteristics of the original materials, as well as the expected environmental impacts through the product life cycle. Stochastic multicriteria acceptability analysis (SMAA-TRI), a formal decision analysis method, was used as the foundation for this task. This method allowed us to cluster various nanomaterials in different ecological risk categories based on our current knowledge of nanomaterial physicochemical characteristics, variation in produced material, and best professional judgments. SMAA-TRI uses Monte Carlo simulations to explore all feasible values for weights, criteria measurements, and other model parameters to assess the robustness of nanomaterial grouping for risk management purposes. | [35] | Classification |

| **NRST (Nanomaterial Risk-Screening Tool)** |
| A decision-support framework relating key nanomaterial physicochemical and product characteristics to important hazard and exposure indicators. This framework for aiding risk managers’ decisions under uncertainty provides the foundation for the development of a transparent and adaptable screening tool that can inform the management of potential risks. | [36] | Screening |

| **NanoRiskCat** |
| A screening tool that can identify, categorize and rank exposures and effects of nanomaterials used in consumer products based on data available in the peer-reviewed scientific literature and other regulatory relevant sources of information and data. The primary focus was on nanomaterials relevant for professional end users and consumers as, as well as nanomaterials released into the environment. The wider goal of NanoRiskCat is to help manufacturers, downstream end users, regulators, and other stakeholders to evaluate, rank and communicate the potential for exposure and effects through a tiered approach in which the specific applications of a given nanomaterial are evaluated. | [37,38] | Screening |

| **CB NanoTool** |
| The tool estimates an emission probability (without considering exposure controls) and severity band and provides advice on what engineering controls to use. It includes nine domains covering handling of liquids, powders, and abrasion of solids. Combines hazard “severity” and exposure “probability” scores in a matrix to obtain a level of risk and associated controls out of 4 possible levels of increasing risk and associated controls. | [39-41] | Control-banding |

| **Precautionary Matrix for Synthetic Nanomaterials (Swiss Precautionary Matrix)** |
| This tool helps to determine if exposure needs to be controlled, providing advice on whether a precautionary approach is required under normal working conditions, in the worst-case scenario and for the environment. | [42] | Screening |

| **Screening Tree Tool** |
| A screening tool to combine the LCA approach with chemical hazard information (human health and environmental hazard) and exposure pathways. This enabled the product designers to efficiently identify which chemicals and raw materials pose significant hazards and the important exposure pathways. This tool can also be used as a screening tool for new designs/product formulations. | [43-45] | Screening |

| **NanoGRID** |
| Designed to guide users through a tiered testing framework to help characterize the durability, degradation, potential for nano-scale material release and environmental health and safety implications of nano-enabled products. | [46] | Screening |

| **ANSES Nano** |
| The ANSES CB nanotool was developed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to be applied for conducting risk assessment and risk management of work with manufactured nanomaterials or nano-enabled products in industrial settings. | [47,48] | Control-banding |
The Sustainable Nanotechnology Decision-Support System (SUNDS) addresses current nanotechnology risk assessment and management needs. The SUNDS conceptual decision framework expands the focus from nanotechnology risk assessment and management to emerging risk governance needs. It has a two-tier structure comprising screening and advanced tools to address varying data availability and stakeholder needs.

NanoSafer is a combined control-banding and risk management tool that enables assessment of the risk level and recommended exposure control associated with production and use of manufactured nanomaterials (e.g., nanoparticles, nanoflakes, nanofibers, and nanotubes) in specific work scenarios. In addition to manufactured nanomaterials, the tool can also be used to assess and manage emissions from nanoparticle-forming processes. Uses data on material properties, processes, and production facilities to estimate occupational risk. The tool uses the Risk Quotient (i.e., the ratio of an exposure dose to a human effect threshold) to estimate risk deterministically.

The upcoming new version, NanoSafer 2, will be capable of estimating exposure from spray processes. In addition, NanoSafer 2 can perform nano-specific hazard assessment based on read-across between MNs based on specific material properties and hazard indicators, tested for performance against in vivo experiments.

NanoSafer

Assessment and mitigation of nano-enabled product risks on human and environmental health. To develop innovative methodologies to evaluate and manage human and environmental health risks of nano-enabled products, considering the whole product life cycle. Using this tool, industry will be able to evaluate and efficiently mitigate possible health risks for workers, consumers, and the environment associated with the use of nanotechnologies. [51] - http://www.guidenano.eu/

GUIDEnano

Assessment and mitigation of nano-enabled product risks on human and environmental health. To develop innovative methodologies to evaluate and manage human and environmental health risks of nano-enabled products, considering the whole product life cycle. Using this tool, industry will be able to evaluate and efficiently mitigate possible health risks for workers, consumers, and the environment associated with the use of nanotechnologies. [52] - http://www.guidenano.eu/

ECETOC TRA v3.1

To assess risks associated with nanotechnology operations. Control-banding (CB) strategies (a qualitative risk characterization and management strategy) offer simplified solutions for controlling worker exposures to constituents that are found in the workplace in the absence of firm toxicological and exposure data. Combines hazard “severity” and exposure “probability” scores in a matrix to obtain a level of risk and associated controls out of 4 possible levels of increasing risk and associated controls.

LICARA nanoscan

The main goal of LICARA is to develop a structured lifecycle approach for nanomaterials that enables the balance of health/environmental risks of nanomaterials in view of paucity of data against their benefits, and that further allows a comparison with the risks and the benefits of the conventional (non-nano) products. It estimates economic, environmental, and social opportunities. This tool is specifically intended for use by SME to support them in communicating with regulators, and potential clients and investors.

EGRET2

ESIG has developed a tool (termed the ESIG GES Risk and Exposure Tool or “EGRET”) that enables users to construct their own consumer CSA/ES for a particular area of use within the ESIG/ESVOC library. This library was constructed based on the results of the various communication and use mapping activities that have been undertaken with major Downstream User (DU) groups (e.g., the consumer use of solvents in coatings, which is in turn described by a set of product categories and sub-categories).

BAUA Sprayexpo 2.3

SprayExpo is an Excel model for calculation the airborne concentration of the respirable, the thoracic and the inhalable fraction of aerosols containing biocidal substances in indoor environments originating from the release of liquid biocidal sprays.

Stoffenmanager Nano

Stoffenmanager Nano allows you to qualitatively assess occupational health risks from inhalation exposure to Manufactured Nano-Objects (MNO). Risk Management Measures may be selected or included in the Action Plan. Stoffenmanager Nano is a “work-in-process” online tool that reflects the current knowledge of risks related to working with nanomaterials.

ANSES Nano

The ANSES CB nanotool was developed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to be applied for conducting risk assessment and risk management of work with manufactured nanomaterials or nano-enabled products in industrial settings.

Table S6. Risk concern-assessment tools descriptions and references.

| Tool Name | Description | References | Sector |
|-----------|-------------|------------|--------|
| SUNDS     | The Sustainable Nanotechnology Decision-Support System (SUNDS) addresses current nanotechnology risk assessment and management needs. The SUNDS conceptual decision framework expands the focus from nanotechnology risk assessment and management to emerging risk governance needs. It has a two-tier structure comprising screening and advanced tools to address varying data availability and stakeholder needs. | [49,50] | Risk assessment |
| NanoSafer | NanoSafer is a combined control-banding and risk management tool that enables assessment of the risk level and recommended exposure control associated with production and use of manufactured nanomaterials (e.g., nanoparticles, nanoflakes, nanofibers, and nanotubes) in specific work scenarios. In addition to manufactured nanomaterials, the tool can also be used to assess and manage emissions from nanoparticle-forming processes. Uses data on material properties, processes, and production facilities to estimate occupational risk. The tool uses the Risk Quotient (i.e., the ratio of an exposure dose to a human effect threshold) to estimate risk deterministically. The upcoming new version, NanoSafer 2, will be capable of estimating exposure from spray processes. In addition, NanoSafer 2 can perform nano-specific hazard assessment based on read-across between MNs based on specific material properties and hazard indicators, tested for performance against in vivo experiments. | [51] | Risk assessment |
| GUIDEnano | Assessment and mitigation of nano-enabled product risks on human and environmental health. To develop innovative methodologies to evaluate and manage human and environmental health risks of nano-enabled products, considering the whole product life cycle. Using this tool, industry will be able to evaluate and efficiently mitigate possible health risks for workers, consumers, and the environment associated with the use of nanotechnologies. | [52] - http://www.guidenano.eu/ | Risk assessment |
| ECETOC TRA v3.1 | To assess risks associated with nanotechnology operations. Control-banding (CB) strategies (a qualitative risk characterization and management strategy) offer simplified solutions for controlling worker exposures to constituents that are found in the workplace in the absence of firm toxicological and exposure data. Combines hazard “severity” and exposure “probability” scores in a matrix to obtain a level of risk and associated controls out of 4 possible levels of increasing risk and associated controls. | [53] | Risk assessment |
| LICARA nanoscan | The main goal of LICARA is to develop a structured lifecycle approach for nanomaterials that enables the balance of health/environmental risks of nanomaterials in view of paucity of data against their benefits, and that further allows a comparison with the risks and the benefits of the conventional (non-nano) products. It estimates economic, environmental, and social opportunities. This tool is specifically intended for use by SME to support them in communicating with regulators, and potential clients and investors. | [54] | Risk assessment |
| EGRET2 | ESIG has developed a tool (termed the ESIG GES Risk and Exposure Tool or “EGRET”) that enables users to construct their own consumer CSA/ES for a particular area of use within the ESIG/ESVOC library. This library was constructed based on the results of the various communication and use mapping activities that have been undertaken with major Downstream User (DU) groups (e.g., the consumer use of solvents in coatings, which is in turn described by a set of product categories and sub-categories). | [55] | Risk assessment |
| BAUA Sprayexpo 2.3 | SprayExpo is an Excel model for calculation the airborne concentration of the respirable, the thoracic and the inhalable fraction of aerosols containing biocidal substances in indoor environments originating from the release of liquid biocidal sprays. | [56] | Risk assessment |
| Stoffenmanager Nano | Stoffenmanager Nano allows you to qualitatively assess occupational health risks from inhalation exposure to Manufactured Nano-Objects (MNO). Risk Management Measures may be selected or included in the Action Plan. Stoffenmanager Nano is a “work-in-process” online tool that reflects the current knowledge of risks related to working with nanomaterials. | [57] | Risk assessment |
| ANSES Nano | The ANSES CB nanotool was developed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to be applied for conducting risk assessment and risk management of work with manufactured nanomaterials or nano-enabled products in industrial settings. | [47,48] | Risk assessment |
| Tool Name                      | Description                                                                                                                                                                                                 | Reference(s) |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Control-banding nanotool      | Control-banding (CB) strategies offer simplified solutions for controlling worker exposures to constituents that are found in the workplace in the absence of firm toxicological and exposure data. These strategies may be particularly useful in nanotechnology applications, considering the overwhelming level of uncertainty over what nanomaterials present as potential work-related health risks and how these risks can be assessed and managed appropriately. The CB nanotool is a novel CB approach being used at the Lawrence Livermore National Laboratory (LLNL), by both experts and non-experts, to assess risks associated with nanotechnology operations and prescribe appropriate engineering controls. CB nanotool creates a severity and probability risk matrix as an output, which contains four different risk levels.                                                                 | [39–41] Risk assessment |
| Precautionary Matrix for Synthetic Nanomaterials (Swiss Precautionary Matrix) | This tool helps to determine if exposure needs to be controlled, providing advice on whether a precautionary approach is required under normal working conditions, in the worst-case scenario and for the environment.                                                                                                   | [42] Risk assessment |
| SimpleBox4Nano (SB4N)         | Multimedia mass balance model, development of the SimpleBox model. Air, water, soil, sediment compartments. Computes steady state concentrations in all compartments at local, regional, or continental scale. Mechanistic representations of processes. Parameters may be estimated from theory or experiment. Could be applied to dynamic predictions.                                                                                                                   | [58] Risk assessment |
| NanoDUFLOW                    | Nano enable extension of the DUFLOW hydrological mode. NanoDUFLOW accounts for the ENP transformation processes homo- and hetero-aggregation, dissolution, and degradation, coupled with the transport processes sedimentation, resuspension, and burial to deeper sediment layers. Aggregation and sedimentation are based on Von Smoluchowski and Stokes theories. Aggregation is calculated from the collision frequency for peri- and ortho-kinetic aggregation as well as aggregation due to differential settling, and attachment efficiencies. Hetero-aggregation is modeled for five ENP size classes interacting with five SS size classes leading to 25 classes of hetero-aggregates, all modeled in place and time. | [59,60] Risk assessment |
| MendNano                      | Multimedia mass balance model. Air, water, soil, sediment, biota compartments. Handles size distributions of ENM. Computes concentrations in each compartment over time. Processes: dry and wet deposition to foliage and ground, foliage washoff, aerosolization, wind resuspension, soil-water runoff, hetero-aggregation, dissolution, sedimentation, sediment resuspension, and burial, biotic uptake, and elimination, plant root uptake.                                                                 | [61] Risk assessment |
| RedNano                       | Integrated simulation tool for assessing the potential release and environmental distribution of nanomaterials based on lifecycle assessment approach and multimedia compartmental modeling coupled with mechanistic intermediate transport processes. The RedNano simulation tool and its web-based software implementation enables scenario analysis to assess the response of an environmental system to various release scenarios. RedNano incorporates the MendNano model. | [62] Risk assessment |
| GWAVA with water quality module | Aquatic-only model predicts Predicted Environmental Concentrations (PECs) for river reaches across Europe. Hydrology includes STP discharges, runoff, and water abstraction. Emissions based on per capita NM loadings to sewage and sewage discharge per grid cell. NM transformations modeled via lumped 1st order kinetic loss. | [63,64] Risk assessment |
| ConsExpo nano                 | Tool for the assessment of consumer exposure to nanomaterials via inhalation (spray scenario as well as custom scenarios). The outcome of the assessment is an alveolar load in the lungs as one of the most critical determinants of inflammation of the lungs is both the magnitude and duration of the alveolar load of a nanomaterial. To estimate the alveolar load arising from the use of nano-enabled spray products, ConsExpo nano combines models that estimate the external aerosol concentration in indoor air, with models that estimate the deposition in and clearance of inhaled aerosol from the alveolar region.                                                                 | [65]-https://www.consexponano.nl/ Risk assessment |
| Stochastic Materials Flow Model | This model treats input parameters, such as nano-specific production and consumption volumes, fate pathways and transfer coefficients as probability distributions (Monte Carlo, Bayesian and Markov Chain) that are built based on empirical data and expert judgment. Therefore, the outputs of the model are distributions of possible PECs, and its application always includes analysis of variability and uncertainty.                                                                                                           | [66,67] Risk assessment |
| Dynamic probabilistic material flow model (DP-MFA) | A customized dynamic probabilistic material flow model (DP-MFA) to predict the former, current and future mass-flows of four ENM (nano-TiO2, nano-ZnO, nano-Ag, and CNT) to technical and environmental compartments and the resulting concentrations in these compartments over time.                                                                                                                        | [68] Risk assessment |
| SOP/Tool | Description | Reference |
|----------|-------------|-----------|
| MFA model 1 | MFA (Material flow analysis) model for estimating PECs for MNs. Simple system of mathematical algorithms for estimating concentrations in water, soil, and air for a range of exposure scenarios based on data on MN production volumes and uses. | [69] Risk assessment |
| MFA model 2 | MFA (Material flow analysis) model for estimating PECs for MNs. First model to consider releases of MNs from consumer products in different lifecycle stages; concentrations in air, soil, water, groundwater, and sediments. Certain processes considered important for MNs (aggregation/agglomeration, sedimentation, resuspension, degradation and transformation) not considered in the estimations. | [70] Risk assessment |
| Explorative particle flow analysis (PFA) | Dynamic, quantitative environmental fate model based on colloidal chemistry. Estimates particle number concentrations in the aquatic environments resulting from processes such as materials inflow, homo- and hetero-agglomeration/aggregation and sedimentation, which are considered driving forces behind the transport of MN in waters and their potential elimination from them. | [71,72] Risk assessment |
| REACHnano ToolKit | A web-based toolkit to support the risk assessment and promote the safe use of NM along their life cycle. Contains an inventory with information about ca. 30 commonly used NM. Environmental risk assessment is done through a model of flow analysis probabilistic matter (PMFA). The occupational risk assessment tool is based on a combination of control-bandning approach, exposure estimation tools, and new templates of exposure scenarios developed specifically for the case of NM. Users may estimate the exposure depending on the operative conditions and applied risk management measures. Once all the necessary data is introduced, the model estimates if one (or more) scenarios can be dangerous for the worker. | [http://tools.lifereachnano.eu/] Risk assessment |
| NanoRiskCat | A screening tool that can identify, categorize and rank exposures and effects of nanomaterials used in consumer products based on data available in the peer-reviewed scientific literature and other regulatory relevant sources of information and data. The primary focus was on nanomaterials relevant for professional end users and consumers as, as well as nanomaterials released into the environment. The wider goal of NanoRiskCat is to help manufacturers, downstream end users, regulators, and other stakeholders to evaluate, rank and communicate the potential for exposure and effects through a tiered approach in which the specific applications of a given nanomaterial are evaluated. | [37,38] Risk assessment |
| PBPK model | A generic physiologically based pharmacokinetic (PBPK) model for nanomaterials, kinetic tool for estimating internal human exposure (post-exposure absorption, distribution and excretion (ADME) of MN). Can be used to characterize the ADME profiles of the MN for a diverse range of species based on particle type and physicochemical properties. Can also help to develop MN-specific uncertainty factors for interspecies differences in kinetics (e.g., between rodents and humans). PBPK modeling may facilitate extrapolation in exposure duration, e.g., tissue concentration levels for chronic exposure. An adaptation and extension of an earlier PBPK model for larger particles, calibrated using data from EU ENPRA, NANOMMUNE, and NANOTEST projects. | [73] Risk assessment |
| NANEX Exposure Scenario Data Library | Library of 9 occupational exposure scenarios for a variety of manufactured nanomaterials | [9,29] Risk assessment |
| Nano to go® | Guidance document prepared within the EU FP7 NanoValid project for the safe handling of nanomaterials. Contents include a brochure on “Safe handling of nanomaterials and other advanced materials at workplaces” and reports on case studies. | [74] http://www.nanosafetycluster.eu/nanoToGo/ Risk assessment |
| Multiple-Path Particle Dosimetry Model (MPPD v 2.11) | Particle dosimetry model for airborne particles. The MPPD model is a computational model that can be used for estimating human and rat airway particle dosimetry. The model is applicable to risk assessment, research, and education. The MPPD model calculates the deposition and clearance of monodisperse and polydisperse aerosols in the respiratory tracts of rats and human adults and children (deposition only) for particles ranging in size from ultratine (0.01 µm) to coarse (20 µm). | [75,76] Risk assessment |
| SOP Tiered Approach for the assessment of exposure to airborne nano-objects in workplaces | This SOP covers the overall strategy of assessing exposure to airborne nano-objects in workplaces, following a tiered approach, which contains 3 hierarchical tiers: tier 1: information gathering, tier 2: basic assessment and tier 3: expert assessment. This SOP describes the general procedure, whereas the measurements in tier 2 and tier 3 are described in three main SOPs: Screening, Sampling, and Expanded Measurement. Each of these main SOPs is accompanied by sub-SOPs describing the use of instruments, sample preparation, and data evaluation. | [77] Risk assessment |
Table S7. Risk evaluation tools descriptions and references.

| Tool name | Description | References | Sector |
|-----------|-------------|------------|--------|
| SUNDS     | The Sustainable Nanotechnology Decision-Support System (SUNDS) addresses current nanotechnology risk assessment and management needs. The SUNDS conceptual decision framework expands the focus from nanotechnology risk assessment and management to emerging risk governance needs. It has a two-tier structure comprising screening and advanced tools to address varying data availability and stakeholder needs. | [49,50] | Risk characterization |
| NanoSafer | NanoSafer is a combined control-banding and risk management tool that enables assessment of the risk level and recommended exposure control associated with production and use of manufactured nanomaterials (e.g., nanoparticles, nanoflakes, nanofibers, and nanotubes) in specific work scenarios. In addition to manufactured nanomaterials, the tool can also be used to assess and manage emissions from nanoparticle-forming processes. | [51] | Risk characterization |
| NanoRiskCat | A screening tool that can identify, categorize and rank exposures and effects of nanomaterials used in consumer products based on data available in the peer-reviewed scientific literature and other regulatory relevant sources of information and data. The primary focus was on nanomaterials relevant for professional end users and consumers as, as well as nanomaterials released into the environment. The wider goal of NanoRiskCat is to help manufacturers, downstream end users, regulators, and other stakeholders to evaluate, rank and communicate the potential for exposure and effects through a tiered approach in which the specific applications of a given nanomaterial are evaluated. | [37,38] | Risk characterization |
| Species Sensitivity Distribution (SSD) for nanomaterials | A Monte Carlo probabilistic approach is used to generate Species Sensitivity Distribution (SSD) that is then compared with probability distributions of Predicted Environmental Concentrations (PEC) to estimate environmental risks. | [80,81] | Risk characterization |
| Work health and safety assessment tool for handling engineered nanomaterials | A nano-risk assessment tool to assist regulators, research laboratories, and organizations in managing engineered nanomaterials. This tool consists of a questionnaire, which helps to register the chemical composition and the physical form of the nanomaterials manufactured or used, and the safety measures applied to nanoparticle exposure prevention at the workplace. | [82] | Risk characterization |
| REACHnano ToolKit | A web-based toolkit to support the risk assessment and promote the safe use of NMs along their life cycle. Contains an inventory with information about ca. 30 commonly used NMs. Environmental risk assessment is done through a model flow analysis probabilistic matter (PMFA). The occupational risk assessment tool is based on a combination of control-banding approach, exposure estimation tools, and new templates of exposure scenarios developed specifically for the case of NMs. Users may estimate the exposure depending on the operative conditions and applied risk management measures. Once all the necessary data is introduced, the model estimates if one (or more) scenarios can be dangerous for the worker. | http://tools.lifereachnano.eu/ | Risk characterization |
| nanoinfo.org | A web-platform built to support the nanoinformatics effort by developing and providing state-of-the-art resources and tools dedicated to environmental impact assessment of engineered nanomaterials (ENMs). Consists of: * LearnNano: lifecycle assessment of the environmental release of ENMs * MendNano: multimedia compartmental simulation model of the environmental distribution of ENMs * ToxNano: toxicity data analysis of ENMs that supports high-throughput screening and high content studies * NanoEIA: in silico environmental impact analysis platform that enables evaluation of potential impacts and thus can assist in developing risk management options in support of safe-by-design of ENMs considering multicriteria analyses. | [62] | Risk characterization |
| FINE | Baseline probabilistic model that incorporates nano-specific characteristics and environmental parameters, along with elements of exposure potential, hazards, and risks from MN. Bayesian networks in combination with expert elicitation as a tool for nanomaterial risk forecasting. | [83,84] | Risk characterization |
The Sustainable Nanotechnology Decision-Support System (SUNDS) addresses current nanotechnology risk assessment and management needs. The SUNDS conceptual decision framework expands the focus from nanotechnology risk assessment and management to emerging risk governance needs. It has a two-tier structure comprising screening and advanced tools to address varying data availability and stakeholder needs.

The tool estimates an emission probability (without considering exposure controls) and severity band and provides advice on what engineering controls to use. It includes nine domains covering handling of liquids, powders, and abrasion of solids. Combines hazard “severity” and exposure “probability” scores in a matrix to obtain a level of risk and associated controls out of 4 possible levels of increasing risk and associated controls.

Ranks potential health risks from workplace inhalation exposure to MN and proposes effective RMM. It concerns single particles as well as agglomerates or aggregates and applies to MN that meet all of the following criteria: i) particles are not (water) soluble; ii) particles are synthetically produced and not released as unintentional by-product of e.g., incomplete combustion processes; iii) the size of the primary particles is smaller than 100 nm and/or the specific surface area of the nanopowder is larger than 60 m²/g.

The ANSES CB nanotool was developed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to be applied for conducting risk assessment and risk management of work with manufactured nanomaterials or nano-enabled products in industrial settings.

This tool helps to determine if exposure needs to be controlled, providing advice on whether a precautionary approach is required under normal working conditions, in the worst-case scenario and for the environment.

NanoSafer is a combined control-banding and risk management tool that enables assessment of the risk level and recommended exposure control associated with production and use of manufactured nanomaterials (e.g., nanoparticles, nanoflakes, nanofibers, and nanotubes) in specific work scenarios. In addition to manufactured nanomaterials, the tool can also be used to assess nanoparticle-forming processes.

A screening tool that can identify, categorize and rank exposures and effects of nanomaterials used in consumer products based on data available in the peer-reviewed scientific literature and other regulatory relevant sources of information and data. The primary focus was on nanomaterials relevant for professional end users and consumers as, as well as nanomaterials released into the environment. The wider goal of NanoRiskCat is to help manufacturers, downstream end users, regulators, and other stakeholders to evaluate, rank and communicate the potential for exposure and effects through a tiered approach in which the specific applications of a given nanomaterial are evaluated.

A low-cost/evidence-based tool for assessing and managing the risks associated with exposure to Carbon Nanofiber.

An assessment strategy based on the protocol that XL Insurance uses for calculating insurance premiums for chemical industries. The protocol is mainly used to perform risk assessment for the manufacture of nanomaterials, by focusing on the characteristics of the materials and production processes.

The main purpose of the tool is to provide small and medium sized enterprises (SMEs), large companies, and other relevant stakeholders with an easy to use tool to select proper measures to achieve a high level of protection of the human health and the environment against ENMs, assisting them in the selection of adequate personal protective equipment (PPE) and engineering controls (EC) in order to prevent exposure to ENMs and release in the workplace.

Table 58. Risk management decision-making support tools descriptions and references.

| Tool Name | Description | References | Sector |
|-----------|-------------|------------|--------|
| SUNDS | The Sustainable Nanotechnology Decision-Support System (SUNDS) addresses current nanotechnology risk assessment and management needs. The SUNDS conceptual decision framework expands the focus from nanotechnology risk assessment and management to emerging risk governance needs. It has a two-tier structure comprising screening and advanced tools to address varying data availability and stakeholder needs. | [49,50] | Risk management |
| CB Nanotool | The tool estimates an emission probability (without considering exposure controls) and severity band and provides advice on what engineering controls to use. It includes nine domains covering handling of liquids, powders, and abrasion of solids. Combines hazard “severity” and exposure “probability” scores in a matrix to obtain a level of risk and associated controls out of 4 possible levels of increasing risk and associated controls. | [39–41] | Risk management |
| Stoffenmanager Nano | Ranks potential health risks from workplace inhalation exposure to MN and proposes effective RMM. It concerns single particles as well as agglomerates or aggregates and applies to MN that meet all of the following criteria: i) particles are not (water) soluble; ii) particles are synthetically produced and not released as unintentional by-product of e.g., incomplete combustion processes; iii) the size of the primary particles is smaller than 100 nm and/or the specific surface area of the nanopowder is larger than 60 m²/g. | [57] | Risk management |
| ANSES Nano | The ANSES CB nanotool was developed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to be applied for conducting risk assessment and risk management of work with manufactured nanomaterials or nano-enabled products in industrial settings. | [47,48] | Risk management |
| Precautionary Matrix for Synthetic Nanomaterials (Swiss Precautionary Matrix) | This tool helps to determine if exposure needs to be controlled, providing advice on whether a precautionary approach is required under normal working conditions, in the worst-case scenario and for the environment. | [42] | Risk management |
| NanoSafer | NanoSafer is a combined control-banding and risk management tool that enables assessment of the risk level and recommended exposure control associated with production and use of manufactured nanomaterials (e.g., nanoparticles, nanoflakes, nanofibers, and nanotubes) in specific work scenarios. In addition to manufactured nanomaterials, the tool can also be used to assess nanoparticle-forming processes. | [51] | Risk management |
| NanoRiskCat | A screening tool that can identify, categorize and rank exposures and effects of nanomaterials used in consumer products based on data available in the peer-reviewed scientific literature and other regulatory relevant sources of information and data. The primary focus was on nanomaterials relevant for professional end users and consumers as, as well as nanomaterials released into the environment. The wider goal of NanoRiskCat is to help manufacturers, downstream end users, regulators, and other stakeholders to evaluate, rank and communicate the potential for exposure and effects through a tiered approach in which the specific applications of a given nanomaterial are evaluated. | [37,38] | Risk management |
| A low-cost/evidence-based tool | A low-cost/evidence-based tool for assessing and managing the risks associated with exposure to Carbon Nanofiber. | [86] | Risk management |
| XL Insurance Database | An assessment strategy based on the protocol that XL Insurance uses for calculating insurance premiums for chemical industries. The protocol is mainly used to perform risk assessment for the manufacture of nanomaterials, by focusing on the characteristics of the materials and production processes. | [87,88] | Risk management / Insurance sector |
| Nano-specific Risk Management Library | The main purpose of the tool is to provide small and medium sized enterprises (SMEs), large companies, and other relevant stakeholders with an easy to use tool to select proper measures to achieve a high level of protection of the human health and the environment against ENMs, assisting them in the selection of adequate personal protective equipment (PPE) and engineering controls (EC) in order to prevent exposure to ENMs and release in the workplace. | RIVM | Risk management |
Table S9. Safety-by-design-monitoring tools descriptions and references.

| Tool name               | Description                                                                                                                                                                                                 | References | Sector |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------|
| ProSafe SbD Implementation Concept | SbD implementation concept based on the NANoREG SbD concept. The four main elements are:  
#1 The workflows in industrial innovation processes or actor-specific needs  
#2 The Safety Dossier  
#3 The Safety Profile  
#4 Harmonized inventory of SbD protocols, procedures, and data | [89]        | SbD    |
| CENARIOS               | CENARIOS, the first certifiable nano-specific risk management and monitoring system. CENARIOS provides a “State-of-the Art” hazard and risk assessment, encompassing risk monitoring tools to minimize the potential risks. | [90]        | Monitoring |
References

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