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Gov4Nano
meeting the needs of nanotechnology

Deliverable Report

Deliverable D7.3	Selected monitoring instruments and recommendations for their implementation
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Abbreviations and acronyms

Acronym	Description
AHP	Analytical Hierarchy Process (MCDA method)
API	Application Programming Interface
APM	Adaptative Policymaking
ASTM	American Society for Testing and Materials
CAGR	Compound Anual Growth Rate
CEN	European Committee for Standardization
CIP	Competitiveness and Innovation Programme
CSR (index)	Corporate Social Responsibility
DG	Directorate-General
EHS	Environmental, Health and Safety
EIC	Enhanced European Innovation Council
ELECTRE	Elimination and Choice Expressing Reality (MCDA method)
EU	European Union
EUON	European Union Observatory for Nanomaterials
FAIR	Findable, Accessible, Interoperable and Re-usable
FAO	Food and Agriculture Organization of the United Nations
FET	Future and Emerging Technologies
FP7	Framework Programme 7
FSA	Food Standard Agency
GM	Genetically modified
HEAL	Health and Environment Alliance
IEC	International Electrotechnical Commission
IRGC	International Risk Governance Council
ISO	International Organization for Standardization
JRC	Joint Research Center
M&E	Monitoring and Evaluation
MAUT	Multi-attribute utility theory (MCDA method)
MCDA	Multiple-Criteria Decision Analysis
NM	Nanomaterials
NRGC	Nano Risk Governance Council
OECD	Organisation for Economic Co-operation and Development
PROMETHEE	Preference Ranking Organization Method for Enrichment of Evaluation (MCDA method)
REACH	Registration, Evaluation, Authorization and restriction of Chemicals (Regulation (EC) nº 1907/2006)
RSS	Really Simple Syndication
RTD	Real-Time Delphi
SCCS	Scientific Committee on Consumer Safety
SMART	Specific, Measurable, Achievable, Relevant and Time bound
SME	Small and Medium Enterprise
SWOT or TOWS	Strength, Weaknesses, Oportunities and Threats
S(S)bD	Safer-and-Sustainable by Design
SWCNT	Single-Walled Carbon Nanotubes
TDMA	Titanium Dioxide Manufacturers
URL	Uniform Resource Locator
USD	United States Dollar
WP	Work Package
WPMN	Working Party on Manufactured Nanomaterials
WSM	Weighted Sum Method (MCDA method)

1 Summary

In Task 7.2 a monitoring and evaluation (M&E) system was developed to establish the criteria to be used by the Nano Risk Governance Council (NRGC) to monitor its progress and impact indicators. When the NRGC is formed, this M&E system will ensure that the NRGC periodically assesses its own performance and improves the outputs, outcomes and impacts of the activities it performs.

The M&E system includes different areas which were defined based on trends and factors for the development of the NRGC design, so the performance of the risk governance field could be monitored. The 6 areas of interest were:

- Risk management and risk assessment,
- Risk governance,
- Rules and regulations,
- Innovation and sustainability,
- Research, and
- Stakeholders.

All these areas were grouped in 6 different clusters, which include the defined indicators and sub-indicators to be monitored and evaluated by the NRGC. The 6 clusters consisted of:

- Standardization,
- FAIR data and data quality,
- Risk governance and innovation,
- Funding and value of investment,
- Safer-and-Sustainable by Design (S(S)bD)[1], and
- Communication.

The main goal of Task 7.3 is the definition of success criteria and the identification of potential instruments for monitoring and evaluating each of the indicators and sub-indicators already defined. To this end, a publicly available data and bibliographic search of existing instruments in the market was required. This deliverable summarizes the results of such search, together with examples of applicability of such instruments to monitor and evaluate the defined indicators in previous activities within the GOV4NANO project.

Among the identified instruments for monitoring and evaluation of the defined indicators and sub-indicators, we can find:

- Software-based instruments (e.g. KB Suite or Horizon Scanning).
- Market analysis.
- Surveys / Questionnaires.
- Expert committee / expert opinions (including the use of the Real Time Delphi methodology).

The proposed M&E system in task 7.2 will be tested in future steps (within task 7.4). Each of these steps are necessary to make the monitoring more specific and tangible.

[1] The “sustainability“ dimension was considered relevant during the development of GOV4NANO project Therefore, it has been additionally included as part of the clusters’ categories.

2 Description of task

The goal of Task 7.3 is to identify instruments that the NRGC can use to monitor scientific evidence and emerging needs, and to continuously evaluate not only progress in risk governance across sectors, but also its own agility for governance initiatives. Task 7.2 established a list of indicators and sub-indicators related to six clusters covering the different areas of interest for the development of the NRGC design. Task 7.3 builds upon the work performed in Tasks 7.1 and 7.2, defining the parameters, success criteria and instruments for monitoring and evaluating these sub-indicators.

A list of monitoring instruments has been created as a toolbox in this task, and these instruments have been analysed to identify strengths and weaknesses for each of them in terms of their capacity and suitability to address monitoring needs across the target regulatory sectors (i.e., chemicals, biocides, cosmetics, food, medicine). The instruments identified in this deliverable comprise manual or automated website scanning tools, market analysis tools, surveys and questionnaires, expert opinion/committees, and risk assessment tools between others. Existing and innovative methods and tools, such as Horizon Scanning, KB Suite, Multiple-Criteria Decision Analysis, Delphi method, OECD Trustlab, Corporate Social Responsibility Index or Blockchain will be described and assessed in this deliverable.

This task also aims to prioritise which indicators and monitoring instruments to apply as part of the "monitoring dashboard" of the NRGC (Task 7.4).

3 Description of work and methodology

3.1 Background of the task

A monitoring and evaluating (M&E) system was previously developed in Task 7.2 to enable the future Nano Risk Governance Council (NRGC) to monitor its progress and impact. Areas were defined based on trends and factors for the development of the NRGC design, so that the performance of the risk governance field could be monitored. The six areas (defined within WP5) consisted of: 1) risk management and risk assessment, 2) risk governance, 3) rules and regulations, 4) innovation and sustainability, 5) research and 6) stakeholders. Within these areas, twenty-two sub-areas were identified and aligned to topics from the International Risk Governance Council (IRGC) and user needs developed in deliverable 6.2. These were then grouped into six clusters consisting of: standardization (cluster 1), FAIR data and data quality (cluster 2), Safe-and-Sustainable-by-Design (S(S)bD) (cluster 3), risk governance and innovation (cluster 4), funding and value of investment (cluster 5) and communication (cluster 6).

The indicators were formulated in order to demonstrate progress in a transparent way, tuned to the broad spectrum of stakeholders and disciplines and functional to the tasks of the NRGC. The sub-indicators, included under each indicator, were developed using SMART (Specific, Measurable, Achievable, Relevant and Time bound) criteria.

Table 1: Summary of number of indicators and sub-indicators for each defined cluster.

Cluster	Title	Number of indicators
1	Standardization	11 indicators / 24 sub-indicators
2	Data quality	6 indicators / 12 sub-indicators
3	Innovation and governance	8 indicators / 17 sub-indicators
4	Funding & Value of Investment	7 indicators / 10 sub-indicators
5	S(S)bD	14 indicators / 30 sub-indicators
6	Communication	7 indicators / 18 sub-indicators

3.2 Description of the work carried out and the methodology

In this task, several instruments potentially useful to monitor and evaluate the different indicators and sub-indicators within the different cluster have been identified. Moreover, it has been defined the success criteria for each one of the sub-indicators and assigned to each one the most suitable tools for its monitoring. Finally, a prioritisation of the different sub-indicators in terms of relevance and ease of implementation has been performed to support future steps with the monitoring and evaluation process (task 7.4).

3.2.1 Identification and assessment of M&E tools

The different tools described and evaluated in this report were identified in bibliographic searches of existing instruments in the market and during brainstorming activities in internal meetings between the partners involved in WP7 – Task 7.3. The several instruments identified were discussed with the "Task 7.3 – Core Group" deciding on the monitoring system, and later presented and discussed with the Consortium partners. The members of the "Task 7.3 – Core Group" are detailed under Section 7 of this document.

The identified instruments were divided in different categories: manual or automated website scanning tools, market analysis tools, surveys and questionnaires, expert opinion/committees… Tools were selected and evaluated following the following criteria: ready to use, cost, easiness to use, efficiency, and previous use in monitoring by other policy-making institutions.

3.2.2 Defining success criteria for each sub-indicator

In order to establish which instruments could be used for monitoring each sub-indicator, it was necessary to set the success criteria for each one of them. Hence, it was required to define the metrics to be measured, when possible, to determine that the indicators and/or sub-indicators

have been successfully monitored and evaluated. The analysis of the different indicators and sub-indicators, grouped in 6 clusters, were performed individually, and discussed inside the core working group in charge of this task. The defined success criteria are shown in Tables 10-15 in section 4.2.2.

3.2.3 Assigning M&E instruments to the different indicators

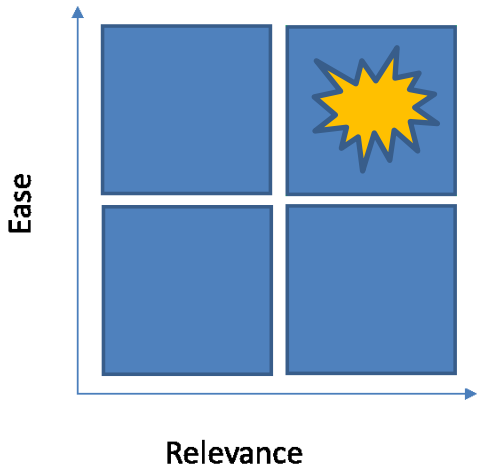
An individual analysis of each indicator and sub-indicator was also performed and compared to the list of identified tools in order to determine which instruments (if any) could be suitable for its monitoring. The assignation of tools was discussed inside the core working group and presented to the rest of the WP7 – Task 7.3 partners for feedback. Also, a SLIDO activity was carried out during the 5th Consortium Meeting (12th-13th April 2021) to collect the opinion and get feedback from all partners involved in task 7.3. The results for this activity can be found in the Annexes section.

The tools assigned to each indicator and sub-indicator are shown in Tables 10-15 in section 4.2.2. When required, we divided the instruments in monitoring or evaluation tools.

3.2.4 Prioritisation of indicators

For the prioritisation of the different indicators and sub-indicators a scoring system was developed based on ease of implementation and relevance of the indicators. In terms of ease of implementation, we have considered as factors: the availability of data, the availability of an existing instrument and availability of existing measure. Relevance is measured against the number of actors/processes influenced by that indicator: relevant to the process of risk governance, to the council or to stakeholders. All factors are equivalent in weighting and are scored from 1 to 5, being 1 the lowest relevance and ease value and 5 the maximum. The final score for an indicator is obtained by adding the points scored for each factor, being a scoring of 30 the maximum. Indicators with the highest ease and relevance will be prioritised to be tested in future steps within task 7.4.

Figure 1: Representation of the criteria for prioritisation of indicators



4 Results

4.1 Overview of monitoring instruments that could be of value for the NRGC Monitoring and Evaluation (M&E) System

The WP7 – Task 7.3 working group has identified potential instruments which could help the NRGC to monitor and evaluate the success criteria of the established indicators and sub-indicators. The identified instruments or tools have been divided in different categories: manual or automated website scanning tools, market analysis tools, surveys and questionnaires and expert

opinion/committees. Below each instrument has been described and its suitability to be applied to the M&E process has been evaluated by identifying strengths and weaknesses in terms of its capacity to address monitoring needs and minimum data requirements across the target regulatory sectors.

4.1.1 Manual / Automated website scanning

One of the identified categories includes instruments where the search, in a manual or automated way, of specific keywords is required.

Plenty of software-based instruments are available in the market. Within this section, the analysis has been focused on ***KB Suite***, a professional tool used by INERIS for monitoring of any changes or news related to nanomaterials, the ***Horizon Scanning*** tool and the ***Innovation Radar Platform***.

4.1.1.1. KB Suite

Interest of strategic watch solutions for indicator's monitoring

A strategic watch tool could be an interesting solution to measure certain defined sub-indicators. For more than 10 years, INERIS has set up a thematic watch activity, based on the professional monitoring tool of the KB Crawl company, called KB Suite (https://www.kbcrawl.com/en/solutions-en/).

KB Suite is a price tagged strategic intelligence (commercial) solution that allows to process the entire information chain, from collection, through analysis, to distribution. It is composed of 3 modules: Crawler, Pilot and Platform.

Crawler is a solution for automating the collection and processing of multiple information sources:

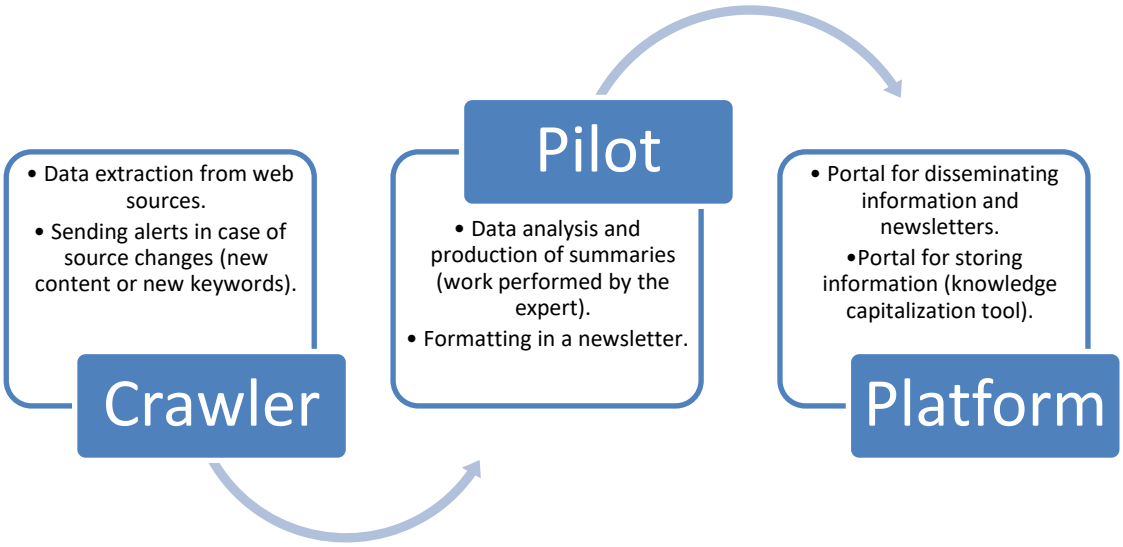
- Track multiple types of sources (URL, website, blog, social networks, RSS, databases, etc.),
- Define what needs to be monitored on the source (for example: any new content or specific keywords),
- Target the desired surveillance areas on the site,
- Schedule monitoring and alerts.

This tool, thus, allows monitoring updates from a set of pre-selected and integrated information sources on the Internet. The system sends e-mail alerts when changes have been made to a source, such as the publication of a new article or the appearance of a new keyword. The intervention of an expert is then required to process the alerts and select the relevant information.

At this stage of the monitoring cycle, the other modules are useful. Pilot allows you to edit information, classify it, summarize it (if necessary) and format it in a deliverable such as a newsletter. Finally, Platform provides a portal to disseminate information.

These three elements are presented below in the global diagram of the monitoring process of the KB Crawl solution:

Figure 2: Global diagram of the monitoring process of KB Suite



Other strategic intelligence solutions exist on the market, price tagged or free, among which we can cite, as examples, the following:

- AMI Enterprise Intelligence (https://www.bertin-it.com/en/intelligence/enterprise-intelligence-solution-veille-strategique-intelligence-competitive/);
- Digimind (https://www.digimind.com/market-intelligence);
- KeyWatch (https://www.iscope.fr/en/keywatch/).
- Inoreader (https://www.inoreader.com/).

Note that these solutions may cost in a range of 15,000.00 and 50,000.00 euros per year.

KB Suite allows users to monitor social networks (social media monitoring), but within certain limits. The tool gives privileged access to two social networks, Twitter and YouTube. For example, keywords can be monitored in Twitter and YouTube, or follow the timeline of a Twitter user or a YouTube channel. However, it should be noted that Twitter provides limited access to its content through the APIs that the company makes available (only 1% of public messages posted). Some specialized social media monitoring platforms, such as Meltwater (https://www.meltwater.com/en), Visibrain (https://www.visibrain.com/en/) or Talkwalker (https://www.talkwater.com/), have entered into a partnership with Twitter guaranteeing them access to all Twitter content (also called "firehose"). It is not the case with KB Suite, in the sense that KB Suite can only access a part of the content. Therefore, this tool does not allow exhaustive monitoring of Twitter. In addition, monitoring keywords on Facebook is also not possible through that tool.

So, KB Crawl can only allow a partial social media monitoring. Therefore, the complementary use of other tools would be needed to ensure a real exhaustive monitoring.

Examples of sources which can be monitored

The sub-indicators that may be monitored by this tool are those for which sources of information can be identified beforehand. The question to be asked would therefore be "which websites, RSS feeds, social networks, etc. can regularly provide the NRGC updated information on a specific topic?". Then, it must be made sure that the source of information can technically speaking be monitored.

As an example, the following websites have been identified as relevant information sources to monitor the number of new standards published:

Table 2: Example of sources to monitor the number of new standards published

Standardization organization	Technical committee	Source name	URL or RSS feed
ISO	ISO/TC 229 - Nanotechnologies	Standards and projects (RSS feed)	https://www.iso.org/fr/contents/data/committee/38/19/381983.catalogue.rss
CEN	CEN/TC 352 - Nanotechnologies	Published standards	https://standards.cen.eu/dyn/www/f?p=204:32:0:::FSP_ORG_ID,FSP_LANG_ID:508478,25&cs=18E152154F73BA190A16C4D279047F5FD
IEC	IEC/TC 113 – Nanotechnology for electrotechnical product and systems	TC 113 Publications	https://www.iec.ch/dyn/www/f?p=103:22:4510325757250::::FSP_ORG_ID,FSP_LANG_ID:1315,25
ASTM	ASTM International – TC E56 Nanotechnology	Standards and Work items for Committee E56	https://www.astm.org/RSS/COMMITTEES/E56.rss

The following websites have been identified as relevant information sources to identify new test guidelines applicable to nanomaterials:

Table 3: Example of sources to monitor the number of new test guidelines applicable to nanomaterials published

Organization	Source name	URL
OECD	Publications in the Series on the Safety of Manufactured Nanomaterials	http://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm
EUON	Overview of REACH information requirements and available methods	https://euon.echa.europa.eu/fr/reach-test-methods-for-nanomaterials

Example of a newsletter produced with KB Suite's monitoring tool

INERIS uses KB Suite tool to publish a periodical newsletter on nanomaterials, in French, on the INERIS website (https://www.ineris.fr/fr/recherche-appui/focus/nanosecurite/bulletin-de-veille-thematique-nanomateriaux).

Strategic thematic monitoring is usually structured into the following key topics:

- Regulation,
- Research,
- Stakeholder view,
- Standardization,
- Events.

These are a few articles on nanomaterials' field which have taken from the September / October 2019 newsletter, whose summaries have been translated into English to illustrate the type of deliverable which could be achieved using this tool.

Figure 3: Example of newsletter obtained through KB Suite

Regulation

Test guidelines for safety testing of nanomaterials

08/10/2019
Source : European Union Observatory for Nanomaterials (EUON)

The revision of the REACH annexes to include specific information requirements for nanomaterials will come into force on January 1, 2020. In order to help companies to comply with these requirements and to evaluate the nanoforms of the substances they register, the European Observatory for Nanomaterials (EUON) has published a list of guidelines available or under development for the safety testing of nanomaterials. The Observatory plans to maintain and update this list to include additional guidelines and standards for testing nanomaterials.

Guidance on the safety assessment of nanomaterials in cosmetics

31/10/2019
Source : Scientific Committee on Consumer Safety (SCCS)

The Scientific Committee on Consumer Safety (SCCS) published on October 31, 2019 a new version of its guidelines for the safety assessment of nanomaterials in cosmetics: "*Guidance on the Safety Assessment of Nanomaterials in Cosmetics*". This document updated, among other things, the chapter on hazard identification to focus on alternative methods and data requirements for the human health safety assessment of a nanomaterial as a cosmetic ingredient. It also introduced new subsections, for example on coatings, nano-carriers and encapsulated nanomaterials, immunotoxicity, *in silico* methods and grouping and read-across approaches.

Research

Nanomaterial grouping: Existing approaches and future recommendations

29/10/2019
Source : Joint Research Centre (JRC)

The Joint Research Centre (JRC) of the European Union presents a review article published in the journal *NanoImpact* on existing methods for grouping nanomaterials: "*Nanomaterial grouping : Existing approaches and future recommendations*". Grouping and read-across approaches are based on similarity between substances to fill data gaps without additional testing. The article presents the challenges of applying these approaches to nanomaterials and recommendations based on the experience gained during the EU Horizon 2020 NanoReg2 project.

Study finds EU regulatory framework ready for the next generation of nanomaterials

19/09/2019
Source : European Union Observatory for Nanomaterials (EUON)

According to a study commissioned by the European Nanomaterials Observatory (EUON), the current EU regulatory framework for characterizing and identifying "next generation" nanomaterials would be suitable for the majority of them and no significant changes would be needed in the near future. However, the study notes that "*further guidance would benefit companies registering nanomaterials under the REACH Regulation*".

Stakeholders views

European civil society groups raise questions about industry-funded study on E171 toxicity and call on decision-makers to support the French ban on unnecessary food additive

12/09/2019
Source : Health and Environment Alliance (HEAL)

In this press release, civil society groups across Europe react to the publication of an American study on E171 published in the journal *Food & Chemical Toxicology* which concludes that the additive has no adverse effects: "*Evaluation of immunologic and intestinal effects in rats administered an E 171-containing diet, a food grade titanium dioxide (TiO_2)*". They question the scientific rigor of a study financed by professional federations, all of which have commercial interests in this field, such as the federation of titanium dioxide manufacturers (TDMA). The NGOs say they are "*puzzled by a number of elements in the study*" which, in their opinion, "*require in-depth scrutiny by the scientific community and health and safety agencies*". They call on European decision-makers to maintain the French ban on E171 and even call on them to consider extending the French measure to the European Union.

Have your say on future studies on nanomaterials

15/10/2019
Source : European Union Observatory for Nanomaterials (EUON)

The European Observatory on Nanomaterials (EUON) can conduct up to 3 studies annually to address knowledge gaps on nanomaterials that are of interest to the general public and the research community. The EUON is looking for topic suggestions for its upcoming studies, which may include questions relating to the health and safety of nanomaterials, including hazard and risk assessment, exposure to nanomaterials or worker safety and protection. Those who wish to do so may suggest a subject for study to the Observatory until January 15, 2020, provided that the study is based on documentary research or surveys and does not require laboratory research.

Standardization

ISO/TS 11251:2019 - Nanotechnologies — Caractérisation des composés volatils dans les nanotubes de carbone à simple paroi (SWCNT) utilisant l'analyse des gaz émis par chromatographie en phase gazeuse couplée à la spectrométrie de masse

25/09/2019
Source : ISO

New standard published

ASTM E3144 - 19 Standard Guide for Reporting the Physical and Chemical Characteristics of Nano-Objects

01/09/2019
Source : ASTM International

New standard published

Events

Revised REACH information requirements for nanoforms: are you ready?

Source : ECHA

November 12, 2019, webinar

4.1.1.2. Horizon scanning

Horizon Scanning is "a technique for detecting 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" (OECD 2019. n.d.a.). It is then a forecasting tool that has been used by many institutions and governments to assist the policy-making process identifying and addressing important needs or gaps regarding new issues on different domains such as environmental studies, health care or food safety (Sutherland et al. 2009; Carlsson and Jorgensen 1998; FAO 2014).

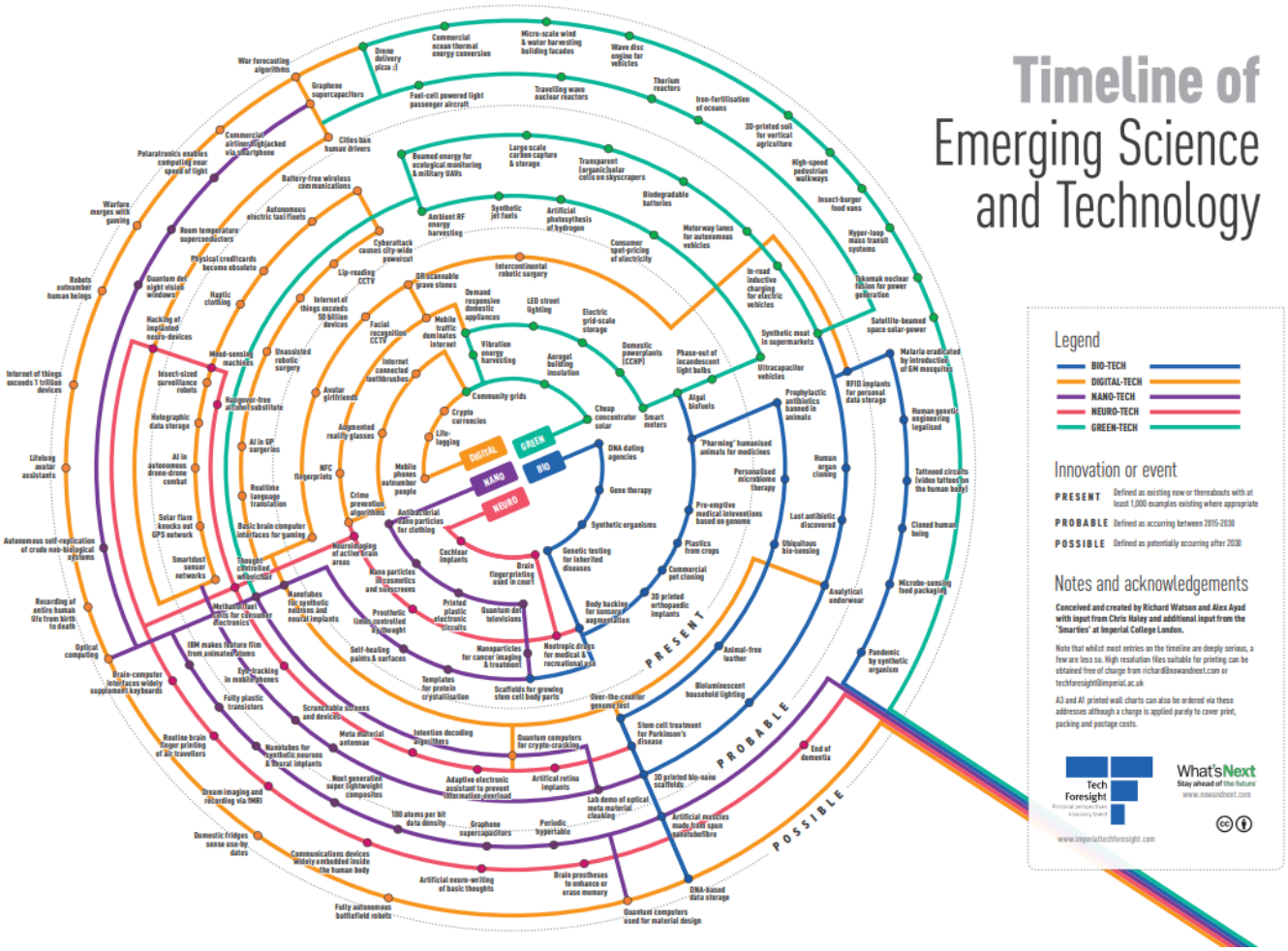
Horizon scanning activities are usually performed following several steps in an iterative way: signal collection, sense-making process, and reporting. For developing a successful horizon-scanning process, the European Union (EU) Directorate-General (DG) for Research and Innovation has outlined a series of considerations (European Commission, 2015). The first one is to clearly stablish the objectives in order to determine the best approach and the expected outcomes. Some of the usual purposes of Horizon Scanning are:

- to deepen the understanding of the driving forces affecting future development of a policy or strategy area,
- to create new and resilient strategies adaptable to changing external conditions,
- to build consensus amongst a range of stakeholders,
- to identify opportunities and technologies, or
- to identify gaps in understanding or under-used technologies.

Another important aspect to consider is if the scanning process will be carried out in an automatised manner or through expert 'scanners', or a combination of both. The experts performing the scan still need to define the criteria used in the searching and filtering process, as well as the keywords that will be used and the information sources (from the whole internet to specific databases) that will be used. Some of the methods used for Horizon Scanning are desk research, automated or semi-automated literature search from internet or specific databases, patents searches, scientific journals search, social media scans, expert opinions (conferences, interviews, surveys…). Other important considerations are the time horizon, that can be short-, medium- or long-term, and the frequency of the activity, if continuous scanning or a stand-alone activity. Finally, once the process is finished or in a regular way, it is necessary to define how and when the scanning results will be communicated: in reports, dossiers, infographics, newsletters, or internet platforms, in regular or continuous and irregular basis.

In comparison to other web monitoring tools (such as KB Suite), Horizon Scanning should help the policy-making bodies to make decisions with a longer-term strategic view, to make present choices more resilient to future uncertainties. It is not just an internet monitoring tool, it also analyses, combines and confronts the information to generate a better understanding of a specific issue and to make accurate predictions. Thus, this tool can be used in multiple indicators, but it can be especially useful for monitoring indicators like "Minimal data requirements for nanomaterials across domains" or "Adequate test guidelines and test guidance for nanomaterials for chemicals, food and feed, cosmetics, biocides, nanomedicine, medical devices and consumer products" in Cluster 1 (Standardisation) and "Foresight – Monitoring technological trends for regulatory preparedness" in Cluster 5 (S(S)bD). Overall, Horizon Scanning is a ready-to-use technology, and it has been previously and efficiently used in policy contexts, although it is a complex and laborious approach as it is not a fully automatised process.

Figure 4: Example of an infographic generated using Horizon Scanning in the scanning report "Timeline of emerging science & technology" performed by the Imperial College London and Now&Next (2014) (EmergingScienceTech-5 (nowandnext.com).



4.1.1.3. Innovation Radar Platform

The Innovation Radar (https://www.innoradar.eu/) is a European Commission initiative to identify high potential innovations and innovators in EU-funded research and innovation projects. This platform facilitates to the general public or to professional or businessperson the access to the outputs of EU innovation funding. It also aims to encourage the development of a dynamic ecosystem of innovators, entrepreneurs, funding agencies and investors that can help getting innovations to the market. It provides insights from the following areas of Horizon 2020: Digital, Future and Emerging Technologies (FET), Space, Marie Skłodowska Curie, Energy, SME Instrument, Enhanced Innovation European Council pilot (EIC), Flagships (Graphene), Raw Materials and Bio Economy.

The Innovation Radar platform builds on the information and data gathered by independent experts involved in reviewing ongoing projects funded by the EU (under Horizon 2020, Framework Programme 7 or the Competitiveness and Innovation Programme). These experts also provided an independent view regarding the innovations in the projects and their market potential.

The user can type one or more keywords in the "search" field to reveal innovations of relevance and add some additional filters as the level of maturity, the topic, "go-to-market" needs or organisation type.

Innovations are categorised in 4 different maturity levels (Market Ready, Tech Ready, Business Ready and Exploring) based on the scores of the Innovation Potential and the Innovator Capacity Indicators. Inside the Innovation Potential Indicator, three factors in the innovation development process are evaluated: innovation readiness (related to the technical maturity and time to get to the potential commercialisation), innovation management (commitment to the project consortium

to bring the innovation to the market), and market potential (demand and potential barriers). The Innovation Capacity Indicator takes into consideration the innovator's ability and potential and the innovator's environment.

This tool can be applied for monitoring several indicators inside Cluster 3 (Innovation and governance), to efficiently identify and track the state of new technologies being developed inside the European Commission framework. This instrument is ready-to-use, available to everyone without cost and easy to use.

4.1.2 Market analysis reports

A market analysis studies the attractiveness and the dynamics of a special market within a special industry. It is part of the industrial analysis and thus in turn of the global environmental analysis. Through all these analyses, the strengths, the weaknesses, the opportunities, and threats (SWOT) of a company can be identified. Finally, with the help of a SWOT analysis, adequate business strategies of a company will be defined. The market analysis is also known as a documented investigation of a market that is used to inform a firm's planning activities, particularly around decisions of inventory, purchase of capital equipment, promotional activities, and many other aspects.

The global industrial sector can also carry out market analysis, considering the main elements of this assessment:

- Market size,
- Market trends,
- Market growth rate,
- Market opportunity,
- Market profitability,
- Industry cost structure,
- Distribution channels,
- Success factors, and
- Applications.

In terms of nanomaterials, the global nanomaterials market size was valued at USD 8.5 billion in 2019 and is expected to reach USD 57,608.26 million by 2026, growing at a compound annual growth rate (CAGR) of 19.86% during the forecast period from 2021 to 2026. High potential for product adoption for aerospace applications, to improve the strength and durability of aircraft parts, is expected to drive the market over the forecast period.

Rapid developments in healthcare technology, growth in the medical diagnostics industry, and various advantages of medicinal imaging applications are anticipated to drive the market.

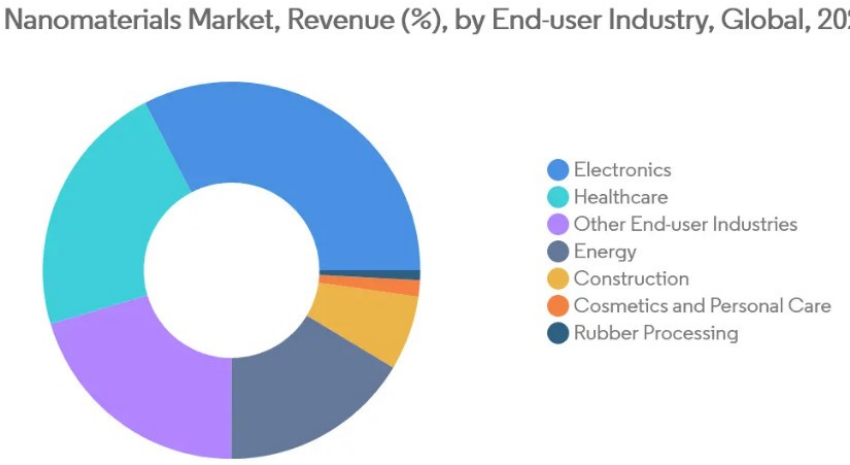
In the electronics industry, the demand for nanomaterials has been greatly increasing, owing to the major advances in computing and electronics, leading to faster, smaller, and more portable systems that can manage and store larger and larger amounts of information. In the electronics industry, nanoparticle copper suspensions have been developed as a safer, cheaper, and more reliable alternative to the lead-based solder and other hazardous materials commonly used to fuse electronics in the assembly process.

Furthermore, increased focus on research concerning nanotechnology and rising government spending on biotechnology and pharmaceutical R&D is expected to augment growth of the nanomaterials market.

However, current pandemic situation due to COVID-19 and higher costs of technology is expected to hinder the growth of the market studied.

In terms of geographic development, Asia-Pacific is expected to drive the market growth rate during the forecast period.

Figure 5: Nanomaterial Market, Revenue (%), by End-user Industry, Global, 2020. Source: Mordor Intelligence

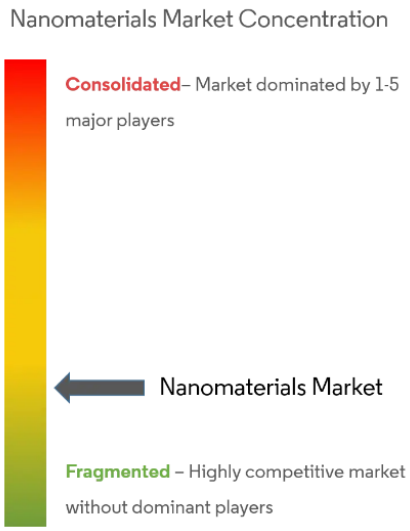


The major players on the nanomaterials market are:

- American Elements
- Chengdu Organic Chemicals Co. Ltd (Timesnano)
- Jiangsu Cnano Technology Co. Ltd
- Cabot Corporation
- ACS Material.

Despite of that, the nanomaterial market is not consolidated yet. Figure 6: Current nanomaterials market concentration. Source: Mordor Intelligence shows the current situation of the nanomaterial market, where the main conclusion is that there is still place for new companies / entities in the market without suffering the effects of the dominated players.

Figure 6: Current nanomaterials market concentration. Source: Mordor Intelligence



In terms of market segmentation, it exists different categories to divide the scope of market:

- **Product type:** nanoparticles (nanometals, nanometal oxides, complex oxides), nanofibers, nanotubes, nanoclays or nanowires.
- **Structure type:** non-polymeric organic nanomaterials (eg. carbon black) or polymeric nanomaterials (eg. coatings and adhesives).
- **End-user industry:** Healthcare, Electronics, Energy, Construction, Rubber, Personal care and other end-user industries.
- **Geography:** Asia-Pacific (China, India, Japan, South Korea, ASEAN Countries, Rest of Asia-Pacific), North America (United States, Canada, Mexico), Europe (Germany, United Kingdom, Italy, France, Rest of Europe), South America (Brazil, Argentina, Rest of South America) and Middle-East and Africa (Saudi Arabia, South Africa, Rest of Middle-East and Africa).

Market analysis reports could allow NRGC to have a complete view of how the nanomaterial market evolves through the years, as well as be able to monitor and evaluate regulatory changes related to the governance of nanomaterials. This kind of reports could be useful for certain defined indicators, such as "Identifying the barriers for developing new technology" or "Inventory of global investments in nanotechnology" (cluster 3 – innovation & governance).

4.1.2.1 OECD reports

As nanomaterials started to be used in commercial applications, the Organisation for Economic Co-operation and Development (OECD) identified the need to analyse the potential safety concerns caused by manufactured nanomaterials. EHS launched a programme of work in 2006 to ensure that the approaches for hazard, exposure and risk assessment for manufactured nanomaterials are of a high quality, science-based and internationally harmonised.

Just like any other chemical substance, nanomaterials must be assessed for their safety using appropriate tools and methodologies. For that reason, the OECD Programme on Manufactured Nanomaterials and the OECD Test Guidelines Programme collaborate to identify and develop standardised methods that can be used to generate relevant and reliable data.

"Science based support for regulation of manufactured nanomaterials" is one of the reports which has been issued by OECD on that direction. This report summarises the discussions at the "Science Based Support for Regulation of Manufactured Nanomaterials" conference. The objective of the conference was to discuss the regulatory relevance of new research and initiatives results in the field of nanosafety and to identify the outstanding and future regulatory challenges.

The conference was organised across 4 main themes: nanomaterials identification and characterisation, exposure and fate, nanomaterials hazards, and nanomaterials tiered testing and tools for Risk Assessment.

For this aim, scientists, risk assessors and legal advisors from EU member states and OECD member states involved in FP7/H2020 projects or OECD WPMN activities met and discussed in groups the regulatory relevant areas of concern, including physicochemical identification and characterisation, exposure, fate and kinetics, ecological and health effects as well as testing and assessment strategies. These topics are of crucial interest for the monitoring and evaluation of the indicators under cluster 1 (standardization).

The report (OECD, 2016) summarises the discussions at the conference and highlights the findings of the experts. It also includes summaries of the presented lectures and a plenary panel discussion. It features a compilation of conclusions and recommendations for regulatory questions regarding assessing risk for human health and environment.

4.1.3 Surveys

Surveys and questionnaires are the best way to get direct feedback from the relevance audience regarding topics of interest.

Designing a survey involves much more than just choosing what questions to ask. The main factors that influence on the success or failure of the goals to achieve, are summarize in the following bullet points:

- **The mode of data collection.** Differences exist between online surveys and in-person interviews. Actions, words, phrasing, colour choice and layout will play a major role to interpretate the results.
- **Impact of survey fatigue.** The type of question could generate fatigue to the respondents, and, therefore, the ratio of success could be substantially decreased in comparison to other methods to address the topic. Sometimes, these questions are necessary, but it is needed not to abuse of them.
- **The effect of survey question wording.** Writing questions with the right wording is one of the most difficult parts of creating surveys, and this is the key to obtain the desired results from the prepared questions. Use of esoteric language, inaccurate terminology or highly technical words should be avoid, especially when the audience is not expert on the matter. Providing clear instructions is a delicate balancing act.
- **How the questions are ordered.** Each survey should follow a logical flow. Jumping from one topic to another may confuse the respondents and cause them to skip questions or abandon the survey altogether. It is recommended to take several looks to the questions before launching the survey, to avoid inconsistencies in the logical flow.
- **Different survey question formats.** Depending on the level of detail the interviewer wants to achieve, the survey will include the right blend of quantitative and qualitative questions.
- **Accuracy of the received answers.** Regardless of people's intentions, respondents will not always be able to provide accurate information. To get the best possible data about subjective topics (attitudes and opinions), it is highly recommended to use language that reflects how the respondents think and talk about the topic the interviewer is asking about.
- **Bias in self-reported behaviour.** Respondents do not mentally categorize events by periods of time. The interviewer should consider the appropriate reference periods for the type of behaviour it is required to recall. Respondents could easily answer how much time they spent doing a certain activity during this week but answering how much time they dedicate for the same activity in a year could not be as reliable.
- **Clear question structure.** Questions have three distinct parts (question stem, additional instructions, and response options) and each must work in harmony with the others to get high quality data. If respondents are confused about how to answer a certain question, this could lead to confusing survey results.
- **Visual survey design.** The verbal part of a survey is crucial to achieve the desired goal, but survey design elements must also be considered.
- **The final survey analysis plan.** The type of information it is requested and the question format that it is chosen must be based on the research objective and the type of analysis is planned to be carried out once the date has been collected. It must also be considered if it is necessary to replicate the survey results, track certain events or just run a one-time ad-hoc analysis on the results.

If all these aspects are considered, the survey will produce valid data that will allow make decisions with confidence.

The following sub-sections include examples of different initiatives which have taken place in the past years about surveys or questionnaires related to different topics that can be related to the defined clusters in Task 7.2. Ideas from these initiatives could be taken into consideration in the

moment of preparing surveys to monitor & evaluate several of the defined indicators and sub-indicators.

4.1.3.1 OECD Trustlab

Trustlab (OECD, 2017a) is an innovative OECD initiative that aims to improve existing measures of trust as well as understand what drives trust and how policymakers might go about restoring it. The OECD is partnering with researchers from a set of world-class institutions to improve measures of trust and disentangle the drivers of a concept that is still poorly understood. Trustlab combines cutting-edge techniques drawn from behavioural science and experimental economics with an extensive survey on the policy and contextual determinants of trust in other people and trust in institutions.

"Trust and its determinants", an OECD Statistics Working Paper, describes the results of the Trustlab data collection implemented is 6 OECD countries (France, Germany, Italy, Korea, Slovenia and the United States) between November 2016 and November 2017.

This OECD paper represents a good starting point to prepare a relevant survey to estimate the trustiness on the NRGC.

During the Trustlab Experiment, several factors were studied:

- The self-reported levels of trust on Institutions (Parliament, Trust in government, Media, Financial institutions, Judicial system, Interpersonal trust, People from other religion, Immigrants, Police, Your family) by the people the selected countries in the study, on a scale from zero to ten.
- The level of trust in other people, considering the highest achieved education level and the equivalised household income.
- The level of trust in governments, considering the highest achieved education level and the equivalised household income.
- Study of variables, such openness, fairness, responsiveness, reliability, integrity (petty corruption) or integrity (high level corruption) which could drive low levels of trust in governments.

Once the experiment was over, several lessons were learned, which are summarized in the following bullet points:

- The government and the parliament are the least trusted institutions in most countries surveyed.
- High levels of education and income are associated with higher levels of trust in other people and also with higher trust in the government.
- There are substantial differences in perceptions of government competence and values between countries, but perceptions of integrity and responsiveness are low across the board.
- Perceptions of high-level corruption are the strongest determinant of trust, followed by satisfaction with services and government reliability and responsiveness.
- Experimental measures of altruism and expected trustworthiness go hand in hand with survey trust.

The main results from this experiment are as follows:

1. Self-reported measures of trust in institutions are validated experimentally.
2. Self-reported measures of trust in others capture a belief about trustworthiness (as well as altruistic preferences), whereas experimental measures rather capture willingness to cooperate and one's own trustworthiness. Therefore, both measures are loosely related, and should be considered complementary rather than substitutes.
3. Perceptions of institutional performance strongly correlate with both trust in government and trust in others.

4. Perceived government integrity is the strongest determinant of trust in government.
5. In addition to indicators associated with social capital, such as neighbourhood connectedness and attitudes towards immigration, perceived satisfaction with public services, social preferences, and expectations matter for trust in others.
6. There is a large scope for policy action, as an increase in all significant determinants of trust in government by one standard deviation may be conducive to an increase in trust by 30 to 60%.

"Ethnic bias, economic success and trust", another Trustlab study, looked at trust between ethnic groups in the United States and Germany. The ethnic in-group bias, defined as the propensity to favour members of one's own ethnic group in terms of monetary payoff in online trust game, is significant in both countries.

In the United States, members of the three largest ethnic groups trust people from their own ethnic group more than those from other groups. African Americans have a larger in-group bias than White Americans and Hispanics. Ethnic differentiation is not selective, as each group tends to have lower trust in the two other ethnic groups at roughly the same rate.

In contrast, ethnic differentiation is strongly selective in Germany: subjects of German parentage discriminate twice as much against Turkish descent participants as against Eastern European descent participants. Members of both ethnic minorities in Germany trust each other less than their own ethnic group, but do not discriminate against ones of German parentage.

It was also examined whether releasing information on the trustee being rich reduces ethnic differentiation, while conjecturing that this is a way to remove the stereotype that ethnic minorities are "undeserving poor" and show that discrimination by the ethnic majority is indeed reduced. People of Turkish descent who are rich tend to be more trusted than lower-income people of Turkish descent. However, releasing information on income can backfire, as it can increase mistrust within minorities.

Finally, it was shown that group loyalty exists not only according to ethnicity but also according to income, as rich German parentage subjects trust other rich in-group members significantly more than do non-rich Germans.

4.1.3.2 The Trust Project – FSA

The Food Standards Agency in the United Kingdom commissioned two research studies on trust in relation to food:

- Trust in a changing world - Rapid Evidence Assessment, and
- Trust in a changing world - Deliberative Forums.

These studies, in the same way it happened to the OECD Trustlab Experiments, could also be used as reference to prepare surveys and be able to monitor and evaluate the performance of the NRGC through the defined indicators and sub-indicators in task 7.2.

Trust in a changing world

To put that study into context, it is important to realize that to be effective and influential, regulatory bodies cannot take public trust for granted. Otherwise, they will struggle with stakeholder acceptance of communications, co-operation, and public health may be put at risk.

The main goal of that study was to identify what indicates trustworthiness to consumers in the food industry and food regulator and make recommendations on how to meet these expectations.

Regarding the **"Rapid Evidence Assessment"**, the main findings were:

- Many different trust concepts, terms and definitions were identified in the literature. These include generalised trust, social trust, political trust, distributed trust and

consumer confidence. There is an important distinction between low trust and distrust.
- All these concepts are relevant to food in some way, although determining what might drive or prevent trust in food will also be dependent on: the nature of the food industry and regulator; who holds the most power in the system; and what consumers are most concerned about in the food system.
- At a more general level, trust was found to be influenced by: media coverage and crises; endorsement of others; confirmation bias; perceptions of complexity; familiarity; honesty; consistency; independence; ability; and good intentions.

In the case of **"Deliverable Forums"**, the following bullet points summarize the main findings:

- Trust is a complex social necessity. There are 3 core steps in understanding trust decisions: Context; 'Social Trust' (Intention); 'Cognitive Trust' (Delivery).
- Loss of social trust is most damaging, while cognitive trust is more resilient.
- The context for food sector decisions makes trust easier for the public. The food sector also has major advantages in both the social and cognitive trust spheres.
- The current high levels of trust in FSA do not seem to be based on detailed understanding of FSA performance. As the public learn more about the food sector, this can increase concern. However, learning more about the FSA's role increases trust in FSA.
- Overall, the public want a visible, powerful FSA protecting their interests in the food system while maintaining proactive consumer communications that help the public empower themselves.

The research reports can be found on the website[2] from Food Standards Agency (UK).

4.1.4 Expert committees, expert opinion

The risks of emerging technologies are governed by policy and management decisions, the outcomes of which should ideally be monitored and evaluated, so that these policies can be adapted to achieve the target objectives. This form of Adaptive Policymaking (APM) is particularly suitable for solving problems that involve significant uncertainty such as the assessment and management of nanotechnology risks. The APM can be implemented by creating groups/committees of domain experts collaborating with policy makers and stakeholder representatives under the umbrella of the NRGC. These expert groups can discuss best strategies to address specific issues and then monitor the results of implementing those based on pre-defined evaluation criteria/indicators and on reaching consensus on whether the policies/decisions achieved the expected results, or if it is necessary to change the approach. The discussions can take place in workshops where different instruments can be applied to facilitate the analysis of background information and support decision making (e.g., SWOT analysis, TOWS matrix, Balanced Scorecards, flowcharts, Wild Card scenarios). These committees can evaluate both the process of developing a policy and provide an assessment of the efficacy of this policy compared to an alternative one or the one already in place. This can increase the chances of reaching policy goals and makes better use of the background information that is gathered during the policy analysis phase to support the decision-making process. The latter is particularly important for timely risk governance decisions as policymakers often react to uncertainty by initiating more research, which can take years and delay necessary actions.

4.1.4.1 Delphi method

The Delphi method was developed at the RAND Corporation in the late 1950s as an effective method for collecting and converging expert opinions to achieve a consensus on a specific issue. Since then, the technique has been extensively used in a broad spectrum of topics and applied in forecasting, foresight, decision making, and policy research involving experts, in any problem in which the synthesis of expert opinion is necessary or desired.

[2] https://www.food.gov.uk/research/research-projects/trust-in-a-changing-world

It is a systematic method with rigorously designed questionnaires which are completed in an anonymous way by a panel of experts. After each round, a facilitator summarises the experts' feedback, and the results are presented to the whole group and the panel members complete the questionnaires again. This feedback of information from one round to the next usually includes the average or median of responses (for numerically answered questions), modes, frequency distributions, as well as reasons for holding extreme positions. In this way the participants can revise their opinions after seeing the views of the other experts. After several rounds, the process tends to move the group's responses toward consensus, although reaching consensus is not necessarily the central objective or a measure of success (Lu et al. 2020).

Discussing controversial issues in person may lead to conflict or to a biased conclusion due to the prevalence of the majority's opinion. By introducing the anonymity factor, this method overcome issues as conformity and controversiality. Therefore, the Delphi method is well suited for topics with a degree of uncertainty and complexity, research questions can only be answered through subjective judgement and require significant multifaceted consideration.

In the recent years, an updated version of the Delphi method, called Real-time Delphi (RTD), has been developed using computer software and an online interface to increase the efficiency of the process (Gordon and Pease 2006). RTD approach uses a continuous round-less procedure, instead of the sequential rounds of the original method, reducing in this way the time needed to conduct the studies. It also uses advanced artificial intelligence and natural language processing for analysing the non-numerical responses, greatly improving the processing of the results. Other advantages are that the experts can revise their answers more times, capacity of handling a larger number of participants and the automation of the analysis (von der Gracht et al. 2011).

This instrument can be applied for evaluating indicators where a broad consensus between different sectors or experts in the nanomaterials field is required. For example, it may be especially useful for indicators as the "Discussion of the nanomaterial definition and how they effect on reporting requirements" or the "Development of minimal data requirements for nanomaterials across domain", both inside Cluster 1 (Standardisation). It is easy to use and there are several websites that provide frameworks for conducting Delphi like https://mesydel.com, https://www.edelphi.org or https://www.surveymonkey.com. It has also been successfully implemented in forecasting and public policy issues where a decision-making process is required, as for instance for the creation of the eLAC Action Plans in Latin America (Hilbert et al. 2009).

4.1.5 Others

4.1.5.1 Multiple-Criteria Decision Analysis (MCDA)

Multi-Criteria Decision Analysis (MCDA) is a risk assessment tool to support the decision-making process in a scenario with different alternatives and multiple decision criteria. It provides a coherent framework for evaluating different alternatives based on a multi-perspective synthesis. Each of the decision criteria is assigned with a relative weight or importance using numerical scores and thus it influences on the overall assessment (final score). Performance of the different alternatives according to individual criteria are also evaluated and then aggregated into an overall score. Individual scores may be simply summed or averaged, or a weighting mechanism can be used to favour some criteria more heavily than others (Linkov et al. 2007). In this way, MCDA methods utilize a decision matrix of criteria and performance scores that integrates risk levels, uncertainty and valuation, which enables evaluation and ranking of many alternatives.

There are various MCDA methods like Weighted Sum Method (WSM), Multi-attribute utility theory (MAUT), Analytical Hierarchy Process (AHP) Elimination and Choice Expressing Reality (ELECTRE), Preference Ranking Organization Method for Enrichment of Evaluation (PROMETHEE), goal programming etc. Each method synthesizes information differently, require different types of value information and follow different optimisation algorithms.

MCDA can be used for supporting the decision-making process for comparing various nanomaterials in terms of human or environmental safety, by combining not only hazard-related parameters but also parameters related to other aspects as economic or stakeholder preferences. This can be useful for the monitoring of some of the indicators in Cluster 1 (Standardisation), as the "Development of regulatory pharmacokinetic requirements for human health" and the "Development of regulatory fate requirements", where the inputs from scientists, but also other stakeholders like industrial partners or society can be needed. It is also a powerful approach for the engagement of stakeholders with divergent or convergent values and priorities. It brings consistency, transparency and rigour to the decision-making process. However, this tool relies on the opinions of experts that stablish the scoring system. This instrument has been previously used in areas like human health and climate mitigation and development.

4.1.5.2 Corporate Social Responsibility Index (CSR Index)

The European Commission (EC) states CSR is a "concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis; being socially responsible means not only fulfilling legal expectations, but also going beyond compliance and investing "more" into human capital, the environment and the relations with stakeholders" (Commission of the European Communities, 2001).

The International Organization for Standardization (ISO) defines CSR as the "responsibility of an organization for the impacts of its decisions and activities on society and the environment, through transparent and ethical behaviour that: contributes to sustainable development, including health and the welfare of society; takes into account the expectations of stakeholders; is in compliance with applicable law and consistent with international norms of behaviour; and is integrated throughout the organization and practiced in its relationships" (ISO 26000:2010).

The companies' responsibilities towards society can be classified in four categories: the "Economic Responsibility", to produce and sell the products and services that society demand; the "Legal Responsibility", to act within the legal framework; the "Ethical Responsibility", to act under ethical behaviour beyond the law; and finally, the "Philanthropic Responsibility", to perform philanthropic activities that provide economic support to specific social programs (Diez-Cañamero et al. 2020)

A companies CSR can be measured by external agencies by following a three-step process to develop a CSR assessment and rating (Marquez et al. 2005):

1. Agency compiles available external information about company
2. Agency sends out detailed questionnaire to company
3. Agency interviews key informants internally and externally

Reports are then prepared and commercialized to interested parties, generally consumers, investors and rated companies.

Numerous criteria can be applied in developing a CSR rating. Some agencies rely on an internal team of experts in labour relations, environmental sustainability, military and defence issues, international human rights, animal welfare and community banking practices to assess corporate performance in different broad areas as: workplace, environment, product safety and impact, international operations and human rights, community relations…

The CSR Index, more than an instrument for monitoring a specific indicator, could be used to evaluate and rank the performance of different industrial actors or country members in terms of following and applying the NRGC policies. This could fit in indicators as "Alignment of innovation with regulation - development of readiness levels to align innovation to science and safety policy" inside Cluster 3 (Innovation and governance). It could also be applied as a self-assessment tool in the institution for a self-evaluation of its performance or regarding the different stakeholders and monitor their satisfaction level with the institution.

4.1.5.3 Blockchain

Blockchain is a data structure used to create a public or private distributed digital transaction ledger which, instead of resting with a single provider, is shared among a distributed network of computers. A block is the basic part of a blockchain which records the transactions, and once completed, goes into the blockchain as a permanent database. There is also a cryptographic signature to identify each block and each block refers to the signature of the previous one in the chain, therefore that chain can be traced back to the very first block created in the chain. As the data is stored in a distributed and redundant fashion in the blockchain, and each node verifies each transaction, it is tough for malicious nodes (corrupted parties) to attack and manipulate the data to their advantage. An important advantage of using Blockchain is that it does not require a centralized authority to determine what is true or what is false; instead, multiple distributed parties come to a consensus that is entered into the ledger and after that can be accessed by anyone (Shrestha et al 2020, Shen et al 2020).

Task 7.3 initiated a Task Force on "blockchain technologies" in collaboration with WP1. The objective of this Task Force is to investigate the possible role of these technologies to promote data sharing and improving the FAIRness of the nanosafety data. The Task Force is chaired by Lorenzo Zullo (Chemycal, Third Party to NIA) and it aims at delivering a roadmap on this topic. This roadmap will be a guidance on how to use blockchain technology to enable secure and controlled exchange of information between actors along nanotechnology supply chains (e.g., developers, producers, downstream users) and other stakeholders (e.g., regulators) in a trusted environment. This can not only help to accelerate the innovation market penetration of nanotechnologies but can help to address regulatory concerns early in the innovation process, which can shorten the time of novel nano-enabled products to reach the market. A work plan of the Task Force was developed and was submitted to the Gov4Nano MC for information purposes with the objective to tune this activity with related tasks in the other WPs.

4.2 Selection of monitoring instruments tailored to the prioritized (sub)indicators and recommendations for their implementation.

4.2.1 Prioritisation of the sub-indicators

Taking as reference the indicators and sub-indicators which were identified during the performance of task 7.2, first partners involved in task 7.3 prioritize the ones which their relevance and easy implementation were considered for the NRGC.

Each indicator and sub-indicator have been categorized, according to 6 criteria, in a scale from 1 to 5, where 1 represents the lowest priority to address and 5 is the highest priority. The column "score" is estimated as the sum of the previous columns. Indicators above 24 points should be addressed in a first step; indicators with a score between 12 and 24 points should be addressed in a second phase; finally, indicators with a score below 12 points should be considered for implementation with a lowest priority, in terms of relevance.

The criteria to prioritize the defined indicators have been classified in two main categories:

- **Ease and readiness for implementation.** Three variables have been selected for categorization:
    - Availability of resources: the more data, information, tools, frameworks and/or other resources are available, the higher value this variable is assigned.
    - Availability of existing instrument(s): a higher value will be assigned when more instruments exist (see section 4.2.2), and they are easy and ready to use.
    - Availability of existing way for measurement: a higher value will be assigned when the way to measure the success of a specific instrument is easy to implement (see section 4.2.2).

- **Relevance (the value the M&E could provide to them).** In this specific case, the main points of focus are:
    - Relevance to the process of risk governance.
    - Relevance to specific interested parties:
        - The council.
        - Stakeholders (or to specific stakeholders); in other words, interested parties which are involved in the risk governance.

The following tables summarize the assigned values to each of the above-mentioned variables by the member of the core working group.

Table 4: Categorization of the priority to address indicators and sub-indicators under cluster 1 (Standardisation)

Indicator	Sub-indicator	Ease for implementation			Relevance			Score
		Availability of resources	Availability of existing instrument	Availability of existing measure	Process of risk governance	Council	Stakeholders	
Agreement on revised definition of nanomaterials. Shift in NM definition and how they affect improvements/further complications in complying with the physical/chemical data and other data requirements across all legislations between different domains	Inventory on the discussion of the nanomaterial definition and how they affect on reporting requirements (Pchemdata and other requirements).	4	3	2	5	5	5	24
	Inventory of activities towards a harmonised definition of nanomaterials across domains.	4	3	2	5	5	5	24
	Monitor the discussion on the description of novel/smart/advanced materials	3	3	2	5	5	5	23
Reliable and relevant physico-chemical methods for regulatory risk assessment.	Development of minimal data requirements for nanomaterials across domains (see D7.1)	4	3	2	5	5	5	24
	Investigate the methods used for identification and characterization of nanomaterials to	5	3	2	5	5	5	25

	generate the minimal data requirements							
Hazard (Reliable and harmonized methods for hazard assessment for nanomaterials).	Test guidelines and test guidance are applicable to nanomaterials.	4	2	2	5	5	5	23
	Adequate test guidelines and test guidance for nanomaterials are necessary for chemicals, food and feed, cosmetics, biocides, nanomedicine, medical devices and consumer products.	3	2	2	5	5	5	22
Pharmacokinetics and fate	Development of regulatory pharmacokinetic requirements for human health (see D7.1)	3	2	2	5	3	4	19
	Development of test guidelines and test guidance applicable for pharmacokinetic properties.	3	2	2	3	3	4	17
	Development of regulatory fate requirements (see D7.1)	3	2	2	5	4	4	20
	Development of test guidelines and test guidance applicable for fate properties.	3	2	2	5	4	4	20

Exposure (reliable and harmonized methods and models for exposure and release to nanomaterials)	Development of exposure models which are successfully calibrated with experimental data to nanomaterials.	4	2	2	5	5	5	23
	Development of exposure methods (test guidance and guidance documents, for measures including dissolution, dispersion, dustiness, worker air monitoring methods, etc.)	4	2	2	5	5	4	22
	Inventory of specific exposure models for nanomaterials used by regulatory authorities specifically for worker exposure.	5	3	2	5	5	5	25
	Inventory of specific exposure models for nanomaterials used by regulatory authorities specifically for environmental exposure.	4	3	2	5	5	4	23
	Inventory of specific exposure models for nanomaterials used by regulatory authorities specifically for consumer exposure.	3	3	2	5	5	4	22
Alternative testing/assessment	Inventory of alternative	4	2	2	5	4	4	21

methods (also for grouping and read across)	testing/assessment methods suitable for nanomaterials (e.g. in vitro methods, HCS/HTP methods, omics, and (Q)SAR methods).							
	Alternative (integrated) testing/assessment method test guidance applicable to nanomaterials.	4	2	2	5	4	4	21
Risk assessment methods	Updated nano-specific risk assessment (software) methods if new information is available	4	2	2	5	5	5	23
Cluster workgroup developed to monitor the successful implementation of scientific knowledge, data and tools by standardization bodies.	Monitoring review and report.	2	2	2	2	2	1	11
Inventory (Tour de table, OECD) to monitor efficacy of test guidance & guidance documents process (as perceived by international members)	Uptake of requests of international members in OECD test guidelines procedures.	2	2	2	5	5	5	21
Survey of OECD, ISO, CEN to monitor satisfaction in	Satisfaction of the international members in having	4	3	3	2	2	2	16

standardization bodies	the scientific knowledge, data and tools being taken up by the standardization bodies.							
Monitoring review and report methodology	Standardized method for putting together the periodic review.	5	3	3	1	1	1	14
	Reflection of standardized method resulting in possible updates.	5	3	3	4	4	4	23

Table 5: Categorization of the priority to address indicators and sub-indicators under cluster 2 (FAIR data and data quality)

Indicator	Sub-indicator	Ease for implementation			Relevance			Score
		Availability of resources	Availability of existing instrument	Availability of existing measure	Process of risk governance	Council	Stakeholders	
EHS/FAIR data	Harmonized templates for FAIR nanosafety data (specific for different types of experiments; templates available for the different toxicological endpoints)	5	3	3	5	5	5	26
	Harmonized ontologies (nanosafety data following harmonized ontology)	4	3	3	5	5	5	25
Data infrastructure (databases)	Data standards (including curation). Follow development on the simplification of GuideNano framework.	4	2	2	5	5	5	23
	Follow the progression of FAIRness in currently available databases (maturity of the FAIRness of the databases)	3	2	2	4	4	4	19
	Development of network of interoperable databases (eNanoMapper, NanoCommons database, Nikc (US)).	4	3	3	5	5	5	25

	The goal is to make them all accessible with one query (interoperable). Monitor progress of NanoInformatics Knowledge Commons US-EU Data Integration Team.							
Linkage of FAIR databases to optimal risk assessment software/tools/platforms that contains risk assessment methods across EU regulatory domains.	Inventory of the ability of platforms containing risk assessment software and other tools to access and efficiently export data from FAIR databases.	3	2	2	5	5	5	22
Cluster workgroup: Consider FAIR data network (link to WP1, GoFAIR Implementation Network; AdvancedNano just started). Manifesto – document where goals of network are written.	Stakeholder support (think of number of activities in network and number of participants). Survey to different groups: • NanoSafety Cluster WG-F • EU-US Community of Research (COR) • EMMC (European Materials Modeling Council) • EMCC (European Materials	5	3	3	5	5	3	24

	Characterization Council). • EuMaT (European Technology Platform for Advanced Engineering Materials and Technologies)							
	Stakeholder awareness	3	3	3	5	5	4	23
	Knowledge sharing	3	3	3	5	5	5	24
	A working process to facilitate FAIR data implementation.	3	3	3	4	5	5	23
Process to facilitate FAIR data implementation	Standardized method for putting together the periodic review.	3	3	3	4	4	2	19
	Reflection of standardized method resulting in possible updates.	3	3	3	4	4	3	20

Table 6: Categorization of the priority to address indicators and sub-indicators under cluster 3 (Innovation & Governance)

Indicator	Sub-indicator	Ease for implementation			Relevance			Score
		Availability of resources	Availability of existing instrument	Availability of existing measure	Process of risk governance	Council	Stakeholders	
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).	3	3	3	1	5	5	20
	Identify the barriers for developing new technology.	3	2	2	3	5	5	20
	Survey and Inventory of stakeholder satisfaction and stakeholder needs (Surveys need to be stakeholder specific (regulators, industry, researchers, education, society, etc.)).	3	3	3	3	5	5	22
	Regulatory satisfaction and regulatory needs (survey and inventory)	3	3	3	3	5	5	22
Impact of nanotechnology innovation investments	Inventory of global investments in nanotechnology.	3	3	3	1	5	5	20
	Research projects involving nanotechnology innovations (Inventory).	2	3	3	1	4	4	17

Knowledge platform	Transdisciplinary and trans domain innovation knowledge exchange (conference, survey)	2	2	2	1	4	4	15
	A trusted digital platform and forum (use and number of users)	2	3	3	1	4	4	17
Digital program to monitor how funding agencies are distributing funding	Periodic review report.	5	2	2	1	2	2	14
	Money invested in nanotechnology innovations (Digital Inventory)	5	2	2	1	2	4	16
Foresight Research on market change to allocate funding to right projects	Report on market change (see for instance https://ati.ec.europa.eu/ systematic monitoring of technological trends and reliable, up-to-date data on advanced technologies)	4	2	2	1	2	2	13
Cluster workgroup with a management system	Periodic monitoring review report including strategies, directions, instructions and control mechanisms.	2	2	2	1	2	3	12
Alignment of innovation with regulation. Development of readiness levels to align innovation to science and safety policy (monitor concept development)	Development of an innovation system which includes societal readiness levels.	1	1	1	3	3	2	11
	Development of an innovation system which include regulatory readiness levels	1	1	1	3	3	2	11
	Alignment of technology readiness levels with	3	1	1	2	3	3	13

	societal and regulatory readiness levels.							
Monitoring process for periodic review	Standardized method for putting together the periodic review	3	3	3	2	2	2	15
	Reflection of standardized method resulting in possible updates.	3	3	3	2	2	2	15

Table 7: Categorization of the priority to address indicators and sub-indicators under cluster 4 (Funding & Value of Investment)

Indicator	Sub-indicator	Ease for implementation			Relevance			Score
		Availability of resources	Availability of existing instrument	Availability of existing measure	Process of risk governance	Council	Stakeholders	
Research questions taken on by funding agencies	Inventory on research questions (based on regulatory needs) taken on by funding agencies.	4	3	3	2	2	2	16
Research questions funded by funding agencies	Inventory on research questions (based on regulatory needs) funded by funding agencies.	4	3	3	2	2	4	18
	Inventory of proposals accepted, or test guidance/guidance documents under development.	4	3	3	2	4	4	18
	Inventory of proposals completed that lead to guidance documents or test guidance.	4	3	3	4	4	4	22
Research questions requiring FAIR data	Inventory on research questions requiring FAIR data.	3	3	3	2	3	4	18
Research leading to solutions to regulatory needs as a result of	Inventory of the development of solutions to regulatory needs	3	3	3	2	3	4	18

research funded through funding agencies.	through calls from funding agencies.							
Digital program to monitor indicators among funding agencies	Periodic review report of indicators	3	2	2	2	2	2	13
Cluster workgroup to perform monitoring review	Periodic review	2	2	2	2	2	2	12
Monitoring process for periodic review	Standardized method for putting together the periodic review.	3	3	3	2	2	2	15
	Reflection of standardized method resulting in possible updates.	3	3	3	2	2	3	16

Table 8: Categorization of the priority to address indicators and sub-indicators under cluster 5 (S(S)bD)

Indicator	Sub-indicator	Ease for implementation			Relevance			Score
		Availability of resources	Availability of existing instrument	Availability of existing measure	Process of risk governance	Council	Stakeholders	
Nano specific hazard information	Availability of early hazard assessment tools (inventory)	4	3	3	5	4	4	23
	Identification of data gaps (regulators) (Inventory)	4	3	3	4	4	4	22
	Academic showcases of S(S)bD	3	3	3	5	5	5	24
	Industrial showcases of S(S)bD	3	3	3	5	5	5	24
Nano specific exposure information	Availability of early exposure assessment tools (inventory)	4	3	3	5	5	5	25
	Identification of data gaps (regulators) (inventory)	4	3	3	5	5	5	25
	Academic showcases of S(S)bD	3	3	3	5	5	5	24
	Industrial showcases of S(S)bD	3	3	3	5	5	5	24
Research dedicated to S(S)bD	Research dedicated to S(S)bD	4	3	3	3	4	5	22
Incentives for S(S)bD	Incentives for all relevant stakeholders (subsidies, shorter time	2	2	2	4	5	5	20

	to marker, customer education)							
Worker safety	Nano-related worker incidents (inventory). See, for instance: • MODERNET • Check new and emerging risk database (NERDB)	4	3	3	4	5	5	24
	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)	5	3	3	5	5	5	26
Risk perception	Workers perceived relative risks of nanomaterials they handle (vs. what an	4	3	3	5	5	5	25

	expert would conclude on relative risks).							
	Consumer choices (vs. what an expert would conclude on relative risks) (Market analysis)	4	3	3	5	5	4	22
Knowledge platform	Transdisciplinary and trans domain knowledge	2	2	2	4	4	4	18
	Trusted digital platform or forum	2	3	3	4	4	4	20
Foresight – Monitoring technological trends for regulatory preparedness	Market change reporting (see Advanced Technology for Industry; systematic monitoring of technological trends and reliable, up-to-date data on advance technologies	3	2	2	4	4	4	19
Education programs	Embed S(S)bD in curriculum	2	2	2	4	4	4	18
	Provide S(S)bD Workshops	2	3	3	3	4	4	19
	Develop S(S)bD trainings for industry (innovator specific)	2	3	3	3	4	5	20
	Develop S(S)bD training for regulators	2	3	3	3	4	4	19
	Inventory of university specific training vs nationwide programs	2	2	2	3	4	4	17
Monitor for registers and surveillance	Identification of possible new risks in products containing	2	3	3	4	4	5	21

systems for possible new risks in products containing nano	nanomaterials (monitor product registers, alert and surveillance systems for instance: The Nanodatabase, EUON, RAPEX)							
Pre-consultation (industry vs regulators) in a trusted environment	Development of pre-consultation (industry vs regulator)	2	3	3	3	3	3	17
	Industrial showcases (success stories)	4	3	3	4	5	5	24
	Users using this service	1	2	2	4	4	2	15
Grouping and read across	Standardized methods for applying grouping and read across during various stages of innovation	3	3	3	5	5	5	24
	Grouping approaches used in REACH nano-dossiers	4	3	3	5	5	5	25
Cluster workgroup to monitor S(S)bD implementation	Periodic review of (S(S)bD progress	4	2	2	4	4	4	20
Monitoring process for periodic review	Development of standardized method for putting together the periodic review	3	3	3	4	4	2	19
	Reflection of standardized method resulting in updates	3	3	3	3	3	3	18

Table 9: Categorization of the priority to address indicators and sub-indicators under cluster 6 (Communication)

Indicator	Sub-indicator	Ease for implementation			Relevance			Score
		Availability of resources	Availability of existing instrument	Availability of existing measure	Process of risk governance	Council	Stakeholders	
Survey on the trustworthiness of the platform and the NRGC	Citizen trustworthiness (survey)	3	3	3	5	5	5	24
	Multi stakeholder trustworthiness (survey)	3	3	3	5	5	5	24
Citizen friendly section in the platform	Citizen communication (for instance information for citizens including information on product safety)	2	3	3	5	5	5	23
	Citizens' feedback	2	3	3	5	5	5	23
	Inclusion of questions and topics raised by society	2	3	3	5	5	5	23
Knowledge platform	Transdisciplinary and trans domain multi stakeholder knowledge exchange (conference, survey)	2	2	2	5	5	5	21
	Transdisciplinary and trans domain summit for regulators to encourage knowledge sharing	2	2	2	5	5	5	21

	and collaboration (survey)							
	Digital platform or forum (use and number of users)	2	3	3	5	5	5	23
Development of readiness levels to align innovation to science and safety policy (monitor concept development)	Societal readiness levels	1	1	1	5	5	5	18
	Regulatory readiness levels	1	1	1	5	5	5	18
	Alignment of technology readiness levels with societal and regulatory readiness levels	1	1	1	5	5	5	18
Safety and risk management education programmes	Safety and risk management education in curriculum	3	3	3	3	5	5	22
	Safety and risk management workshops	3	3	3	3	5	5	22
	University specific training vs nationwide programs	2	3	3	3	5	5	21
	Safety training for industry (innovator specific)	2	3	3	3	5	5	21
Cluster workgroup to monitor communication	Periodic review (on communication)	2	2	2	3	3	3	15
Monitoring process for periodic review	Development of standardized method for putting	3	3	3	3	3	2	17

	together the periodic review							
	Reflection of standardized method resulting in possible updates	3	3	3	3	3	3	18

4.2.2 Assignation of the success criteria and monitoring instruments to the different sub-indicators

Table 10: Success criteria and potential instruments for monitoring and evaluation of the indicators and sub-indicators under cluster 1 (Standardisation)

Sub-area	Indicator	Sub-indicator	Success criteria (What are the targets or success criteria?)	Measurement (How will it be measured?)
Information and agreement on the definition of nanomaterials and the criteria, procedures, tools and methods for risk assessment and made publicly available	Agreement on revised definition of nanomaterials. Shift in NM definition and how they affect improvements/further complications in complying with the physical/chemical data and other data requirements across all legislations between different domains	Inventory on the discussion of the nanomaterial definition and how they affect on reporting requirements (Pchemdata and other requirements).	List of conclusions from meetings between the different EU institutions / organizations	***MONITORING:*** ***Software-based instruments*** *(KB Crawl / Horizon Scanning). Target web sources like: JRC, ECHA, EFSA, EMA, EU-OSHA, EUON, European scientific committees, OECD, WHO, NIOSH, EU Open Data Portal, Legislative Observatory, Eur-Lex, ISO, CEN, IEC, ASTM.*
			Future meetings schedule for continuous updates	***EVALUATION:*** ***Expert committee*** *- What are the minimal requirements to define NMs, that are common for all the different fields of NMs use. Specificities for each field of application. [Note: a compilation can be found under D7.1 of G4N* ***Real Time Delphi surveys*** *to collect experts' opinions and reach consensus*
Description of novel, smart and/or advanced materials		Inventory of activities towards a harmonised definition of nanomaterials across domains.	Number of activities (meetings, workshops,…) organized for harmonization of nanomaterials' definition	***MONITORING:*** ***Software-based instruments*** *(KB Crawl / Horizon Scanning). Target web sources like: JRC, ECHA, EFSA, EMA, EU-OSHA, EUON, European scientific committees, OECD, WHO, NIOSH, EU Open*

				Data Portal, Legislative Observatory, Eur-Lex, ISO, CEN, IEC, ASTM ***EVALUATION:*** ***Expert committee*** *- Inventory of activities organized and agenda*
		Monitor the discussion on the description of novel/smart/advanced materials	Number of carried-out discussions on novel/smart/advanced materials + Summaries of discussion contents	***MONITORING:*** ***Software-based instruments*** *(KB Crawl or Horizon Scanning) for the number of carried-out discussions.* ***EVALUATION:*** ***Expert committee*** *- Attending discussions and writing minutes.*
	Reliable and relevant physico-chemical methods for regulatory risk assessment.	Development of minimal data requirements for nanomaterials across domains (see D7.1)	Common guideline of minimal data requirements for nanomaterials across domains and legislations / Number of guidelines. Updates (relevant number of modifications) on the guidelines. Identification of relevant minimal data requirements for nanomaterials by the chemical industry.	***MONITORING & EVALUATION:*** ***Software-based instruments*** *Horizon Scanning* ***Expert committee*** *(determination of minimal data requirements by chemical sector).* ***Surveys / questionnaires*** *to different domains of NMs applications (relevant minimal data requirement for stakeholders from different chemical sectors)* ***Real Time Delphi surveys*** *to expert panel and stakeholders (consensus about minimum requirements for each industry sector)*
		Investigate the methods used for identification and characterization of	Number of guidelines published, accepted and adopted by EU members and non-EU members	***MONITORING:*** ***Software-based instrument*** *(KB Crawl or Horizon Scanning).*

		nanomaterials to generate the minimal data requirements	for nanomaterials characterization	***EVALUATION:*** ***Expert committee*** *(evaluation of the methods used for identification are the most suitable ones and how they can be improved) - inventory of guidelines/ISO TC 229, ECHA-REACH, other EU funded projects,…*
	Hazard (Reliable and harmonized methods for hazard assessment for nanomaterials). This indicator links with cluster 5.	Test guidelines and test guidance are applicable to nanomaterials.	Number of guidelines published, accepted and adopted by EU members non-EU members for nanomaterials hazard assessment / Joint meetings of EU projects in progress or finished and ECHA for acceptance and validation of project's results	***MONITORING:*** ***Software-based instruments*** *(KB Crawl / Horizon Scanning) - Inventory of the test guidelines and test guidance.* ***EVALUATION:*** ***Expert committee*** *- Evaluation of the developed test guidelines and test guidance valid to NMs (inventory of guidelines/ISO TC 229, ECHA-REACH, other EU funded projects,…)*
		Adequate test guidelines and test guidance for nanomaterials are necessary for chemicals, food and feed, cosmetics, biocides, nanomedicine, medical devices and consumer products.	Test guidelines for each regulatory requirement	***MONITORING:*** *Inventory of how many requirements have a test guideline (searched using a* ***software-based instrument****, like KB Crawl or Horizon Scanning)*
	Pharmacokinetics and fate	Development of regulatory pharmacokinetic requirements for human health (see D7.1)	New regulation on pharmacokinetic requirements for human health	***MONITORING:*** ***Software-based instrument*** *(KB Crawl / Horizon Scanning) - Collection of data on the progress of the regulatory requirements for pharmacokinetics + Information on available workshops for diffusion.* ***EVALUATION:*** ***Expert committee*** *- Evaluation of the developed regulatory requirements (suitable /*
			Workshops for diffusion between stakeholders	

				adaptability for all chemical sectors)
		Development of test guidelines and test guidance applicable for pharmacokinetic properties.	Number of guidelines published, accepted, and adopted by EU members non-EU members for nanomaterial's pharmacokinetic properties	***MONITORING:*** ***Software-based instrument*** *(KB Crawl / Horizon Scanning) - Collection of information on the progress of the test guidelines and test guidance.* ***EVALUATION:*** ***Expert committee*** *- Evaluation of the developed test guidelines and test guidance (inventory of guidelines/ISO TC 229, ECHA-REACH, other EU funded projects,…)* ***MCDA -*** *To aid the decision-making process*
		Development of regulatory fate requirements (see D7.1)	New regulation on fate requirements	***MONITORING:*** ***Software-based instrument*** *(KB Crawl / Horizon Scanning) - Collection of data on the progress of the regulatory requirements for fate + Information on available workshops for diffusion.* ***EVALUATION:*** ***Expert committee*** *- Evaluation of the developed regulatory fate requirements (suitable / adaptability for all chemical sectors)* ***MCDA -*** *To aid the decision-making process*
			Workshops for diffusion between stakeholders	
		Development of test guidelines and test guidance applicable for fate properties.	Number of guidelines published, accepted, and adopted by EU members non-EU members for nanomaterial's fate properties	***MONITORING:*** ***Software-based instrument*** *(KB Crawl / Horizon Scanning) - Collection of information on the progress of the test guidelines and test*

				guidance. ***EVALUATION:* Expert committee** *- Evaluation of the developed test guidelines and test guidance (inventory of guidelines/ISO TC 229, ECHA-REACH, other EU funded projects,…)*
	Exposure (reliable and harmonized methods and models for exposure and release to nanomaterials)	Development of exposure models which are successfully calibrated with experimental data to nanomaterials.	Number of Official guideline/compilations of exposure models accepted by the EU members to assess exposure and release of nanomaterials. Including information on dose-response data (i.e. DNEL- Derived No-Effect Level, PNEC - Predicted No-Effect-Concentration), as well as limitations of applicability.	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of exposure models validated with experimental data to nanomaterials (including limitations). **EVALUATION: Expert committee** - Evaluation of current models and methods.
		Development of exposure methods (test guidance and guidance documents, for measures including dissolution, dispersion, dustiness, worker air monitoring methods, etc.)	Number of guidelines published, accepted, and adopted by EU members non-EU members for methods to measure each relevant parameter	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of exposure models under development, taking into account experimental data from nanomaterials (including limitations). **EVALUATION: Expert committee** - Approval of the under-development models / methods
		Inventory of specific exposure models for nanomaterials used by regulatory authorities specifically for worker exposure.	Recommendations must be defined by regulators	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of specific occupational exposure models for nanomaterials, recommended by regulatory authorities (including limitations).
			Recommendations must be made publicly available by regulators	
			Stakeholders must be informed on recommendations	

			Recommendations must be applied by industry	**EVALUATION: Expert committee** - Approval of such specific exposure models / methods. **Surveys / questionnaires** could also be used for evaluation of the awareness and acceptance of the models by stakeholders and request for potential improvements (desire of stakeholders).
		Inventory of specific exposure models for nanomaterials used by regulatory authorities specifically for environmental exposure.	Number of specific exposure models for nanomaterials published, accepted and adopted by EU members and used by regulatory authorities specifically for environmental exposure	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of specific environmental exposure models for nanomaterials, recommended by regulatory authorities (including limitations). **EVALUATION: Expert committee** - Approval of such specific exposure models / methods. **Surveys / questionnaires** could also be used for evaluation of the awareness and acceptance of the models by stakeholders and request for potential improvements (desire of stakeholders).
		Inventory of specific exposure models for nanomaterials used by regulatory authorities specifically for consumer exposure.	Number of specific exposure models for nanomaterials published, accepted and adopted by EU members and used by regulatory authorities specifically for consumer exposure including dose-response data (i.e. DNEL-Derived No-Effect Level, PNEC -	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of specific consumer exposure models for nanomaterials, recommended by regulatory authorities (including limitations). **EVALUATION: Expert**

			Predicted No-Effect-Concentration)	**committee** - Approval of such specific exposure models / methods. **Surveys / questionnaires** could also be used for evaluation of the awareness and acceptance of the models by stakeholders and request for potential improvements (desire of stakeholders).
	Alternative testing/assessment methods (also for grouping and read across)	Inventory of alternative testing/assessment methods suitable for nanomaterials (e.g. in vitro methods, HCS/HTP methods, omics, and (Q)SAR methods).	Number of guidelines published, accepted, and adopted by EU members non-EU members for alternative testing/assessment methods suitable for nanomaterials.	**MONITORING:** **Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of alternative testing / assessment methods suitable for nanomaterials (including limitations). **EVALUATION:** **Expert committee** - Approval of such specific exposure models / methods. **Surveys / questionnaires** could also be used for evaluation of the awareness and acceptance of the models by stakeholders and request for potential improvements (desire of stakeholders).
		Alternative (integrated) testing/assessment method test guidance applicable to nanomaterials.	Number of alternative (integrating) testing / assessment methods test guidance applicable to nanomaterials	**MONITORING:** **Software-based instrument** (KB Crawl / Horizon Scanning) - Inventory of alternative testing / assessment methods suitable for nanomaterials (including limitations). **EVALUATION:** **Expert committee** - Approval of such specific exposure models / methods.

				Surveys / questionnaires could also be used for evaluation of the awareness and acceptance of the models by stakeholders and request for potential improvements (desire of stakeholders).
	Risk assessment methods	Updated nano-specific risk assessment (software) methods if new information on hazard is available	Software updates (i.e. GuideNano and others)	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - List of all nano-specific updates on risk assessment (software) methods - including limitations - & Review of new publications on nanomaterials toxicity/REACH regulations (KG Crawl?) **EVALUATION: Expert committee** - Evaluation of the results for the risk assessment methods, considering already generated data.
		Updated nano-specific risk assessment (software) methods if new information on exposure is available		
		Updated nano-specific risk assessment (software) methods if new information on (integrated) risk assessment methods is available		
	Cluster workgroup developed to monitor the successful implementation of scientific knowledge, data and tools by standardization bodies.	Monitoring review and report.	Monitoring review and report: implemented actions derived from the monitoring review (report)	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)
	Inventory (Tour de table, OECD) to monitor efficacy of test guidance & guidance documents process (as perceived by international members)	Uptake of requests of international members in OECD test guidelines procedures.	>= 70% answered questions must be positive feedback	**MONITORING: Software-based instrument** (KB Crawl / Horizon Scanning) - List of the reviewed test guidance / guidance documents discussed in different forums (Tour de table, OECD meetings, ...). **EVALUATION: Surveys / Questionnaires** to international members containing questions related to optimization / update of test

				guidelines and general perception to the industry.
	Survey of OECD, ISO, CEN to monitor satisfaction in standardization bodies	Satisfaction of the international members in having the scientific knowledge, data and tools being taken up by the standardization bodies.	>= 70% answered questions must be positive feedback	**EVALUATION: Surveys / Questionnaires** containing questions related to NRGC members satisfaction
	Monitoring review and report methodology	Standardized method for putting together the periodic review.	Management plan/Guideline to elaborate periodic review	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)
		Reflection of standardized method resulting in possible updates.	Number of implemented improvements in the monitoring procedure	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)

Table 11: Success criteria and potential instruments for monitoring and evaluation of the indicators and sub-indicators under cluster 2 (FAIR data and data quality)

Sub-area	Indicator	Sub-indicator	Success criteria (What are the targets or success criteria?)	Measurement (How will it be measured?)
FAIR databases for safety data of NMs are developed, including data quality and completeness	EHS/FAIR data	Harmonized templates for FAIR nanosafety data (specific for different types of experiments; templates available for the different toxicological endpoints)	Joint meetings of EU projects in progress or finished for acceptance and validation of project's results / Compilation of harmonized templates for each one of the methodologies described in Cluster 1.	***MONITORING: Software-based instrument*** *(KB Crawl / Horizon Scanning) - Inventory of templates for each type of experiment/toxicological endpoint, recommended by regulatory authorities (including limitations).Target web sources like : Nanosafety Data Interface (eNanoMapper), NanoCommons, AdvancedNano GO FAIR implementation network for nanosafety data.*

				Also, projects that produce and/or use data, such as SbD4Nano, SUSnanofab, SABYDOMA, SAbyNA, NanoFabNet, SUNSHINE, GRACIOUS, PATROLS, Evo-Nano, NanoCommons, M3DLoC, NanoExplore, Purenano, RiskGone, NanoRigo, NanoSolveIT, NanoinformaTIX, Hi-Accuracy, Nanoharmony, Nanomet, ASINA, HARMLESS, DIAGONAL. ***Expert committee EVALUATION:*** ***Expert committee*** *- Approval of such templates.* ***Surveys / questionnaires*** *could also be used for evaluation of the awareness and acceptance of the templates by stakeholders and request for potential improvements (desire of stakeholders).*
		Harmonized ontologies (nanosafety data following harmonized ontology)	Fraction of entries in a database which are coupled to an ontology (Count how many ontologies can be found in a specific database and how many times this ontology has been used)	***MONITORING:*** ***Software-based instrument*** *(KB Crawl / Horizon Scanning). Target web sources like : Nanosafety Data Interface (eNanoMapper), NanoCommons, AdvancedNano GO FAIR implementation network for nanosafety data, OpenAIRE, FAIRsharing, FAIRsFAIR. Also projects that produce and/or use data, such as SbD4Nano, SUSnanofab, SABYDOMA, SAbyNA, NanoFabNet, SUNSHINE, GRACIOUS, PATROLS, Evo-*

				Nano, NanoCommons, M3DLoC, NanoExplore, Purenano, RiskGone, NanoRigo, NanoSolveIT, NanoinformaTIX, Hi-Accuracy, Nanoharmony, Nanomet, ASINA, HARMLESS, DIAGONAL. ***EVALUATION:*** ***FAIR evaluation methods*** *(WP1 feedback).* ***Chart statistics*** *(WP1 feedback)*
			Quality of the data which has been incorporated in the ontology (data source, reproducibility of the study…)	**MONITORING:** **FAIR evaluation methods** (WP1 feedback). **Chart statistics** (WP1 feedback)
	Data infrastructure (databases)	Data standards (including curation). Follow development on the simplification of GuideNano framework.		***MONITORING:*** ***Software-based instruments*** *(KB Crawl, Horizon Scanning, …),* ***FAIR evaluation methods.***
		Follow the progression of FAIRness in currently available databases (maturity of the FAIRness of the databases)	New / Existing database containing only curated data obtained using and applying agreed OECD Test Guideline(s) and the OECD Principles of Good Laboratory Practice, and including previous repositories (eNanoMapper, NanoCommons, Nikc,…)	***MONITORING & EVALUATION:*** ***Expert committee*** *- Adherence of studies to established guidelines/ ISO Norms /SOPs as a condition to be taken into consideration. Accessibility by/Compatibility with RA software platforms - Number of RA software linked to the database.* ***Surveys / Questionnaires*** *- satisfaction of users with the database.*
		Development of network of interoperable databases (eNanoMapper, NanoCommons database, Nikc (US)). The goal is to make them all accessible with one query (interoperable). Monitor progress of NanoInformatics Knowledge Commons US-EU Data Integration Team.		

	Linkage of FAIR databases to optimal risk assessment software/tools/platforms that contains risk assessment methods across EU regulatory domains.	Inventory of the ability of platforms containing risk assessment software and other tools to access and efficiently export data from FAIR databases.	Number of RA software / tools / platforms which use FAIR databases' information as input data for the risk assessment methodology. Updated version of RA software using data from FAIR databases	***MONITORING:*** ***Software-based instruments*** *(KB Crawl, Horizon Scanning, …).* ***EVALUATION:*** ***Expert committee*** *- Number of RA tools linked to FAIR databases,* ***Surveys*** *(number of users, satisfaction, gaps detection)*
	Cluster workgroup: Consider FAIR data network (link to WP1, GoFAIR Implementation Network; AdvancedNano just started). Manifesto – document where goals of network are written.	Stakeholder support (think of number of activities in network and number of participants). Survey to different groups: • NanoSafety Cluster WG-F • EU-US Community of Research (COR) • EMMC (European Materials Modeling Council) • EMCC (European Materials Characterization Council). • EuMaT (European Technology Platform for Advanced Engineering Materials and Technologies)	Number of members, number of activities, type of activities, protocols	***MONITORING:*** ***FAIR questionnaire*** *(too early to consider it the most suitable way to monitor).* *Other kind of* ***surveys / questionnaires.***
		Stakeholder awareness	Level of awareness of the activities performed by the Data Quality workgroup	***MONITORING & EVALUATION:*** ***Surveys/questionnaires*** *to stakeholders*
		Knowledge sharing	Number of Member States accepting Mutual Acceptance of Data (MAD) / Number of	***MONITORING & EVALUATION:*** ***Software-***

			workshops organized to advertise updates in data quality standards and accessible curated databases	***based instruments*** *(KB Crawl, Horizon Scanning, …).* ***Expert committee***
		A working process to facilitate FAIR data implementation.	Number of workshops/trainings/online guidance offered to stakeholders on FAIR data implementation on the nanosafety field	***EVALUATION:*** ***Expert committee*** *- determine indicators of successfulness on FAIR data implementation*
	Process to facilitate FAIR data implementation	Standardized method for putting together the periodic review.	Management plan/Guideline to elaborate periodic review	***MONITORING:*** ***Expert committee*** *- determine indicators of successfulness (including internal / external auditors)*
		Reflection of standardized method resulting in possible updates.	Number of implemented improvements in the monitoring procedure	***MONITORING:*** ***Expert committee*** *- determine indicators of successfulness (including internal / external auditors)*

Table 12: Success criteria and potential instruments for monitoring and evaluation of the indicators and sub-indicators under cluster 3 (Innovation & Governance)

Sub-area	Indicator	Sub-indicator	Success criteria (What are the targets or success criteria?)	Measurement (How will it be measured?)
A risk governance system for NMs is established	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	***MONITORING:*** ***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. New nanoproducts registered at ECHA* *Market analysis to detect new patents, products using nanomaterials.* ***Survey / Questionnaire*** *collecting information on new nanomaterials, advanced materials and trends.* ***Innovation Radar Platform***
Current barriers for innovation in NMs are defined and solutions are provided to overcome barrier.		Identify the barriers for developing new technology.	Report on identified the barriers for developing new technology	***MONITORING:*** ***Market gaps analysis/ Surveys*** *to industrial actors.* ***Software-based instruments*** *(KB Crawl, Horizon Scanning, ...). Target web sources like: EU-OSHA's European Risk*

A mechanism is established to stimulate innovations in NMs including a system for structural investment in NM innovation.				*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.* ***Innovation Radar Platform*** ***EVALUATION:*** *Number of nanoproducts getting to the market for each sector compared to patented nanoproducts or products at exploratory phases.* ***Innovation Radar platform*** *- Number of products for each sector in each level of maturity*
		Survey and Inventory of stakeholder satisfaction and stakeholder needs (Surveys need to be stakeholder specific (regulators, industry, researchers, education, society, etc.)).	Number of participants for the survey, report on survey results, list of identified gaps…	**MONITORING: Survey** containing questions related to stakeholder's satisfaction and needs
		Regulatory satisfaction and regulatory needs (survey and inventory)	Number of participants for the survey, report on survey results, list of identified gaps…	***MONITORING:*** ***Survey*** *containing questions related to regulator satisfaction and needs*
	Impact of nanotechnology innovation investments	Inventory of global investments in nanotechnology.	Statistics on global investments in nanotechnology (total amounts, sectors, capital origin…)	**MONITORING: Market analysis / Innovation radar platform**
		Research projects involving nanotechnology innovations (Inventory).	Number of research projects involving nanotechnology	**MONITORING: Software-based instrument** (KB Crawl, Horizon Scanning, ...).

			innovations, innovation sectors, amount funded, …	**Innovation Radar Platform.** **EVALUATION: Expert panel**
	Knowledge platform	Transdisciplinary and trans domain innovation knowledge exchange (conference, survey)	Number of conferences/workshops and number of assistants from each sector	**MONITORING: Software-based instrument** (KB Crawl, Horizon Scanning, ...) - to monitor events. **Surveys / Questionnaires** to different stakeholders. **EVALUATION: Expert panel**
		A trusted digital platform and forum (use and number of users)	Number of users, percentage of satisfaction, activity of the forum (new topics, participants,…)	**MONITORING: Survey / questionnaire** to evaluate the use of the users of the platform and users' satisfaction
	Digital program to monitor how funding agencies are distributing funding	Periodic review report.	Periodic review report	**MONITORING: Software-based instrument** (KB Crawl, Horizon Scanning, ...), **market analysis.** **EVALUATION: Expert panel / Expert committee**
		Money invested in nanotechnology innovations (Digital Inventory)	Money invested in nanotechnology innovations	**MONITORING: OECD reports** (OECD NESTi), OECD innovation statistics, key reports, Social Medial mentions, Funding agencies reports. Most voted (SLIDO): **Expert committee** (86%).
	Foresight Research on market change to allocate funding to right projects	Report on market change (see for instance https://ati.ec.europa.eu/ systematic monitoring of technological trends and reliable, up-to-date data on advanced technologies)	Market changes on the tendency to invest on innovation related to nanomaterials	**MONITORING: Market analysis** (65%) - e.g. "https://ati.ec.europa.eu/" + **funding agencies reports.** **EVALUATION: Expert committee** (65%), including expert review
	Cluster workgroup with a management system	Periodic monitoring review report including strategies,		**EVALUATION: Expert committee**

		directions, instructions and control mechanisms.		
	Alignment of innovation with regulation. Development of readiness levels to align innovation to science and safety policy (monitor concept development)	Development of an innovation system which includes societal readiness levels.	Definition of the Societal Readiness Levels (SRL) - Establish an innovation system network between innovators, investors, regulatory bodies and social actors, consumers	**MONITORING & EVALUATION: Expert committee** - determination of the possible different levels and adequation of them. **Innovation Radar Platform** - Inventory of innovations categorized by maturity level. **Surveys/ Questionnaires** on society / consumer needs and nanotechnology advancements awareness. ***CSR Index***
		Development of an innovation system which include regulatory readiness levels	Definition of the Regulatory Readiness Levels (RRL) - Establish an innovation system network between innovators, investors, regulatory bodies and social actors, consumers	**MONITORING & EVALUATION: Expert committee** (57%) - determination of the possible different levels and adequation of them. **Software-based instruments** (KB Crawl, Horizon Scanning, …) could be also an option. **Innovation Radar Platform** - Inventory of innovations categorized by maturity level. **Surveys / Questionnaires** to regulatory bodies. ***CSR Index***
		Alignment of technology readiness levels with societal and regulatory readiness levels.	Level of alignment between TRL and SRL / RRL	**MONITORING & EVALUATION: Expert committee, Innovation Radar Platform** ***CSR Index***

	Monitoring process for periodic review	Standardized method for putting together the periodic review	Management plan/Guideline to elaborate periodic review	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)
		Reflection of standardized method resulting in possible updates.	Number of implemented improvements in the monitoring procedure	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)

Table 13: Success criteria and potential instruments for monitoring and evaluation of the indicators and sub-indicators under cluster 4 (Funding & Value of Investment)

Sub-area	Indicator	Sub-indicator	Success criteria (What are the targets or success criteria?)	Measurement (How will it be measured?)
Adoption of regulatory questions and needs by research funding (DOA)	Research questions taken on by funding agencies	Inventory on research questions (based on regulatory needs) taken on by funding agencies.	List of topics funded by each funding agency, most funded topics	***EVALUATION:*** ***Expert committee/Funding agencies reports***
			List of research questions received by the funding agencies (grouped by topics)	***MONITORING:*** ***Software-based instruments*** *(KB Crawl, Horizon Scanning). Target web sources like : National research funding Agencies (like in France ANR, ANSES,ADEME…), EU Research and innovation, JRC, CORDIS, EU Nanosafety cluster, Funding & Tenders Portal, NNI, AZoNano, Nanowerk*
	Research questions funded by funding agencies	Inventory on research questions (based on regulatory needs) funded by funding agencies.	List of EU funded regulatory-related projects and funding agencies/Statistics on dedicated amount of funding per topic yearly	***MONITORING:*** ***Software-based instrument*** *(KB Crawl, Horizon Scanning, ...) - Topics and funding dedicated to each one/Funding agencies reports*
			Number of received research questions which has been funded by funding agencies (group by topics / categories)	***MONITORING:*** ***Software-based instruments*** *(KB Crawl, Horizon Scanning). Target web sources like: National research funding Agencies (like in France ANR, ANSES,ADEME…), EU Research and innovation, JRC, CORDIS, EU Nanosafety cluster, Funding & Tenders Portal, NNI, AZoNano, Nanowerk*
		Inventory of proposals accepted, or test guidance /	List of ongoing EU funded projects and funding agencies	***MONITORING:*** ***Software-based instrument*** *(KB Crawl, Horizon Scanning, ...) - Number of accepted proposals or*

		guidance documents under development.		*guidance documents under development/Funding agencies reports*
		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	***MONITORING:*** ***Software-based instrument*** *(KB Crawl, Horizon Scanning, ...) - Number of completed proposals leading to guidance documents/Funding agencies reports*
	Research questions requiring FAIR data	Inventory on research questions requiring FAIR data.	List of research questions requiring FAIR data (grouped by topics)	***MONITORING:*** ***Software-based instrument*** *(KB Crawl, Horizon Scanning) - to find the questions - +* ***Expert committee*** *- to decide if FAIR data is applicable*
			List of grants requiring FAIR data funded by each funding agency / Statistics on topics and research questions requiring FAIR data	***EVALUATION:*** ***Expert committee/Funding agencies reports***
	Research leading to solutions to regulatory needs as a result of research funded through funding agencies.	Inventory of the development of solutions to regulatory needs through calls from funding agencies.	List of completed EU funded projects and main outcomes/Statistics on number of completed proposals leading to solutions to regulatory needs	***MONITORING:*** ***Software-based instrument*** *(KB Crawl, Horizon Scanning, ...) - Number of completed proposals leading to solutions to regulatory needs +* ***Expert committee*** *(80%) - checking Funding agencies reports*
	Digital program to monitor indicators among funding agencies	Periodic review report of indicators	Report including statistics for the previous indicators	***MONITORING:*** ***Software-based instrument*** *(KB Crawl, Horizon Scanning, ...) constant monitoring of previous indicators and generating statistic data and reports published in newsletter form or on website*

				EVALUATION: ***Expert committee***
	Cluster workgroup to perform monitoring review	Periodic review	Number of periodic meetings and outcomes (success for the pre-established KPIs to monitor) of these meetings	***MONITORING:*** ***Expert committee*** *- determine indicators of successfulness (including internal / external auditors)*
	Monitoring process for periodic review	Standardized method for putting together the periodic review.	Management plan/Guideline to elaborate periodic review	***MONITORING:*** ***Expert committee*** *- determine indicators of successfulness (including internal / external auditors)*
		Reflection of standardized method resulting in possible updates.	Number of implemented improvements in the monitoring procedure	***MONITORING:*** ***Expert committee*** *- determine indicators of successfulness (including internal / external auditors)*

Table 14: Success criteria and potential instrument for monitoring and evaluation of the indicators and sub-indicators under cluster 5 (S(S)bD)

Sub-area	Indicator	Sub-indicator	Success criteria (What are the targets or success criteria?)	Measurement (How will it be measured?)
A mechanism is established to identify potential risks, including stimulation of Safe-and-Sustainable-by-Design implementation (S(S)bD)	Nano specific hazard information	Availability of early hazard assessment tools (inventory)	Inventory of more relevant early hazard assessment tools classified for field of application.	***MONITORING:*** ***Software-based instrument*** *(e.g. KB Crawl, Horizon Scanning, ...). Target web sources like: EU-OSHA, OECD, JRC, SbD4Nano, SUSnanofab, SABYDOMA, SAbyNA, NanoFabNet, SUNSHINE, GRACIOUS, PATROLS, Evo-Nano, NanoCommons, M3DLoC, NanoExplore, Purenano, RiskGone, NanoRigo, NanoSolveIT, NanoinformaTIX, Hi-Accuracy, Nanoharmony, Nanomet, ASINA, HARMLESS, DIAGONAL.* ***EVALUATION:*** ***Expert committee*** *- Identification of the limitations of such tools and determination of the proper use in specific cases*
Communication between industry and regulators in the early stages of innovation is facilitated to support safe innovative products to the market (in a trusted environment).		Identification of data gaps (regulators) (Inventory)	List of data gaps and gaps minimization strategy	***MONITORING:*** ***Software-based instrument*** *(e.g. KB Crawl, Horizon Scanning, ...). Target web sources like : EU-OSHA, OECD, JRC, SbD4Nano, SUSnanofab, SABYDOMA, SAbyNA, NanoFabNet, SUNSHINE, GRACIOUS, PATROLS, Evo-Nano, NanoCommons, M3DLoC, NanoExplore, Purenano, RiskGone, NanoRigo,*

				NanoSolveIT, NanoinformaTIX, Hi-Accuracy, Nanoharmony, Nanomet, ASINA, HARMLESS, DIAGONAL. ***EVALUATION:*** ***Real Time Delphi Survey*** *- Expert (regulators) panel*
A mechanism to support safe and sustainable innovation of products is established.		Academic showcases of S(S)bD	Collection (Inventory) of academic showcases of S(S)bD (focused on hazard characterization)	***MONITORING:*** ***Software-based instrument*** *(e.g KB Crawl, Horizon Scanning, …) - List of papers / publications with academic showcases of S(S)bD (hazard assessment).* ***EVALUATION:*** ***Expert committee*** *- Determination if these showcases are relevant to academics.*
A system for structural investment in safety research is established		Industrial showcases of S(S)bD	Collection (Inventory) of industrial showcases of S(S)bD (focused on hazard characterization)	**MONITORING:** **Software-based instrument** (e.g KB Crawl, Horizon Scanning, …) - List of papers / publications with industrial showcases of S(S)bD (hazard assessment). **EVALUATION:** **Expert committee** - Determination if these showcases are relevant to professionals.
A process of sharing trusted sources of information between market players is established.	Nano specific exposure information	Availability of early exposure assessment tools (inventory)	Inventory of early exposure assessment tools	**MONITORING:** **Software-based instrument** (e.g. KB Crawl, Horizon Scanning, ...). Target web sources like: EU-OSHA, OECD, JRC, SbD4Nano, SUSnanofab, SABYDOMA, SAbyNA, NanoFabNet, SUNSHINE, GRACIOUS, PATROLS, Evo-Nano, NanoCommons, M3DLoC, NanoExplore, Purenano,

				RiskGone, NanoRigo, NanoSolveIT, NanoinformaTIX, Hi-Accuracy, Nanoharmony, Nanomet, ASINA, HARMLESS, DIAGONAL. **EVALUATION: Expert committee** - Identification of the limitations of such tools and determination of the proper use in specific cases
A mechanism to ensure workers safety is established.		Identification of data gaps (regulators) (inventory)	List of data gaps and gaps minimization strategy	**MONITORING: Software-based instrument** (e.g. KB Crawl, Horizon Scanning, ...). Target web sources like : EU-OSHA, OECD, JRC, SbD4Nano, SUSnanofab, SABYDOMA, SAbyNA, NanoFabNet, SUNSHINE, GRACIOUS, PATROLS, Evo-Nano, NanoCommons, M3DLoC, NanoExplore, Purenano, RiskGone, NanoRigo, NanoSolveIT, NanoinformaTIX, Hi-Accuracy, Nanoharmony, Nanomet, ASINA, HARMLESS, DIAGONAL. **EVALUATION: Real Time Delphi Survey** - Expert (regulators) panel
A mechanism for regulatory preparedness is established (DOA)		Academic showcases of S(S)bD	Collection (Inventory) of academic showcases of S(S)bD (focused on exposure assessment)	**MONITORING: Software-based instrument** (e.g KB Crawl, Horizon Scanning, …) - List of papers / publications with academic showcases of S(S)bD (exposure assessment). **EVALUATION: Expert committee** - Determination if

				these showcases are relevant to academics.
A mechanism is established to support implementation of safe-an-sustainable-by-design.		Industrial showcases of S(S)bD	Collection (Inventory) of industrial showcases of S(S)bD (focused on exposure assessment)	**MONITORING:** **Software-based instrument** (e.g KB Crawl, Horizon Scanning, …) - List of papers / publications with industrial showcases of S(S)bD (exposure assessment). **EVALUATION:** **Expert committee** - Determination if these showcases are relevant to professionals.
	Research dedicated to S(S)bD	Research dedicated to S(S)bD	Number of publications on S(S)bD, number of EU funded projects, amount granted, projects' topics	**MONITORING:** **Software-based instruments** (KB Crawl, Horizon Scanning, …) - Publications, EU funded projects on S(S)bD.
	Incentives for S(S)bD	Incentives for all relevant stakeholders (subsidies, shorter time to marker, customer education)	List of incentives, list of barriers or gaps to S(S)bD implementation	**MONITORING:** **Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …) - Published Information at the website from different funding agencies. **Surveys** - To relevant stakeholders available and needed incentives ***CSR Index***
	Worker safety	Nano-related worker incidents (inventory). See, for instance: • MODERNET • Check new and emerging risk database (NERDB)	List of workers incidents related to nanomaterials.	**MONITORING:** **Software-based instruments** (KB Crawl, Horizon Scanning, …) - Checking existing and new databases (e.g. NERDB), MODERNET. **EVALUATION:** **Expert committee** - evaluation of the causes for these incidents and determination of the way to

				minimize the number of incidents.
		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)	Laboral risk prevention guidelines for nanomaterials related work, trainings, and workshops to increase workers awareness on safety	**MONITORING: Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …) - Published Information at the website from different funding agencies. **Surveys** - To workers and industry about knowledge on nano-related safety ***MCDA –*** *To aid decision-making process*
	Risk perception	Workers perceived relative risks of nanomaterials they handle (vs. what an expert would conclude on relative risks).	Number of trainings and workshops to increase workers awareness on safety	**MONITORING: Survey/questionnaire** for workers on nanomaterials, safety and laboral risk prevention.
		Consumer choices (vs. what an expert would conclude on relative risks) (Market analysis)	Consumer's perception of the risk associated to materials produced by S(S)bD methods.	**MONITORING: Surveys / Market analysis** - Consumers awareness
	Knowledge platform	Transdisciplinary and trans domain knowledge	Number of conferences on knowledge exchange (webinars, workshops, …)	**MONITORING: Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …) **EVALUATION: Surveys / Questionnaires** - Evaluation of the level of knowledge exchange and what can be improved in the following exchanges (conferences)
		Trusted digital platform or forum	Number of activities on transferring knowledge which have been promoted through the digital platform or forum	**MONITORING: Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …)

	Foresight – Monitoring technological trends for regulatory preparedness	Market change reporting (see Advanced Technology for Industry; systematic monitoring of technological trends and reliable, up-to-date data on advance technologies	Periodic report on technological and market trends	**MONITORING: Horizon Scanning / Market analysis**
	Education programs	Embed S(S)bD in curriculum	Number of courses and education programs containing courses on S(S)bD	**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, …). **Survey / questionnaires** (55%)
		Provide S(S)bD Workshops	Number of activities and workshops on S(S)bD	**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, …). **Survey / questionnaires** (55%)
		Develop S(S)bD trainings for industry (innovator specific)	Number of S(S)bD training activities for industry	**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, …). **Survey / questionnaires** (55%)
		Develop S(S)bD training for regulators	Number of S(S)bD training activities for regulators	**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, …). **Survey / questionnaires** (55%)
		Inventory of university specific training vs nationwide programs		**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, …). **Survey / questionnaires** (55%)
	Monitor for registers and surveillance systems for possible new risks in products containing nano	Identification of possible new risks in products containing nanomaterials (monitor product registers, alert and surveillance		**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, …).

		systems for instance: The Nanodatabase, EUON, RAPEX)		
	Pre-consultation (industry vs regulators) in a trusted environment	Development of pre-consultation (industry vs regulator)		**EVALUATION: Expert committee + surveys/questionnaires**
		Industrial showcases (success stories)		**MONITORING: Software-based instrument** (e.g KB Crawl, Horizon Scanning, …) - List of papers / publications with industrial showcases of S(S)bD (hazard assessment). **EVALUATION: Expert committee** - Determination if these showcases are relevant to professionals.
		Users using this service		**EVALUATION: Surveys / questionnaires**
	Grouping and read across	Standardized methods for applying grouping and read across during various stages of innovation	Updated guidance and methods for industry/registrants on standardized methods for applying grouping and read across during various stages of innovation	**MONITORING: Software-based instruments** (KB Crawl, Horizon Scanning, ...). Target websites: project websites (GRACIOUS, BIORIMA), JRC, ECHA (REACH), EUON, OECD. **EVALUATION: Real Time Delphi Surveys** to expert panel/ Expert symposiums ***MCDA –*** *Risk assessment tool*
		Grouping approaches used in REACH nano-dossiers	Inventory of grouping approaches used in REACH nano-dossiers	**EVALUATION: Expert committee**
	Cluster workgroup to monitor S(S)bD implementation	Periodic review of (S(S)bD progress	Management plan/Guideline to elaborate periodic review	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)

	Monitoring process for periodic review	Development of standardized method for putting together the periodic review		**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)
		Reflection of standardized method resulting in updates	Number of implemented improvements in the monitoring procedure	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)

Table 15: Success criteria and potential instrument for monitoring and evaluation of the indicators and sub-indicators under cluster 6 (Communication)

Sub-area	Indicator	Sub-indicator	Success criteria (What are the targets or success criteria?)	Measurement (How will it be measured?)
A communication platform is established which is accessible to all stakeholders	Survey on the trustworthiness of the platform and the NRGC	Citizen trustworthiness (survey)	Questions related to citizen trustworthiness category	***MONITORING:*** ***Survey*** *containing questions related to citizen trustworthiness (based on OECD Trustlab Experiment and FSA survey)*
A mechanism for transdisciplinary collaboration across regulatory domains is established		Multi stakeholder trustworthiness (survey)	Questions related to stakeholders' trustworthiness category	**MONITORING:** **Survey** containing questions related to stakeholders' trustworthiness (based on OECD Trustlab Experiment and FSA survey)
A transparent system is developed to connect science policy, safety policy and innovation policy	Citizen friendly section in the platform	Citizen communication (for instance information for citizens including information on product safety)	Functionalities of the platform	***MONITORING:*** ***Survey*** - *Evaluation of the functionalities of the platform*
A system is developed to connect research, regulatory oriented science and policy		Citizens' feedback	Functionalities of the platform	**MONITORING:** **Survey** - Acceptance of the functionalities of the platform
Implementation of safety and risk management in education		Inclusion of questions and topics raised by society	Questions and topics raised by society (How many questions are sent by citizens / society on friendly platform section (and are answered))	**MONITORING:** **Survey**. **EVALUATION:** **Expert committee** - Collection of questions and topics through chat/Forum in the platform, e-mail inbox, Social Media, ...
Increased public trust related to safety of NMs	Knowledge platform	Transdisciplinary and trans domain multi stakeholder knowledge exchange (conference, survey)	Number of conferences on knowledge exchange (webinars, workshops, …)	**MONITORING:** **Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …) **EVALUATION:** **Surveys / Questionnaires** - Evaluation of the level of knowledge exchange and what can be

				improved in the following exchanges (conferences)
A mechanism is established to prove, communicate and have information on product safety		Transdisciplinary and trans domain summit for regulators to encourage knowledge sharing and collaboration (survey)	Number of activities carried out by regulators to encourage knowledge sharing and collaboration	**MONITORING: Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …) **EVALUATION: Surveys / Questionnaires** - Evaluation of the level of knowledge exchange and what can be improved in the following exchanges (conferences)
		Digital platform or forum (use and number of users)	Number of activities on transferring knowledge which have been promoted through the digital platform or forum	**MONITORING: Software-based instruments** (e.g. KB Crawl, Horizon Scanning, …)
	Development of readiness levels to align innovation to science and safety policy (monitor concept development)	Societal readiness levels	Definition of the Societal Readiness Levels (SRL)	**MONITORING & EVALUATION: Expert committee** - determination of the possible different levels and adequation of them
		Regulatory readiness levels	Definition of the Regulatory Readiness Levels (RRL)	**MONITORING & EVALUATION: Expert committee** - determination of the possible different levels and adequation of them
		Alignment of technology readiness levels with societal and regulatory readiness levels	Level of alignment between TRL and SRL / RRL	**MONITORING & EVALUATION: Expert committee**
	Safety and risk management education programs	Safety and risk management education in curriculum	Professionals which have participated in educational programs / degrees / workshops where safety and risk management were part of the temary.	**MONITORING: Software-based instrument** (e.g. KB Crawl or Horizon Scanning)

		Safety and risk management workshops	Workshops (by country) including safety and risk management in the temary.	**MONITORING: Software-based instrument** (e.g. KB Crawl or Horizon Scanning)
		University specific training vs nationwide programs	University degrees / educational programs including safety and risk management in the temary.	**MONITORING: Software-based instrument** (e.g. KB Crawl or Horizon Scanning)
		Safety training for industry (innovator specific)	Trainings on safety for industrial professionals (innovation practices must be part of the temary)	**MONITORING: Software-based instrument** (e.g. KB Crawl or Horizon Scanning)
	Cluster workgroup to monitor communication	Periodic review (on communication)	Number of periodic meetings and outcomes (success for the pre-established KPIs to monitor) of these meetings	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)
	Monitoring process for periodic review	Development of standardized method for putting together the periodic review	Management plan/Guideline to elaborate periodic review	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)
		Reflection of standardized method resulting in possible updates	Number of implemented improvements in the monitoring procedure	**MONITORING: Expert committee** - determine indicators of successfulness (including internal / external auditors)

5 Evaluation and conclusions

Monitoring and evaluating instruments are key elements to put into context the achieved level of success of the indicators and sub-indicators the Nano Risk Governance Council (NRGC) has considered in advance. This level of success will allow the NRGC determine whether sufficient action on a specific topic has been taken and the obtain results should be the basis to set new priorities towards the long-term objective of the Council in the risk governance field.

Instruments of different nature were devised in this deliverable. In an initial stage, a brainstorming by the members of the core working group was required to list relevant instruments to achieve the goals of the NRGC. A bibliographic search was carried to figure out the strengths and weaknesses of applicability for the monitoring and evaluation of the indicators and sub-indicators defined in task 7.2. Most of the defined indicators could be used for monitoring and/or evaluating their performance by using, at least, one of the described instruments under section 3 of this deliverable, but the most efficient way to approach this monitoring and evaluation should imply the complementary use of more than one instrument at the same time for an specific indicator, as for example the use of automated software-based instruments in combination to expert evaluations.

Thereafter, the definition of, at least, one success criterion for each indicator and sub-indicator was necessary to be able to assign the considered instruments for monitoring and evaluating their performance. As mentioned in Table 1: Summary of number of indicators and sub-indicators for each defined cluster., the number of indicators and sub-indicators in each of the 6 defined clusters (standardization, FAIR data and quality data, innovation and governance, funding and value of investment, S(S)bD, and communication) was so high that, without a prioritization of these indicators, based on criteria of easy implementation and relevance for the players on the process, the task of assignation of instruments would have been affordable. It was assigned a value from 1 to 5 to each variable considered for the prioritization. The final score was calculated by adding the assigned values to these variables. This score allowed the core working group to evaluate which indicators had a highest priority to be addressed, classifying them in three levels: high priority, medium priority and low priority. Most of the indicators were included in the medium priority category. Each of these steps was necessary to make the monitoring more specific and therefore more tangible.

In future steps, within task 7.4 and 7.5, the information provided in the results section will need to be re-evaluated, in order to estimate the feasibility of implementation. Aspects as the frequency of monitoring and evaluation of instruments, the actor who might be responsible for such monitoring and evaluation and the way the success criteria should be reported will also be part of the next steps in the process.

In terms of outputs from the process, it would be also required to define the means of verification (how the data related to the indicator is collected), as well as the quality and completeness of the collected data.

The impact of the monitoring and evaluating step, together with the lessons learned during the progress, will allow the NRGC to evaluate the success of the performed tasks and evolve on the goals to be achieved in medium or long-term by the council.

6 Deviations from the work plan

D7.3 – "Selected monitoring instruments and recommendations for their implementation" was supposed to be submitted on M24. Task 7.3 started on February 2021 (M26), due to a delay on the finalization of the previous tasks. Due to that delay, the performance of this task and the submission of the associated deliverable were postponed 6 months from the original agreement.

This deviation also affected to the performance of the upcoming tasks within WP7.

7 Performance of the partners

Task partners performed actions according to the task description. In addition, an overarching core group was established. This core group consisted of Danail Hristozov (EMERGE), Rob Aitken (IOM), Yvette Christopher de Vries (IOM), Marie-Louise Bilgin (IenW), James Baker (NIA), Mary Gulumian (NIOSH), Charlene Andraos (NIOSH), Anna Leymarie (INERIS), Jacques Bouillard (INERIS), Nynke Krans (RIVM), Cornelle Noorlander (RIVM), Lya Hernandez (RIVM), Gemma Janer (LEITAT), Socorro Vázquez (LEITAT) and Rubén Álvarez (LEITAT).

8 References

Software-based instruments:

- KB Suite:

  KB Crawl website. https://www.kbcrawl.com/en/solutions-en/

- Horizon Scanning:

  OECD, 2019. Overview of methodologies, futures thinking in brief, future schooling. n.d.a. https://www.oecd.org/site/schoolingfortomorrowknowledgebase/futuresthinking/overviewofmethodologies.html

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  Food and Agriculture Organization of the United Nations (FAO). "Horizon Scanning and Foresight: An overview of approaches and possible applications in Food Safety." (2014).

  European Commission, 2015. Models of horizon scanning: How to integrate horizon scanning into European research and innovation policies. http://publications.europa.eu/resource/cellar/88ea0daa-0c3c-11e6-ba9a-01aa75ed71a1.0001.01/DOC_1 .

- Innovation Radar Platform:

  The EU Innovation Radar Platform website: https://www.innoradar.eu/

Market Analysis:

Nanomaterials Market Size, Share & Trends Analysis Report By Product (Carbon Nanotubes, Titanium Dioxide), By Application (Medical, Electronics, Paints & Coatings), By Region, And Segment Forecasts, 2020 – 2027. https://www.grandviewresearch.com/industry-analysis/nanotechnology-and-nanomaterials-market

Nanomaterials market - growth, trends, COVID-19 impact, and forecasts (2021 - 2026). https://www.mordorintelligence.com/industry-reports/nanomaterials-market

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Cetre, S., et al. (2020), "Ethnic bias, economic success and trust: Findings from large sample experiments in Germany and the United States through the Trustlab platform", OECD Statistics Working Papers, No. 2020/04, OECD Publishing, Paris, https://doi.org/10.1787/f6d0b7dd-en.

- The Trust Project (FSA, UK):

(Crown, 2018). "Trust in a changing world. Deliberative forums research report for FSA". https://www.food.gov.uk/sites/default/files/media/document/trust-deliberative-forums-research-fsa-2018.pdf

(FSA). "Food Standards Agency (UK) – Research project: Trust in a changing world". https://www.food.gov.uk/research/research-projects/trust-in-a-changing-world

Expert committee:

- Delphi Method:

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Hilbert, Martin; Miles, Ian; Othmer, Julia (2009). "Foresight tools for participative policy-making in inter-governmental processes in developing countries: Lessons learned from the eLAC Policy Priorities Delphi". Technological Forecasting and Social Change. 15 (2): 880–896. doi:10.1016/j.techfore.2009.01.001

Other instruments:

- Multiple-Criteria Decision Analysis (MDCA):

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- Corporate Social Responsibility Index (CSR index):

Commission of the European Communities. Green Paper: Promoting a European Framework for Corporate Social Responsibility. 2001. Available online: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0366&from=EN

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9 Appendix

As part of the 5th Consortium Meeting for GOV4NANO project, which took place on April 12th, 2021 and April 13th, 2021, a SLIDO activity was carried out in order to involve all partners of the project in task 7.3 and get additional feedback from not-involved partners in this task to support on the correct performance of this task.

The following tables and figures summarize the obtained results from that activity.

Table 16: Summary of the received answers in the SLIDO activity

Question	Number of received answers
Q1 – Which of the following instruments do you consider to be suitable to evaluate and monitor "Money invested by funding agencies in nanotechnology innovation"?	21
Q2 – In case you have selected "Other" in the previous question, please be more precise on your answer.	7
Q3 – Which of the following instruments do you consider to be suitable to evaluate and monitor "Research funding allocation on market change"?	17
Q4 – In case you have selected "Other" in the previous question, please be more precise on your answer.	4
Q5 – Which of the following instruments do you consider to be suitable to evaluate and monitor "Implementation of a Regulatory Readiness Level system for alignment of innovation and regulation"?	14
Q6 – In case you have selected "Other" in the previous question, please be more precise on your answer.	2
Q7 – Which of the following instruments do you consider to be suitable to evaluate and monitor "Research funding allocation to cover regulatory needs"?	10
Q8 – In case you have selected "Other" in the previous question, please be more precise on your answer.	0
Q9 – Which of the following instruments do you consider to be suitable to evaluate and monitor "Educational programs related to S(S)bD"?	11
Q10 – In case you have selected "Other" in the previous question, please be more precise on your answer.	0

Figure 7: Results from the question: "Q1. Which of the following instruments do you consider to be suitable to evaluate and monitor "Money invested by funding agencies in nanotechnology innovation"?"

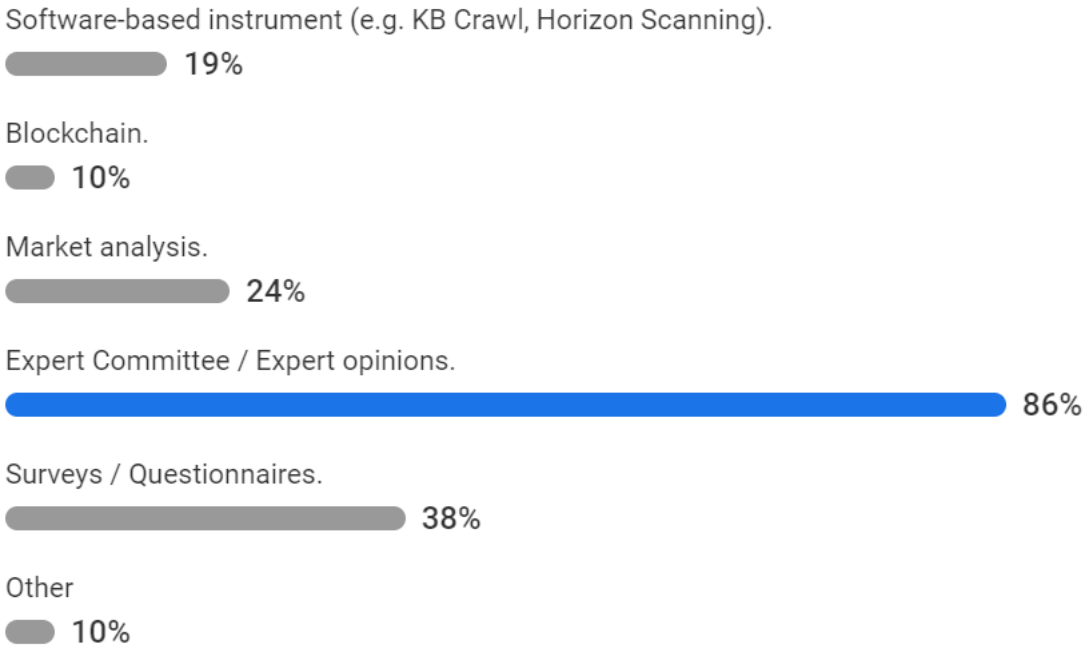

Figure 8: Received answers from the question: "Q2. In case you have selected "Other" in the previous question, please be more precise on your answer"

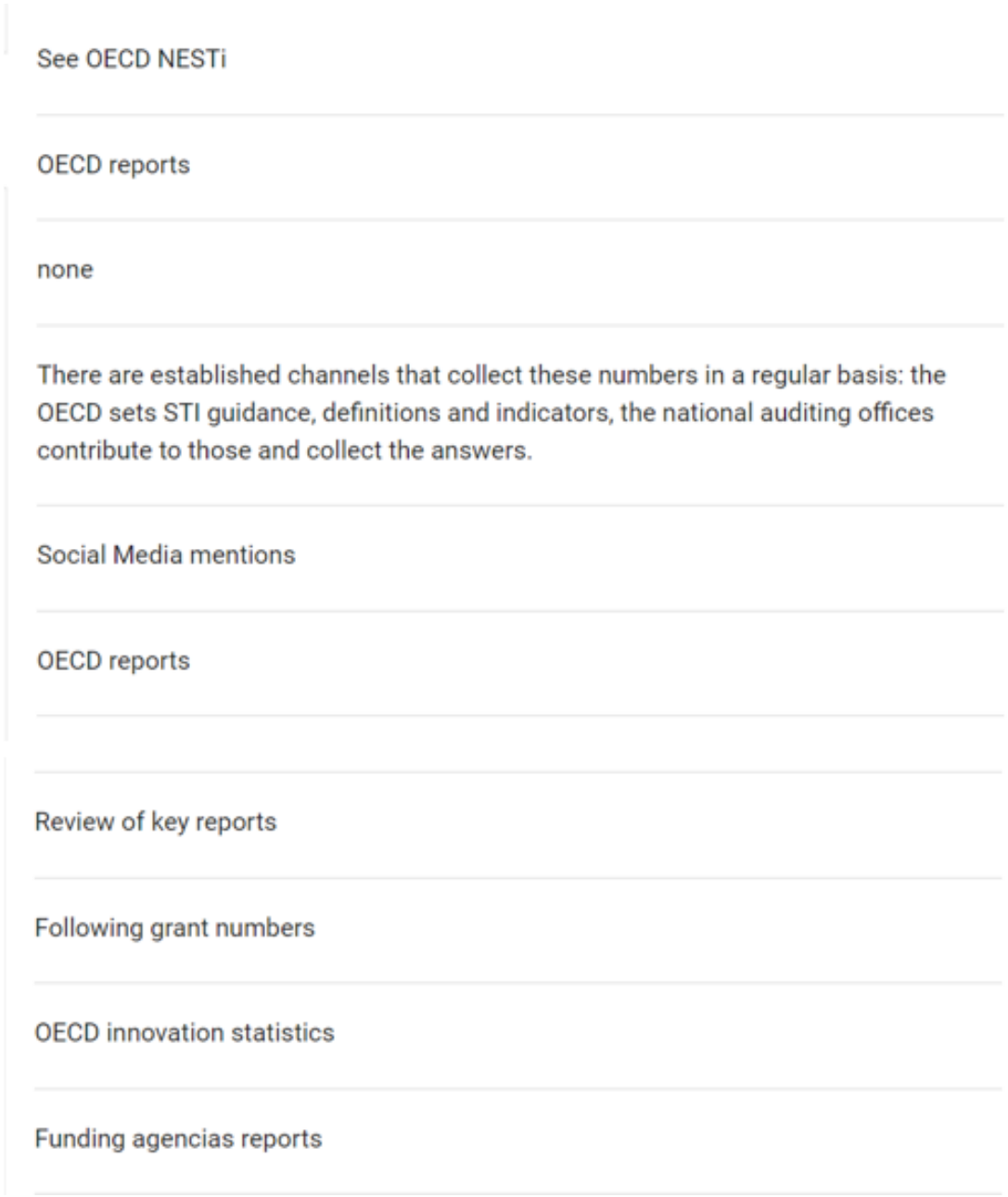

Figure 9: Results from the question: "Q3. Which of the following instruments do you consider to be suitable to evaluate and monitor "Research funding allocation on market change"?"

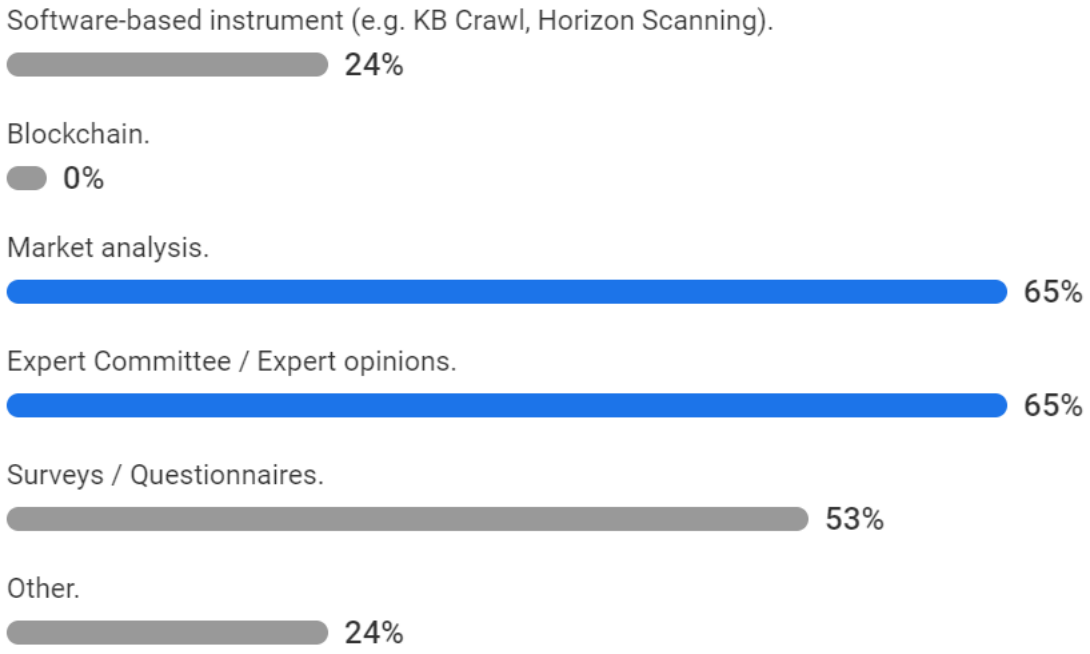

Figure 10: Received answers from the question: "Q4. In case you have selected "Other" in the previous question, please be more precise on your answer"

This needs to be centralised to be comparable.

Funding agencies reports

Funding agencies reports

Expert review

Figure 11: Results from the question: "Q5. Which of the following instruments do you consider to be suitable to evaluate and monitor "Implementation of a Regulatory Readiness Level system for alignment of innovation and regulation"?"

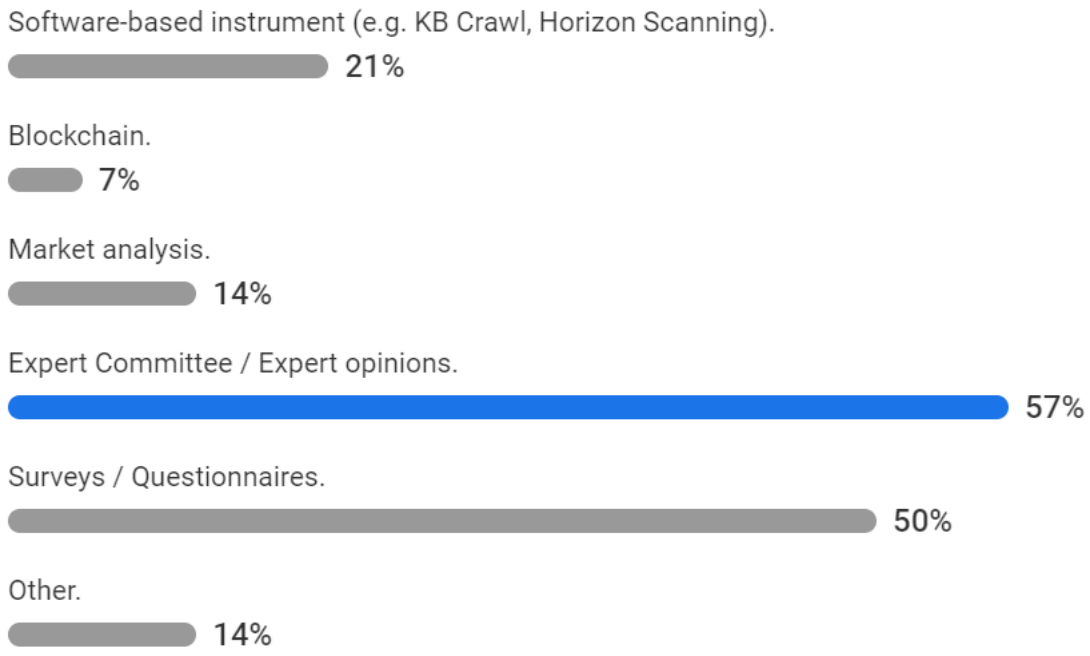

Figure 12: Received answers from the question: "Q6. In case you have selected "Other" in the previous question, please be more precise on your answer"

Crawl and Machine reading of tegulatory documents and guidances?

It is hard to identify an instrument, since it has not been really defined

Figure 13: Results from the question: "Q7. Which of the following instruments do you consider to be suitable to evaluate and monitor "Research funding allocation to cover regulatory needs"?"

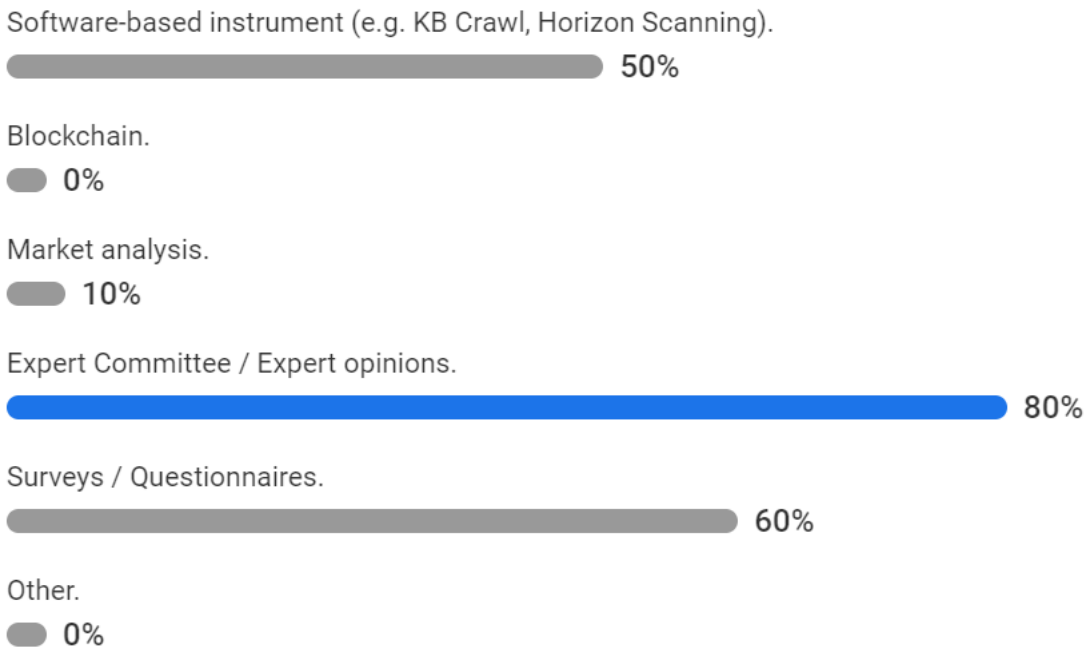

Figure 14: Results from the question: "Q9. Which of the following instruments do you consider to be suitable to evaluate and monitor "Educational programs related to S(S)bD"?"