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Gov4Nano
meeting the needs of nanotechnology

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Abbreviations and acronyms

ASTM	**American Society for Testing and Materials**
CEN	□□ro□ean □o□□ittee for □tandardi□ation
CSS	□□e□i□a□□trate□□for □□stainabi□it□
DNF	□edi□ated □anote□□hno□o□□□□ir□
DSTI	□ire□torate for □□ien□e □e□□hno□o□□□and □nno□ation
EUON	□□ro□ean □nion □bser□ator□for □ano□ateria□s
FAIR	□indab□e□□□□essib□e□□ntero□erab□e and □e□□sab□e
IRGC	□nternationa□□is□□o□ernan□e □o□n□i□
ISO/TC	□nternationa□□r□ani□ation for □tandardi□ation□□e□□ni□a□□o□□ittee
M&E	Monitorin□and □□a□□ation
NM	□ano□ateria□s
NRGC	□ano □is□□o□ernan□e □o□n□i□
OECD	□r□anisation for □□ono□i□□o□o□eration and □e□e□o□□ent
R&D	□esear□□and de□e□o□□ent
SMART	□□e□ifi□□Meas□rab□e□□□□ie□ab□e□□e□e□ant and □i□e bo□nd
SbD	□afe b□desi□n
S(S)bD	□afer□and□□□stainab□e b□□esi□n

1 Summary

The purpose of this task (Task [illegible]) is to establish a system for monitoring progress in risk governance of nanotechnologies. In this task a system has been developed and demonstrated to achieve this purpose. The system comprises a set of [illegible] numerical indicators each expressed as a ratio of the current state to some future desired state. By operating the system on a periodic basis, progress towards the desired state can be monitored.

Task [illegible] is built on and further develops the findings of Tasks [illegible] to Tasks [illegible]. In Task [illegible] a monitoring and evaluation (M[illegible]) system was developed for monitoring the performance of the risk governance field. In developing the M[illegible] system six areas of risk governance were identified for monitoring: (1) risk management and risk assessment, (2) governance issues and regulations, (3) innovation and sustainability, (4) research, (5) and stakeholders. For each of these areas relevant sub-areas were identified and aligned to topics from the international risk governance community [illegible] and user needs that had been identified under [illegible]. Sub-areas were then categorised under [illegible] clusters: standardisation [illegible], data and data quality, risk governance and innovation, funding and value of investment, safer and sustainable by design [illegible] and communication. Clusters were evaluated for indicators and sub-indicators that could be taken forward by Task [illegible]. An overview of the relations main areas, sub-areas and clusters can be found in Annex [illegible].

In Task [illegible] the instruments that can be used to monitor scientific evidence and emerging needs, continuously evaluate progress in risk governance across sectors, and monitor its ability for governance initiatives were identified. This was done by defining parameters and success criteria and identifying potential instruments for monitoring and evaluating each of the indicators and sub-indicators listed under Task [illegible].

In Task [illegible] a monitoring scheme by applying pragmatic selection criteria to the [illegible] indicators and sub-indicators presented under Tasks [illegible] and [illegible] was developed. The final scheme comprises [illegible] indicators for monitoring the progress of different aspects of each of the six clusters and altogether facilitates progress monitoring of risk governance of nanomaterials.

The proposed system is described in this report and comprises:

- A description of the [illegible] indicators;
- Methodology for calculation of each indicator;
- Data sources to be used to calculate each indicator;
- A database in which to store the input data and calculated indicator values; and
- A design for a dashboard (web based) on which the indicator values can be visualised.

2 Description of task

Partners: Lead: [illegible]M; Partners: [illegible]M[illegible]M[illegible]
[illegible]M

In keeping with the original remit of the [illegible], we have developed a monitoring scheme based on the minimum data curation requirements and standards, the criteria, indicators and monitoring instruments identified and/or developed in Tasks [illegible] and [illegible] that are tuned to an international setting for a broad range of stakeholders in various disciplines. An additional task was to give a cost estimate for integrating the monitoring scheme within the [illegible] by the end of the [illegible]Nano project. However, in the absence of a true [illegible] office, this is less relevant at this time and so not discussed in this report.

3 Description of work & methodology

3.1 Background of the task

Under Task [illegible] a monitoring and evaluating [illegible]M[illegible] system was developed to enable the future of a Nano Risk Governance organisation to monitor its progress and impact and to facilitate the monitoring of the performance of the risk governance of nanomaterials. [illegible] areas were defined based on trends and factors for the development of the original planned [illegible] design so that the performance of the risk governance field could be monitored.

The six areas consisted of [illegible] risk management and risk assessment; [illegible] risk governance; [illegible] rules and regulations; [illegible] innovation and sustainability; [illegible] research; and [illegible] stakeholders. Twenty-two sub-areas were identified within these areas and aligned to topics from the international risk governance community [illegible] and user needs developed in deliverable [illegible]. These were then grouped into six clusters: harmonisation/standardisation (cluster [illegible]), data and data quality (cluster [illegible]), safe and sustainable by design (cluster [illegible]), risk governance and innovation (cluster [illegible]), funding and value of investment (cluster [illegible]) and communication (cluster [illegible]). Areas, sub-areas and clusters are related to each other as illustrated in Annex [illegible].

Indicators were formulated so that progress could be demonstrated in a transparent way, the broad spectrum of stakeholders and disciplines would be taken into account and they would be functional to the tasks of the original planned [illegible]. The sub-indicators under each indicator were developed using [illegible]M[illegible] ([illegible]pecific, Measurable, [illegible]chievable, Relevant and Time bound) criteria.

In Task [illegible] potential useful instruments to monitor and evaluate the different indicators and sub-indicators within the different clusters were identified. Success criteria for each of them were defined and for each of them the most suitable monitoring tools were assigned. The final toolbox comprised [illegible] indicators, [illegible] sub-indicators (Table [illegible], Additional [illegible]). A prioritisation scheme based on relevance and ease of implementation was developed to facilitate the selection of indicators under Task [illegible].

3.2 Description of the work carried out

In this task [illegible] the toolbox of indicators and their monitoring instruments were closely examined and, focussing on the practical aspects of the prioritisation scheme, indicators for a system for monitoring the progress of risk governance of nanomaterials were selected and metrics for quantifying success derived. The process is outlined in the diagram below.

Briefly, a prioritisation scheme was applied to the full list of indicators for progress monitoring identified under Task [illegible] resulting in a shortlist of indicators based on pragmatic considerations such as availability of data and ease of implementation. In discussions during meetings and a workshop with work package partners (December 2nd [illegible], February [illegible]th, March [illegible]th, [illegible] April [illegible]th, [illegible]th, [illegible]st [illegible]th) the shortlist was assessed for its fitness for purpose including comparing each indicator against SMART principles and defining appropriate metrics to track success. The final scheme consists of [illegible] indicators covering [illegible] of the clusters relevant for risk governance.

Task 7.3 Instruments for (cross)sectoral progress monitoring

[illegible] indicators and [illegible] sub-indicators covering [illegible] different aspects of risk governance: standardisation [illegible] data and data quality [illegible] governance and innovation, funding and value of investment, communication

Application of prioritisation scheme with focus on pragmatic items (practicability score)

Shortlist of indicators

[illegible] indicators and [illegible] sub-indicators covering [illegible] different items of risk governance

- *Assessment against SMART criteria*
- *Definition of metric to measure success*

Task 7.4 Scheme for monitoring progress in implementation of risk governance

[illegible] indicators covering [illegible] different aspects of risk governance: standardisation [illegible] data and data quality [illegible] governance and innovation, communication

Figure 1: Outline of the process used for devising a scheme for monitoring progress in risk governance of nanotechnology

4 Results

4.1 Practicability score for shortlisting indicators

In phase [illegible] each indicator was rated on [illegible] the ease and readiness with which it could be implemented and [illegible] its relevance. The overall level of ease was quantified by applying a rating scale from [illegible] to [illegible] to assess each indicator for availability of resources, availability of existing instruments and availability of existing measures. Likewise, an overall score for each indicator's relevance was obtained by rating its relevance to the process of risk governance, and to stakeholders (Table [illegible]). Cut-off points for categorising indicators into lowest, middle and highest priority were set at [illegible] to [illegible] and [illegible], respectively, with a maximum attainable total score of [illegible].

Table 1: Scoring scheme for prioritisation of indicators devised in Task 7.3

Ease and readiness for implementation	Availability of resources	The more data/information/tools/frameworks and/or other resources are available, the higher value (1-5)
	Availability of existing instrument	The more instruments, the higher the value (1-5)
	Availability of existing way to measure	A higher value will be assigned when the way to measure the success of a specific instrument is easy to implement (1-5)
Relevance	Process of risk governance	The greater the relevance to the process of risk governance the higher the value (1-5)
	Domain(s)	The greater the relevance to the domain(s), the higher the value (1-5)
	Stakeholders	The greater the relevance to specific stakeholders (i.e. interested parties involved in risk governance) (1-5)

In Task 7.3, greater weight was given to the elements under 'Ease and readiness for implementation'. A practicability rating was assigned to each indicator or sub-indicator based on overall score, the 'availability of existing instrument(s)' and 'availability of way of measurement'. Where necessary, the 'availability of resources' would have been considered after the initial shortlist based on the first two elements were obtained. The prioritisation scheme, also described in Figure 2, was:

– Practicability score 1 - overall score > 24 AND availability of existing instrument(s) ≥ 3

– Practicability score 2 - overall score > 24 AND availability of way to measure ≥ 3

– Practicability score 3 - overall score ≥ 12 ≤ 24 AND availability of way to measure ≥ 3

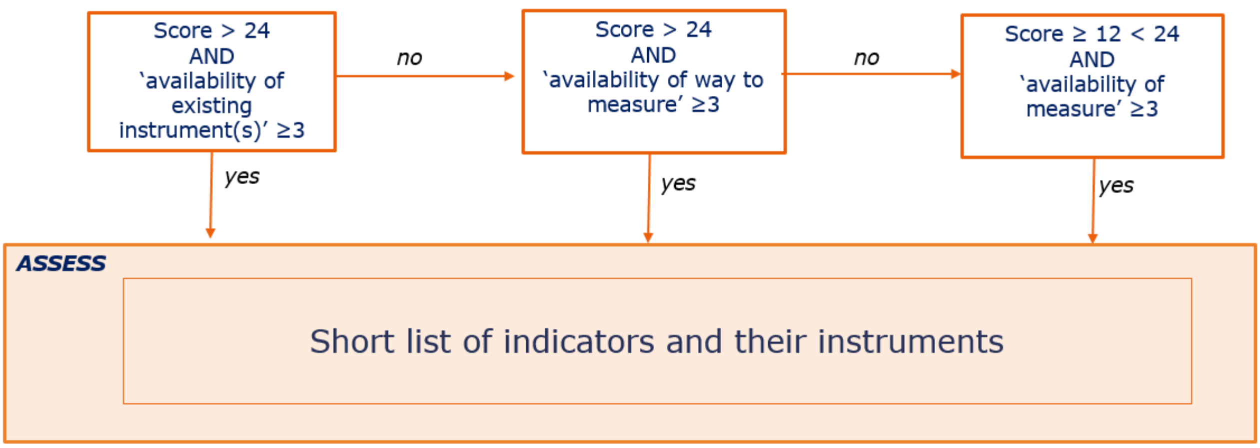

Figure 2: Pragmatic criteria used to shortlist indicators

Based on practicability scores the original long list of [illegible] indicators ([illegible] sub-indicators) was reduced to [illegible] indicators ([illegible] sub-indicators) across all clusters (Table [illegible]).

Table 2: Number of shortlisted indicators

Cluster	Title	Original number of indicators	Number of shortlisted indicators
[illegible]	Standardisation	[illegible] indicators ([illegible] sub-indicators)	[illegible] indicators ([illegible] sub-indicators)
[illegible]	Data Quality	[illegible] indicators ([illegible] sub-indicators)	[illegible] indicators ([illegible] sub-indicators)
[illegible]	Innovation and Governance	[illegible] indicators ([illegible] sub-indicators)	[illegible] indicators ([illegible] sub-indicators)
[illegible]	Funding/Value of Investment	[illegible] indicators ([illegible] sub-indicators)	[illegible] indicators ([illegible] sub-indicators)
[illegible]	[illegible]	[illegible] indicators ([illegible] sub-indicators)	[illegible] indicators ([illegible] sub-indicators)
[illegible]	Communication	[illegible] indicators ([illegible] sub-indicators)	[illegible] indicators ([illegible] sub-indicators)

4.2 Refinement and final selection of indicators and sub-indicators

Finally, each indicator was assessed against SMART criteria and for its ability to monitor the progress of one of the six aspects of risk governance defined under the clusters as illustrated in Table [illegible]. Where it was relevant to do so, indicators were reformulated and a suitable metric to measure success was defined.

Table 3: Illustration of how shortlisted indicators were examined under SMART principles

What aspect of risk governance is being monitored with this indicator?
Standardisation
What is the proposed indicator/sub-indicator and success criteria?
Indicator: Reliable and relevant (physico-chemical) methods for regulatory risk assessment Sub-indicator: Investigate the methods used for identification and characterisation of nanomaterials to generate the minimal data requirements Success criteria: Number of recommended guidelines published/accepted and adopted by EU members and non-EU members for nanomaterials characterisation
Is this indicator ***specific?***
Yes, it is concerned with acceptance and adoption of a specific aspect of standardisation (identification and characterisation of nanomaterials) among particular groups (EU members and non-EU members) in order to achieve a particular goal (availability of reliable and relevant physico-chemical methods for regulatory risk assessment).
Is this indicator ***measureable?***
Yes
Is this indicator ***attainable?***
Yes, data for this indicator can be collected through a survey/questionnaire as part of a larger survey among EU and non-EU members engaged in adoption or development of nanotechnologies.
Is this indicator ***relevant*** to the aspect of risk governance being monitored/evaluated?
Yes, development of guidelines and their subsequent adoption by EU and non-EU members would facilitate standardisation of approaches for identification and characterisation of nanomaterials.
Can this indicator be tracked across ***time*** such that progress can be monitored and it is repeatable over time?

Yes. However for monitoring progress in terms of acceptance and adoption of the guidelines by EU and non-EU members, it is useful to divide this indicator into (i) number of recommended guidelines published and (ii) number of recommended guidelines accepted and adopted.

Reformulation of indicator following examination under SMART principles

Indicator(s):

(i) How many guidelines that investigate methods for identification and characterization of nanomaterials have been published or are under development?

(ii) What proportion of EU/non-EU members have accepted and adopted published guidelines for identification and characterization of nanomaterials?

Impact:

- Facilitates monitoring of developments in identification and characterisation of nanomaterials.
- Allows for monitoring the uptake (ease and speed) of recommended guidelines on nanomaterial identification and characterisation across EU/non-EU members engaged in nanotechnology use and/or development.

Relevance: The greater the proportion of EU/non-EU members that adopt the recommended guidelines, the greater the amount of high-quality standardised data that are available for regulatory risk assessment.

4.2.1 The monitoring scheme

The monitoring system is intended to be a practical system that can be employed by any one of the chosen organisational forms that may eventually be established through [illegible]'s envisaged, it is a simple, readily updateable system comprising a manageable number of indicators, many of them automatically or semi-automatically generated, and associated instruments. It is intended that it should be possible to maintain the system with moderate resources, facilitating regular updating. The proposed system comprises the following elements:

- A description of the [illegible] indicators;
- Methodology for calculation of each indicator;
- Data sources to be used to calculate each indicator;
- A database in which to store the input data and calculated indicator values; and
- A design for a dashboard (web based) on which the indicator values can be visualised.

The [illegible] indicators cover all but one of the clusters (Table [illegible]) with further details provided in Annex [illegible]. For each of these an indicator of success (measure that resolves to a single number or proportion) is defined so that trends across time can be tracked. This is illustrated for one of the indicators based on a combination of actual data on the number of dedicated nanotechnology firms (DNFs)[1] in OECD countries and fictional data generated for the purposes of this example.

This indicator falls under cluster [illegible] Standardisation. Its purpose is to investigate the uptake of standard methods for identification and characterization of nanomaterials that generate the minimum data requirements by actors in the nanotechnology sector.

The success criteria is described as "*standard methods accepted and adopted by the majority (≥ 85 %) of DNFs in EU and non-EU member countries*". The indicator of success is defined as "*the proportion of DNFs in OECD countries that have adopted published guidelines on identification and characterisation of nanomaterials.*" It is calculated as follows:

[1] DNFs are nanotechnology firms that devote at least 75% of their production of goods and services, or R&D, to nanotechnology while DNF-R&D devote at least 75% of their total R&D to nanotechnology.

$$\frac{\textit{Number of DNFs in OECD countries that have adopted guidelines on characterization of nanomaterials.}}{\textit{Total number of DNFs in OECD countries.}}$$

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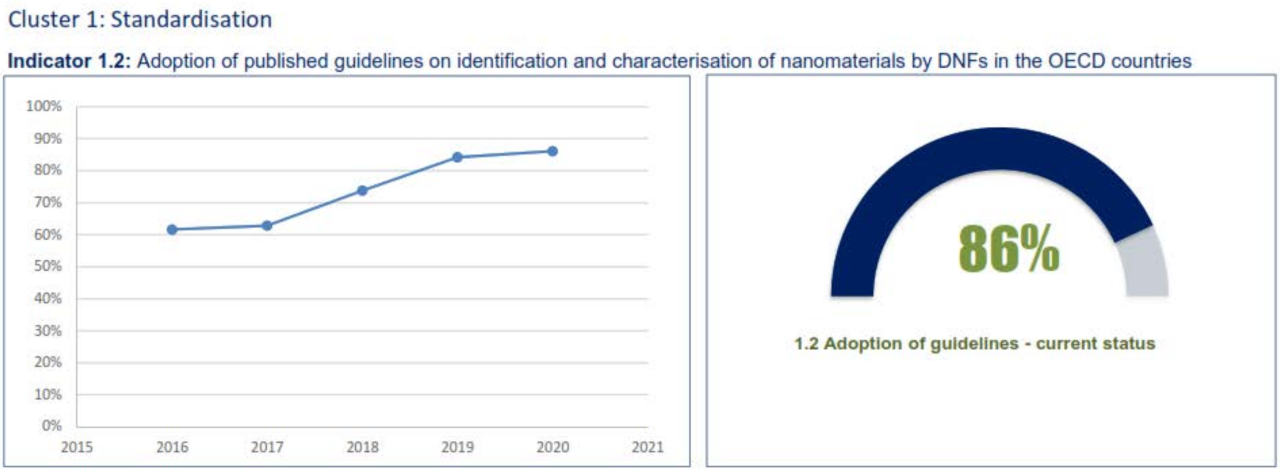

Figure 3: Trends in the proportion of DNFs in OECD countries that have adopted published guidelines on identification and characterisation of nanomaterials and the status of this indicator in 2020 (the most recent year for which data on number of DNFs exist). Numerator data were based on fictional data

4.2.2 Data sources

□□e too□s t□at are □sed to obtain data for t□e indi□ators are □□□Man□a□or □□to□ated website s□annin□ and web□based too□s □□□ □□r□e□s t□at □i□□ □□ different as□e□ts of ris□ □o□ernan□e □erfor□an□e and □□□□standin□□o□□ittee t□at □ses o□t□□t fro□ t□e ot□er □e□e□ents□

Manual or Automated website scanning and web-based tools

□n website s□annin□□□e□words □in□ed to infor□ation of interest are □sed to □at□er data and□or □onitor □□an□es□□□e software□based too□s t□at □o□□d be □sed for a□to□ated s□annin□ in□□□de □bri□on s□annin□□□□ □raw□and t□e □o□□□ano □o□□□eteness □onitor b□ □M□□□□ w□i□e web□ based too□s s□□□as e□anoMa□□er and □oresi□□t □et□ods in □enera□□ro□ide i□□ortant data and

[2] https://www.oecd.org/sti/nanotechnology-indicators.htm

information required for calculating indicator metrics. Most of these have already been comprehensively described in Deliverable D7.3[3].

Briefly, horizon scanning is a forecasting tool that is used to detect *“early signs of potentially important developments through a systematic examination of potential threats and opportunities, with emphasis on new technology and its effects on the issue at hand”* (□□ersen □□□□□□□). It can be conducted manually through experts or be automated. However, it always involves an iterative process of scanning, analysing, synthesising and communicating information.

□□□rawl is part of the larger □□□□ite software package. It supports tracking and surveillance of user-defined information or site areas from multiple sources (e.g. □□□□□□□ website, blogs, social networks□□□□) and databases, and includes a facility to schedule monitoring and alerts.

The Completeness Monitor[4] is a freely available web-based tool specifically developed by □M□□□□ as a collaboration between □□□ and □□□□, as □□□□ for estimating metadata completeness. So far completeness is automatically evaluated with respect to physicochemical, exposure and ecotoxicological data available in the eNanoMapper database, however it can be extended to other databases. Completeness scores are evaluation in real time, evaluated every □□ days and stored to a database. This tool is employed for one of the key indicators under cluster □ (□□□□ data and data quality indicator □□□□) where the success criteria pertains to completeness of hazard, exposure and physicochemical data.

eNanoMapper[5] is a publicly available, searchable database that hosts characterisation data and biological and toxicological information on nanomaterials. Data can be uploaded or downloaded to the database. One of its objectives includes *“Improving the utilisation of data through the implementation of a modular infrastructure for data* ***storage, searching and sharing****, based on open standards and semantic web technologies, minimum information standards and established security solutions”*. It has applicability to indicators on standardisation and □□□□ data and data quality.

Surveys

Under Work Package □ □□eliverable □□□ recommendations for an Organisational form for Nano Risk Governance under present policy was put forward[6] (see section □□□□). It is proposed that a roundtable of stakeholders would be part of the two most promising organisational forms. This would include an expert group selected from a stakeholder database that should be established and maintained and from which information needed for several indicators can be obtained through an annual survey (□□□□□□□).

An additional source of indicator relevant data would be from the OECD's Directorate for Science, Technology and Innovation (□□□□□□□□). The □□□□ includes number of firms active in nanotechnology[7] among their key nanotechnology indicators. They make a distinction between nanotechnology firms and dedicated nanotechnology firms (□□□□□), with the latter defined as firms that devote at least □□□ of their production of goods and services, or □□□□ to nanotechnology. It lists the number of nanotechnology and dedicated nanotechnology firms in each country and has been reported since □□□□ with the most recent data reported for □□□□□.

Both sources (expert group and nanotech firms identified by the □□□□□□) can be queried by surveys using a combination of general and indicator specific questions. The survey would comprise both short, simple closed-ended questions scored on a Likert scale (e.g. □□□□□ score □□□□) and open-ended questions. The latter would require more in depth post analysis but would provide additional

[3] Deliverable D7.3_G4N_Selecting monitoring instruments and recommendations for their implementation
[4] https://completeness-monitor.greendecision.eu/
[5] https://www.enanomapper.net/
[6] D5.5 G4N Development of conditions for an Organisational Form for Nano Risk Governance in the context of present policy goals
[7] https://www.oecd.org/sti/nanotechnology-indicators.htm

information that would inform our understanding of the progress of risk governance from the viewpoint of a diverse group of stakeholders.

Box 1: Example survey questions

General questions

- For the following elements give a score between [illegible] and [illegible] to rate how well the system devised for risk governance of nanotechnology is performing:

  i) Findability of information and relevant services;
  ii) Accessibility to information and relevant services;
  iii) Ease of use
  iv) Usefulness of content

- How well connected is research (regulatory oriented science and policy) on nanotechnology?
- Do you use the system?
- How could the system be improved?

For specific indicators example questions include:

Standardisation

- Are you familiar with the [illegible] nanotechnologies standards?
- Do you adhere to the [illegible] standards that are relevant for your area of nanotechnology research or the nanotechnology goods and services that you produce?

S(S)bD

- Has your organisation incorporated nanomaterials specific risk prevention guidelines, trainings or workshops to increase workers' awareness on safety during working with nanomaterials?

Standing committee

As part of the roundtable activities envisaged in [illegible], a standing committee could be formed to take ownership of the scheme and take responsibility for regularly updating the indicators. A small amount of resources would be required for this activity.

Table 4: Progress monitoring indicators

Cluster name	Indicator	Sub-indicator	Success criteria	Indicator-of-success measure
Standardisation	Reliable and relevant physico-chemical methods for regulatory risk assessment.	Investigate the methods used for identification and characterization of nanomaterials to generate the minimum data requirements	The minimum data requirements on identification and characterization of nanomaterials are covered by the guidelines that have been published or are under development.	Proportion of the minimum data requirements on nanomaterial identification and characterisation that have been covered by published guidelines or are being considered by guidelines that are under development.
		Investigate the uptake of standard methods for identification and characterization of nanomaterials that generate the minimum data requirements	Standard methods accepted and adopted by the majority (≥ 85%) of EU members and non-EU members	Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that have adopted the published guidelines for identification and characterization of nanomaterials.
	Exposure (reliable and harmonized methods and models for exposure and release of nanomaterials)	Inventory of exposure models for assessing environmental and occupational exposure of nanomaterials that are used by regulatory authorities.	Recommendations on exposure models must be defined and made available to the public and to stakeholders by regulators.	Proportion of publicly-available exposure models for environmental and occupational exposure of nanomaterials that are based on regulatory recommendations..
		Investigate the use of publicly-available, regulator recommended nano-specific environmental and occupational exposure modelling tools.	publicly-available, regulator-recommended exposure modelling tools employed by the majority (≥ 85%) of EU members and non-EU members.	Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that employ publicly-available, regulator-recommended, nano-specific environmental and occupational exposure modelling tools.
FAIR data and data quality	EHS/FAIR data	Harmonized templates for FAIR nanosafety data (specifically for different types of experiments and for the different toxicological endpoints)	Templates required for FAIR nanosafety data (i.e. for all types of experiments and endpoints) are inventoried and made available to relevant actors.	Proportion of the templates needed for FAIR nanosafety data for all types of experiments and endpoints that are available for use by stakeholders and other relevant actors.

Cluster name	Indicator	Sub-indicator	Success criteria	Indicator-of-success measure
		Harmonized templates for FAIR nanosafety data (specifically for different types of experiments and for the different toxicological endpoints)	Templates are used by all stakeholders	Proportion of stakeholders & stakeholder groups that use the harmonised templates required for FAIR nanosafety data.
	Data completeness	• Hazard data completeness • Exposure data completeness • Physicochemical data completeness	Completeness of hazard, exposure and physicochemical data	Data completeness score associated with key parameters that is evaluated based on the physicochemical and hazard data currently in the eNanoMapper database using an algorithm. The results are shown in real time and are updated every 15 min in this online tool developed especially for the Gov4Nano monitoring scheme: [illegible]
Innovation and governance	Information on new innovation in nanomaterials including commercialisation for each domain; chemicals, consumer products, nanomedicine, medical devices, food and feed, biocides and cosmetics	Annual survey of new (nano)materials including advanced (multicomponent) nanomaterials and trends (e.g. patents, foresight).	Publication of statistics on number of new products, type of nanomaterials used, applications, innovation maturity level, market readiness.	Year-on-year trends on new or advanced nanomaterials
Funding and value of investment	Research questions funded by funding agencies	Inventory of proposals completed that lead to guidance documents or test guidance.	List of completed EU funded projects and main outcomes/Statistics on number of guidance documents obtained in completed proposals	No metric defined

Cluster name	Indicator	Sub-indicator	Success criteria	Indicator-of-success measure
S(S)bD	Nano specific hazard information	Academic & industrial showcases of S(S)bD	An inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization) is established.	Completeness of the inventory based on evaluation by an expert committee.
		Investigate the use of academic & industrial showcases of S(S)bD (focussed on hazard characterization) by EU and non-EU members.	The inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization) is used by the majority (≥ 85%) of EU members and non-EU members.	The majority (>85%) of EU members and non-EU members engaged in nanotechnology utilise the inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization).
		Investigate the adoption of S(S)bD principles	S(S)bD principles have been incorporated in the design and development of nanotechnologies	Proportion of publications on new or updated nanotechnology products or services where S(S)bD principles had been integrally incorporated in the development.
	Worker safety	Nano-specific worker guidelines applicable to nanomaterials. See, for instance: •OSHA (Occupational Safety and Health Administration) •WHO •CDC NIOSH (Centre for Disease Control National institute for Occupational Safety and Health)	Risk prevention guidelines, trainings and workshops are employed to increase workers' awareness on safety with regards to nanomaterial-related work.	Proportion of nanotechnology companies that use nanomaterial-specific risk prevention guidelines, trainings and workshops to increase workers' awareness on safety during nanomaterials-related work.
	Risk perception	Workers perceived risks of nanomaterials they handle (vs. what an expert would conclude on their risks).	Workers' risk perception accurately reflect their level of risks in the workplace.	Agreement between workers' perception of their risks and their actual risk (as assessed by experts on nanomaterial risk) (Cohen's kappa)

Cluster name	Indicator	Sub-indicator	Success criteria	Indicator-of-success measure
	Barriers to implementation of S(S)bD	Real and perceived barriers to implementation of S(S)bD in the nanotech sector. These have been noted as: "(i) the terminology around SbD at the start of the project (ii) the lack of data available (iii) the cost of the testing required to produce data (iv) the time invested in the planning, data gathering and interpretation (v) a clear path to demonstrate the SbD result, and (vi) the lack of regulation. " (Sanchez et al. 2020)	Reduction in barriers to implementation of S(S)bD	Proportion of barriers to S(S)bD removed or mitigated (Progress in FAIR data)
Communication	Knowledge platform	A platform that facilitates sharing of knowledge across different nanotechnology sub-sectors/areas; notably research, regulation and policy.	All knowledge-sharing functionalities of the platform are realised.	Completeness of system developed to connect research, regulatory-oriented science and policy
	Knowledge platform	Transdisciplinary and trans domain summit for regulators to encourage knowledge sharing and collaboration (survey)	Activities are carried out by regulators to encourage knowledge sharing and collaboration.	Completeness of an established knowledge platform(s) or system for knowledge sharing.

4.2.3 Web-based dashboard

The indicators would be housed on a web-based dashboard which design would help stimulate dialog around risk governance of nanotechnology. A few designs were considered such as the:

- [Scottish National Indicator Performance][8]
- [Doomsday clock][9] where "□□□□ effective risk governance is the target and how close we are to that achievement is clearly visualised."

The chosen design illustrated in Annex □ should allow users to investigate the trends in an aspect of risk governance covered by the □ clusters for which indicators have been defined.

Features of the suggested web-based dashboard include for each indicator a sheet with infographics indicating:

- The cluster to which the indicator belongs
- A short description of the indicator
- A line graph showing the performance trend of the indicator over the most recent □□year period (at least)
- A half-circle infographic showing the current status of the indicator and colour-coded (green, orange or red) to indicate how close it is to achieving a preset target, and
- An overview of all the indicators for the cluster over the most recent □□year period (at least) in the form of a heat map with six different levels (Annex □, Figure □).

The overall performance of risk governance of nanotechnology can be displayed with two different levels of detail. In both cases the dashboard would show:

- A line graph with the trend in overall performance of risk governance over the most recent □□year period.
- A colour-coded half-circle infographic to indicate the current status of risk governance of nanotechnology overall.

Additionally, it would also include one of the following:

- A list showing risk governance performance at the cluster level, e.g. this would show how each aspect of risk governance of nanotechnology (e.g. standardisation (□□□)) has performed over the most recent □□year period (Annex □, Figure □).
- A list showing how each indicator has performed over the most recent □□year period (Annex □, Figure □).

It is proposed that the dashboard be hosted on the Portal and maintained by the standing committee.

5 Evaluation and conclusions

A monitoring scheme consisting of □□ indicators that cover □ different aspects of risk governance, namely standardisation (□□□), data and data quality, innovation and governance (□□□), and communication has been designed.

The indicators are intended to provide an indication of the state of risk governance. They do not, nor are they intended to describe the full state, but regularly updating them will provide an indication of the progress of the state. As □□□□ of the data to calculate the indicators would need to be obtained via survey or using one of the automated tools discussed, it has not been possible within the project to provide initial values for the indicators.

[8] https://nationalperformance.gov.scot/measuring-progress/national-indicator-performance
[9] https://thebulletin.org/doomsday-clock/current-time/

□□□□ Implementation of the scheme will be the responsibility of whatever organisational form emerges in the post project phase. One of the considerations in deciding the scheme were that while automated scanning is favourable due to its lower resource requirements, complete automatization is not possible since input from experts (including from a house of governors) would be required to update criteria/sources of information for criteria and for maintenance of the scheme on a webpage. Likewise, surveys while relatively simple to design would require expert input for design and identification and administering to a relevant group. Therefore, considerable financial resource is still required for these first two elements. Together with the financial resource that would be required for a standing committee that would synthesize the outputs from the first two elements, the costs of establishing and maintaining the monitoring scheme would need to be carefully considered prior to its implementation.

Some redesign of the scheme and/or selection of indicators may be desirable or necessary to deal with resource limitations or to changing priorities going forward.

6 Deviations from the work plan

According to the DoA, this work package would provide a cost estimate for integrating the monitoring scheme within the □□□□ by the end of the GoNano project. However, changes to the nature of the □□□□ office in response to the Commission's request around the □□□ and the □□ Green Deal meant that an actual □□□□□ office was not be established within the timeframe of this project but that options for an organisational form will be suggested. In the absence of an actual □□□□□ office a cost estimate was not discussed in this report.

7 Performance of the partners

Partners: □□□M, □en□, □□□M □□□□□□□□□□□□M□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□ partners participated in the various meetings and workshops, including in the initial stages. Members of □□□□□□□□M has contributed to the refinement of several indicators and sub-indicators.

□□□□□□□ acted as a connection in-between what was already done in the different tasks of the □□□ and what was about to be done in task □□□□□□. □e□ participated in the different meetings and workshops organised by □□M.

8 References

□□ersen □□□□□□□□□□□ "□□tures □□in□in□ Methodologies and □□tions for □d□ation" □n □□in□ □□enarios, *Rethink Education*, □□□□ □□blishin□ □aris□ □tt□s□□□doi□or□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□en.

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Annex 1: The sub-areas identified under each area and their categorisation into clusters

Areas	Sub-areas	Cluster
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Annex 2: A database of indicators for monitoring progress of risk governance of nanotechnology

A printout of the database of indicators is provided.

WP 7.4 - A scheme for monitoring progress in implementation of risk governance of nanotechnology

Cluster **Standardisation**

Sub-area Description of novel, smart and/or advanced materials

Indicator 1.1

Reliable and relevant physico-chemical methods for regulatory risk assessment.

Sub-indicator

Investigate the methods used for identification and characterization of nanomaterials to generate the minimum data requirements

Success criteria

The minumum data requirements on identification and characterization of nanomaterials are covered by the guidelines that have been published or are under development.

Indicator-of-success metric

Proportion of the minimum data requirements on nanomaterial identification and characterisation that have been covered by published guidelines or are being considered by guidelines that are under development.

Numerator

The data requirements for identification and characterisation of nanomaterials that have been published or are under development by official bodies and standardisation committees e.g. CEN, ISO, ASTM

Sources of information for numerator

KB crawl of relevant websites e.g. CEN, ISO, ASTM, EU Nanosafety Cluster, eNanomapper

Denominator

The minimum number of data requirements required for identification and characterization of NMs for used in regulatory risk assessment.

Sources of information for denominator

Expert survey of representatives from regulatory bodies and from industry to determine the miniumum data requirements for regulatory risk assessment.

Other sources of information

na

Impact of this indicator

Facilitates monitoring of developments in identification and characterisation of nanomaterials.

Baseline_description

Baseline to be established by first running of KB crawl (or other strategic watch tool)

Frequency

annually

Target

100%

Reporting

Roundtable

Responsibility

Roundtable

Cluster **Standardisation**

Sub-area Description of novel, smart and/or advanced materials

Indicator 1.2

Reliable and relevant physico-chemical methods for regulatory risk assessment.

Sub-indicator

Investigate the uptake of standard methods for identification and characterization of nanomaterials that generate the minimum data requirements

Success criteria

Standard methods accepted and adopted by the majority (≥ 85 %) of EU members and non-EU members

Indicator-of-success metric

Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that have adopted the published guidelines for identification and characterization of nanomaterials.

Numerator

Number of DNFs in OECD countries that have adopted guidelines on characterization of nanomaterials.

Sources of information for numerator

(i) Surveys/questionnaires to monitor adoption of guidelines by OECD countries. (ii) KB crawl (or other automated monitoring software) of umbrella nanotech organisations in respective countries and OECD websites.

Denominator

Total number of DNFs in OECD countries.

Sources of information for denominator

(i) OECD's Directorate for Science Technology and Innovation (DSTI) generate data on numbers of Nanotechnology Firms, Nanotechnology R&D firms, Dedicated Nanotechnology Firms (DNFs) and Dedicated nanotechnology R&D (DNF-R&D) firms as part of their suite of Key Nanotechnology Indicators in OECD. https://www.oecd.org/sti/nanotechnology-indicators.htm (ii) Nanotechnology firm surveys. Note: DNFs are nanotechnology firms that devote at least 75% of their production of goods and services, or R&D, to nanotechnology while DNF-R&D devote at least 75% of their total R&D to nanotechnology.

Other sources of information

na

Impact of this indicator

Allows for monitoring the uptake (ease and speed) of recommended guidelines on nanomaterial characterisation.

Baseline_description

Baseline to be established by first running of the stakeholder survey and automated monitoring survey (KB Crawl)

Frequency

annually

Target

85 % within 5 years

Reporting

Roundtable

Responsibility

Roundtable

Cluster **Standardisation**

Sub-area Description of novel, smart and/or advanced materials

Indicator 1.3	Sub-indicator
Exposure (reliable and harmonized methods and models for exposure and release of nanomaterials)	Inventory of exposure models for assessing environmental and occupational exposure of nanomaterials that are used by regulatory authorities.
Success criteria	**Indicator-of-success metric**
Recommendations on exposure models must be defined and made available to the public and to stakeholders by regulators.	Proportion of publically-available exposure models for environmental and occupational exposure of nanomaterials that are based on regulatory recommendations.
Numerator	**Sources of information for numerator**
Number of regulator-recommended, nanotech-specific environmental and occupational exposure models.	KB crawl / Horizon Scanning of websites of regulatory bodies (e.g. RIVM https://www.consexponano.nl/) for information on exposure models for nanomaterials that have been recommended by regulatory bodies.
Denominator	**Sources of information for denominator**
Number of publically-available exposure models for environmental and occupational exposure of nanomaterials	Software-based monitoring instruments to monitor academic and industrial platforms. Academic: PubMed, Web of Science, Google Scholar etc. Industrial OECD reports.

Other sources of information

na

Impact of this indicator

Facilitates monitring the availability of exposure monitoring tools needed for regulatory risk assessment.

Baseline_description

Baseline to be established by first running of automated monitoring survey (KB Crawl and Horizon Scanning)

Frequency	Target
annually	100% within 5 years
Reporting	**Responsibility**
Roundtable	Roundtable

Cluster **Standardisation**

Sub-area Description of novel, smart and/or advanced materials

Indicator 1.4	Sub-indicator
Exposure (reliable and harmonized methods and models for exposure and release to nanomaterials)	Investigate the use of publically-available, regulator recommended nano-specific environmental and occupational exposure modelling tools.

Success criteria	Indicator-of-success metric
Publically-available, regulator-recommended exposure modelling tools employed by the majority (≥ 85%) of DNFs in EU members and non-EU members.	Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that employ publically-available, regulator-recommended, nano-specific environmental and occupational exposure modelling tools.

Numerator	Sources of information for numerator
Number of DNFs in OECD countries that employ publically-available, regulator-recommended, nano-specific occupational exposure modelling tools for worker exposure	Surveys/questionnaires to monitor use of regulator-recommended exposure modelling tools

Denominator	Sources of information for denominator
Total number of DNFs in OECD countries.	(i) OECD's Directorate for Science Technology and Innovation (DSTI) generate data on numbers of Nanotechnology Firms, Nanotechnology R&D firms, Dedicated Nanotechnology Firms (DNFs) and Dedicated nanotechnology R&D (DNF-R&D) firms as part of their suite of Key Nanotechnology Indicators in OECD. https://www.oecd.org/sti/nanotechnology-indicators.htm (ii) Nanotechnology firm surveys. Note: DNFs are nanotechnology firms that devote at least 75% of their production of goods and services, or R&D, to nanotechnology while DNF-R&D devote at least 75% of their total R&D to nanotechnology.

Other sources of information

na

Impact of this indicator

Allows for monitoring the uptake (ease and speed) of harmonised methods and models for exposure and release of nanomaterials. This information can be used to inform the approach for encouraging uptake of regulator-recommended, nanotech-specific methodologies.

Baseline_description

Baseline to be established by first running of the survey.

Frequency	Target
annually	100% within 5 years

Reporting	Responsibility
Roundtable	Roundtable

Cluster **FAIR data and data quality**

Sub-area FAIR databases for safety data of NMs are developed, including data quality and completeness

Indicator 2.1	Sub-indicator
EHS/FAIR data	Harmonized templates for FAIR nanosafety data (specifically for different types of experiments and for the different toxicological endpoints)

Success criteria	Indicator-of-success metric
Templates required for FAIR nanosafety data (i.e. for all types of experiments and endpoints) are inventorised and made available to relevant actors.	Proportion of the templates needed for FAIR nanosafety data for all types of experiments and endpoints that are available for use by stakeholders and other relevant actors.

Numerator	Sources of information for numerator
Number of available data templates defined as necessary	Screen databases, stakeholder surveys, expert meetings/interviews for templates that are available for use.

Denominator	Sources of information for denominator
Number of required templates	Stakeholder surveys, expert meetings/interviews e.g. Results of joint meetings of EU projects.

Other sources of information

Inventory of the number of developed templates for nanosafety data using databases such as eNanoMapper, NanoCommons database, Nikc (US).

Impact of this indicator

Available templates for FAIR nanosafety data will lead to harmonized FAIR data generation and use.

Baseline_description

Baseline to be established by first running of the survey. There are existing templates developed in earlier EU-projects (related to eNanomapper). New templates for FAIR nanosafety data were developed in WP1.

Frequency	Target
annually	100% within 3 years.

Reporting	Responsibility
Open access, freely available report	Suggestions: Organisational Form of Nano Risk Governance, NSC workgroup FAIR data, Advanced Nano IN

Cluster **FAIR data and data quality**

Sub-area FAIR databases for safety data of NMs are developed, including data quality and completeness

Indicator 2.2	Sub-indicator
EHS/FAIR data	Harmonized templates for FAIR nanosafety data (specifically for different types of experiments and for the different toxicological endpoints)
Success criteria	**Indicator-of-success metric**
Templates are used by all stakeholders	Proportion of stakeholders & stakeholder groups that use the harmonised templates required for FAIR nanosafety data.
Numerator	**Sources of information for numerator**
Number of stakeholders/stakeholder groups using the harmonized templates.	Check stakeholders/stakeholder groups that use the templates in the databases
Denominator	**Sources of information for denominator**
Number of stakeholders/stakeholder groups	Define number of stakeholders & stakeholder groups by means of surveys and interviews.

Other sources of information

Explore by means of surveys if relevant data generators use the templates.

Impact of this indicator

Available templates for FAIR nanosafety data will lead to harmonized FAIR data generation and use.

Baseline_description

There are existing templates developed in earlier EU-projects (related to eNanomapper). New templates for FAIR nanosafety data are developed in WP1.

Frequency	Target
annually	1) 100% within 3 years 2) 50% of stakeholders & 100% of stakeholder groups within 5 years
Reporting	**Responsibility**
Open access, freely available report	Suggestions: Organisational Form of Nano Risk Governance, NSC workgroup FAIR data, AdvancedNano IN

Cluster **FAIR data and data quality**

Sub-area FAIR databases for safety data of NMs are developed, including data quality and completeness

Indicator 2.3	Sub-indicator
Data completeness	• Hazard data completeness • Exposure data completeness • Physicochemical data completeness

Success criteria	Indicator-of-success metric
Completeness of hazard, exposure and physicochemical data	Data completeness score associated with key parameters

Numerator	Sources of information for numerator
#Required properties (parameters) for which there is data available	eNanoMapper, extendable to other databases; Data to be obtained by automatic computation of CSs from data available in databases.

Denominator	Sources of information for denominator
#Required properties (parameters)	Same as for numerator

Other sources of information

Impact of this indicator

A measure of data completeness is fundamental for many tasks (e.g., modelling, risk assessment). This indicator serves also as an incentive to provide more complete data and to fill gaps in databases.

Baseline_description

Frequency	Target
real time	Yearly improvement of at least xx% (note however that it is unlikely that databases of "old" projects will be updated)

Reporting	Responsibility
This indicator will be publicly available through a web application (see comments)	Automatically computed (see comments)

Cluster **Innovation and governance**

Sub-area A risk governance system for NMs is established

Indicator 3.1	Sub-indicator
Information on new innovation in nanomaterials including commercialisation for each domain; chemicals, consumer products, nanomedicine, medical devices, food and feed, biocides and cosmetics	Annual survey of new (nano)materials including advanced (multicomponent) nanomaterials and trends (e.g. patents, foresight).

Success criteria	Indicator-of-success metric
Publication of statistics on number of new products, type of nanomaterials used, applications, innovation maturity level, market readiness.	Year-on-year trends on new or advanced nanomaterials

Numerator	Sources of information for numerator
na	na

Denominator	Sources of information for denominator
na	na

Other sources of information

1) Horizon scanning, 2) foresight methods, 3) early warning system. For example new nanoproducts registered at ECHA, market analysis to detect new patents, products using nanomaterials, scientific publications, surveys or interviews on new nanomaterials, advanced materials and trends. Software-based instruments. (KB Crawl, Horizon Scanning, ...). Target web sources like: EU-OSHA's European Risk Observatory (ERO), EU Research and innovation, European Technology Platform for Advanced Engineering Materials and Technologies (EuMaT), Nanomedicine European Technology Platform (ETPN), NIA Nanotechnology Innovation Council, NNI, AZoNano, Nanowerk.

Impact of this indicator

Timely/adequate risk governance cannot be made if trends in the field are not known. Therefore, this can be a very important indicator especially to counter the ever existing policy lag on technological development.

Baseline_description

Unknown for regulators what new nanomaterials will reach the market

Frequency	Target
annually	

Reporting	Responsibility
A notification letter should be written to the authorities on nanotechnology risk regulation who can update the test procedures or regulation of nanomaterials.	Organisational Form of Nano Risk Governance / OECD / Cluster work group

Cluster **Funding and value of investment**

Sub-area Adoption of regulatory questions and needs by research funding (DOA)

Indicator 4.1	Sub-indicator
Research questions funded by funding agencies	Inventory of proposals completed that lead to guidance documents or test guidance.
Success criteria	**Indicator-of-success metric**
List of completed EU funded projects and main outcomes/Statistics on number of guidance documents obtained in completed proposals	This Indicator was not developed further. This is a placeholder for this or any indicator that would cover this area (i.e. Funding and value of investment) of risk governance for nanotechnology.
Numerator	**Sources of information for numerator**
Denominator	**Sources of information for denominator**

Other sources of information

Impact of this indicator

Baseline_description

Frequency	Target
Reporting	**Responsibility**

Cluster **S(S)bD**

Sub-area (i) A mechanism to support safe and sustainable innovation of products is established. (ii) A system for structural investment in safety research is established

Indicator 5.1	Sub-indicator
Nano specific hazard information	Academic & industrial showcases of S(S)bD
Success criteria	**Indicator-of-success metric**
An inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization) is established.	Completeness of the inventory based on evaluation by an expert committee.
Numerator	**Sources of information for numerator**
To be determined from survey	
Denominator	**Sources of information for denominator**

Other sources of information

Software-based monitoring instruments to monitor academic and industrial showcases and standardisation organisations. Academic platforms: PubMed, Web of Science, Google Scholar etc. Industrial platforms: OECD reports. Standards organisations: IEC, CEN, ISO.

Impact of this indicator

Baseline_description

This will be established following the initial run of software-based monitoring instruments and subsequent evaluation by an expert committee.

Frequency	Target
annually	100% within 3 years (i.e. inventory is established and procedures for ongoing update and evaluation is in place)
Reporting	**Responsibility**
Roundtable	Roundtable

Cluster **S(S)bD**

Sub-area (i) A mechanism to support safe and sustainable innovation of products is established. (ii) A system for structural investment in safety research is established

Indicator 5.2

Nano specific hazard information

Sub-indicator

Investigate the use of academic & industrial showcases of S(S)bD (focussed on hazard characterization) by EU and non-EU members.

Success criteria

The inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization) is used by the majority (≥ 85%) of EU members and non-EU members.

Indicator-of-success metric

The majority (>85%) of EU members and non-EU members engaged in nanotechnology utilise the inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization).

Numerator

The number of EU and non-EU members engaged in nanotechnology that utilise the inventory of academic and industrial showcases of S(S)bD

Sources of information for numerator

Software-based monitoring instruments to monitor: academic and industrial showcases; and standardisation organisations: IEC, CEN..

Denominator

The number of EU and non-EU members engaged in nanotechnology

Sources of information for denominator

(i) OECD's Directorate for Science Technology and Innovation (DSTI) generate data on numbers of Nanotechnology Firms, Nanotechnology R&D firms, Dedicated Nanotechnology Firms (DNFs) and Dedicated nanotechnology R&D (DNF-R&D) firms as part of their suite of Key Nanotechnology Indicators in OECD. https://www.oecd.org/sti/nanotechnology-indicators.htm (ii) Nanotechnology firm surveys. Note: DNFs are nanotechnology firms that devote at least 75% of their production of goods and services, or R&D, to nanotechnology while DNF-R&D devote at least 75% of their total R&D to nanotechnology.

Other sources of information

-

Impact of this indicator

Would allow determination of the extent of engagement with the principles of SSbD in the nanotech world and inform whether measures for promoting uptake are successful or need to be revised.

Baseline_description

To be determined upon first running of software-based monitoring instruments

Frequency

annually

Target

Within 3 years there is an indication that at least 85% of EU and non-EU members are engaged with S(S)bD.

Reporting

Roundtable

Responsibility

Roundtable

Cluster **S(S)bD**

Sub-area (i) A mechanism to support safe and sustainable innovation of products is established. (ii) A system for structural investment in safety research is established

Indicator 5.3	Sub-indicator
Nano specific hazard information	Investigate the adoption of S(S)bD principles
Success criteria	**Indicator-of-success metric**
S(S)bD principles have been incorporated in the design and development of nanotechnologies	Proportion of publications on new or updated nanotechnology products or services where S(S)bD principles had been integrally incorporated in the development.
Numerator	**Sources of information for numerator**
Number of publications on new or updated nanotechnologies where S(S)bD principles are integral part of the nanotechnology development.	Software-based monitoring instruments to monitor academic and industrial showcases. Platforms: Academic: PubMed, Web of Science, Google Scholar etc. Industrial OECD reports.
Denominator	**Sources of information for denominator**
Number of publications on new nanotechnologes across platforms	Software-based monitoring instruments to monitor academic and industrial showcases. Platforms: Academic: PubMed, Web of Science, Google Scholar etc. Industrial OECD reports.

Other sources of information

-

Impact of this indicator

Would give an indication of the extent of uptake of the principles of S(S)bD in the nanotech world and would inform measures for promoting uptake.

Baseline_description

This will be established following the initial run of software-based monitoring instruments and subsequent evaluation by an expert committee.

Frequency	Target
annually	100% within 3 years
Reporting	**Responsibility**
Roundtable	Roundtable

Cluster **S(S)bD**

Sub-area A mechanism is established to support implementation of safe-and-sustainable-by-design.

Indicator 5.4	Sub-indicator
Worker safety	Nano-specific worker guidelines applicable to nanomaterials. See, for instance: •OSHA (Occupational Safety and Health Administration) •WHO •CDC NIOSH (Centre for Disease Control National institute for Occupational Safety and Health)

Success criteria	Indicator-of-success metric
Risk prevention guidelines, trainings and workshops are employed to increase workers' awareness on safety with regards to nanomaterial-related work.	Proportion of nanotechnology companies that use nanomaterial-specific risk prevention guidelines, trainings and workshops to increase workers' awareness on safety during nanomaterials-related work.

Numerator	Sources of information for numerator
Number of nanotechnology firms using nano-specific risk prevention guidelines, trainings and workshops on worker safety in the nanotech environment.	Surveys/questionnaires targeted at DNFs in OECD countries to determine the extent of use of nanotechnology-specific trainings in the sector (above and beyond that employed for conventional chemicals).

Denominator	Sources of information for denominator
Total number of nanotechnology companies in OECD countries	(i) OECD's Directorate for Science Technology and Innovation (DSTI) generate data on numbers of Nanotechnology Firms, Nanotechnology R&D firms, Dedicated Nanotechnology Firms (DNFs) and Dedicated nanotechnology R&D (DNF-R&D) firms as part of their suite of Key Nanotechnology Indicators in OECD. https://www.oecd.org/sti/nanotechnology-indicators.htm (ii) Nanotechnology firm surveys. Note: DNFs are nanotechnology firms that devote at least 75% of their production of goods and services, or R&D, to nanotechnology while DNF-R&D devote at least 75% of their total R&D to nanotechnology.

Other sources of information

-

Impact of this indicator

Would give an indication of the extent of practical implementation of S(S)bD in the sector.

Baseline_description

Baseline to be established by first run of the survey

Frequency	Target
annually	100% within 3 years

Reporting	Responsibility
Roundtable	Roundtable

Cluster S(S)bD

Sub-area A mechanism is established to support implementation of safe-and-sustainable-by-design.

Indicator 5.5

Risk perception

Sub-indicator

Workers perceived risks of nanomaterials they handle (vs. what an expert would conclude on their risks).

Success criteria

Workers' risk perception accurately reflect their level of risks in the workplace.

Indicator-of-success metric

Agreement between workers' perception of their risks and their actual risk (as assessed by experts on nanomaterial risk) (Cohen's kappa)

Numerator

na

Sources of information for numerator

na

Denominator

na

Sources of information for denominator

na

Other sources of information

(i) Survey targeting workers within nanotechnology sectors. Accessed through industry channels e.g. trade unions (ii) Survey targeting nanotech safety experts within Health and Safety establishments in industry and national bodies.
(iii) Risk assessment nanotech-related literature.

Impact of this indicator

Accurate perception of occupational risk is linked to ability to identify source of hazards in the workplace.
Gives an indication of workers' trust in control measures implemented for their safety.

Baseline_description

Baseline to be established by first run of the surveys

Frequency

annually

Target

0.7 to 1 within 3 years

Reporting

Roundtable

Responsibility

Roundtable

Cluster **S(S)bD**

Sub-area A mechanism is established to support implementation of safe-and-sustainable-by-design.

Indicator 5.6

Barriers to implemenation of S(S)bD

Sub-indicator

Real and perceived barriers to implementation of S(S)bD in the nanotech sector. These have been noted as:(i) the terminology around SbD at the start of the project (ii) the lack of data available (iii) the cost of the testing required to produce data (iv) the time invested in the planning, data gathering and interpretation (v) a clear path to demonstrate the SbD result, and (vi) the lack of regulation. (Sanchez et al. 2020)

Success criteria

Reduction in barriers to implementaion of S(S)bD

Indicator-of-success metric

Proportion of barriers to S(S)bD removed or mitigated (Progress in FAIR data)

Numerator

na

Sources of information for numerator

na

Denominator

na

Sources of information for denominator

na

Other sources of information

Surveys/questionnaires to monitor extent of real and perceived barriers

Impact of this indicator

Monitor progress of measures taken to promote or ease the way for the principles of S(S)bD to be adopted.

Baseline_description

Baseline to be established by first running of the survey.

Frequency

annually

Target

100% within 3 years

Reporting

Roundtable

Responsibility

Roundtable

Cluster **Communication**

Sub-area A system is developed to connect research, regulatory oriented science and policy

Indicator 6.1	Sub-indicator
Knowledge platform	A platform that facilitates sharing of knowledge across different nanotechnology sub-sectors/areas; notably research, regulation and policy.
Success criteria	Indicator-of-success metric
All knowledge-sharing functionalities of the platform are realised.	Completeness of system developed to connect research, regulatory-oriented science and policy
Numerator	Sources of information for numerator
Actual score from the survey	Annual stakeholder survey
Denominator	Sources of information for denominator
Maximum for the score from the survey (5 for each question)	Annual stakeholder survey

Other sources of information

Surveys to determine: (i) Number of experts that view it as complete (ii) Level of completeness as assessed by experts ; Platforms supported by national bodies and/or EU commission…

Impact of this indicator

Providing confidence to stakeholders that the system is working

Baseline_description

Baseline to be established by first running of the survey

Frequency	Target
annually	100% complete within 3 years
Reporting	Responsibility
Roundtable	Roundtable

Cluster **Communication**

Sub-area A mechanism is established to prove, communicate and have information on product safety

Indicator 6.2

Knowledge platform

Sub-indicator

Transdisciplinary and trans domain summit for regulators to encourage knowledge sharing and collaboration (survey)

Success criteria

Activities are carried out by regulators to encourage knowledge sharing and collaboration.

Indicator-of-success metric

Completeness of an established knowledge platform(s) or system for knowledge sharing.

Numerator

Actual score from the survey

Sources of information for numerator

Annual stakeholder survey

Denominator

Maximum for the score from the survey (5 for each question)

Sources of information for denominator

Annual stakeholder survey

Other sources of information

Surveys to determine: (i) Number of experts that view it as complete (ii) Level of completeness as assessed by experts ; Platforms supported by national bodies and/or EU commission…

Impact of this indicator

Providing confidence to stakeholders that the system is working

Baseline_description

Baseline to be established by first running of the survey

Frequency

annually

Target

100% complete within 1.5 years

Reporting

Roundtable

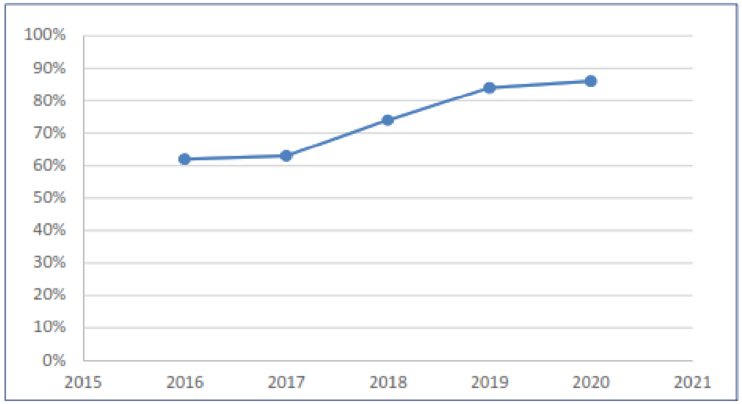
Responsibility

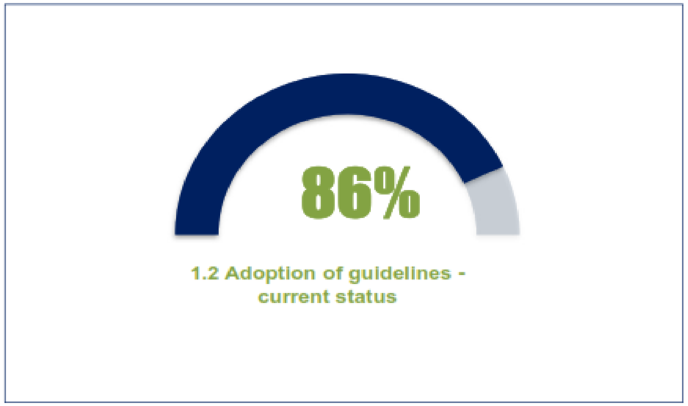
Roundtable

Annex 3: Suggested design for a web-based dashboard

Cluster 1: Standardisation

Indicator 1.2: Proportion of DNFs in OECD countries that have adopted the published guidelines for identification and characterization of nanomaterials.





Five-year performance trends of all 4 indicators under cluster 1: standardisation

	2016	2017	2018	2019	2020	Target
1.1 Proportion of the minimum data requirements on nanomaterial identification and characterisation that have been covered by published guidelines or are being considered by guidelines that are under development.	55%	60%	70%	80%	80%	100%
1.2 Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that have adopted the published guidelines for identification and characterization of nanomaterials.	62%	63%	74%	84%	86%	85%
1.3 Proportion of publically-available exposure models for environmental and occupational exposure of nanomaterials that are based on regulatory recommendations.	45%	60%	75%	79%	80%	100%
1.4 Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that employ publically-available, regulator-recommended, nano-specific environmental and occupational exposure modelling tools.	50%	65%	65%	80%	80%	85%
Risk governance performance with regards to standardisation	57%	67%	77%	87%	88%	100%

Data sources denominator: https://www.oecd.org/sti/KNI1-number-of-firms-active-in-nanotech-2022.xlsx

Data sources numerator: **Fictional data and meant for illustrative purposes only!!**

Figure A3.1: Suggested design for web-based dashboard for each indicator indicating most recent trends in its performance, its current status and the status of other indicators in the cluster that the indicator belongs

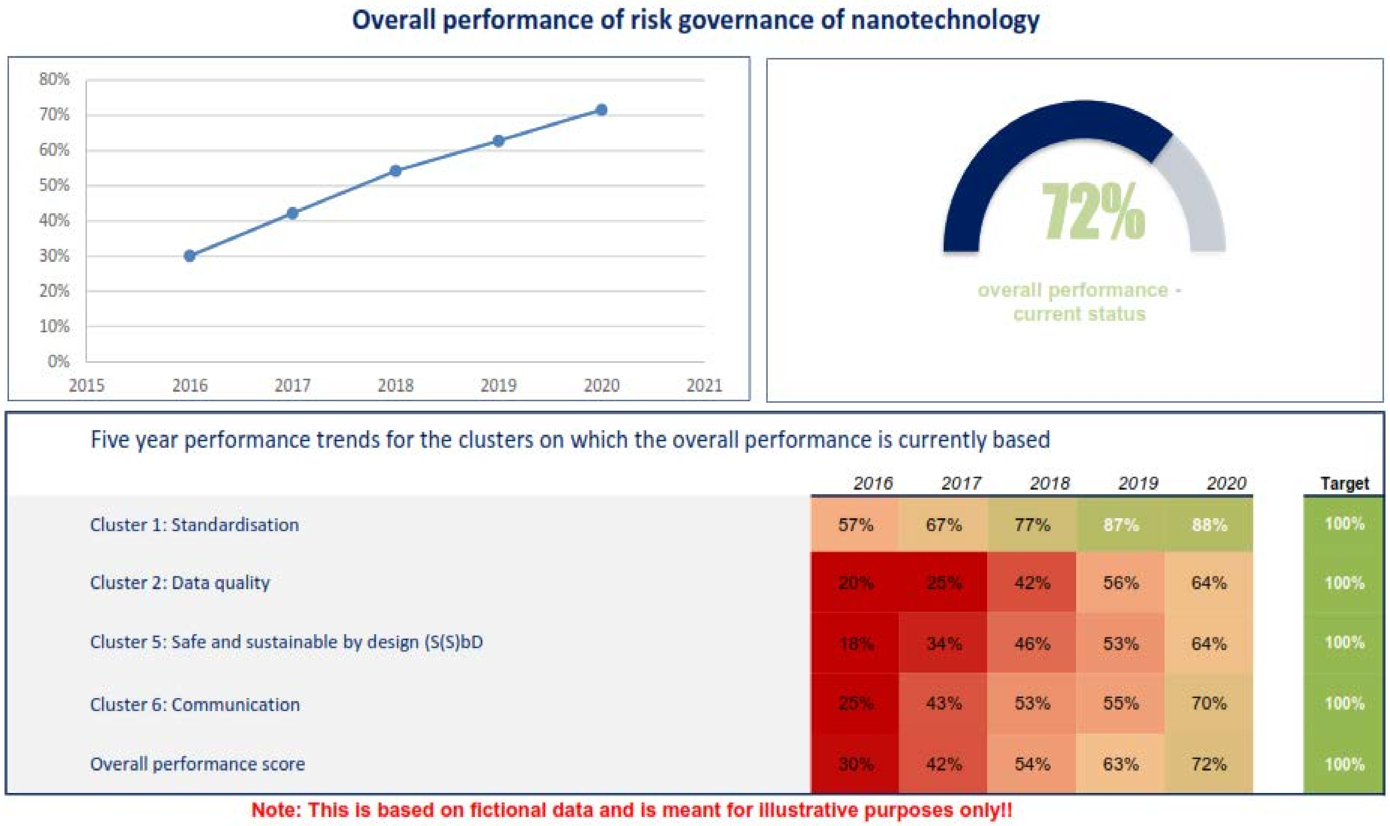
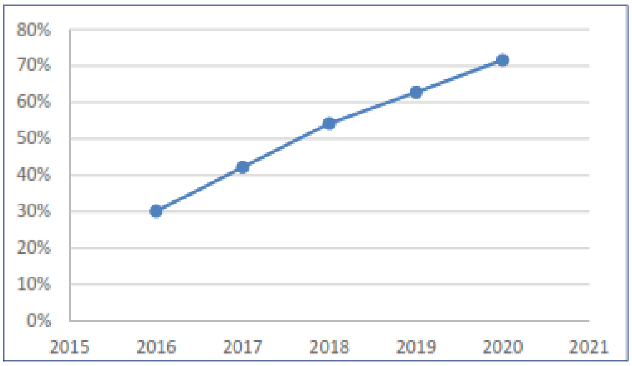
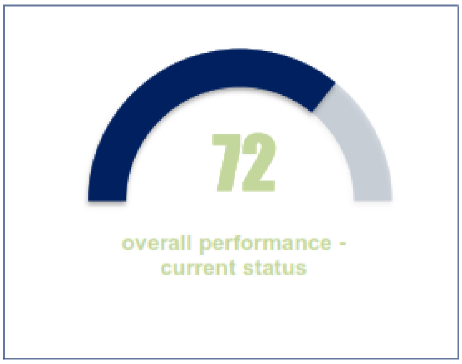


Figure A3.2: Suggested design for a web-based dashboard with infographics displaying most recent trends in overall performance of risk governance of nanotechnology, current status and, performance trends for each of the clusters used to monitor overall progress

Overall performance of risk governance of nanotechnology





Five year trends for the indicators on which the overall performance is currently based

	Indicator	2016	2017	2018	2019	2020	Target
1.1	Proportion of the minimum data requirements on nanomaterial identification and characterisation that have been covered by published guidelines or are being considered by guidelines that are under development.	55%	60%	70%	80%	80%	100%
1.2	Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that have adopted the published guidelines for identification and characterization of nanomaterials.	62%	63%	74%	84%	86%	85%
1.3	Proportion of publically-available exposure models for environmental and occupational exposure of nanomaterials that are based on regulatory recommendations.	45%	60%	75%	79%	80%	100%
1.4	Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that employ publically-available, regulator-recommended, nano-specific environmental and occupational exposure modelling tools.	50%	65%	65%	80%	80%	85%
2.1	Proportion of the templates needed for FAIR nanosafety data for all types of experiments and endpoints that are available for use by stakeholders and other relevant actors.	25%	35%	50%	60%	65%	100%
2.2	Proportion of stakeholders & stakeholder groups that use the harmonised templates required for FAIR nanosafety data.	25%	30%	45%	68%	68%	100%
2.3	Data completeness score associated with key parameters	0.1	0.1	0.3	0.4	0.6	1
5.1	Completeness of the inventory of academia and industrial showcases fof of S(S)bD	0.2	0.45	0.5	0.55	0.6	1
5.2	The proportion of EU members and non-EU members engaged in nanotechnology utilise the inventory of academic and industrial showcases of S(S)bD (focused on hazard characterization).	10%	25%	30%	25%	40%	85%
5.3	Proportion of publications on new or updated nanotechnology products or services where S(S)bD principles had been integrally incorporated in the development.	20%	25%	35%	50%	65%	100%
5.4	Proportion of nanotechnology companies that use nanomaterial-specific risk prevention guidelines, trainings and workshops to increase workers' awareness on safety during nanomaterials-related work.	15%	35%	55%	65%	75%	100%
5.5	Agreement between workers' perception of their risks and their actual risk (as assessed by an experts on nanomaterial risk) (Cohen's kappa)	0.20	0.40	0.50	0.50	0.70	1
5.6	Proportion of identified barriers to S(S)bD removed or mitigated (Progress in FAIR data)	20%	30%	50%	65%	65%	100%
6.1	Completeness of system developed to connect research, regulatory-oriented science and policy	30%	35%	45%	50%	65%	100%
6.2	Completeness of an established knowledge platform(s) or system for knowledge sharing.	20%	50%	60%	60%	75%	100%
	Overall performance score	30%	42%	54%	63%	72%	100%

Note: This is based on fictional data and is meant for illustrative purposes only!!

Figure A3.3: Suggested design for a web-based dashboard with infographics displaying most recent trends in overall performance of risk governance of nanotechnology, current status and, performance trends for each of the indicators used to monitor overall progress

Annex 4: Addendum - Provisional estimate of the baseline of risk governance monitoring dashboard based on an informal survey of experts.

Background: □nder t□e ori□ina□□o□ for tas□□□□it was □ro□osed t□at we test t□e □ro□ress □onitorin□s□ste□ t□at wo□ld be de□e□o□ed□in□□din□establis□in□a baseline for as □an□of t□e indi□ators as □ossible□□□is wo□ld □a□e fallen □nder t□e re□it of t□e □□□□ □ad s□□□an or□anisation been establis□ed □nder □or□□a□□a□e □as ori□ina□□□ intended□□owe□er□in t□e absen□e of a □□□□□or an alternati□e or□anisational for□□we □a□e de□e□o□ed a *Provisional estimate of the baseline of risk governance monitoring dashboard of nanomaterials* based □ri□ari□□on an infor□a□s□r□e□of e□□erts t□at attended t□e □[□] and fina□□o□□□ano □onsorti□□ □eetin□in □o□e on □□□□□[□] □ebr□ar□ □□□□□□□e re□ort on t□e o□t□o□e of t□at e□er□ise in t□is addend□□ to t□e de□i□erable □□□□□

Aim□□□e obje□ti□e was to obtain a □ro□isional baseline of t□e stat□s of ris□□o□ernan□e of nano□aterials b□s□r□e□in□e□□erts in t□e field□

Method□□ollowin□fa□iliarisation wit□indi□ators □nder ea□□ □l□ster and t□eir e□□e□ted o□era□i□□a□t on ris□□o□ernan□e□□arti□i□ants at t□e □[□] □o□□□ano □onsorti□□ □eetin□ □□o□e□□□□□□[□] □ebr□ar□□□□□□were re□□ested to assess t□eir stat□s b□res□ondin□to t□e followin□□□estions□

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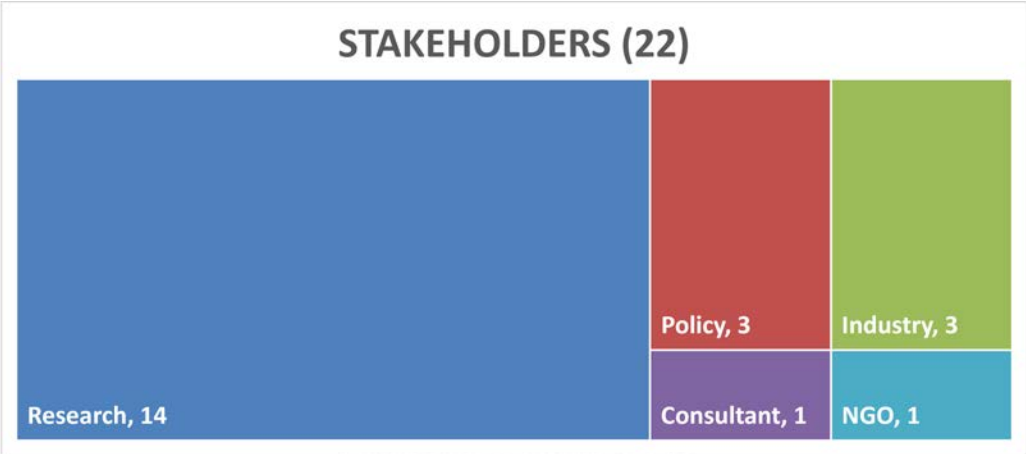
[illegible] The proportion of [illegible] members and non-[illegible] members engaged in nanotechnology that utilise the inventory of academic and industrial showcases of [illegible] focused on hazard characterization.

[illegible] The proportion of publications on new or updated nanotechnology products or services where [illegible] principles had been integrally incorporated in the development.

[illegible] The agreement between workers' perception of their risk and their actual risk as assessed by experts on nanomaterial risk [illegible].

In addition to this exercise an evaluation of the data completeness indicator was carried out using the tool developed by [illegible] as a collaboration between [illegible] and [illegible].[10][11] This tool that falls under the [illegible] data and data quality cluster calculates a data completeness score associated with the parameters that is evaluated based on the physicochemical and hazard data currently in the eNanoMapper database using an algorithm. It is fully automated and continuously updated and as such does represent the actual status of the indicator.

Results and findings: Of the [illegible] participants present, [illegible] responded. Not surprisingly given the nature of the conference, most respondents were from the research sector, followed by policy and industry players.



At least [illegible] responses were received for five of the [illegible] questions pertaining to progress monitoring indicators and no response for [illegible] ([illegible]).

The responses suggest that the aspect of risk governance closest to target is *the availability of FAIR nanosafety data templates to stakeholders and other relevant groups'* with [illegible] respondents estimating that more than [illegible] of the needed templates are available. This was not equalled by their assessment of the use of those templates with a[illegible] respondents to [illegible] indicating that they believed that under [illegible] of stakeholders used the templates and most [illegible] believed this to be less than [illegible]. This indicates the need for better dissemination/awareness of existing templates or assessment of their useability and/or accessibility to stakeholders ([illegible]).

Responses to questions around [illegible] suggest that engagement with the principles of [illegible] and its implementation is seen as low. Most rated the extent of engagement or implementation as less than [illegible] and the majority of these were estimated as less than [illegible]. This speaks to the usefulness of the related indicator (not used in this survey) that calls for monitoring the removal or mitigation of barriers to [illegible] ([illegible]).

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[10] Basei G, Rauscher H, Jeliazkova N, Hristozov (2022). A methodology for the automatic evaluation of data quality and completeness of nanomaterials for risk assessment purposes. NANOTOXICOLOGY 2022: 16(2) 195-216

[11] https://completeness-monitor.greendecision.eu/

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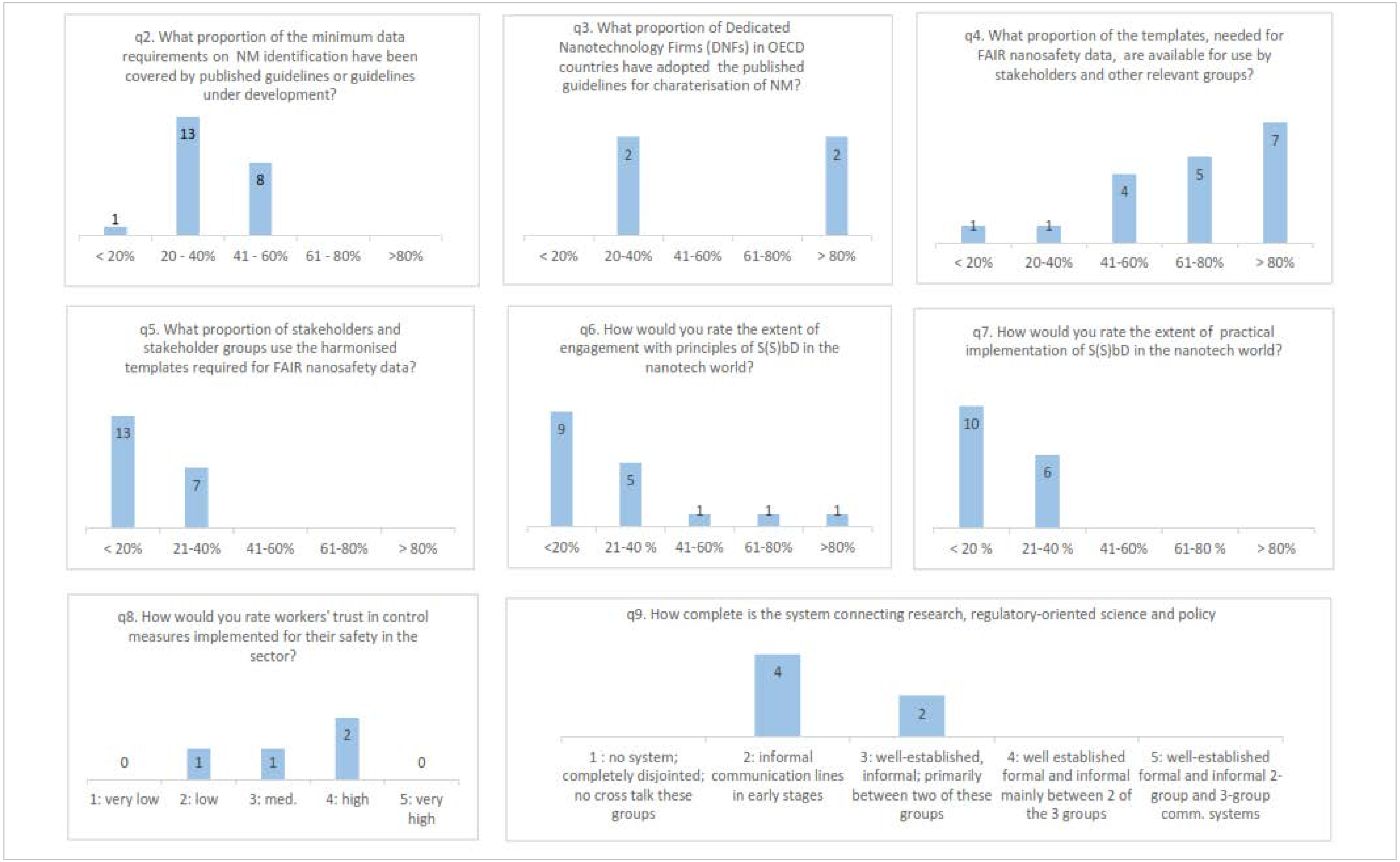

Figure A4.1: Overview of responses on four aspects of risk governance of nanomaterials (Standardisation (q2, q3), FAIR data and data quality (q4. q5), S(S)bD (q6, q7, q8), and Communication (q9)

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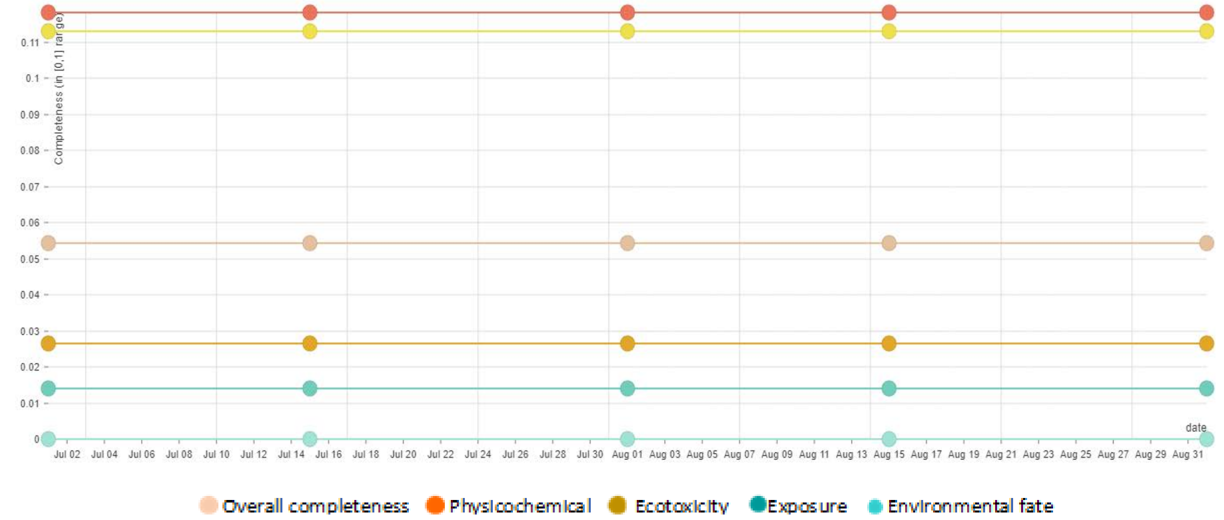

Figure A4.2: Overall completeness score

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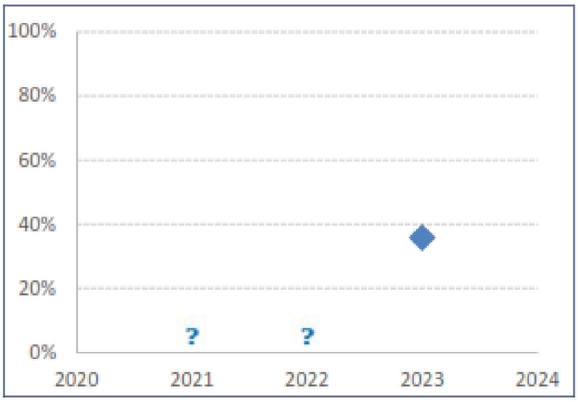
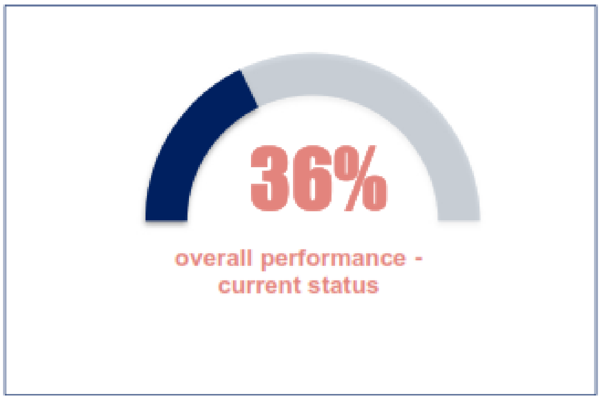
Overall performance of risk governance of nanotechnology





Overall performance based on **informal survey of experts on select indicators**

		March 2023	**Target**
q2	Proportion of the minimum data requirements on nanomaterial identification and characterisation that have been covered by published guidelines or are being considered by guidelines that are under development.	36%	100%
q3	Proportion of Dedicated Nanotechnology Firms (DNFs) in OECD countries that have adopted the published guidelines for identification and characterization of nanomaterials.	60%	85%
q4	Proportion of the templates needed for FAIR nanosafety data for all types of experiments and endpoints that are available for use by stakeholders and other relevant actors.	68%	100%
q5	Proportion of stakeholders & stakeholder groups that use the harmonised templates required for FAIR nanosafety data.	17%	100%
q6	How would you rate the extent of engagement with principles of S(S)bD in the nanotech world?	27%	85%
q7	How would you rate the extent of practical implementation of S(S)bD in the nanotech world?	18%	100%
q8	On a scale of 1 to 5 (1 being the least), how would you rate workers' trust in control measures implemented for their safety in the sector?	55%	100%
q9	Completeness of system developed to connect research, regulatory-oriented science and policy.	37%	100%
	Completeness of hazard, exposure and physicochemical data (FAIR data and data quality)	5%	100%
	Overall performance score	36%	100%

Figure A4.3: Overall performance of risk governance of nanotechnology based on 9 of the 16 indicators from the progress monitoring system