National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Nanotechnology and Safe-by-Design

Inventory of results on Safe-by-Design Horizon 2020 projects from 2013 to 2020

RIVM report 2021-0108

N. Krans | L. Hernandez | C. Noorlander

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Synopsis

Nanotechnology and Safe-by-Design
Inventory of research into Safe-by-Design Horizon 2020 projects from 2013 to 2020.

A safe, clean, and healthy living environment is important for Europe. The Dutch government aims to ensure that all new materials and technological developments will be safe for people and the environment by 2050. To achieve this, all developments have to be safe and healthy, starting in the design stage: Safe-by-Design.

For this report, RIVM prepared an overview of studies into Safe-by-Design conducted in Europe between 2013 and 2020. Many of the projects were part of the European research program, Horizon 2020. The focus was on research projects regarding the safety of nanomaterials. The different behaviour of these very small materials in comparison with 'normal-sized' materials can pose an environmental risk.

The overview was commissioned by the Ministry of Infrastructure and Water Management to support Dutch environmental policy, of which Safe-by-Design is an important topic. It is intended to inform and inspire policymakers and industry, among others.

The overview contains 74 studies, each of which is summarized and subdivided into four policy themes: research, education, industry, and policy (strategic positioning). The results are also presented per theme, such as teaching materials for education and guidelines and tools for industry.

This inventory serves as a solid base to formulate additional activities and recommendations to advance the process of Safe-by-Design to implementation.

Keywords: Safe-by-Design, inventory, nanomaterials, safety, strategic positioning, policy tracks

Publiekssamenvatting

Nanotechnologie en Safe-by-Design
Inventarisatie van onderzoek naar Safe-by-Design gedaan binnen Horizon 2020-projecten van 2013 tot 2020

Een veilige, schone en gezonde leefomgeving is heel belangrijk voor Europa. De Nederlandse overheid streeft ernaar dat alle nieuwe materialen en technologische ontwikkelingen in 2050 veilig zijn voor mensen en milieu. Dit wordt gedaan door ze al vanaf de ontwerpfase veilig en gezond te laten zijn. Dit concept heet Safe-by-Design.

Het RIVM heeft een overzicht gemaakt van onderzoeken die tussen 2013 en 2020 in Europa zijn gedaan naar Safe-by-Design. De projecten waren meestal onderdeel van het Europese onderzoeksprogramma Horizon 2020. Het RIVM richtte zich hierbij op onderzoeksprojecten over de veiligheid van nanomaterialen. Nanodeeltjes zijn hele kleine deeltjes, die zich anders kunnen gedragen dan 'normale' deeltjes en daardoor een risico vormen.

Het overzicht is gemaakt in opdracht van het ministerie van Infrastructuur en Waterstaat. Dit is uitgevoerd om milieubeleid te ondersteunen waarvan Safe-by-Design een belangrijk onderdeel is. Het overzicht kan gebruikt worden voor onder andere beleidsmakers en de industrie te informeren en inspireren.

In het overzicht staan 74 onderzoeken beschreven, die elk zijn samengevat en onderverdeeld in vier beleidsthema’s: onderzoek, onderwijs, industrie en beleid (strategisch positioneren). Per thema zijn de resultaten van die onderzoeken weergegeven, zoals lesmateriaal bij onderwijs, en handleidingen en instrumenten bij industrie.

Deze inventarisatie vormt een goede basis om vervolgactiviteiten te formuleren die de transitie naar Safe-by-Design-implementatie bevorderen.

Kernwoorden: Safe-by-Design, inventarisatie, nanomaterialen, veiligheid, strategisch positioneren, beleidssporen

Contents

Summary

This report gives an overview of a catalogue of Safe-by-Design (SbD) related activities conducted as part of the European Horizon 2020 (H2020) programme. Projects that performed research on either SbD applicability or safety research for future SbD applicability were both considered. The H2020 project inventory was performed for SbD in all domains, mostly focusing on nanotechnology. Moreover, nanomaterial safety research projects with no direct SbD purpose were also included as some safety research relates to SbD aspects.

From the total of approximately 30,000 projects which have been subsidised by H2020 in the past seven years, 74 SbD-related projects were selected. These were assigned to four pillars that form the basis of the Dutch Ministry I&W Safe-by-Design policy programme; 1) research, 2) education, 3) industry and 4) strategic positioning. Thereafter, a summary was made of all data from these projects and classified in sub-groups, for example tools, training, and frameworks. This inventory concludes with observations and open questions related to the projects' results.

Once the project results have been analysed in greater depth, recommendations for future steps can be developed. The inventory can then be used to support various actors (policy makers, regulators, industry, etc.) in taking further steps towards SbD implementation. This work can also be used to inform several organisations that address SbD, e.g., the Safe-by-Design Policy International Network (SPINE), Organisation for Economic Co-operation and Development (OECD), the NanoSafetyCluster (NSC), and the European Committee for Standardization (CEN). The report can also be made more widely available by being hosted on the I&W SbD website. Lastly, the findings can be used to perform a gap analysis to clarify research needed to further implement and embed SbD.

1 Introduction

The world currently faces a number of societal challenges, reflected by the United Nations Sustainability Goals (UN SGs) which address poverty, inequality, climate change, environmental degradation, peace and justice.[1,2,3] The European Green Deal (European Union's new growth strategy) has set the EU on a course to become a sustainable climate neutral and circular economy by 2050.[4,5] One of the Green Deal ambitions is to work towards a safe and sustainable living environment.

Designing for safety has a long tradition in several engineering disciplines, and recently this strategy has been applied to deal with the uncertainties associated with emerging technologies such as nanotechnology. Safe-by-Design (SbD) is an approach that aims to ensure minimal hazard, reducing uncertainties and risks for humans and the environment, starting at an early phase of the innovation process and covering the complete innovation value chain, including research.[5] The Ministry of Infrastructure and Water Management (I&W) describes SbD as follows: '*Safe-by-Design is about including safety at the earliest possible stage of product and process development. The intention is to prevent environmental risks and to ensure a clean, healthy, and safe living environment. Safe-by-Design forms part of the government's environmental policy.*'[6]

SbD is important for achieving policy ambitions such as the European Green Deal where it is proposed as one of the approaches to help achieving goals such as the circular economy (EU Action Plan for Circular Economy) and moving towards a zero pollution (pollution-free) environment.[7,8,9] The Green Deal ambitions and goals are supported by platforms like the Horizon Europe research and innovation programme.

The SbD concept needs to be further elaborated towards Safe-and Sustainable-by-Design (SSbD). While the concept of Safe-by-Design is gaining ground in various international policy arenas, the next challenge is to bring this to full implementation, while expanding the concept from SbD to SSbD. This will require the creation of incentives for industry to apply S(S)bD, dialogues, and co-creation between regulators and industry to develop acceptable and applicable ways of implementation, and timelines to address the urgency of achieving these goals by 2030.

This inventory of knowledge gathered in H2020 Projects relating to SbD was performed in order to identify (novel) tools, strategies, and synergies. The goal of this report is to catalogue and reflect on all

[1] Green Deal (https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en)
[2] The Chemical Strategy for Sustainability (https://ec.europa.eu/environment/strategy/chemicals-strategy_nl)
[3] https://www.un.org/sustainabledevelopment/sustainable-development-goals/
[4] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[5] https://www.safe-by-design-nl.nl/default.aspx
[6] https://www.safe-by-design-nl.nl/home+english/about+safe-by-design/default.aspx
[7] https://www.climatechangenews.com/2019/12/12/eu-releases-green-deal-key-points/ ; https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52019DC0640&from=EN
[8] https://ec.europa.eu/environment/circular-economy/
[9] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

knowledge identified in these projects in order to see what is needed to bring SbD closer to practical implementation and towards safer (and eventually more sustainable) innovations. The empirical base of this work comprises the output and descriptions of H2020 projects. Building on this information, we have categorised activities and results in terms of the four policy pillars of the I&W SbD program: education, research, industry, and strategic positioning.[4] There is a need for reciprocity between the three pillars of education, research, and industry, to bring SbD to future implementation. Strategic positioning is needed to bring all policy pillars together.

This inventory includes facts and figures of relevant projects that will fuel further international actions towards implementation of S(S)bD, such as actions by the Safe-by-Design Policy International Network (SPINE), Organisation for Economic Co-operation and Development (OECD), and the NanoSafetyCluster, or the European Committee for Standardization (CEN). Moreover, it can form a starting point for future calls in the Horizon Europe programme. This report can also lead to recommendations regarding the gaps and future steps needed to bring SbD closer to practical implementation.

2 Methods

To make an inventory of all projects under Horizon 2020 (H2020) which applied or could contribute to the applicability of SbD, a list was first obtained from the H2020 website. From the approximately 30,562 projects, a selection was made based on the search terms 'safe, SbD, safe by design, nano, risk, risk assessment, harmonised test methods, education safety nano, education safe nano, education safer nano, safety, safety by design, innovation, safety-by-design, safer, safer by design and safer-by-design'. These results cover a wide range of domains namely: nanomaterials, ecotoxicology, toxicology, medicine, food and feed, cosmetics, biocides, consumer products, and chemicals.

In addition to this website, a search with the same search terms was applied to projects related to H2020. Of the resulting 476 projects, 29 were added to the assessment. Furthermore, a selection of websites was found using the Google search engine, with search terms including 'safe by design and nano'. These websites were links to course materials, programmes, and training programmes specifically related to SbD; they are listed in this overview as 'not a H2020 project'.

The description of SbD on the I&W website was used as a criterion to filter the relevant projects within H2020.[10,11] The projects listed below were found using the keywords mentioned above but were excluded from the inventory as they did not meet these criteria. These reasons varied from projects just having SbD applicability in engineering, focused mostly on 'worker safe' by preventing accidents (LIGHTHOUSE, NewControl). Others, such as PRESTIGE were focused on innovating, and design driven instead of safety driven. Moreover, several projects (BATMAN, eJUMP, LISA, SaferACC and COFBAT) employed a substitution strategy more than SbD. Additional projects (SPIDER) focused more on reducing materials, making the project interesting within a sustainability context but not necessarily for SbD. Lastly, there were projects (NOVACHIP, ANAPRINT) where the SbD applicability was unclear.

The resulting 74 projects were then sorted by their contribution to the practical applicability to SbD as stated by I&W, based on four equally relevant pillars; research, education, industry, and strategic positioning. These were then subdivided in categories by the relations with each group, e.g. guidelines helpful for industry, courses used for education, and research papers added to research, as shown in Table 1. Additional information on each of the projects, such as the projects related to impact and strategic plan, can be found in the appendix. The appendix only includes information on projects subsidised by H2020. Conferences (e.g., ENF2015, 2017 and 2019) had no additional data and are excluded from the Appendix.

[10] https://www.government.nl/ministries/ministry-of-infrastructure-and-water-management
[11] https://www.safe-by-design-nl.nl/home+english/about+safe-by-design/default.aspx

Table 1 Subdivision of results into the four pillars

Research	Education	Industry	Strategic Positioning
(Nano) Safety Research	Workshops	Tools	International Support
(Nano) SbD Research	Courses	Guidelines	Stakeholder Support
	Programmes	Case studies (SbD)	Creating Awareness*
	Safety & SbD Training	Case studies (Safety)	Projects that have put SbD on a national or EU strategic agenda
		Frameworks	
		Databases	
		Networking platform	
		Platform for tools	
		Foresight	
		Datasets	

*Public awareness and/or awareness for researchers

Data obtained from the Cordis website such as publications, documents, conference proceedings, data sets, book chapters, thesis dissertations, and communication documents have been added to Supplementary Information.

3 Results

The H2020 projects are categorised in four pillars corresponding with the I&W policy strategy: 1) research (57 projects), 2) education (31), 3) industry (60), and 4) strategic positioning (14). It is important to note that some projects have results relevant to multiple pillars and are therefore presented in different pillars. For better readability, we have chosen to add the results in Chapter 6.

All SbD results have been summarised, evaluated and discussed. The report has been divided into the results based on the pillars so that learnings can be taken from each pillar separately, or from the inventory as a whole.

4 Discussion and evaluation

4.1 General observations

Table 2 shows the number of projects with the results in categories for each of the pillars of research, education, industry, and strategic positioning.

Table 2 Number of projects (in brackets) that have produced results in each of the categories for each pillar. The number is lower than the actual projects in the research pillar as not all projects have yet obtained results

Research (56)	**Education (31)**	**Industry (60)**	**Strategic Positioning (13)**
(Nano) Safety Research (36)	Workshops (17)	Tools (13)	International Support (9)
(Nano) SbD Research (16)	Courses (7)	Guidelines (26)	Stakeholder Support (3)
	Programs (1)	Case studies (SbD) (12)	Creating Awareness* (3)
	Safety & SbD Training (12)	Case studies (Safety) (6)	Projects that have put SbD on a national or EU strategic agenda (3)
		Frameworks (10)	
		Databases (8)	
		Networking platform (7)	
		Platform for tools (8)	
		Foresight (2)	
		Datasets (6)	

*Public awareness and/or awareness for researchers

Some general observations with regard to the European Union H2020 Research and Innovation Programme projects relating to SbD:

- Projects often run independently from each other. The NanoSafetyCluster acts as a connector.
- Projects aim to include coordinated efforts to deliver tools and guidelines to standardization bodies such as the OECD WPMN, ISO and CEN.
- In some instances, the sustainability of developed websites, platforms or tools is an issue. For example, the SeeingNano project made an application for civic engagement, but the application was removed from the Apple app store and Google play store. This is also the case for older project websites which are either hard to find, contain no content, or are no longer online.

4.2 Evaluation of the SbD results of H2020 projects

This section presents a short overview of the results of each project, adding a reflection for each of the pillars. Examples are given from the project lists in each category.

4.2.1 Research

General observations

- Fifty-six projects have produced research results on SbD.
- Of these projects, thirty-six deal with (eco)toxicological and risk assessment aspects of chemicals and nanomaterials. Project examples include EU-ToxRisk and NANOVALID. The ultimate goal of EU-ToxRisk is to deliver testing strategies to enable reliable, animal-free, hazard and risk assessment of chemicals. NANOVALID focuses on the development of new reference methods and certified reference materials. Both these projects (and many others) have future SbD applicability possibilities,
- Sixtgeen of the projects are specifically on SbD (nano) research, e.g., NanoBioMat. The aim of this project is to design, develop, produce, and characterise novel nanostructured bioactive materials for biomedical applications.
- No project has succeeded in linking datasets related to the functionality of nanomaterials with those databases gathering safety data for SbD applicability, however the NanoReg2 project has made an initial attempt.

Reflection

A large number of (nano)safety research projects have been performed, however only a few publications have specifically focussed on SbD. This matches the growing interest in S(S)bD in the field of chemical safety, recently specifically mentioned by the new European Chemicals strategy. Due to this EU incentive, the expectation is that research will focus more on S(S)bD the near future.

Only a few H2020 projects include practical industrial case studies (for instance NANoREG, NanoReg2, NanoBioMat). Several projects have developed tools for industrial applications, however co-creation is necessary to obtain support and acceptance by all stakeholders (industry, regulators, policy makers) in this process.

Regulators are often not involved in H2020 projects, although their involvement is imperative in order to bring SbD in line with regulatory goals and issues.

4.2.2 Education

General observations

- Thirty-one projects have produced results focusing on Education.
- Of these, 17 workshops have been given or are being given by e.g., the Debye Spring School and those given within SUN. This latter includes a workshop called ‘Nanotechnology School’ which aims to transfer state of the art knowledge on achieving safe nanoproducts to the new generation nano environmental, health and safety (EHS) professionals. In the Netherlands, universities in collaboration with I&W mostly give SbD workshops/courses.

These are available to a wide public (industry and master/PhD students) and are generally focused on research and development. Some SbD workshops were a one-time initiative (Debye workshop), some are structural and included in the curriculum (Twente/Saxion, Eindhoven, Delft).

- Seven courses are currently run within projects or at universities. TU Delft gives an online webinar on SbD: NANOGENTOOLS. This is a Massive Open Online Course (MOOC) focused on applications, regulatory and safety aspects of nanomaterials.
- Twelve projects give safety training, most focused specifically on materials (e.g., bionanomaterials or chemicals). These are mixed training courses directed at a wide audience, depending on the project. For example, BIORIMA is a project that hosted a training school especially designed for personnel from research and academic institutions as well as from industry, governmental agencies and hospital departments. It covered the latest trends in safe biomedicine, giving participants an in-depth understanding of key topics such as advanced nano-biomaterials, fate & exposure scenarios, hazard to human health & environment, and risk assessment & risk management. In general, the target audiences were: research and academic institutions, industry, governmental agencies, hospital department and medical personnel, engineers, PhDs, non-experts, and project partners.
- One project (NanoBioMat) has developed specific a SbD training course for medicinal chemistry, chemistry, biology and biochemistry students.

Reflection
Education has created many opportunities for different stakeholders to take part in workshops, and safety/SbD training courses. These have been mostly developed specifically for research and industry.

There is currently no SbD training course available to regulators. Courses for regulators on S(S)bD are highly relevant to achieving implementation of the policy goals.

There is only one national programme (Labex Serenade in France) which focuses solely on SbD. This programme is extensive (focusing on out-reach, education and research for a multitude of stakeholders) and can be used as an example for SbD education in other countries or for education on a European level.

4.2.3 *Industry*

General observations

- Sixty projects have produced results that are related to Industry.
- Of these, thirteen are on the development of tools, e.g., MARINA and SAF€RA. The MARINA project published an article on 'frameworks and tools for risk assessment of manufactured nanomaterials' which focuses, amongst others, on the need for tool and framework development for nanosafety data. The SAF€RA project produced a bioinformatics tool for automated enzyme screening. A catalogue of different tools was made in the EC4SafeNano project. Unfortunately, this catalogue has not been

transferred between the project and relevant stakeholders. Transparency and re-usability of tools is important to save efforts in future projects to improve SbD implementation. The CALIBRATE project has developed a toolbox/portal also addressing SbD. This portal will be developed further in the Gov4Nano project.

- Twenty-six projects have developed recommendations for safety including proposals for AOPs, SOPs, Test Guidelines (TGs) and best practice guidelines, standardisation guidelines, and guidance documents. The NANOMET project aims to standardise test methods to characterise properties specific to nanomaterials. Five projects of these 26 specifically focus on SbD. One of these projects is NanoReg2 provides guidance on the practical implementation of SbD in the nano-technology community.
- Six projects produced case studies on safety and 12 included case studies specifically on SbD. OptiNanoPro is a safety project which used nanotechnology to safely deliver demonstrators of packaging materials. Within the SbD case studies, the BASMATI and DIMAP projects both designed nanomaterial products (inks) regarding safety at every step of the innovation process. The NanoReg2 project has shown positive results using industrial case studies on how SbD could be implemented. Unfortunately, whether these case studies have led to further implementation of SbD in the involved industries remains unknown.
- Ten frameworks were developed in the projects. Examples of projects working on a framework are GRACIOUS and NANORIGO. GRACIOUS focused mainly on streamlining the risk assessment process and generating a highly innovative science-based framework to enable practical application of grouping, leading to read-across and classification of nanomaterials/nanoforms. NANORIGO is a recent project and aims to develop a Risk Governance Framework for the safety of nanomaterials, risk assessment, hazard and exposure, human health and environment, and risk mitigation including regulatory aspects of SbD.
- Eight databases were found in the list of projects, e.g., PROSAFE and SbD4Nano. The PROSAFE deliverable included detailed database mapping through a rigorous information gathering exercise to examine recent (3.5 years) and current nano-EHS data management activities and resources from the EU, the US and beyond. SbD4Nano is a more recent project (April 2020) with the aim of creating a new software interface where product information can be exchanged between the supply chain participants such as regulators, researchers and industry.
- Seven networking platforms were found such as the NanoSafetyCluster and EC4SafeNano. EC4SafeNano aims were to set up an independent, science-based, managed centre (hub) linked with several networks (spokes) to act at the interface between research organisations, industry, regulatory bodies, and society. The NanoSafetyCluster is not an H2020 project, but mainly focuses on creating international research nanosafety partnerships. Lastly, a communication portal is presently being set-up by the NMBP-13 projects, including Gov4Nano NANORIGO and RISKGONE.

- Eight platforms for tools were developed in the projects. Two examples are the 'open e-infrastructure' from OpenRiskNet and the (not yet developed) NanoSolveIT 'Knowledge platform'. Both of these projects are working on developing an e-platform for multiple stakeholders in different fields including nanomaterials.
- Six datasets were found in the projects, which mostly included nanomaterial toxicity data, e.g., in NanoSteeM and PATROLS.

Reflection
Many results were obtained in various categories in the Industry pillar. Interestingly, only a few case studies focusing on S(S)bD were developed in the different projects. Due to the low number of case studies, it is hard to reflect on the potential implementation of SbD for industry. Moreover, industries involved in the development of these case studies to date (such as in the NanoReg2) are positive in their evaluation of implementing SbD, but the financial investments may be a barrier to addressing SbD early in the innovation process.

Even though several tools and guidelines regarding (nano)safety and S(S)bD, have been developed, more attention should be paid to acceptance and/or use of these instruments. Platforms for tools and networking platforms such as the NanoSafetyCluster are continuously used for knowledge-sharing between several stakeholder groups. The large group of participants and the thematic working groups, as well as the longevity in the NanoSafetyCluster, shows the importance of platforms.[12]

4.2.4 *Strategic Positioning*

General observations

- Thirteen projects have produced results relevant for strategic positioning.
- Nine of these have created documents to support international activities, such as a white paper. The NANoREG and NanoReg2 projects are the main source of these, with later additions from the NMBP-13 (NANORIGO, RISKGONE and Gov4Nano) projects. Moreover, REFINE has hosted a knowledge exchange conference (KEC) to build solutions for knowledge-sharing on regulatory challenges in nanotechnology.
- Three projects worked on stakeholder support (GoNano, NanoRog2 and NanoBioNet). The GoNano project especially has taken great efforts to enabling co-creation between citizens, researchers, industry, societal organisations, and policy makers across Europe to align future nanotechnologies with societal needs and concerns.
- Three projects (GoNano, SeeingNano and NanoReg2) have put effort into raising awareness and creating societal engagement. Societal engagement has become increasingly important, with citizens demanding actions to meet EU agreements.
- Lastly, three projects have specifically worked towards putting SbD on the political agenda. NANoREG, NanoReg2, and PROSAFE actively collaborated by participating in several meetings such as the NanoSafety Cluster (NSC), OECD, ECHA, Nanomaterials

[12] https://www.nanosafetycluster.eu/

Working Group (NMWG) and CASG Nano. Moreover, important connections were continued with potential partners on global scale.

Reflection
Within the strategic positioning pillar, a number of projects (NANoREG, Prosafe and the NMBP-13 projects (NANORIGO, RISKGONE and Gov4Nano) have contributed to positioning S(S)bD on the political agenda. S(S)bD has obtained support from the European Commission, given that SbD forms an integral part of the European Union's Horizon 2020 Research and Innovation Programme, and the recently published EU Chemical Strategy for Sustainability. The current H2020 projects Gov4Nano[13], NANORIGO[14], and RiskGONE[15] aim to develop an agile operational Nano Risk Governance system, where SbD is one of the elements to be addressed. Internationally, the NanoSafety Cluster[16] and the OECD[17] both have a working group addressing SbD.

[13] https://www.gov4nano.eu/
[14] https://cordis.europa.eu/project/rcn/220129/factsheet/en
[15] https://riskgone.wp.nilu.no/
[16] https://www.nanosafetycluster.eu/archive/old-working-group-structure/SbD-and-Industrial-Innovation-WG9.html
[17] https://www2.nanotec.or.th/en/?p=11656

5 Conclusions

This report provides an inventory of knowledge gathered in Horizon 2020 projects relating to SbD. The goal of this report was to catalogue and evaluate the results identified in these projects. The empirical base of this work is to query and self-represent the H2020 projects; not to evaluate their aims and claims. We assigned the projects to the four pillars that form the basis of the Dutch Ministry Safe-by-Design policy programme: 1) Research, 2) Education, 3) Industry and 4) Strategic positioning with 56, 31, 60 and 13 projects per category, respectively.

Even though much has been published on safety data, there is still a lack of specific SbD research data. This indicates that SbD is a growing field and, due to the incentive given by the EU, the expectation is that there will be a continuing growth in coming years in the S(S)bD research field. In the Education pillar, many opportunities have been created for different stakeholders to take part in workshops, courses and safety/SbD training programmes. The Chemicals Strategy on Sustainability recognizes the conditional role of competence and skills development for implementation of SbD. The activities can be regarded as a sound foundation for growth. The courses have mostly been developed specifically for research and industry. Noteworthy is that there are currently no SbD training programmes for regulators.

Practical industry case studies (for instance NANoREG, NanoReg2, NanoBioMat) are still in their infancy, as only few projects have included them. Industries involved in these case studies (such as in the NanoReg2) are positive in their evaluation. Nevertheless, financial barriers appear to form a major drawback for these stakeholders.

The three governance projects Gov4Nano, RISKGONE, NANORIGO stress the need for involvement and connection between stakeholders in the quadruple helix. There is a lack of involvement in and connection between the larger part of H2020 SbD projects.

This inventory is solely based on observations of results obtained in projects relevant for SbD within H2020. Further recommendations on future SbD implementations will require more in-depth study of the results and answers to these questions. One of these questions entails the interpretation of SbD in these different studies and in what way SbD is used to enhance safety. A clearer definition of SbD is required; this could be analysed from this inventory for the nanotechnology domain. The case studies can be used as implementation examples for the future, and may therefore need further analysis. Moreover, there is a need to better analyse the information flow from projects, e.g., is there enough dissemination towards new projects and to other stakeholders, and if so, how is this done?

The wide scope of this inventory is valuable for a large variety of purposes, such as for the OECD Safe Innovation Approach Ad Hoc

Group[18], SPINE network, information on the SbD website, CEN for SbD (led by TEMAS Ag Technology and Solutions), or to inform the NanoSafetyCluster[19]. Moreover, this report can be used to advise the Dutch Ministry regarding further steps towards S(S)bD implementation. Further research is needed, for example analysing the results of these projects in more detail. Lastly, this report can be used to develop a gap analysis of S(S)bD research in Europe.

[18] Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products
[19] https://www.nanosafetycluster.eu/

6 Results

6.1 Pillar 1 – Research

The research pillar has a two-fold purpose. Firstly, it focuses on the deployment of research that contributes to the further development and practical implementation of SbD by researchers and designers. Secondly, it focuses on the researchers themselves, with the aim of making them sensitive to safety aspects related to their research and to have them reflect on their role and responsibilities. It is important to note that some of the projects have relevant results in multiple pillars and are therefore listed in different pillars.

Table 1, the 'overview of projects', presents general information about each project, in alphabetical order. it shows the abbreviation and full name of the project (with link to the (CORDIS) website), the pillar(s) in which this project obtained results, the discipline in which the project was active, the outcome in short, the SbD aspect in one or two sentences, and a short description. The tables hereafter show the projects and links to the results sub-divided over different topics. In each research pillar the results are sub-divided into (nano) safety research and (nano) SbD research, and mostly include scientific publications on either of these topics.

6.1.1 Overview of projects

Table 3 Overview of the projects with results in the research pillar.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	Education, Research, Industry	Multidisciplinary, Nano	Guidelines, Training courses, Scientific Publications	Nano decision tool for facilitating decision-making regarding choice of techniques and SOPs.	ACEnano introduces confidence, adaptability and clarity into nanomaterial risk assessment by developing a widely implementable and robust tiered approach to nanomaterials' physicochemical characterisation. This will simplify and facilitate contextual (hazard or exposure) description and its transcription into a reliable nanomaterials grouping framework.
ASINA Anticipating Safety Issues at the Design Stage of NAno Product Development	Industry, Research, Education	Multidisciplinary, Nano	No results yet (project started March 2020 and ends August 2023) Expected Roadmap, case studies, SbD training, tools	Apply SbD in the production value chains of coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. Develop a ROADMAP to generalise the above-mentioned results.	The EU-funded ASINA project will study the production value chains of two representative categories of nano-enabled products: coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. The project seeks to formulate design hypothesis and make design decisions by applying an SbD management methodology (the ASINA-SMM), moulded on industrial six sigma practices, to ensure easy implementation in nano-manufacturing processes. ASINA will provide a ROADMAP to generalise ASINA-SMM and maximise the positive impacts of further products designed to improve environmental quality and human health/wellness.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
BASMATI Bringing innovAtion by Scaling up nanoMATerials and Inks for printing	Research, Industry	Battery research, Nano	Case studies on batteries, Scientific Posters	Recommend best practices and safe design of active nanomaterials in conductive and electrochemical inks for screen and inkjet printing.	BASMATI addresses the development of active nanomaterials and their formulation in conductive and electrochemical inks for screen and inkjet printing. As a case study, these functional inks will be applied in a printed thin film battery. BASMATI's general objective is to develop pilot lines for material synthesis and ink formulation, ensuring large volume fabrication of new products with improved properties for printing.
BIORIMA Biomaterial Risk Management	Education, Research, Industry	Medicine, Bio-nanomaterials	Training and Integrated risk management framework, Scientific Publications	Framework for allocating validated tools and methods for materials, exposure, hazard and risk identification/assessment, and to manage and reduce the risk for specific nanobiomaterials.	BIORIMA aims to develop an Integrated Risk Management framework for nanobiomaterials (NBM) used in medical devices (MD) and advanced therapeutic medical devices (ATMP) The BIORIMA IRM framework is a structure on which the validated tools and methods for materials, exposure, hazard and risk identification/assessment, and management are allocated plus a rationale for selecting and using them to manage and reduce the risk for specific NBM used in MD and ATMP.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	Education, Research, Industry	Multidisciplinary, Nano	Framework, Training, Scientific Publications	Develop a nanotool and framework based on a suite of tested and calibrated manufactured nano-specific risk prioritisation.	Currently, none of the existing REACH compliance models are suited or validated for risk assessment of manufactured nanomaterials, and many existing exposure limits are not appropriate for nanomaterials. caLIBRAte will address this by developing a 'system of systems', based on a suite of tested and calibrated manufactured nano-specific risk prioritisation and control banding tools.
Debye Springschool Workshop Nanosafety (Not an H2020 project)	Research, Education	Multidisciplinary, Nano	Workshop, scientific publication	A workshop on nanosafety including SbD.	The Debye Springschool is held at Utrecht university every two years. In the 2018 edition, the theme was nanomaterials for Daily Life. A lecture was held by the RIVM on nanosafety, followed by a scientific publication on the safety of nanomaterials from studies by the university's PhD researchers.
DIMAP Novel nanoparticle enhanced Digital Materials for 3D Printing and their application shown for the robotic and electronic industry	Research, Industry	Multidisciplinary, Nano, 3D printing	Guidelines, Case studies (on 3D printing), scientific publications	Apply SbD to 3D printing.	DIMAP advances the state-of-the art of additive manufacturing (AM) through modifications of their fundamental material properties, mainly using nanoscale material-enhanced inks. SbD approaches include workplace safety, risk assessment, collaboration with EU safety clusters, and life cycle assessment. An established roadmap at the end of project will enable identification of future development needs in related fields in order to allow Europe to compete at the forefront of the AM revolution.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
EU-ToxRisk An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century	Research, Industry	Toxicity	Scientific publications, adverse outcome pathways (AOPs)	EU-ToxRisk will integrate advancements in cell biology, omics technologies, systems biology, and computational modelling to define the complex chains of events that link chemical exposure to toxic outcomes. This can become a future SbD application.	The focus of this project is on two areas: repeated dose systemic toxicity using the lung, kidney, liver, and nervous system as examples of potential target organs; and developmental and reproductive toxicity. It will also provide guidance for its universal application, allowing to push the entire field forwards in an integrated manner. The ultimate goal is to deliver testing strategies to enable reliable, animal-free hazard and risk assessment of chemicals.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Scientific publications, Training school, Nano risk governance model, nano risk governance council	Develop a nano risk governance council (NRGC) that will support SbD practices. It will explore upcoming tools and approaches such as Findable, Accessible, Interoperable and Re-usable (FAIR) databases and blockchain technology.	The Gov4Nano project will develop the first implementation of a future-proof operational Nano Risk Governance Model (NRGM) that addresses the needs of the transdisciplinary field and innovative (and key enabling) character of nanotechnology. The Gov4Nano project will design and establish a Nanotechnology Risk Governance Council (NRGC) to create a trustworthy and objective international umbrella for the risk governance of nanotechnologies.
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	Education, Research, Industry	Multidisciplinary, Nano	Framework, Guidance, Database, Training	Develop a framework with a guidance, database on e-nanomapper, and tools for logically grouping nanomaterials.	The GRACIOUS project will develop a highly innovative science-based framework that supports the assessment of risks posed by the ever-increasing array of nanomaterials on the market and under development. The framework will streamline the process for assessing their risk by logically grouping nanomaterials thereby allowing extrapolation between (read-across) nanomaterials, reducing the need to assess exposure to and toxicity on a case by case basis.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
GUIDEnano Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance tool for nanotech industries	Research, Industry	Multidisciplinary, Nano	GUIDEnano tool, scientific publications	Develop a web-based risk assessment guidance tool for nano-enabled products and for future SbD applicability.	The GUIDEnano project will generate a risk assessment web-based tool, which also incorporates guidance on the selection of risk management options. To reach these goals, the project will build on the state-of-the-art on risk assessment and management by validating critical assumptions in the risk assessment process, generating new predictive models, and developing novel risk management solutions.
HISENTS High level Integrated SEnsor for NanoToxicity Screening The follow up of HISENTS is SABYDOMA	Research, Industry	Multidisciplinary, Nano (and Nanomedicine)	Framework, guidelines, new test methods, Scientific Publications	Create a platform capable of nanosafety assessment using high-throughput screening and SbD concept development.	HISENTS aims to deliver an advanced nanosafety platform capable of providing high-throughput toxicity screening for the risk assessment of novel nanomaterials. The platform will be made up of an integrated set of miniaturised modules each representing critical human physiological functions from molecular interactions, through to cell, organ, and organism effects.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
in3 An integrated interdisciplinary approach to animal-free chemical and nanomaterial safety assessment	Research	Multidisciplinary, Chemicals, Nano	Scientific Publications	SbD can be applied through the synergistic development and utilisation of *in vitro* and *in silico* tools for human chemical and nanomaterial (NM) safety assessment.	The in3 project aims to drive the synergistic development and utilisation of *in vitro* and *in silico* tools for human chemical and nanomaterial (NM) safety assessment. The project focuses on differentiation of human induced Pluripotent Stem Cells to toxicologically relevant target tissues. The tissues are exposed to common compounds and the data generated and prediction tools generated will be used to develop modernised safety assessment approaches combining cheminformatics, mechanistic toxicology, and biokinetics into computational models which can account for donor and tissues specific effects.
Labex Serenade Laboratory of Excellence for Safe(r) Ecodesign Research and Education applied to NAnomaterial DEvelopment	Education, Research	Multidisciplinary, SbD	Programs and Training on SbD, Scientific Publications	Outreach on SbD to education and research.	SERENADE is a Labex, i.e., and Excellence laboratory funded for 8 years by the French "Investissements d'Avenir" project. Labex SERENADE aims to build a dynamic network of academic research laboratories and industries to design tomorrow's nanomaterials that will be safer for both humans and the environment. SERENADE addresses nanosafety for the entire life cycle of nanoproducts, from the earliest production stages (pristine nanoparticles) to the end-of-life (recycling, disposal).

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
LEE-BED Innovation test bed for development and production of nanomaterials for lightweight embedded electronics	Research	Multidisciplinary, Nano	No results yet (project started in January 2019 and ends December 2022)	Establish an Open Innovation Test Bed to de-risk and accelerate the development and manufacturing of nanomaterials and lightweight embedded electronics for the benefit of European industry.	Access to a Test Bed will help establish the industrial eco-systems, R&D investments, and new supply chains, supporting market entry as well as providing global competitive advantage, leading to growth and job creation. Unique to LEE-BED will be the development of tailored services, including technical, business, patent mapping, safety, and life-cycle analysis modelling. LEE-BED will also provide funding services for LEE-BED access to SMEs and post-project capital. LEE-BED will guide the European industry towards sustainable implementation of innovative technologies, making them stronger and more globally competitive.
MARINA Managing Risks of Nanoparticles	Research, Industry	Multidisciplinary, Nano	Scientific publications, data sets, guidelines, and tools	Develop risk management methods for nanomaterials including materials, exposure, hazard, and risk which can be used for SbD applicability. This project collaborated with NANOVALID and QUALITYNANO.	MARINA set out to develop specific reference methods for all the main steps in managing the potential risk of engineered nanomaterials (ENM). It addressed the four central themes in the risk management paradigm for ENM: Materials, Exposure, Hazard and Risk.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
MODCOMP Modified cost-effective fibre-based structures with improved multi-functionality and performance	Research, Industry	Nano, Carbon Nanofibers	Scientific publications	Develop fibre-based materials with improved safety and functionality.	MODCOMP aims to develop novel engineered fibre-based materials for technical, high value, high performance products for non-clothing applications at realistic cost, with improved functionality and safety. Demonstrators will be designed to fulfil scalability towards industrial needs and focus on TRL5/TRL6. End users from a wide range of industrial sectors (transport, construction, leisure, and electronics) will adapt the knowledge gained from the project and test the innovative high added value demonstrators.
MolNANOtox Nanomaterial surface interactions at the molecular level and their impact on ecotoxicity	Research	Nano safety research, (eco)toxicity	Scientific publications	Use spectroscopy to characterise the surface coating of engineered nanomaterials (ENM) to understand the bio-nano interactions and impact on the environment.	The overall objective of the project was to characterise the fundamental interactions occurring at the surface of ENM and its impact on environmental ENM chemistry and bio-nano interactions with a range of analytical and imaging techniques.
NanoBBB Transport of Engineered Nanomaterials across the blood-brain-barrier	Research	Multidisciplinary, Nano	In progress (no results yet) (Project started April 2018 and ended October 2020)	Understand the behaviour and fate of ENMs in the brain contributing to safer ENM design.	This project will allow us to systematically understand the behaviour and fate of certain engineered nanomaterials (ENMs) in brain and contribute to safer ENM design. The nano blood brain barrier (BBB) also offers industry placements for on-a-chip technology development and an NGO to host the *in-vivo* experiments enabling validation of the model.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	Education, Research, Industry, Strategic Positioning	Bionano-materials, Medicine	SbD training, guidelines, bringing networks together, Scientific Publications	Bring together research groups to create novel bioactive nanomaterials for medical application.	The aim of the project is to design, develop, produce, and characterise novel nanostructured bioactive materials for biomedical applications. The idea is to bring together research groups specialised in material science and experts in bio-active materials and review the nanomaterials' application in medicine.
NanoCommons The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators	Research, Industry	Multidisciplinary, Nano	Foresight, Scientific Publications, Knowledge Portal	Create a platform with computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and bench-marking of their predictive power, user friendly for all stakeholders (regulators and industry).	NanoCommons creates a community framework and infrastructure for reproducible science, and in particular for *in silico* workflows for nanomaterials safety assessment. The platform provides a user-friendly interface for a suite of computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and benchmarking of their predictive power.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANODEFINE Development of an integrated approach based on validated and standardised methods to support the implementation of the EC recommendation for a definition of nanomaterial	Research, Industry	Multidisciplinary, Nano		Provide insights on how to define and characterise nanomaterials which can lead to SbD applicability.	Nanotechnology is a key enabling technology. Still, existing uncertainties concerning EHS need to be addressed to explore its full potential. One challenge is the development of methods that reliably identify, characterise and quantify nanomaterials (NM) both as substance and in various products and matrices.
NanoERA Nanomaterials Ecological Risk Assessment: A study of the long-term effects and risks of nanoscale Iron Oxide [now n-CuPc] used in plastic composites in the aquatic environment	Research	Nano safety research, (eco)toxicity	Scientific Publications	To develop concepts and methods, and to generate data to predict the long-term ecological effects and risks of nanoscale Cu-Pchalocyanine in the aquatic environment and on human health.	An analysis of the physicochemical properties of nanoscale Cu-Pchalocyanine changes in environmental (i.e., freshwater and sediment) and biological (cell culture) media, and how these changes affect the biological interactions of these materials. The generated (eco)toxicological effects data will be used to derive dose-response relationships and to quantitatively estimate the long-term ecological risks of nanoscale Cu-Pchalocyanine.
NanoFASE Nanomaterial FAte and Speciation in the Environment	Education, Research, Industry	Multidisciplinary, Nano	Workshop, Case Studies, Scientific Publications, Framework, Factsheets, Toolbox	Develop a set of concepts and approaches to underpin the Exposure Assessment Framework.	NanoFASE will provide an integrated exposure assessment framework (e.g., protocols, models, parameter values, guidance) The aim is to reach a level of engineered nanomaterials' fate and exposure assessment at least comparable with that of conventional chemicals.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Safety training, Scientific publications, Design tool, Guidelines	High throughput *in vitro* tests for the safety assessment of nanomaterials and for the early application of SbD.	NANOGENTOOLS combines genomics (toxicogenomics), proteomics and multidisciplinary science to develop fast *in vitro* high throughput (HTS) assays, with molecular based computational models to gain a better understanding of the molecular fundamentals of nanotoxicity, and initiate the development of online nanosafety assays for use by SMEs during product development.
NanoLabels Labelling of engineered nanomaterials for nanosafety tracing	Research	Multinano-disciplinary, Nano	Scientific Publications	Design labels for nanomaterials to trace them in the environment which will help understand nanosafety and support the SbD concept.	The objective of NanoLabels is to assign "ownership" or "source" to ENMs using different labelling techniques thereby enabling their tracing in the environment. The project not only helps scientific community to understand fundamental questions in nanosafety, i.e., the biological and environmental behaviour (uptake, translocation, transformation) by improving the tracing ability, but also provide a labelling strategy that can be adopted by industry to facilitate applications such as nanosafety assessments before ENMs enter the market and environment, as well as for product authentication and tracking.
NANOMILE Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology	Research, Industry	Multidisciplinary, Nano	Scientific publications, Case studies	To create a fundamental understanding of nanomaterial interactions with living systems for SbD applicability.	The overarching objective of NanoMILE is to formulate an intelligent and powerful paradigm for the mode(s) of interaction between manufactured Nanomaterials (MNMs) and organisms or the environment, to allow the development of a single framework for the classification of nanomaterial safety and the creation of a universally applicable framework for nanosafety.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoNextNL Innovating with Micro and Nanotechnology (Not a H2020 project)	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Theses and Tools	A Dutch national research program for nanotechnology which employs SbD aspects.	NanoNextNL is the Dutch national research and technology programme for micro and nano technology. The Programme consists of 10 themes and a Valorisation Programme. There are three different themes: general themes, application themes, and risk analysis and technology assessment.
NANoREG A common European approach to the regulatory testing of nanomaterials	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Workshop, Scientific Publications, Toolbox, Guidelines, Case Studies, Framework, e-Nanomapper, Policy and legislation/ regulation relevance	A risk assessment framework suitable for SbD applicability.	The innovative and economic potential of Manufactured Nano Materials (MNMs) is threatened by a limited understanding of the related environment, health, and safety (EHS) issues. While toxicity data are continuously becoming available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM drives the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Workshops, Scientific Publications, Tools, Guidelines, Case Studies, Framework, Databases, Foresights, Stakeholder Support, International Support, Creating Awareness	Develop the Safe Innovation Approach (SbD, regulatory preparedness, trusted environments).	The NanoReg2 project, built around the challenge of coupling SbD to the regulatory process, will demonstrate and establish new principles and ideas based on data from value chain implementation studies to establish SbD as a fundamental pillar in the validation of novel manufactured nanomaterials (MNM). Grouping concepts developed by NanoReg2 can be regarded as a major innovation, as guidance documents on NM grouping will not only support industries or regulatory agencies but will also strongly support the commercial launch of a new NM.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Training, Scientific Publications, Nano risk governance framework, Nano risk governance council	Develop a nano risk governance council (NRGC). The ultimate aim of NANORIGO is to deliver a Risk Governance Framework for the safety of nanomaterials, for risk assessment, hazard and exposure, human health and environment, and risk mitigation including regulatory aspects of SbD.	NANOtechnology RIsk GOvernance aims to develop and implement a transparent, transdisciplinary Nanotechnology Risk Governance Framework and a related Risk Governance Council to guide all stakeholders in the sustainable development of nanotechnologies in Europe. NANORIGO will collaborate on this with RiskGone and Gov4Nano (also funded under the NMBP13-2018 Call).
NanoRiskSD Engineered Nanomaterials: Novel Approaches for Risk Assessment and SbD (Not a H2020 project)	Research	Multidisciplinary, Nano	No results yet (project started September 2020 and ends August 2022) Intelligent test strategies and SbD approaches	The overarching goal of this project is to identify novel approaches for hazard and risk assessment of NMs and to implement them in intelligent testing strategies (ITS).	The overarching goal of NanoRiskSD is to identify novel approaches for hazard and risk assessment of NMs and to implement them in intelligent testing strategies (ITS). The project will focus on developing intelligent testing strategies (ITS), NM toxicity mechanisms, and on SbD approaches. The knowledge obtained will be used to establish SbD principles, permitting the implementation of safety considerations in early product development.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANOSOLUTIONS Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM): Systems Biology Approaches to Understand Interactions of ENM with Living Organisms and the Environment	Research, Industry	Multidisciplinary, Nano	Datasets, Scientific Publications	Develop tools for safety classifications for engineered nanomaterials.	The overarching aim of the NANOSOLUTIONS consortium is to provide a means to develop a safety classification for engineered nanomaterials (ENM) based on an understanding of their interactions with living organisms at molecular, cellular and organism levels. The objective is to determine the "biological identity" of ENM, and subsequently develop a computer program that, from the properties of ENM, can predict their ability to cause health or environmental hazards. New innovative methods are needed for the ENM risk assessment of ENM safety, i.e.,, ENM SAFETY CLASSIFIER. This will allow the crucial transition from descriptive toxicology to predictive toxicology.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoSolveIT Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT)	Research, Industry	Multidisciplinary, Nano	Scientific publications, platform (NanoSolveIT e-platform), modelling tools	NanoSolveIT aspires to introduce an *in silico* Integrated Approach to Testing and Assessment (IATA) for the environmental health and safety of nanomaterials (ENM), implemented through a decision support system packaged as both a stand-alone open software and via a Cloud platform.	NanoSolveIT's aims to advance nanoinformatics well beyond the state-of-the art by developing and implementing innovative modelling techniques and tools that will be integrated within NanoSolveIT IATA and then incorporated into a sustainable interoperable product, the NanoSolveIT e-platform, which will become an essential element for supporting industrial and regulatory nano-risk governance and the anticipated nano-risk governance council established in the EU H2020 NMBP-13-2018 call.
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	Education, Research, Industry	Chemistry, Physics, Nano	Guidelines, Training, Scientific Publications	Identify all safety risks from the labs via technology development up to the application of nanoelectronics.	The goal of the NanoStreeM project is to promote good practices by identifying and implementing standards, identifying gaps in methodologies, and providing directions for further investigations in order to support governance of the occupational risk induced by the use of nanomaterials in semiconductor industry.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANOVALID Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials	Research, Industry	Multidisciplinary, Nano	Guidelines (SOPs), Data sets, Scientific publications	Develop risk management methods for nanomaterials including materials, exposure, hazard, and risk which can be used for SbD applicability. This project collaborated with MARINA and QUALITYNANO.	The main objective of NanoValid is the development of new reference methods and certified reference materials, including methods for characterisation, detection/quantification, dispersion control and labelling, as well as hazard identification, exposure. and risk assessment of ENs. In cooperation with other relevant projects, relevant standardisation and regulatory bodies, the most suitable test materials and methods will be selected and tested, and new nanomaterials synthesised, characterised, and stabilised for final method validation.
npSCOPE Integrated EU Strategy, Services and International Coordination Activities for the Promotion of Competitive and Sustainable Nanofabrication Industry	Research	Multidisciplinary, Nano	Scientific publications	Develop an instrument (electron microscope/gas field ion source) that can measure physico-chemical properties of nanomaterials both in their pristine form or embedded in complex matrices such as biological tissues which can aid in SbD applicability.	The nanoparticle-scope (npSCOPE) is a research project funded by the European Commission H2020 bringing together nine partners with the aim of developing a new integrated, optimised instrument to provide a comprehensive physico-chemical characterisation of nanoparticles, both in their original form and embedded in complex matrices such as biological tissue.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
OpenRiskNet Open e-Infrastructure to Support Data Sharing, Knowledge Integration and in silico Analysis and Modelling in Risk Assessment	Research, Industry	Multidisciplinary	Integrated different approaches into one Platform	Provide an open e-Infrastructure resources and services to a variety of communities requiring chemical risk assessment, including chemicals, cosmetic ingredients, therapeutic agents, and nanomaterials, needed for SbD applicability.	OpenRiskNet is a 3-year project with the main objective of developing an open e-Infrastructure providing resources and services to a variety of communities requiring risk assessment, including chemicals, cosmetic ingredients, therapeutic agents, and nanomaterials. OpenRiskNet works together with a network of partners, organised in an Associated Partners Programme.
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	Education, Research, Industry	Multidisciplinary, Nano	Safety training, Scientific publications, guidelines and case studies	Introduction of nanotechnology and SbD in production lines for packaging and automotive and photovoltaic material production.	With the use of nanotechnology both in bulk and surface application, OPTINANOPRO will deliver demonstrators of packaging with improved barrier properties as well as with repellent properties resulting in easy-to-empty features that will, on the one hand, reduce waste at consumer level and, on the other, improve their acceptability by recyclers.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PANDORA Probing safety of nano-objects by defining immune responses of environmental organisms	Education, Research	Multidisciplinary, Nano	Scientific publications, Safety training	Create a multidisciplinary environment where young researchers will contribute at studying the effects of NP on the immune system responses of environmental organisms, which will have future SbD applicability.	In a highly multidisciplinary environment, eleven Early-Stage Researchers (ESR) will be trained on the issue of immuno-nanosafety. The focus on the effects of NP on the functionality of the immune system, and consequently on the overall health protection of the target organism, will be broadened from human health to encompass a variety of environmental organisms (plants, invertebrates, marine, earth). The programme will therefore lay the basis for an integrated approach to environmental nanosafety that includes immunosafety as a key element.
PATROLS Physiologically Anchored Tools for Realistic nanOmaterialL hazard aSsessment	Research, Industry	Multidisciplinary, Nano	Guidelines, Datasets, Scientific publications	Develop tools and methods (3D tissue models for lung, gastrointestinal and liver) to minimise animal testing and categorise engineered nanomaterials.	PATROLS is an international project combining a team of academics, industrial scientists, government officials, and risk assessors to deliver advanced and realistic tools and methods for nanomaterial safety assessment. PATROLS will provide an innovative and effective set of laboratory techniques and computational tools to more reliably predict potential human and environmental hazards resulting from engineered nanomaterial (ENM) exposures. These tools will minimise the necessity of animal testing and will support future categorisation of ENMs in order to support safety frameworks.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PEPTICAPS Design of polyPEPTIdes diblock copolymers as emulsifiers to produce safe, controlled and reliable novel stimuli-responsive nanoCAPSules for skin care applications	Research, Industry	Cosmetics	Scientific publications, Project can be used as case study for safety of nanomaterials	Design nanocapsules for cosmetics including risk and safety assessment in the early stages of the innovation process.	PeptiCaps aims at producing and validating a new family of smart nanocapsules to encapsulate and protect fragile active ingredients for the treatment of skin conditions affecting a wide number of people, such as irritant and allergic contact dermatitis, skin UV-damage, and pigmentation. The nanocapsules will be designed to encapsulate, either hydrophilic or lipophilic actives, and more importantly, the release of these compounds will be triggered by the changes in pH and enzyme concentration characteristic of the skin conditions, ensuring delivery at the site to be treated.
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Courses, Scientific Publications, Guidelines, Pilots/Case studies	Produce a practical guideline and standards for companies developing a strategy for Responsible Research and Innovation (RRI) which includes SbD.	The overarching goal of the PRISMA project is: -to help companies to implement Responsible Research and Innovation (RRI) in their innovation and social responsibility strategies, -to provide evidence on how RRI can improve innovation processes and products, and -to show how RRI leads to trust from society (thus strengthening the market position of companies).

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
QSAREACH QSAR computational models' self-using platform for EC Regulation-REACH	Research, Industry	Multidisciplinary	Scientific publications, tools	Platform with QSAR models of (eco)toxicology of chemicals and nanomaterials demonstrating the safety of these substances according to EC-REACH Regulation.	QSAR computational models represent significant savings in time, resources, and money as their applicability is easy and immediate. This business need for the final development of a novel high scalable technological platform giving easy access to experienced and non-experienced end-users in the European chemical industry small and medium enterprises (SMEs) is our market opportunity. These platform will include QSAR models of (eco)toxicology of chemicals -including nanomaterials (NMs)- to comply with the strict EC Regulation, where assays with animals in some specific domains, such as cosmetics, are completely forbidden.
QUALITYNANO A pan-European infrastructure for quality in nanomaterials safety testing	Research, Industry	Multidisciplinary, Nano	Scientific publications, guideline	Create a scientific & technical space in which all stakeholder groups can engage, develop, and share scientific best practice in the field for the future of SbD. This project collaborated with MARINA and NANOVALID.	QualityNano is a Research Infrastructure for nanosafety assessment. QualityNano's core aim is the creation of a 'neutral' scientific & technical space in which all stakeholder groups can engage, develop, and share scientific best practice in the field.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
REFINE Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	Research, Industry, Strategic Positioning	Bionanomaterials	Regulatory science framework, guidelines (white paper), Knowledge exchange conferences, thesis dissertation	Regulatory Science Framework for Nano(bio)material -based community which facilitates SbD.	REFINE will gather a wide community of stakeholders in regulation, industry, science, technology development, patients, and end-users, into a Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicine. Aims: to set up/ build a Regulatory Science framework to close the gap on the existing development of nanomedicine products. We will set a sustained forum that enables regulators, scientist, and developers to liase and develop: -a clear overview of current and anticipated regulatory concerns, including harmonisation, -a gap analysis where regulatory concerns and scientific evidence do not match up. - a heuristic to transfer new scientific evidence into regulatory strategies, and to translate regulatory concerns into hot spots in the standard testing cascades.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
RISKGONE Risk Governance of Nanotechnology	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Webinars, Scientific publications, OECD guidelines, Nano risk governance council.	Develop a nano risk governance council (NRGC) that will help SbD practices. Develop tools to identify the environmental and human health impacts of nanomaterials for SbD applicability.	RISKGONE (Science-based Risk Governance of Nano-Technology) is an EU H2020 project aiming at providing solid procedures for consistent risk governance of engineered nanomaterials.The project will develop new tools or modify existing ones to identify the environmental and human health impacts of a number of nanomaterials with greater certainty. These tools and the results of tests using them will then be integrated into the work of a European Risk Governance Council (ERGC), a group of individuals with different areas of expertise on nanomaterials tasked to provide governance decisions on the safety of the specific materials. A risk governance framework consisting of the tools and the ERGC will be developed to address nanomaterial safety governance in a coherent and scientifically robust way.
SAF€RA Coordination of European Research on Industrial Safety towards Smart and Sustainable Growth	Industry	Engineering	Safe-design tool for safer processes	Tools and partnership for safer processes.	The scope of SAF€RA includes research on the prevention of major accidents, with off-site consequences and risks to the environment and society, and in particular the economic benefits of industrial safety solutions, safe innovative processes, preparedness and response Moreover, it covers protection of the environment, new methods to enhance the creation of a safety culture, and prudent attitudes, risk reduction strategies, reference technologies for life extension of aged and repaired structures, as well as products and systems required to improve industrial safety.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SAFEnano Effect of water and wastewater treatment on the properties of engineered nanomaterials (ENMs) in context of their fate, toxicity and interaction with other contaminants	Research	Multidisciplinary, Nano, Ecotoxicity	Short summary of scientific results	Investigate the fate of nanoparticles in soil, sediment and sewage slugs, and the effect of these materials on living organisms. This is relevant for SbD applicability.	Our research is mainly focused on fate (especially bioavailability and ecotoxicity) of different contaminants in the environment as well as the development and improvement of methods to remove these contaminants from water, soil and sediments.
ShuttleCat Shuttle Catalysis for Reversible Molecular Construction	Research	Homogeneous catalysis	Scientific Publications	Design safer catalytic reactions that do not use or release CO gas. Example of process related SbD applicability.	Homogeneous catalysis is one of the pillars of modern chemical synthesis because it enables the sustainable preparation of molecules that find applications in medicinal chemistry, agrochemistry, and materials science. However, many catalytic reactions use hazardous reagents, are unpractical at laboratory-scale, or limited in scope. Moreover, while a relatively broad set of catalytic reactions is available to construct chemical bonds, methods to cleave them, which could find applications in biomass and waste valorisation, are rare.
SinFonia Synthetic biology-guided engineering of Pseudomonas putida for biofluorination	Research	Biotechnology	Scientific Publications	Build sustainable and safe process alternatives for fluorinating agents by using bacteria and enzymes.	SinFonia aims to biologically produce novel fluorochemicals. Materials containing the element fluorine are extremely important in today's world, with applications in electronics, healthcare, automotive and wearables. Currently these fluorochemicals are exclusively synthesised using chemical methods, something SinFonia wants to change.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SmartNanoTox Smart Tools for Gauging Nano Hazards	Research, Industry	Multidisciplinary, Nano	Scientific publications, guidance documents, a framework and case studies on safety.	*In vivo, in vitro* and *in silico* research of respiratory toxicity pathways for a representative set of nanomaterials and relating them to interactions and molecular modelling. This approach can be used for SbD applicability.	In this project, using a comprehensive self-consistent study, which includes *in vivo*, *in vitro* and *in silico* research, we address main respiratory toxicity pathways for representative set of nanomaterials, identify the mechanistic key events of the pathways, and relate them to interactions at the bionano interface via careful post-uptake nanoparticle characterisation and molecular modelling. This approach will allow us to formulate a novel set of toxicological mechanism-aware endpoints that can be assessed by means of easily applicable, economic tests. Using the exhaustive list of endpoints and pathways for the selected nanomaterials and exposure routes, we will facilitate clear discrimination between different pathways and relate the toxicity pathway to the properties of the material via intelligent QSARs.
SOS-Nano Structure – Oxidative Stress relationships of metal oxide nanoparticles in the aquatic environment	Research	Ecotoxicity	Scientific Publications	Investigate the Structure – Oxidative Stress relationships of metal oxide nanoparticles in the aquatic environment.	The SOS-Nano project addressed one of the most pressing cutting-edge issues of econanotoxicology: to find a structural property of nanoparticles (NPs) to predict their potential toxicity in marine aquatic environments. By using an *in vivo* exposure system, the SOS-Nano project tested the suitability of two paradigms for ranking the hazard of metal oxide NPs: 1) NPs physical-electrochemical properties (i.e., bandgap energy and dissolution) for predicting oxidative stress potential, and 2) oxidative stress generation for predicting biological impact.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
STARNANO Spheroids as a Tool to Assess Realistic long-term effects of mixtures of nanomaterials and chemicals	Research	Nanomaterials, Graphene, Mixtures	Report from Cordis website	Research on mixtures and importance for multicomponent advanced materials, using graphene related materials (GRM) as a case study to develop a method to measure combined effects.	The main objective of this project was to assess the combined effects of nanomaterials (NMs) and environmentally relevant pre-existing contaminants. Specific Objective 1. To determine the mechanisms of toxic action of individual NMs or chemicals; Specific Objective 2. To determine the effect of co-exposure of one NM and an organic substance on their cytotoxicity. The case study uses Graphene-related materials (GRM).
SUN Sustainable Nanotechnologies	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Workshops, Scientific Publications, Case studies on SbD and Safety, Framework and Guidelines, International Support, Tools	An integrated approach addressing the complete product lifecycle to assess health and environmental risks for SbD applicability in nanotechnology.	The Sustainable Nanotechnologies (SUN) project is based on the idea that the current knowledge on environmental and health risks of nanomaterials – while limited – can nevertheless guide nanomanufacturing to avoid liabilities if an integrated approach addressing the complete product lifecycle is applied.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
ToxEcoGraphene Assessment of ecocorona acquired by Graphene Family Nanomaterials during exposure to biofilms and fate following uptake	Research	Multidisciplinary, Nano, Graphene	Conference Proceedings	Evaluate the environmental fate of graphene for SbD applicability.	Various physicochemical properties were studied, including the flake dimensions, particulate state, surface chemistry etc. Investigation of GFN fate in natural media has been conducted by focusing on the aggregation kinetics and stability of GFN in aquatic environments. A second objective was the evaluation of GFN toxicity to biofilms was another objective by focusing on hetero-aggregation and eco-corona growth on GFN surface and assessing changes in community structures as a function of exposure concentrations and durations. A third objective was the implementation of the main research conclusions in order to mitigate identified environmental impact and design-out potential hazards related to GFN technology and applications.
IZADI-NANO2INDUSTRY Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery.	Research, Industry	Multidisciplinary, Nano	Scientific publications, guidelines, case studies on SbD.	Replace toxic or hazardous substances by less hazardous or less reactive substances.	In IZADI-NANO2INDUSTRY conventional materials and injection moulding, casting, and coating manufacturing processes will be improved by nanotechnology and combined to enable industrial scale production of new performance-enhanced components. The project will establish the value chain for nanomaterial-enabled improved performance products, and finally will validate the technologies through three components in industrial environment (TRL 7).

6.1.2 *(Nano) Safety research*

Links are given to the Cordis factsheets for all the scientific publications and test methods of the projects listed above. This includes projects solely looking at improving safety, risk assessment, development of new test methods for materials, as well as monitoring and identification of safety aspects of materials.

Table 4 Results of the projects on (nano) safety research which can be applied in the future for SbD

Project Name and Link to EU Factsheet	Documents Output
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	List of scientific publications
BIORIMA Biomaterial Risk Management	List of scientific publications
EU-ToxRisk An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century	List of scientific publications (on the Cordis website) List of scientific publications extended (on the EU-ToxRisk website)
HISENTS High level Integrated SEnsor for NanoToxicity Screening	List of scientific publications New test methods (genotoxicity) Epigenetic Effects of Nanomaterials
in3 An integrated interdisciplinary approach to animal-free chemical and nanomaterial safety assessment	List of scientific publications
MARINA Managing Risks of Nanoparticles	List of scientific publications
MODCOMP Modified cost-effective fibre-based structures with improved multi-functionality and performance	List of scientific publications
MolNANOtox Nanomaterial surface interactions at the molecular level and their impact on ecotoxicity	List of scientific publications
NanoCommons The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators	List of scientific publications

Project Name and Link to EU Factsheet	Documents Output
NANODEFINE Development of an integrated approach based on validated and standardised methods to support the implementation of the EC recommendation for a definition of nanomaterial	List of scientific publications
NanoERA Nanomaterials Ecological Risk Assessment: A study of the long-term effects and risks of nanoscale Iron Oxide [now n-CuPc] used in plastic composites in the aquatic environment	List of scientific publications
NanoLabels Labelling of engineered nanomaterials for nanosafety tracing	List of scientific publications
NANOMILE Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology	List of scientific publications
NanoNextNL Innovating with Micro and Nanotechnology	Theses on the project website
NANoREG A common European approach to the regulatory testing of nanomaterials	List of scientific publications
NANOSOLUTIONS Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM): Systems Biology Approaches to Understand Interactions of ENM with Living Organisms and the Environment	List of scientific publications
NanoSolveIT Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT)	List of scientific publications
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	List of scientific publications

Project Name and Link to EU Factsheet	Documents Output
NANOVALID Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials	List of scientific publications
npSCOPE Integrated EU Strategy, Services and International Coordination Activities for the Promotion of Competitive and Sustainable Nanofabrication Industry	List of scientific publications
OpenRiskNet Open e-Infrastructure to Support Data Sharing, Knowledge Integration and in silico Analysis and Modelling in Risk Assessment	List of scientific publications
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	List of scientific publications
PANDORA Probing safety of nano-objects by defining immune responses of environmental organisms	List of scientific publications
PATROLS Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment	List of scientific publications
PEPTICAPS Design of polyPEPTIdes diblock copolymers as emulsifiers to produce safe, controlled and reliable novel stimuli-responsive nanoCAPSules for skin care applications	List of scientific publications
QSAREACH QSAR computational models' self-using platform for EC Regulation-REACH	List of scientific publications
QUALITYNANO A pan-European infrastructure for quality in nanomaterials safety testing	List of scientific publications
REFINE Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	Thesis Dissertation

Project Name and Link to EU Factsheet	Documents Output
SAF€RA Coordination of European Research on Industrial Safety towards Smart and Sustainable Growth	List of scientific publications (engineering and safety processes)
SAFEnano Effect of water and wastewater treatment on the properties of engineered nanomaterials (ENMs) in context of their fate, toxicity and interaction with other contaminants	Short summary of scientific results
SSinFonia Synthetic biology-guided engineering of Pseudomonas putida for biofluorination	List of scientific publications
SmartNanoTox Smart Tools for Gauging Nano Hazards	List of scientific publications
SOS-Nano Structure – Oxidative Stress relationships of metal oxide nanoparticles in the aquatic environment	Results of the project
STARNANO Spheroids as a Tool to Assess Realistic long-term effects of mixtures of nanomaterials and chemicals	Reporting on STARNANO from Cordis
SUN Sustainable Nanotechnologies	List of scientific publications
ToxEcoGraphene Assessment of ecocorona acquired by Graphene Family Nanomaterials during exposure to biofilms and fate following uptake	Conference Proceedings

6.1.3 *(Nano) SbD research*

Links to the Cordis factsheets for all the scientific publications and test methods of projects listed above. These projects give information on how to apply SbD, or how to develop frameworks and governance systems that include SbD.

Table 5 Results of the projects on (nano) SbD research.

Project Name and Link to EU Factsheet	Documents Output
BASMATI Bringing innovAtion by Scaling up nanoMATerials and Inks for printing	Scientific Poster representing the results of the project
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	List of scientific publications
Debye Springschool Workshop Nanosafety (not a H2020 project)	Scientific Publication
DIMAP Novel nanoparticle enhanced Digital Materials for 3D Printing and their application shown for the robotic and electronic industry	List of scientific publications
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	List of scientific publications
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	List of scientific publications
GUIDEnano Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance tool for nanotech industries	List of scientific publications
Labex Serenade Laboratory of Excellence for Safe(r) Ecodesign Research and Education applied to NAnomaterial DEvelopment	List of scientific publications
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	List of scientific publications

Project Name and Link to EU Factsheet	Documents Output
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	List of scientific publications
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	List of scientific publications
NANORIGO Establishing a Nanotechnology Risk Governance Framework	List of scientific publications (in progress, project started January 2019 and ends February 2023)
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	List of scientific publications
RISKGONE Risk Governance of Nanotechnology	List of scientific publications Risk Governance of Nanomaterials: Analysis of Operating Practices of Existing Bodies
ShuttleCat Shuttle Catalysis for Reversible Molecular Construction	List of scientific publications
IZADI-NANO2INDUSTRY Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery.	List of scientific publications

6.2 Pillar 2 - Education

One of the strategic lines to achieve the 2050 policy goals is to anchor the SbD concept to education. The education pillar focuses on creating awareness of safety early in the innovation process while ensuring that the knowledge and skillsets to proactively account for safety aspects in designing materials, products, and processes are acquired by a new generation of engineers, technologists and material scientists. By applying SbD, designers can contribute significantly to risk management and develop a sense of responsibility towards safety early in their education, leading to a new culture of safety and innovation. It is important to note that some of the projects have results relevant to multiple pillars.

Table 1, the 'overview of projects' shows the general information on each project in alphabetical order. It shows the abbreviation and full name of the project (with link to the (CORDIS) website), the pillar(s) in

which this project obtained results, the discipline in which the project was active, the outcome in short, the SbD aspect in one or two sentences, and a short description. The tables hereafter show the projects and links to their results sub-divided in different topics. In the education pillar the results are sub-divided into workshops, courses, programmes and safety/SbD training, and include links to where information on these results can be found.

6.2.1 Overview of projects

Table 6 Overview of the projects that have obtained results in the education pillar.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	Education, Research, Industry	Multidisciplinary/ Nano	Guidelines, Training, Scientific Publications	Nano decision tool for facilitating decision-making in choice of techniques and SOPs.	ACEnano will introduce confidence, adaptability, and clarity into nanomaterial risk assessment by developing a widely implementable and robust tiered approach to nanomaterials' physicochemical characterisation. This will simplify and facilitate contextual (hazard or exposure) description and its transcription into a reliable nanomaterials grouping framework.
ASINA Anticipating Safety Issues at the Design Stage of NAno Product Development	Industry, Research, Education	Multidisciplinary, Nano	No results yet (project started March 2020 and ends August 2023) Expected Roadmap, case studies, SbD training, tools	Apply SbD in the production value chains of coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. Develop a ROADMAP to generalise the above-mentioned results.	The EU-funded ASINA project will study the production value chains of two representative categories of nano-enabled products: coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. The project aims to formulate design hypothesis and make design decisions by applying an SbD management methodology (the ASINA-SMM), moulded on industrial six sigma practices, to ensure an easy implementation in nano-manufacturing processes. When completed, ASINA will provide a ROADMAP to generalise ASINA-SMM, maximising the positive impacts of further products designed to improve environmental quality and human health/wellness.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
BIORIMA Biomaterial Risk Management	Education, Research, Industry	Medicine/ Bionanomaterials	Training and Integrated risk management framework, Scientific Publications	Framework for allocating validated tools and methods for materials, exposure, hazard, and risk identification/assessment, and to manage and reduce the risk for specific nanobiomaterials.	BIORIMA aims to develop an Integrated Risk Management framework for nanobiomaterials (NBM) used in medical devices (MD) and advanced therapeutic and medical devices (ATMP)). The BIORIMA IRM framework is a structure on which the validated tools and methods for materials, exposure, hazard and risk identification/assessment and management are allocated. It includes a rationale for selecting and using them to manage and reduce the risk for specific NBM used in MD and ATMP.
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	Education, Research, Industry	Multidisciplinary/ Nano	Framework, Training, Scientific Publications	Develop a nanotool and framework based on a suite of tested and calibrated manufactured nano-specific risk prioritisation tools.	Currently, none of the existing REACH compliance models are suited or validated for risk assessment of manufactured nanomaterials, and many existing exposure limits are not suitable for nanomaterials. caLIBRAte will address this by developing a 'system of systems', based on a suite of tested and calibrated manufactured nano-specific risk prioritisation and control banding tools.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Debye Springschool Workshop Nanosafety (not a H2020 project)	Research, Education	Multidisciplinary, Nano	Workshop, scientific publication	A workshop on nanosafety including SbD.	The Debye springschool is held at Utrecht university every two years. In the 2018 edition the theme was nanomaterials for Daily Life. A lecture was held by the RIVM on nanosafety, followed by a scientific publication regarding the safety of nanomaterials by PhD students at the university.
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Education, Industry	Multidisciplinary, Nano	Summary of tools, guidelines, trainings. Platform and case studies.	Provide an independent, science-based, managed Centre (hub) linked with several networks (spokes) to act at the interface between research organisations, industry, regulatory bodies, and civil society which is necessary for SbD applicability.	EC4SafeNano seeks to develop 'fit-for-purpose' solutions and provide access to reliable data and experiences to help solve environmental and health and safety challenges that hinder the development of safe and sustainable innovation for nanotechnology. EC4SafeNano further aims to establish principles for the safe management of nanotechnology and to assist public and private organisations and industry in the application of these principles.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
GoNano Governing Nanotechnologies through societal engagement	Education, Strategic Positioning, Industry	Multidisciplinary, Nano	Workshops, Guidelines (white paper), Platform, knowledge database, concept development and stakeholder support	Develop a pilot project in each of the nanotechnology areas (Health, Energy and Food) to engage citizens with researchers, professional users, societal organisations, industry, and policy makers and to co-create concrete suggestions for future nanotechnologies on several aspects such as safety.	Nanotechnologies – the purposeful engineering of matter on an atomic or molecular scale – have given rise to great expectations in recent years, unlocking new research opportunities in areas as diverse as energy, healthcare, electronics, food, and construction. At the same time, concerns have been raised about possible unintended consequences of the use of nanomaterials. The EU-funded GoNano project enables co-creation between citizens, researchers, industry, societal organisations, and policy makers across Europe to align future nanotechnologies with societal needs and concerns.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Scientific publications, Training school, Nano risk governance model, nano risk governance council	Develop a nano risk governance council (NRGC) that will support SbD practices. It will explore upcoming tools and approaches such as Findable, Accessible, Interoperable and Re-usable (FAIR) databases and blockchain technology	The Gov4Nano project will develop the first implementation of a future-proof operational Nano Risk Governance Model (NRGM) that addresses the needs of the transdisciplinary field and innovative (and key enabling) character of nanotechnology. The Gov4Nano project will design and establish a Nanotechnology Risk Governance Council (NRGC) to create a trustworthy and objective international umbrella for the risk governance of nanotechnologies.
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	Education, Research, Industry	Multidisciplinary, Nano	Framework, Guidance, Database, Training	Develop a framework with guidance, and a database on e-nanomapper, and tools for logically grouping nanomaterials.	The GRACIOUS project aims are to develop a highly innovative science-based framework that supports the assessment of risk posed by the ever-increasing array of nanomaterials on the market and under development. The framework will streamline the process for assessing their risk by logically grouping nanomaterials, thereby allowing extrapolation between (read-across) nanomaterials and reducing the need to assess exposure and toxicity on a case-by-case basis.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Labex Serenade Laboratory of Excellence for Safe(r) Ecodesign Research and Education applied to NAnomaterial DEvelopment	Education, Research	Multidisciplinary, SbD	Programmes and Training on SbD, Scientific Publications	Outreach on SbD to education and research.	SERENADE is a Labex and Excellence laboratory funded for 8 years by the French "Investissements d'Avenir" project. Labex SERENADE aims to build a dynamic network of academic research laboratories and industries to design tomorrow's nanomaterials that will be safer for both humans and the environment. SERENADE addresses nanosafety throughout the entire life cycle of nanoproducts, from the earliest production stages (pristine nanoparticles) to the end-of-life (recycling, disposal).
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	Education, Research, Industry, Strategic Positioning	Bionanomaterials / Medicine	SbD training, guidelines, bringing networks together, Scientific Publications	Bring together research groups to create novel bioactive nanomaterials for medical application.	The project's aim is to design, develop, produce and characterise novel nanostructured bioactive materials for biomedical applications. The idea is to bring together research groups specialised in material science and experts in bio-active materials and review the nanomaterials' application in medicine..

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoCommons The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators	Research, Industry	Multidisciplinary/ Nano	Foresight, Scientific Publications, Knowledge Portal	Create a platform with computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and benchmarking of their predictive power, user friendly for all stakeholders (regulators and industry).	NanoCommons aims to create a community framework and infrastructure for reproducible science, and in particular for *in silico* workflows for nanomaterial safety assessment. The platform provides a user-friendly interface for a suite of computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and benchmarking of their predictive power.
NanoFASE Nanomaterial FAte and Speciation in the Environment	Education, Research, Industry	Multidisciplinary/ Nano	Workshop, Case Studies, Scientific Publications, Framework, Factsheets, Toolbox	Develop a set of concepts and approaches to underpin the Exposure Assessment Framework.	NanoFASE will provide an integrated exposure assessment framework (e.g., protocols, models, parameter values, guidance). The ambition is to reach a level of engineered nanomaterial fate and exposure assessment at least comparable with that of conventional chemicals.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Safety training, Scientific publications, Design tool, Guidelines	High throughput *in vitro* tests for the safety assessment of nanomaterials and for the early application of SbD.	NANOGENTOOLS combines genomics (toxicogenomics), proteomics and multidisciplinary science to develop fast *in vitro* high throughput (HTS) assays, with molecular based computational models for a better understanding of the molecular fundamentals of nanotoxicity. It will also initiate the development of online nanosafety assays for use by SMEs during product development.
NanoNextNL Innovating with Micro and Nanotechnology (not a H2020 project)	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Theses and Tools	A Dutch national research program for nanotechnology which employs SbD aspects.	NanoNextNL is the Dutch national research and technology programme for micro and nano technology. The programme consists of 10 themes and a valorisation programme. There are three different themes: general themes, application themes, and risk analysis and technology assessment.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANoREG A common European approach to the regulatory testing of nanomaterials	Education, Research, Industry, Strategic Positioning	Multidisciplinary/ Nano	Workshop, Scientific Publications, Toolbox, Guidelines, Case Studies, Framework, e-Nanomapper, Policy and legislation/ regulation relevance	A risk assessment framework suitable for SbD applicability.	The innovative and economic potential of Manufactured Nano Materials (MNMs) is threatened by a limited understanding of the related environment, health, and safety (EHS) issues. While toxicity data are increasingly available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM is driving the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods.
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Education, Research, Industry, Strategic Positioning	Multidisciplinary/ Nano	Workshops, Scientific Publications, Tools, Guidelines, Case Studies, Framework, Databases, Foresights, Stakeholder Support, International Support, Creating Awareness	Develop the Safe Innovation Approach (SbD, regulatory preparedness, trusted environments)	The NanoReg2 project, built around the challenge of coupling SbD to the regulatory process, will demonstrate and establish new principles and ideas based on data from value chain implementation studies to establish SbD as a fundamental pillar in the validation of novel manufactured nanomaterials (MNM). Grouping concepts developed by NanoReg2 can be regarded as a major innovation, as guidance documents on NM grouping will not only support industries or regulatory agencies but will also strongly support the commercial launch of a new NM.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Education, Research, Industry, Strategic Positioning	Multidisciplinary/ Nano	Training, Scientific Publications, Nano risk governance framework, Nano risk governance council	Develop a nano risk governance council (NRGC). The ultimate aim of NANORIGO is to deliver a Risk Governance Framework for the safety of nanomaterials, for risk assessment, hazard and exposure, human health and environment, and risk mitigation. It includes regulatory aspects of SbD.	NANOtechnology RIsk GOvernance aims to develop and implement a transparent, transdisciplinary Nanotechnology Risk Governance Framework and a related Risk Governance Council to guide stakeholders regarding the sustainable development of nanotechnologies in Europe. NANORIGO will collaborate on this with RiskGone and Gov4Nano (also funded under the NMBP13-2018 Call).
NanoSAFE Nanosafe Digital Conference	Education	Multidisciplinary, Nano	Conference (workshops)	SbD and Eco-conception as innovation drivers	The Nanosafe Conference will share the latest R&D results on environmental, health and safety issues related to nanomaterials and beyond.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Nanosafety (not a H2020 project) Description of the course	Education	Multidisciplinary, Nano	Course and workshop on nanosafety	Training programme on how to apply SbD	The objective of Nanosafety is to increase our understanding of the fundamental connections between particle properties and human and environmental toxicology, as well as of emissions and exposure in all stages of the lifecycle of a nanomaterial. The research aims at providing the tools needed to implement Safe(r)-by-design in the development and production of novel materials.
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	Research, Industry	Chemistry, Physics, Nano	Guidelines, Training, Scientific Publications	Identify safety risks from the labs via technology development up to the application of nanoelectronics.	The goal of the NanoStreeM project is to promote good practices by identifying and implementing standards, identifying gaps in methodologies, and providing directions for further investigations in order to support governance of the occupational risk induced by the use of nanomaterials in the semiconductor industry.
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	Education, Research, Industry	Multidisciplinary, Nano	Safety training, Scientific publications, guidelines and case studies	Introduce nanotechnology and SbD in production lines for packaging and automotive and photovoltaic material production.	With the use of nanotechnology both in bulk and surface applications, OPTINANOPRO will deliver demonstrators of packaging with improved barrier properties as well as with repellent properties, resulting in easy-to-empty features that will, on the one hand, reduce waste at consumer level and, on the other, improve their acceptability by recyclers.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PANDORA Probing safety of nano-objects by defining immune responses of environmental organisms	Education, Research	Multidisciplinary, Nano	Scientific publications, Safety training	Create a multidisciplinary environment where young researchers will contribute by studying the effects of NP on the immune system responses of environmental organisms. This will have future SbD applicability.	In a highly multidisciplinary environment, 11 Early Stage Researchers (ESR) will be trained on the issue of immuno-nanosafety. The focus on the effects of NP on the functionality of the immune system, and consequently on the overall health protection of the target organism, will be broadened from human health to encompass a variety of environmental organisms (plants, invertebrates, marine, earth). The programme will therefore lay the basis for an integrated approach to environmental nanosafety that includes immunosafety as a key element.
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Courses, Scientific Publications, Guidelines, Pilots/Case studies	Produce a practical guideline and standards for companies aiming at developing a strategy for Responsible Research and Innovation (RRI) which includes SbD.	The overarching goals of the PRISMA project are: -to help companies implement Responsible Research and Innovation (RRI) in their innovation and social responsibility strategies; -to provide evidence on how RRI can improve innovation processes and products; -to show how RRI leads to societal trust (thus strengthening the market position of companies).

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PRORISK Best chemical risk assessment professionals for maximum Ecosystem Services benefit	Education, Industry	Multidisciplinary	Training material, Platform	Training in advanced environmental risk assessment for future SbD application.	The EU-funded PRORISK project will create a platform for training a network of early-stage researchers in this field. As future experts, the researchers will be trained to address the challenges of the risk assessment paradigm shift. Specifically, the project will develop and integrate mechanistic understanding, in-depth analyses of chemical-biological interactions and exposure, and functioning of ecosystems. The goal is to empower the researchers to develop new regulatory missions to protect ecosystem services.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
RISKGONE Risk Governance of Nanotechnology	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Webinars, Scientific publications, OECD guidelines, Nano risk governance council.	Develop a nano risk governance council (NRGC) that will help SbD practices. Develop tools to identify the environmental and human health impacts of nanomaterials for SbD applicability.	RISKGONE (Science-based Risk Governance of Nano-Technology) is an EU H2020 project aiming at providing solid procedures for consistent risk governance of engineered nanomaterials. The project will develop new tools or modify existing ones to identify the environmental and human health impacts of a number of nanomaterials with greater certainty. These tools and the results of tests using them will then be integrated into the work of a European Risk Governance Council (ERGC), a group of individuals with different areas of expertise on nanomaterials tasked to provide governance decisions on the safety of the specific materials. A risk governance framework consisting of the tools and the ERGC will be developed to address nanomaterial safety governance in a coherent and scientifically robust way.
SUN Sustainable Nanotechnologies	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Workshops, Scientific Publications, Case studies on SbD and Safety, Framework and Guidelines, International Support, Tools	An integrated approach addressing the complete product lifecycle to assess health and environmental risks for SbD applicability within nanotechnology.	The Sustainable Nanotechnologies (SUN) project is based on the idea that the current knowledge on environmental and health risks of nanomaterials – while limited – can nevertheless guide nanomanufacturing to avoid liabilities if an integrated approach addressing the complete product lifecycle is applied.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SUSNANOFAB Integrated EU Strategy, Services and International Coordination Activities for the Promotion of Competitive and Sustainable Nanofabrication Industry	Education, Industry	Multidisciplinary, Nano	No results yet (projects started March 2020 and ends February 2023) Expected: Platform and training	A network for sustainable nanofabrication which may include SbD applicability.	The EU-funded SUSNANOFAB project aims to introduce an integrated and concerted effort focusing on sustainable nanofabrication. The project, which can also rely on international cooperation, will provide an 'EU-wide strategic roadmap on nanofabrication'. The basis of the project will include setting up a large set of training, workshop, and brokerage services fostering access to the infrastructures related to the nanomaterials field. Finally, the development of the SUSNANOFAB Digital Platform will promote networking activities and matchmaking between the technology providers and potential customers interactively.
TU Delft Web lecture Safe by Design	Education	SbD	Course	Lecture on the SbD process.	This online lecture explains why it is so important that for those working in research and innovation, especially regarding emerging technologies, they can anticipate which risks might emerge in the context of work, the product under development, or specific contexts of product application from the very first stage in the research and development (R&D) process. To do so, the lecture introduces the SbD concept and how this relates to responsible research and innovation.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
VITO SAFE INNOVATION/SBD	Education	Multidisciplinary, Nano	Workshop	Latest research and support tools on SbD applicability and Safe Materials.	The workshop 'Safe Innovation/SbD' approach was used in the H2020 NANOTUN3D and SIM-VLAIO Met@link projects as part of the Nanotechnology Industries Association's latest webinar in the Nano in Action series on nanosafety. The webinar tackled the latest research and support tools that will advance the development of safe materials. Workshop participants learn more about VITO's Safe Innovation approach as well as about other H2020 projects.
Vrije Universiteit Amsterdam Winter-school Safe-and-Sustainable-By-Design: Product Development 2.0	Education	SbD	Course	Course on Safe and Sustainable by design.	In this interactive practical course, students get a short yet solid introduction is given to the concept of Safe-and-Sustainable-by-Design. Thus, processes and tools associated with S(S)bD will be presented with a focus on sustainability. By combining the pro-active and anticipative integration of considerations regarding safety and sustainability in (technical) pathways of research & development, a new and reflective way of thinking and acting is stimulated.

6.2.2 *Workshops*

Links to all reports, deliverables, training programmes, summaries, and documents written that summarise a workshop. These workshops include safety workshops, SbD workshops, and workshops on how to use certain tools dealing with nanosafety or SbD.

Table 7 Results of projects with workshops on either safety or SbD

Project Name and Link to EU Factsheet	**Documents Output**
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	Report on outcomes of kick-off stakeholder workshop: initial strategy for benchmarking, training, decision tree development
BIORIMA Biomaterial Risk Management	Stakeholder Workshop
Debye Springschool Workshop Nanosafety (not a H2020 project)	Debye Springschool Workshop
GoNano Governing Nanotechnologies through societal engagement	Working Paper on the designs and outcomes of workshop round 1 Background report for each of the selected topic areas Briefing report containing the outcome of the face-to-face deliberation and envisioning workshops with the citizens as input for the co-creation workshops with the professional stakeholders D3.1- Information material for citizens' workshops D4.1- Background material for stakeholder workshops D4.2- Working paper on GoNano stakeholder workshops D4.2B- Outcomes of co-creation workshops round 2

Project Name and Link to EU Factsheet	Documents Output
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	WORKSHOP – TRAINING FOR ACADEMIA, INDUSTRY, RESEARCH, SUPPLIERS (21 MARCH 2019) WORKSHOP – IMPLEMENTATION OF SBD APPROACH FOR POLYMERIC NANOBIOMATERIALS USED FOR DRUG DELIVERY. CASE STUDY: CHITOSAN (21 FEBRUARY 2019) CONFERENCE – GREEN NANOCHEMISTRY – APPLICATION OF THE SAFE BY DESIGN PRINCIPLE FOR OBTAINING NEW NANOMATERIALS (7 JUNE 2018)
NanoCommons The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators	Training course on using the e-infrastructure
NanoFASE Nanomaterial FAte and Speciation in the Environment	Open workshop / conference on airborne ENM: Measurements, Implications and Modelling.
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	Workshop on the standardisation of new tools for assessment of nanosafety Nanotechnology Round Table Summary of all Workshops done in Project
NanoNextNL Innovating with Micro and Nanotechnology	SbD workshop: starting an early dialogue in innovation process
NANoREG A common European approach to the regulatory testing of nanomaterials	Innovation and Regulatory testing of nanomaterials - first results of NANoREG

Project Name and Link to EU Factsheet	Documents Output
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Nanomaterials: Industrial Workshop on SbD OECD joint workshop: Scientific Workshop on Grouping of Nanomaterials. NanoReg2 and Gracious H2020 projects JRC publishes summary from NanoReg2 Workshop on Regulatory Preparedness for Innovation in Nanotechnology Training workshop Deliverable Report D6.8 Rapid Prototypes Workshop: Developing Trusted Environments Report on NanoReg2 - OECD conference on grouping Document on the feasibility to come to organised pre-regulatory safety dossiers
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Training for three different stakeholder groups. (in progress, project started January 2019 and ends February 2023)
Nanosafety (not a H2020 project) Description of the course	Nanosafety Workshop
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	Report on the 3 open stakeholders workshops
RISKGONE Risk Governance of Nanotechnology	Webinars on safety of nanomaterials and testing methods, adverse outcome pathways (AOPs).
SUN Sustainable Nanotechnologies	1st Sustainable Nanotechnology School 2nd Sustainable Nanotechnology School The ESRIC Super-Resolution Summer School Plan for use and dissemination of knowledge 2nd Dissemination progress report
VITO SAFE INNOVATION/SBD	Online video to the workshop

6.2.3 *Courses*

Links are given to all conferences and courses dealing with nanosafety or SbD. Several courses on SbD given at European universities are also included.

Table 8 Results of projects with courses on nanosafety or SbD

Project Name and Link to EU Factsheet	**Documents Output**
GoNano Governing Nanotechnologies through societal engagement	D6.3- Report collecting the materials and participant list from the Winter School*
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	MOOC on Nanosafety and risks of nanotechnology
NanoSAFE Nanosafe Digital Conference	The conference General information on the conference
Nanosafety Description of the course	Education for professionals on NanoSafety Application to the course
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	MOOC 'Responsible Innovation: Building tomorrow's responsible firms'
TU Delft Web lecture Safe by Design	Web lecture Safe by Design Information on EcoDesign EcoDesign_Checklist_DelftUniversity.pdf
Vrije Universiteit Amsterdam Winter-school Safe-and-Sustainable-By-Design: Product Development 2.0	Safe-and-Sustainable-By-Design: Product Development 2.0

6.2.4 *Programs*

One link was found that led to a programme given by Labex Serenade, teaching specific SbD courses.

Table 9 Results of projects with an SbD teaching program

Project Name and Link to EU Factsheet	**Documents Output**
Labex Serenade Laboratory of Excellence for Safe(r) Ecodesign Research and Education applied to NAnomaterial DEvelopment	Programme on SbD aspects

6.2.5 *Safety and SbD training*

Links to all training courses, schools, webinars, and lectures on this topic. Courses etc. on nanomaterial safety were also included.

Table 10 Results of training projects on nanosafety or SbD.

Project Name and Link to EU Factsheet	**Documents output**
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	Refined strategy for benchmarking, training, decision tree development
BIORIMA Biomaterial Risk Management	Training Public Plan Training school 2nd Edition Training School 1st Interprofessional Nano Training School 1st BIORIMA Training School organised in Venice
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	Project webinars on project website and social media
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Summary of Tools, Guidelines, Methods, SOPs, Best Practices and Training on Nano Initial and final Commented inventory of available tools, methods, approaches, best practices
GoNano Governing Nanotechnologies through societal engagement	D6.1 – A collection of training material for researchers and engineers*

Project Name and Link to EU Factsheet	Documents output
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	Nanosafety Training School – From Basic Science to Risk Governance
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	Insights from the Horizon 2020 BIORIMA, GRACIOUS and NanoInformaTIX Projects Joint Training School GRACIOUS launches a Nano Training School Successful workshop on Harmonisation of Standard Operating Procedures Training
Labex Serenade Laboratory of Excellence for Safe(r) Ecodesign Research and Education applied to NAnomaterial DEvelopment	Nanotechnologies, safer by design and business development Summer school and international educative initiative
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	TRAINING MODULES FOR STUDENTS (SbD training) POLYMERIC NANOBIOMATERIALS FOR MEDICAL APPLICATIONS. TRAINING FOR ACADEMIA, INDUSTRY, RESEARCH, SUPPLIERS IMPLEMENTATION OF SBD APPROACH FOR POLYMERIC NANOBIOMATERIALS USED FOR DRUG DELIVERY. CASE STUDY: CHITOSAN COMPUTATIONAL METHODS TO PREDICT THE BIOLOGICAL EFFECTS OF ADDITIVES USED IN MEDICAL APPLICATIONS NANOMATERIALS BASED-PRODUCTS AWARENESS NANOMATERIALS AND NANOSTRUCTURES: SYNTHESIS AND CHARACTERISATION
NANOGENTOOLS Development and implementation of a new generation of nanosafety assessment tools	NANOGENTOOLS Autumn EU School "Advanced Training in understanding the safety of nanomaterials"

Project Name and Link to EU Factsheet	Documents output
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	Report on establishment of a NanoStreeM Safety Community Internal training package available for operators and maintenance engineers inside the consortium. Training package available for safety professionals to conduct risk banding, risk assessments and monitoring.
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	Slides on Safety Training
PANDORA Probing safety of nano-objects by defining immune responses of environmental organisms	Safety training

6.3 Pillar 3 – Industry

The Industry pillar is important because the design and development of new products and processes are largely industry driven. As SbD has an important place in company practice, industry is a large target group. In this pillar, research is conducted on how SbD can be implemented and which aspects of SbD to focus on. It is important to note that some projects have relevant results in multiple pillars.

Table 1, the 'overview of projects' shows the general information on each project in alphabetical order. It shows the abbreviation and full name of the project (with link to the (CORDIS) website), the pillar(s) in which this project obtained results, the discipline in which the project was active, the outcome in short, the SbD aspect in one or two sentences, and a short description. The following tables show the projects and links to the results of the projects sub-divided in different topics. This includes tools, guidelines, case studies focused on safety/SbD, frameworks, databases, networking platforms, platforms for tools, foresights and datasets.

6.3.1 Overview of projects

Table 11 Overview of projects with results in the industry pillar.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	Education, Research, Industry	Multidisciplinary/ Nano	Guidelines, Training, Scientific Publications	Nano decision tool for facilitating decision-making in choice of techniques and SOPs.	ACEnano aims to introduce confidence, adaptability and clarity to nanomaterial risk assessment by developing a widely implementable and robust tiered approach to nanomaterials' physicochemical characterisation. This will simplify and facilitate contextual (hazard or exposure) description and its transcription into a reliable nanomaterials grouping framework.
ASINA Anticipating Safety Issues at the Design Stage of NAno Product Development	Industry, Research, Education	Multidisciplinary, Nano	No results yet (project started March 2020 and ends August 2023) Expected Roadmap, case studies, SbD training, tools	Apply SbD in the production value chains of coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. Develop a ROADMAP to generalise the above-mentioned results.	The EU-funded ASINA project will study the production value chains of two representative categories of nano-enabled products: coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. The project seeks to formulate design hypothesis and make design decisions by applying an SbD management methodology (the ASINA-SMM), moulded on industrial six sigma practices, to ensure an easy implementation in nano-manufacturing processes. On completion, ASINA will provide a ROADMAP to generalise ASINA-SMM, maximising the positive impacts of products, designed to improve environmental quality and human health/wellness.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
BASMATI Bringing innovAtion by Scaling up nanoMATerials and Inks for printing	Research, Industry	Battery research, Nano	Case studies on batteries, Scientific Posters	Recommend best practices and safe design of active nanomaterials in conductive and electrochemical inks for screen and inkjet printing.	BASMATI addresses the development of active nanomaterials and their formulation in conductive and electrochemical inks for screen and inkjet printing. As a case study, these functional inks will be applied in a printed thin film battery. BASMATI's general objective is to develop pilot lines for material synthesis and ink formulation, ensuring large volume production of new products with improved properties for printing.
BioNanoMet (not a H2020 project)	Industry	Multidisciplinary, Nano	Networking platform	Provide a network for health, safety, data, sustainability and enabling technologies. This network can be used to discuss SbD issues.	BioNanoNet represents a critical network node and has the clear aim to establish contacts efficiently and selectively among its members and potential customers, including those from industry, in each of the network's thematic fields. Due to the multidisciplinary expertise of the individual members (national and international organisations, research organisations and universities), we offer our customers efficient solutions. The initiation and coordination of national and international research projects along the entire value chain is another important mission. BioNanoNet brings together researchers conducting medical and pharmaceutical research to increase the international competitiveness and visibility of all stakeholders.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
BIORIMA Biomaterial Risk Management	Education, Research, Industry	Medicine/ Bionanomaterials	Training and Integrated risk management framework, Scientific Publications	Framework for allocating validated tools and methods for materials, exposure, hazard and risk identification/assessment and manage and reduce the risk for specific nanobiomaterials.	BIORIMA aims to develop an Integrated Risk Management framework for nanobiomaterials (NBM) used in medical devices (MD) and advanced therapeutic and medical devices (ATMP). The BIORIMA IRM framework is a structure on which the validated tools and methods for materials, exposure, hazard and risk identification/assessment and management are allocated plus a rationale for selecting and using them to manage and reduce the risk for specific NBM used in ATMP and medical devices.
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	Education, Research, Industry	Multidisciplinary/ Nano	Framework, Training, Scientific Publications	Develop a nanotool and framework based on a suite of tested and calibrated manufactured nano-specific risk prioritisation.	Currently, none of the existing REACH compliance models are suited or validated for risk assessment of manufactured nanomaterials, and many existing exposure limits are not suitable for nanomaterials. caLIBRAte will address this by developing a 'system of systems', based on a suite of tested and calibrated manufactured nano-specific risk prioritisation and control banding tools.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
DIMAP Novel nanoparticle enhanced Digital Materials for 3D Printing and their application shown for the robotic and electronic industry	Research, Industry	Multidisciplinary, Nano, 3D printing	Guidelines, Case studies (on 3D printing), scientific publications	Apply SbD to 3D printing	DIMAP advances the state-of-the art of additive manufacturing (AM) through modifications of fundamental material properties, mainly by using nanoscale material enhanced inks. SbD approaches include workplace safety, risk assessment, collaboration with EU safety cluster, and life cycle assessment. On project completion, an established roadmap will enable the identification of future development needs in related fields in order to ensure Europe will be able to compete at the forefront of the AM revolution.
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Education, Industry	Multidisciplinary, Nano	Summary of tools, guidelines, trainings. Platform and case studies.	Provide an independent, science-based, managed centre (hub) linked to several networks (spokes) to act at the interface between research organisations, industry, regulatory bodies, and civil society. This is necessary for SbD applicability.	EC4SafeNano aims to develop 'fit-for-purpose' solutions and provide access to reliable data and experience to help solve the environment, health and safety challenges that hinder the development of safe and sustainable innovation for nanotechnology. EC4SafeNano further aims to establish principles for the safe management of nanotechnology and to assist public and private organisations and industry in the application of these principles.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
ENF2015 EuroNanoForum 2015 ENF2017 EuroNanoForum 2017 EFN2019 EuroNanoForum 2019	Industry	Multidisciplinary, Nano	Multidisciplinary hub/forum	Network of scientists, industrialists and policy makers to initiate future cooperation in research and innovation, to discuss strategic research priorities, and to build partnerships for future calls. This network forms a podium to discuss SbD issues.	The conference will focus on nano and materials technologies, strengthening European competitiveness and supporting renewal and recovery from the economic crisis. The event will review the status of European nanotechnology, including the latest progress in nanoscience, innovations, and business. The conference will also build on agendas of previous conferences such as commercialisation and start-ups.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
EU-ToxRisk An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century	Research, Industry	Toxicity	Scientific publications, adverse outcome pathways (AOPs)	EU-ToxRisk will integrate advances in cell biology, omics technologies, systems biology, and computational modelling to define the complex chains of events that link chemical exposure to toxic outcome. This can be useful when applying SbD in the future.	The focus of this project is on two areas: repeated dose systemic toxicity, using the lung, kidney, liver and nervous system as examples of potential target organs; and developmental and reproductive toxicity. It will also provide guidance for universal application, propelling the entire field forward in an integrated manner. The ultimate goal is to deliver testing strategies to enable reliable, animal-free hazard and risk assessment of chemicals.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
GoNano Governing Nanotechnologies through societal engagement	Education, Strategic Positioning, Industry	Multidisciplinary, Nano	Workshops, Guidelines (white paper), Platform, knowledge database, concept development and stakeholder support	Develop a pilot project in each of the nanotechnology areas (Health, Energy and Food) which should engage citizens with researchers, professional users, societal organisations, industry, and policy makers to co-create concrete suggestions for future nanotechnologies on several aspects such as safety.	Nanotechnologies – the purposeful engineering of matter on an atomic or molecular scale – have given rise to great expectations in recent years, unlocking new research opportunities in areas as diverse as energy, healthcare, electronics, food, and construction. At the same time, concerns have been raised about possible unintended consequences of the use of nanomaterials. The EU-funded GoNano project enables co-creation between citizens, researchers, industry, societal organisations, and policy makers across Europe to align future nanotechnologies with societal needs and concerns.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Scientific publications, Training school, Nano risk governance model, nano risk governance council	Develop a nano risk governance council (NRGC) that will support SbD practices. It will explore upcoming tools and approaches such as Findable, Accessible, Interoperable and Re-usable (FAIR) databases and blockchain technology	The Gov4Nano project will develop the first implementation of a future-proof operational Nano Risk Governance Model (NRGM) that addresses the needs of the transdisciplinary field and innovative (and key enabling) character of nanotechnology. The Gov4Nano project will design and establish a Nanotechnology Risk Governance Council (NRGC), to create a trustworthy and objective international umbrella for the risk governance of nanotechnologies.
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	Education, Research, Industry	Multidisciplinary/ Nano	Framework, Guidance, Database, Training	Develop a framework with a guidance, database on e-nanomapper, and tools for logically grouping nanomaterials.	The GRACIOUS project will develop a highly innovative science-based framework that supports the assessment of risk posed by the ever-increasing array of nanomaterials on the market and under development. The framework will streamline the process for assessing their risk by logically grouping nanomaterials, thereby allowing extrapolation between (read-across) nanomaterials and reducing the need to assess exposure and toxicity on a case by case basis.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
GUIDEnano Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance tool for nanotech industries	Research, Industry	Multidisciplinary, Nano	GUIDEnano tool, scientific publications	Develop a web-based risk assessment guidance tool for nano-enabled products and for future SbD applicability.	The GUIDEnano project will develop a risk assessment web-based tool which incorporates guidance on the selection of risk management options. To reach these goals, the project will build on state-of-the-art risk assessment and management by validating critical assumptions in the risk assessment process, generating new predictive models and novel risk management solutions.
HISENTS High level Integrated SEnsor for NanoToxicity Screening The follow up of HISENTS is SABYDOMA	Research, Industry	Multidisciplinary/ Nano (and Nanomedicine)	Framework, New test methods, guidelines, Scientific Publications	Create a platform capable of nanosafety assessment using high-throughput screening and SbD concept development.	HISENTS aims to deliver an advanced nanosafety platform capable of providing high-throughput toxicity screening for the risk assessment of novel nanomaterials. The platform will consist of an integrated set of miniaturised modules each representing critical human physiological functions, from molecular interactions through to cell, organ, and organism effects.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
ICARUS-INAS Intregrated Nanostructures Assessment-Service for the biological impact analysis of nanostructures	Industry	Multidisciplinary, Nano	No results yet (project starts December 2020 and ends November 2021) Expected: Tools	Investigate the life cycle of nanomaterials and their products and the impact and toxic effects of nanostructures for future SbD applicability.	The scope of the EU-funded ICARUS-INAS project is to establish a service for assessing the biological impact and toxic effects of innovative nanostructures and recording their life cycle. Using a combination of *in vitro* assays, omics technologies, and toxicology studies, scientists will evaluate the human and environmental safety of specific nanocomposite products at all stages of their life cycle. The project will also offer the possibility to implement these methodologies at the customer's facilities on request.
MARINA Managing Risks of Nanoparticles	Research, Industry	Multidisciplinary, Nano	Scientific publications, data sets, guidelines and tools	Develop risk management methods for nanomaterials including materials, exposure, hazard, and risk which can be used for SbD applicability. This project collaborated with NANOVALID and QUALITYNANO.	MARINA aimed to develop specific reference methods for all the main steps of managing the potential risk of engineered nanomaterials (ENM). It addressed the four central themes in the ENM risk management paradigm: Materials, Exposure, Hazard, and Risk.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	Education, Research, Industry, Strategic Positioning	Bionanomaterials/ Medicine	SbD training, guidelines, bringing networks together, Scientific Publications	Bring together research groups to create novel bioactive nanomaterials for medical application.	The aim of the Project is to design, develop, fabricate and characterise novel nanostructured bioactive materials for biomedical applications. The Project concept is to bring together research groups specialised in material science and experts in bio-active materials and their application in medicine.
NanoCommons The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators	Research, Industry	Multidisciplinary/ Nano	Foresight, Scientific Publications, Knowledge Portal	Create a platform with computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and benchmarking of their predictive power, user friendly for all stakeholders (regulators and industry).	NanoCommons creates a community framework and infrastructure for reproducible science, and in particular for in silico workflows for nanomaterials safety assessment. The platform provides a user friendly interface for a suite of computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and bench-marking of their predictive power.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANODEFINE Development of an integrated approach based on validated and standardised methods to support the implementation of the EC recommendation for a definition of nanomaterial	Research, Industry	Multidisciplinary, Nano	Scientific reports, link to guiding reports	Provide insights into how to define and characterise nanomaterials, which can lead to SbD applicability.	Nanotechnology is a key enabling technology. However, uncertainties concerning EHS need to be addressed to explore its full potential. One challenge is the development of methods that reliably identify, characterise and quantify nanomaterials (NM) both as substance and in various products and matrices.
NanoFabNet International Hub for sustainable industrial-scale Nanofabrication	Industry	Multidisciplinary, Nano	Platform (NanoFabNet hub)	A guided approach to high levels of safety and sustainability, pertaining to sustainable nanofabrication.	The EU-funded NanoFabNet Project will create a strong international network for sustainable nanofabrication, where the structure, business model, and detailed strategies and action plans are designed, agreed and carried by its international stakeholders, in order to yield a self-sustaining collaboration platform: the NanoFabNet Hub. The Hub will be based on an open structure with elements to be developed and validated in a stakeholder-driven approach. With a secretariat at its centre, it will provide an accountable executive that secures its economic sustainability. It will be a one-stop-shop for sustainable nanofabrication and its successful incorporation into high-value industries, by bringing together governmental and academic laboratories with large industries and SMEs, thereby offering a coordination space for collaborative nanofabrication through both P2Ps and PPP.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoFASE Nanomaterial FAte and Speciation in the Environment	Education, Research, Industry	Multidisciplinary/ Nano	Workshop, Case Studies, Scientific Publications, Framework, Factsheets, Toolbox	Develop a set of concepts and approaches to underpin the Exposure Assessment Framework.	NanoFASE will provide an integrated exposure assessment framework (e.g., protocols, models, parameter values, guidance) The ambition is to reach a level of engineered nanomaterials' fate and exposure assessment at least comparable with that of conventional chemicals.
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Safety training, Scientific publications, Design tool, Guidelines	High throughput *in vitro* tests for the safety assessment of nanomaterials and for the early application of SbD.	NANOGENTOOLS combines genomics (toxicogenomics), proteomics and multidisciplinary science to develop fast *in vitro* high throughput (HTS) assays, with molecular based computational models for a better understanding of the molecular fundamentals of nanotoxicity, and it will initiate the development of online nanosafety assays for use by SMEs during product development.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoHarmony Towards harmonised test methods for nanomaterials	Industry, Strategic positioning	Multidisciplinary, Nano	No results yet (Started in April 2020 and end in March 2023) Expected: eight test guidelines (OECD)	Develop test guidelines and guidance documents for eight endpoints where nanomaterial-adapted test methods have been identified as a regulatory priority. This will support SbD applicability.	NanoHarmony will focus on OECD TGs and GDs for eight nanomaterial test endpoints prioritised with the help of ECHA, NMEG, Industry and the Malta Initiative, and the OECD WPMN priority recommendations. NanoHarmony will coordinate the collection and use of available data and information to support the finalisation of test method development. It will also develop a sustainable international network of experts for data analysis and recommendations for test method maturation, plus future regulatory pathways. NanoHarmony will also analyse processes in test method developments to set up a framework structure for seamless and smooth cooperation between all stakeholders for the timely development of test methods ready for regulation.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoInformaTIX Development and Implementation of a Sustainable Modelling Platform for NanoInformatics.	Industry	Multidisciplinary/ Nano	Platform	Create an online platform based on predictive toxicology knowledge, thus enabling sustainable production of engineered nanomaterials (ENM) through SbD and grouping/classifying ENM for risk assessment.	NanoInformaTIX will develop a web-based Sustainable Nanoinformatics Framework (SNF) platform for risk management of engineered nanomaterials (ENM) in industrial manufacturing. The tool will be based on the significant amounts of data on physico-chemical and toxicological and ecotoxicological properties of ENM generated in recent decades, as well as new data coming from research.
NANOMET Development and standardisation of methods for the safety testing of manufactured nanomaterials at OECD	Industry	Multidisciplinary, Nano	Guidelines	Develop test guidelines and guidance documents for the safety assessment of nanomaterials. This will support SbD applicability.	The EU-funded NANOMET project aims to standardise test methods to characterise the properties that are specific to nanomaterials. It will also investigate the adaptations needed to existing testing and assessment methodologies.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANOMICEX Mitigation of risk and control of exposure in nanotechnology based inks and pigments	Industry	Pigments, inks, nanomaterials	Case study	Health and environmental assessment in the pigment/ink industry with the inclusion of nano-additives, considering production, use and disposal).	The main aim of NANOMICEX project was to reduce the potential risk of workers' exposure to the engineered nanoparticles employed in the operative conditions of the inks and pigments industry, by addressing the health and environmental consequences associated with the inclusion of nano-additives for all stages of nanotechnology-based product development (production, use and disposal).
NANOMILE Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology	Research, Industry	Multidisciplinary, Nano	Scientific publications, Case studies	Create a fundamental understanding of nanomaterial interactions with living systems for SbD applicability.	The overarching objective of NanoMILE is to formulate an intelligent and powerful paradigm for the mode(s) of interaction between manufactured Nanomaterials (MNMs) and organisms or the environment to allow the development of a single framework for the classification of nanomaterial safety and the creation of a universally applicable nanosafety framework.
NanoNextNL Innovating with Micro and Nanotechnology (not a H2020 project)	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Theses and Tools	A Dutch national research program for nanotechnology which employs SbD aspects.	NanoNextNL is the Dutch national research and technology programme for micro and nano technology. The programme consists of 10 themes and the valorisation programme. There are three types of theme: general themes, application themes, and risk analysis and technology assessment.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoQSAR Structure-activity relationship modelling of REACH-relevant endpoints to predict the toxicity of engineered nanomaterials	Industry	Toxicology	No results yet (project will start July 2021 and ends July 2023)	Structure-activity relationship modelling to predict the toxicity of engineered nanomaterials for future SbD applicability.	The main objective of the Nano-QSAR project is to develop new scientifically validated QSARs models to predict REACH relevant toxicological, ecotoxicological and environmental endpoints of a priority list of ENMs such as Metal Oxide Nanoparticles (MOx) and Quantum Dots (QD) on the basis of available literature and own experimental data.
NANoREG A common European approach to the regulatory testing of nanomaterials	Education, Research, Industry, Strategic Positioning	Multidisciplinary/ Nano	Workshop, Scientific Publications, Toolbox, Guidelines, Case Studies, Framework, e-Nanomapper, Policy and legislation/ regulation relevance	A risk assessment framework suitable for SbD applicability.	The innovative and economic potential of Manufactured Nano Materials (MNMs) is threatened by a limited understanding of the related environment, health, and safety (EHS) issues. While toxicity data are increasingly available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM is driving the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Education, Research, Industry, Strategic Positioning	Multidisciplinary/ Nano	Workshops, Scientific Publications, Tools, Guidelines, Case Studies, Framework, Databases, Foresights, Stakeholder Support, International Support, Creating Awareness	Develop the Safe Innovation Approach (SbD, regulatory preparedness, trusted environments).	The NanoReg2 project, built around the challenge of coupling SbD to the regulatory process, will demonstrate and establish new principles and ideas based on data from value chain implementation studies to establish SbD as a fundamental pillar in the validation of novel manufactured nanomaterials (MNM). Grouping concepts developed by NanoReg2 can be regarded as a major innovation, as guidance documents on NM grouping will not only support industries or regulatory agencies but will also strongly support the commercial launch of a new NM.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Education, Research, Industry, Strategic Positioning	Multidisciplinary/ Nano	Training, Scientific Publications, Nano risk governance framework, Nano risk governance council	Develop a nano risk governance council (NRGC). The ultimate aim of NANORIGO is to deliver a Risk Governance Framework for the safety of nanomaterials, for risk assessment, hazard and exposure, human health and environment, and risk mitigation. This includes regulatory aspects of SbD.	NANOtechnology RIsk GOvernance aims to develop and implement a transparent, transdisciplinary Nanotechnology Risk Governance Framework and a related Risk Governance Council to guide all stakeholders in the sustainable development of nanotechnologies in Europe. NANORIGO will collaborate on this with RiskGone and Gov4Nano (also funded under the NMBP13-2018 Call).

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoSafetyCluster Strategic Directions Enhancing Synergies (not a H2020 project)	Industry	Multidisciplinary, Nano	Platform	A forum to discuss safety issues also related to SbD. Aspects include toxicology, ecotoxicology, exposure assessment, mechanisms of interaction, risk assessment, and standardisation.	This cluster is an open platform for dialogue and exchange. All stakeholder: researchers, regulators, administrators, industry, societal representatives with an interest in EHS and nanotechnology can participate in Cluster activities whether or not they are a partner in formal European projects.
NANOSOLUTIONS Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM): Systems Biology Approaches to Understand Interactions of ENM with Living Organisms and the Environment	Research, Industry	Multidisciplinary, Nano	Datasets, Scientific Publications	Develop tools for safety classifications for engineered nanomaterials.	The overarching aim of the NANOSOLUTIONS consortium is to provide a means to develop a safety classification for engineered nanomaterials (ENM) based on an understanding of their interactions with living organisms at molecular, cellular, and organism levels. The objective is to determine the "biological identity" of ENM, and subsequently develop software that can predict the ability of ENM properties to cause health or environmental hazards. New innovative methods are needed for the ENM risk assessment of ENM safety, i.e., ENM SAFETY CLASSIFIER. This will allow the crucial transition from descriptive toxicology to predictive toxicology.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoSolveIT Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT)	Research, Industry	Multidisciplinary, Nano	Scientific publications, platform (NanoSolveIT e-platform), modelling tools	NanoSolveIT aspires to introduce an *in silico* Integrated Approach to Testing and Assessment (IATA) for the environmental health and safety of nanomaterials (ENM), implemented through a decision support system packaged as both a stand-alone open software and via a Cloud platform.	NanoSolveIT's aim is to advance nanoinformatics well beyond the state-of-the art by developing and implementing innovative modelling techniques and tools that will be integrated within NanoSolveIT IATA. It will then be incorporated into a sustainable interoperable product, the NanoSolveIT e-platform, which will become an essential element for supporting industrial and regulatory nano-risk governance and the anticipated nano-risk governance council established in the EU H2020 NMBP-13-2018 call.
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	Research, Industry	Chemistry, Physics, Nano	Guidelines, Training, Scientific Publications	Identify safety risks from the labs via technology development, for the application of nanoelectronics.	The goal of the NanoStreeM project is to promote good practices by identifying and implementing standards, identifying gaps in methodologies, and finding directions for further investigations in order to support governance of the occupational risk induced by the use of nanomaterials in the semiconductor industry.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANOVALID Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials	Research, Industry	Multidisciplinary, Nano	Guidelines (SOPs), Data sets, Scientific publications	Develop risk management methods for nanomaterials including materials, exposure, hazard, and risk, to support SbD applicability. This project collaborated with MARINA and QUALITYNANO.	The main objective of NanoValid is the development of new reference methods and certified reference materials, including methods for characterisation, detection/quantification, dispersion control and labelling, as well as hazard identification, exposure, and risk assessment of ENs. In cooperation with other relevant projects and the relevant standardisation and regulatory bodies, the most suitable test materials and methods will be selected and tested, and new nanomaterials synthesised, characterised, and stabilised for final method validation.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
OpenRiskNet Open e-Infrastructure to Support Data Sharing, Knowledge Integration and in silico Analysis and Modelling in Risk Assessment	Research, Industry	Multidisciplinary	Integrated different approaches into one Platform	Provide an open e-Infrastructure resources and services to a variety of communities requiring chemical risk assessment, including chemicals, cosmetic ingredients, therapeutic agents, and nanomaterials, needed for SbD applicability.	OpenRiskNet is a 3-year project with the main objective of developing an open e-Infrastructure providing resources and services to a variety of communities requiring risk assessment, including chemicals, cosmetic ingredients, therapeutic agents, and nanomaterials. OpenRiskNet works together with a network of partners, organised in an Associated Partners Programme.
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	Education, Research, Industry	Multidisciplinary, Nano	Safety training, Scientific publications, guidelines and case studies	Introduce nanotechnology and SbD in production lines for packaging, automotive, and photovoltaic material production.	With the use of nanotechnology both in bulk and surface application, OPTINANOPRO will deliver demonstrators of packaging with improved barrier properties as well as with repellent properties, resulting in easy-to-empty features that will on the one hand reduce wastes at consumer level and, on the other hand, improve their acceptability by recyclers.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PATROLS Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment	Research, Industry	Multidisciplinary, Nano	Guidelines, Datasets, Scientific publications	Develop tools and methods (3D tissue models for lung, gastrointestinal and liver) to minimise animal testing and categorise engineered nanomaterials.	PATROLS is an international project combining a team of academics, industrial scientists, government officials, and risk assessors to deliver advanced and realistic tools and methods for nanomaterial safety assessment. PATROLS will provide an innovative and effective set of laboratory techniques and computational tools to more reliably predict potential human and environmental hazards resulting from engineered nanomaterial (ENM) exposures. These tools will minimise the necessity for animal testing and will support future categorisation of ENMs in order to support safety frameworks.
PLATFORM Open access pilot plants for sustainable industrial scale nanocomposites manufacturing based on buckypapers, doped veils and prepregs	Industry	Multidisciplinary, carbon	Case study	A case study that applies SbD to carbon nanotube-based nano-enabled products.	The three main aims of the H2020 PLATFORM project are to develop open access environmentally friendly pilot lines for the industrial production of three cost-effective, sustainable, nano-enabled products: buckypapers, CNT treated prepreg, and CNT doped nonwoven veils. The project will create a European eco-system for testing, validation and further integration of nanocomposites, and contribute to overcoming the barriers that these advanced materials and manufacturing processes are currently facing when introduced in the market in sectors such as aeronautics and automotive.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	Education, Research, Industry	Multidisciplinary, Nano	Workshops, Courses, Scientific Publications, Guidelines, Pilots/Case studies	Develop a practical guideline and standards for companies aiming at developing a strategy for Responsible Research and Innovation (RRI) which includes SbD.	The overarching goal of the PRISMA project is: -to help companies implement Responsible Research and Innovation (RRI) in their innovation and social responsibility strategies, -to provide evidence on how RRI can improve innovation processes and products, -to show how RRI leads to societal trust, thus strengthening the companies' market position.
PRORISK Best chemical risk assessment professionals for maximum Ecosystem Services benefit	Education, Industry	Multidisciplinary	Training material, Platform	Training in advanced environmental risk assessment for future SbD application.	The EU-funded PRORISK project will create a platform for training a network of early-stage researchers in this field. As future experts, the researchers will be trained to address the challenges of the risk assessment paradigm shift. Specifically, the project will develop and integrate mechanistic understanding, in-depth analyses of chemical-biological interactions and exposure, and functioning of ecosystems. The goal will be to empower researchers to develop new regulatory missions protecting ecosystem services.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PROSAFE Promoting the Implementation of Safe by Design	Industry	Multidisciplinary, Nano	White paper, International support, guidelines, Foresight Exercise, OECD workshop	Recommendations for policymakers and regulators aimed at a more effective and cost-efficient assessment of nanomaterials in a regulatory context and for application for SbD.	In ProSafe, twelve organisations from nine EU member and associated states collaborated to evaluate the results of a wide range of EU projects on Environment, Health and Safety research in the field of nanotechnology. The main outcome of the ProSafe project was the white paper, which integrates and analyses the results of the EU funded projects NANoREG, ProSafe and numerous other nanosafety projects, and translates the findings into 15 recommendations for policy makers and regulators. Deliverables were developed under the umbrella of the ProSafe project and include the report on the OECD-ProSafe Joint Scientific Conference in Paris 2016, the Joint Document, and the White Paper.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
QSAREACH QSAR computational models' self-using platform for EC Regulation-REACH	Research, Industry	Multidisciplinary	Scientific publications, tools	Platform with QSAR models of (eco)toxicology of chemicals and nanomaterials demonstrating the safety of these substances according to EC-REACH Regulation.	QSAR computational models represent significant savings in time, resources, and money as their applicability is easy and immediate. This business need for the final development of a novel high scalable technological platform giving easy access to experienced and non-experienced end-users in the European chemical industry small and medium enterprises (SMEs) is our market opportunity. These platforms will include QSAR models of (eco)toxicology of chemicals - including nanomaterials (NMs)- to comply with the strict EC Regulation, where assays with animals in some specific domains, such as cosmetics, are completely forbidden.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
QUALITYNANO A pan-European infrastructure for quality in nanomaterials safety testing	Research, Industry	Multidisciplinary, Nano	Scientific publications, guideline	Create a scientific & technical space in which all stakeholder groups can engage, develop, and share scientific best practice in the field for the future of SbD. This project collaborated with MARINA and NANOVALID.	QualityNano is a Research Infrastructure for nanosafety assessment. QualityNano's core aim is the creation of a 'neutral' scientific & technical space in which all stakeholder groups can engage, develop, and share scientific best practice in the field.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
R2R Biofluidics Large scale micro-and nanofabrication technologies for bioanalytical devices based on R2R imprinting	Industry	Multidisciplinary, Chemicals	Case study on SbD biofluidics.	The SbD concept was applied in this case study using classical chemical safety assessment.	In the next 4 years, R2R Biofluidics aims to develop a complete process chain for first-time realisation of production lines for two selected bioanalytical lab-on-chip devices based on high throughput R2R nanoimprinting in combination with complementary printing and manufacturing technologies. The consortium, consisting of high qualified experts in the fields of engineering and production technology, chemistry and materials development, and biotechnology and life sciences, will produce two types of demonstrators by realising a complete high-volume process chain for industrial production of bioanalytical lab-on-chip devices by setting up a roll-to-roll (R2R) production line.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
REFINE Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	Research, Industry, Strategic Positioning	Bionanomaterials	Regulatory science framework, guidelines (white paper), Knowledge exchange conferences, thesis dissertation	Regulatory Science Framework for Nano(bio)material-based community which facilitates SbD.	REFINE will gather a wide community of stakeholders in regulation, industry, science, technology development, patients, and end-users, into a Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicine. Aims: to set up/ build a Regulatory Science framework to close the gap on the existing development of nanomedicine products. We will set a sustained forum that enables regulators, scientist, and developers to liase and develop: -a clear overview of current and anticipated regulatory concerns, including harmonisation, -a gap analysis where regulatory concerns and scientific evidence do not match up. - a heuristic to transfer new scientific evidence into regulatory strategies, and to translate regulatory concerns into hot spots in the standard testing cascades.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
RISKGONE Risk Governance of Nanotechnology	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Webinars, Scientific publications, OECD guidelines, Nano risk governance council.	Develop a nano risk governance council (NRGC) that will help SbD practices. Develop tools to identify the environmental and human health impacts of nanomaterials for SbD applicability.	RISKGONE (Science-based Risk Governance of Nano-Technology) is an EU H2020 project aiming at providing solid procedures for consistent risk governance of engineered nanomaterials. The project will develop new tools or modify existing ones to identify the environmental and human health impacts of a number of nanomaterials with greater certainty. These tools and the results of tests using them will then be integrated into the work of a European Risk Governance Council (ERGC), a group of individuals with different areas of expertise on nanomaterials tasked to provide governance decisions on the safety of the specific materials. A risk governance framework consisting of the tools and the ERGC will be developed to address nanomaterial safety governance in a coherent and scientifically robust way.
SABYDOMA Safety BY Design Of nanoMaterials - From Lab Manufacture to Governance and Communication: Progressing Up the TRL Ladder	Industry	Multidisciplinary, Nano	No results yet (project started April 2020 and ends September 2023) Expected platform, case studies and tools.	Build a high-throughput online platforms where nanomaterials are manufactured and screened at the point of production.	One of the main goals of the EU-funded SABYDOMA project is to build high-throughput online platforms where nanomaterials are manufactured and screened at the point of production. Another goal is to extend the impact of SbD nanomaterials to real-world situations. The project will examine four industrial case studies set up by four industrial partners to advance the technology readiness level from 4 to 6.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SAbyNA Simple, robust and cost-effective approaches to guide industry in the development of safer nanomaterials and nano-enabled products	Industry	Multidisciplinary, Nano	No results yet (project started March 2020 and ends February 2024) Expected: Guidance platform	Improve the usability of existing databases, test methods, models, frameworks and tools and integrated them into an interactive and user-friendly web-based guidance.	The EU-funded SAbyNA project aims to develop a user-friendly platform with optimal workflows to support the development of SbD nanomaterials and nano-enabled products. The workflows will integrate SbD strategies and risk mitigation measures along with decision trees that facilitate the identification of the most suitable approaches for workers, consumers, and the environment. Continuous dialogue with different stakeholders and end users will maximise the added value of the project's SbD guidance platform, which will also be demonstrated in real-world industrial case studies
SAF€RA Coordination of European Research on Industrial Safety towards Smart and Sustainable Growth	Industry	Engineering	Safe-design tool for safer processes	Tools and partnership for safer processes.	The scope of SAF€RA includes research on the prevention of major accidents, with off-site consequences and risks to the environment and society, and in particular the economic benefits of industrial safety solutions, safe innovative processes, preparedness and response Moreover, it covers protection of the environment, new methods to enhance the creation of a safety culture, and prudent attitudes, risk reduction strategies, reference technologies for life extension of aged and repaired structures, as well as products and systems required to improve industrial safety.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SbD4Nano Computing infrastructure for the definition, performance testing and implementation of SbD approaches in nanotechnology supply chains	Industry	Multidisciplinary, Nano	Project just started, going to develop a platform and database.	Create an infrastructure to foster dialogue on SbD setups between all actors in the supply chain.	A major challenge for the global nanotechnology sector is the development of safe and functional engineered nanomaterials (ENMs) and nano-enabled products (NEPs). SbD4Nano addresses that problem by creating a comprehensive new e-infrastructure to foster dialogue and collaboration between all actors in the supply chain for a knowledge-driven definition of SbD setups that minimise hazards while optimising technical performances and economic costs.
SinFonia Synthetic biology-guided engineering of Pseudomonas putida for biofluorination	Research, Industry	Biotechnology	Scientific Publications	Build sustainable and safe process alternatives for fluorinating agents by using bacteria and enzymes.	SinFonia aims to biologically produce novel fluorochemicals. Materials containing the element fluorine are extremely important in today's world, with applications in electronics, healthcare, automotive and wearables. Currently these fluorochemicals are exclusively synthesised using chemical methods, something SinFonia wants to change.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SmartNanoTox Smart Tools for Gauging Nano Hazards	Research, Industry	Multidisciplinary, Nano	Scientific publications, guidance documents, a framework and case studies on safety.	*In vivo, in vitro* and *in silico* research of respiratory toxicity pathways for a representative set of nanomaterials and relate them to interactions and molecular modelling. This approach can be used for SbD applicability.	In this project, using a comprehensive self-consistent study, which includes *in vivo*, *in vitro* and *in silico* research, we address main respiratory toxicity pathways for representative set of nanomaterials, identify the mechanistic key events of the pathways, and relate them to interactions at the bionano interface via careful post-uptake nanoparticle characterisation and molecular modelling. This approach will allow us to formulate a novel set of toxicological mechanism-aware endpoints that can be assessed by means of easily applicable, economic tests. Using the exhaustive list of endpoints and pathways for the selected nanomaterials and exposure routes, we will facilitate clear discrimination between different pathways and relate the toxicity pathway to the properties of the material via intelligent QSARs.
SUN Sustainable Nanotechnologies	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Workshops, Scientific Publications, Case studies on SbD and Safety, Framework and Guidelines, International Support, Tools	An integrated approach addressing the complete product lifecycle to assess health and environmental risks for SbD applicability within nanotechnology.	The Sustainable Nanotechnologies (SUN) project is based on the idea that the current knowledge on environmental and health risks of nanomaterials – while limited – can nevertheless guide nanomanufacturing to avoid liabilities if an integrated approach addressing the complete product lifecycle is applied.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SUSNANOFAB Integrated EU Strategy, Services and International Coordination Activities for the Promotion of Competitive and Sustainable Nanofabrication Industry	Education, Industry	Multidisciplinary, Nano	No results yet (projects started March 2020 and ends February 2023) Expected: Platform and training	A network for sustainable nanofabrication which may include SbD applicability.	The EU-funded SUSNANOFAB project aims to introduce an integrated and concerted effort focusing on sustainable nanofabrication. The project, which can also rely on international cooperation, will provide an 'EU-wide strategic roadmap on nanofabrication'. The basis of the project will include setting up a large set of training, workshop, and brokerage services fostering access to the infrastructures related to the nanomaterials field. Finally, the development of the SUSNANOFAB Digital Platform will promote networking activities and matchmaking between the technology providers and potential customers interactively.
SweNanoSafe (not a H2020 project) The national platform for nanosafety (this project is in Swedish and Google Translate was used)	Industry	Multidisciplinary, Nano	Platform	Facilitate collaborations between research and industry and the early integration of safety aspects of the innovation process (for SbD applicability).	A forum for collaboration between academia, authorities, business, and other organisations with an interest in sharing knowledge and experiences as well as discussing, developing, and influencing the implementation of nanosafety in society.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
ZADI-NANO2INDUSTRY Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery.	Research, Industry	Multidisciplinary, Nano	Scientific publications, guidelines, case studies on SbD.	Replace toxic or hazardous substances with less hazardous or less reactive substances.	In IZADI-NANO2INDUSTRY, conventional materials and injection moulding, casting and coating manufacturing processes will be improved using nanotechnology and will be combined to enable industrial scale production of new performance-enhanced components. The project will establish the value chain for nanomaterial-enabled and improved-performance products, and validate the technologies through three components of the industrial environment (TRL 7).

6.3.2 *Tools*

Links to tools integrating SbD or nanosafety research. Moreover, supporting links are given to show how the tools have been constructed.

Table 12 Results of projects that integrate SbD or nanosafety research tools

Project Name and Link to EU Factsheet	**Documents Output**
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	D.3.3 Report on improvements of environmental risk assessment models and user guidance caLIBRAte decision support tools
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Summary of Tools, Guidelines, Methods, SOPs, Best Practices and Training on Nano Initial and final Commented inventory of available tools, methods, approaches, best practices
GUIDEnano Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance tool for nanotech industries	GUIDEnano tool
MARINA Managing Risks of Nanoparticles	Frameworks and tools for risk assessment of manufactured nanomaterials.
NanoFASE Nanomaterial FAte and Speciation in the Environment	NanoFASE ENMs Experimental Toolbox
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	Deliver a user-friendly web interface tool for the computer aided nanoparticles/Nanomaterials design
NanoNextNL Innovating with Micro and Nanotechnology (not a H2020 project)	SbD tools for research and development
NANoREG A common European approach to the regulatory testing of nanomaterials	NANoREG Toolbox for the Safety Assessment of Nanomaterials

Project Name and Link to EU Factsheet	Documents Output
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Safe Innovation Approach (SIA) Toolbox
QSAREACH QSAR computational models' self-using platform for EC Regulation-REACH	List of QSAR models
SAF€RA Coordination of European Research on Industrial Safety towards Smart and Sustainable Growth	ASSESS-RE-TOOL (engineering for safer processes)
SinFonia Synthetic biology-guided engineering of Pseudomonas putida for biofluorination	New Bioinformatics Tool EnzymeMiner by Loschmidt Laboratories
SUN Sustainable Nanotechnologies	Development of modelling tools to predict release and transformation of NOAA Integrated risk evaluation of the consequences of NOAA on ecosystem services The Sustainable Nanotechnologies Project Decision Support System

6.3.3 *Guidelines*

Links to all guidelines integrating SbD or nanosafety. Moreover, it includes links to the factsheets and methods on how these guidelines were developed.

Table 13 Results of projects resulting in guidelines for integrating SbD or nanosafety

Project Name and Link to EU Factsheet	Documents Output
AceNANO Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach	Output guidelines related to key descriptors and risk assessment Guideline for Method and Protocol Standardisation Proficiency testing scheme Guidelines for inter laboratory comparisons (ILC) for validation of harmonised SOPs Interim report on method benchmarking

Project Name and Link to EU Factsheet	Documents Output
DIMAP Novel nanoparticle enhanced Digital Materials for 3D Printing and their application shown for the robotic and electronic industry	Safe by design approach implemented and assessed
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Summary of Tools, Guidelines, Methods, SOPs, Best Practices and Training on Nano Initial and final Commented inventory of available tools, methods, approaches, best practices
EU-ToxRisk An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century	AOPs and key events for adverse effects Mapping ToxCast data to AOPs Workshop on how to use AOP guidelines
GoNano Governing Nanotechnologies through societal engagement	D6.2- Online guidelines and easy-to-understand information for public and stakeholder groups wanting to be involved with nanotechnology R&I D5.3- Collection of the GoNano White papers D4.5- Concrete product suggestions for future nanotechnologies D5.2- Second briefing report on the nanotechnology RI policy context as input to developing the GoNano white papers
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	Advance Nano, GO FAIR Implementation Network (IN)
HISENTS High level Integrated SEnsor for NanoToxicity Screening	Nanosafety: Towards Safer Nanoparticles by Design

Project Name and Link to EU Factsheet	Documents Output
MARINA Managing Risks of Nanoparticles	Grouping and Read-Across Approaches for Risk Assessment of Nanomaterials Ecological risk assessment of engineered nanomaterials Regulatory ecotoxicity testing of nanomaterials–proposed modifications of OECD test guidelines based on laboratory experience with silver and titanium dioxide nanoparticles Environmental Risk Assessment Strategy for Nanomaterials The MARINA Risk Assessment Strategy: A Flexible Strategy for Efficient Information Collection and Risk Assessment of Nanomaterials. Applying quantitative structure-activity relationship approaches to nanotoxicology: current status and future potential Evaluation of existing control measures in reducing health and safety risks of engineered nanomaterials Toward the development of decision supporting tools that can be used for safe production and use of nanomaterials.
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	SbD Guidelines A Methodological SbD Approach for the Development of Nanomedicines
NANODEFINE Development of an integrated approach based on validated and standardised methods to support the implementation of the EC recommendation for a definition of nanomaterial	Link to Technical Reports that could lead to SbD
NANOGENTOOLS Developing and implementation of a new generation of nanosafety assessment tools	Report on the counselling activity of methods and standards of nanosafety with SMEs

Project Name and Link to EU Factsheet	Documents Output
NANOMET Development and standardisation of methods for the safety testing of manufactured nanomaterials at OECD	Guidance documents on nanomaterial safety In progress (project started May 2020 and ends April 2023)
NANoREG A common European approach to the regulatory testing of nanomaterials	Exposure: Improved data for the modelling of the exposure to manufactured nanomaterials Dustiness Mesocosm data Field measurements Improved measurements instruments, tools and methods WP 1: Scientific answers to regulatory issues WP 2: Synthesis, supplying and characterisation WP 3: Exposure through life cycle analysis WP 4: Biokinetics and toxicity testing in vivo WP 5: Advancement of Regulatory Risk Assessment and Testing WP 6: Keeping pace with innovation Final report

Project Name and Link to EU Factsheet	Documents Output
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	NanoReg2 Factsheet: Data Management NanoReg2 Factsheet: Safe Innovation NanoReg2 Factsheet: Implementation of Safe by Design Measures Report on Regulatory Needs for implementing grouping Final version of safe innovation approach, publication Safe Innovations Guidance manual for decisions per gate Initial standardisation plan Guidance on the practical implementation of SbD in the nano-technology community Implementation manual of the Safe Innovations Approach for all users Report on existing Grouping Strategies (NANoREG, OECD, ECHA or others) and available datasets from other projects (e.g., NANoREG, NanoTEST, MARINA) State of the Art Analysis Report on Validated grouping approach Final Standardisation plan Perspectives on how regulations can keep pace with innovation (paper) Document describing a blueprint for the creation of trusted environments per stage gate to share information among stakeholders/actors

Project Name and Link to EU Factsheet	Documents Output
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	Health monitoring guideline Identification of the most appropriate risk assessment methodologies (including gap analysis) for use in the semiconductor industry. Guidance on the use of risk assessment methodology for semiconductor industry (Combined deliverable T3.1 and T3.2). Assessment report: gaps identified about water and wastewater characterisation Recommendations for use of emission monitoring as a complement to risk banding List of standards for air sampling, as applicable in semiconductor activity; Gaps identified Gap analysis on information and data for NP exposure scenarios in semiconductor industryGap analysis on information and data for NP exposure scenarios in semiconductor industry A set of typical relevant exposure scenarios for NPs in the semiconductor industry Public final project report
NANOVALID Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials	SOPs on Material Production and Characterisation SOPs on *in vitro* Toxicity Testing SOPs on *in vivo* Toxicity Testing SOPs on Eco-toxicity Testing NanoToGo (Safe handling of nanomaterials at the workplace)
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	SbD protocol Best Practice Guidance on nano-enhanced materials

Project Name and Link to EU Factsheet	Documents Output
PATROLS Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment	PATROLS MODA The main goal of the activity described in Deliverable 6.7 (D6.7) was to verify the applicability of the modelling data (MODA) tools (template) and ontology proposed by the European Materials Modelling Council (EMMC) modelling for models under development in the PATROLS project.
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	RRI-CSR roadmap Guidelines to Innovate Responsibly The PRISMA Roadmap to Integrate Responsible Research and Innovation (RRI) in Industrial Strategies PRISMA's Responsible Industrial Research and Innovation Toolkit Dialogue Strategy and Stakeholder Mapping Report on Analysis different view technology and business ethicist Report on conditions for success for uptake by industry RRI-Roadmap Companies Link to the PRISMA website with all Roadmaps and Templates
PROSAFE Promoting the Implementation of Safe by Design	Inventory of the harmonised national regulation oriented task White Paper Short report on the White Paper recommendations – published in Particle and Fibre Toxicology Joint Document The ProSafe SbD implementation concept
QUALITYNANO A pan-European infrastructure for quality in nanomaterials safety testing	Immunotoxicity, genotoxicity and epigenetic toxicity of nanomaterials: New strategies for toxicity testing?

Project Name and Link to EU Factsheet	Documents Output
REFINE Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	Reflection Document First Draft of White Paper Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices Report on *in vitro* characterisation of nanoparticle distribution
RISKGONE Risk Governance of Nanotechnology	Draft guidelines regarding the quantification of macro-economic benefits
SmartNanoTox Smart Tools for Gauging Nano Hazards	Position paper on predictive *in vitro* models
SUN Sustainable Nanotechnologies	SUN Risk Management Guidelines Methods to extrapolate and scale–up nanomanufacturing processes Criteria and guiding principles for green nanomanufacturing Report on methods for characterising of the composition and physical properties of NOAA-containing waste Templates and SUN data libraries for NOAA inhalation, dermal and dermal-to-oral exposure measurements, process-specific release potentials and exposure protection measures Guidelines for safe handling of waste flows containing NOAA
IZADI-NANO2INDUSTRY Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery.	Methodological Handbook for SbD and management of Safety risks, Health risks and Environmental risks Market overview and Intellectual Property Status Report - third release IZADI-NANO2INDUSTRY Position Paper - final release Nano2Industry toolkit Roadmap for Standardisation

6.3.4 *Case studies focussing on safety of nanomaterials*

Links to all case studies, demonstrators, reports and summaries of case studies of and for industrial project partners.

Table 14 Results of project case studies focused on the safety of nanomaterials

Project Name and Link to EU Factsheet	**Documents Output**
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Synthetic report on the case studies
NANOMILE Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology	Case studies in the section 'Reports'
NANoREG A common European approach to the regulatory testing of nanomaterials	NANoREG D1 08 DR Case study summary report including feasibility check of the proposed answers NANoREG D1.07 DR Case studies of the different investigated materials
OptiNanoPro Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines	Economic and environmental impact of nano-enhanced automotive parts Economic and environmental impact of packaging solutions Report on the state-of-the art review Validation of packaging for food and cosmetics including food contact safety aspects Economic and environmental impact of nano-enhanced OPV laminates Nanosafety Assessment Report Training Report Slides to Safety Training

Project Name and Link to EU Factsheet	**Documents Output**
SmartNanoTox Smart Tools for Gauging Nano Hazards	Report of end-localization of NPs in relevant cells Identify and score the pathological outcome of the *in vivo* exposures List of NMs *In vivo* samples for transcriptomics studies (instillation) Isolation and archiving of biological samples for subsequent analysis Labelled NPs for tracking in cells and tissues List of nanomaterials and respective doses to be tested as TP benchmark Outcomes of the project (including data sets and codes)
SUN Sustainable Nanotechnologies	Case studies A New Integrated Approach for Risk Assessment and Management of Nanotechnologies Acquisition of pristine nanomaterials and their integration into products Report on characterisation of pristine nanomaterials for (eco)toxicological testing Report on characterisation of NOAA in biological samples from (eco)toxicity tests

6.3.5 *Case studies focussing on SbD*

Links to all case studies, demonstrators, reports, and summaries of case studies of and for industrial project partners.

Table 15 Results of projects with case studies focused on SbD

Project Name and Link to EU Factsheet	**Documents Output**
BASMATI Bringing innovAtion by Scaling up nanoMATerials and Inks for printing	Life Cycle Analysis of printed Li-ion batteries Life Cycle Analysis of inks containing nanomaterials Life Cycle Analysis of nanomaterials Summary of printing processes of nanomaterials
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	Inventory of existing value-chain case-studies
DIMAP Novel nanoparticle enhanced Digital Materials for 3D Printing and their application shown for the robotic and electronic industry	Safe by design approach implemented and assessed Final demonstrators obtained by 3D printing
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	Case studies
NanoFASE Nanomaterial FAte and Speciation in the Environment	NanoFASE Release Pathway Analysis NanoFASE Case Studies: Intentional or deliberate release Ag-NPs fate in the living environment
NANOMICEX Mitigation of risk and control of exposure in nanotechnology based inks and pigments	Final report on Cordis website

Project Name and Link to EU Factsheet	Documents Output
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	DSM Industrial Demonstrator Anvazare Industrial Demonstrator Grupo Anatolin Industrial Demonstrator HiQ-Nano Industrial Demonstrator NANOGAP Industrial Demonstrator Nanomakers Industrial Demonstrator Public version of D4.4 Final Report summarising the industrial case studies demonstration of SbD concepts Final comparative risk assessment for candidate materials after SbD implementation in "hot spots" along the life cycle
PLATFORM Open access pilot plants for sustainable industrial scale nanocomposites manufacturing based on buckypapers, doped veils and prepregs	Implementation of an SbD approach in the development of new open pilot lines for the manufacture of carbon nanotube-based nano-enabled products
PRISMA Piloting RRI in Industry: a roadmap for tranSforMAtive technologies	Report assessing pilots Report: Comparative analysis of the eight pilots Final report on pilots Final report stakeholder dialogues Lessons from the pilots Report on Videos
R2R Biofluidics Large scale micro-and nanofabrication technologies for bioanalytical devices based on R2R imprinting	SbD report

Project Name and Link to EU Factsheet	Documents Output
SUN Sustainable Nanotechnologies	Report on the development of SbyD strategies applied to CuO Report on the development of SbyD strategies applied to WC-Co
ZADI-NANO2INDUSTRY Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery.	Results of the PILOTS validation. Public version

6.3.6 *Frameworks*

Links to current frameworks or those still in progress (unfinished projects) as well as reports on how the frameworks arose and factsheets about the frameworks.

Table 16 Results of projects that have produced a framework.

Project Name and Link to EU Factsheet	Documents Output
BIORIMA Biomaterial Risk Management	Framework (in progress, project ends October 2021)
caLIBRAte Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials	Results from the demonstration of the Risk Governance framework Document on quality criteria for data Results of gap analysis Report addressing the compilation of omics data sets, network inference and benchmarks for gap identification Comprehensive analysis of available tools and methodologies for Horizon Scanning Complete list of requirements for a nano-specific risk governance framework Integrated HRA models, in the format of a suite of computational models and written guidance documentation Review article with completed evaluation and guidance on prioritisation of innovative hazard exposure and risk assessment models towards applications in the stage-gate model

Project Name and Link to EU Factsheet	Documents Output
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	Framework Publication covering the Gracious Framework A framework for grouping and read-across of nanomaterials supporting innovation and risk assessment
HISENTS High level Integrated SEnsor for NanoToxicity Screening	NanoReg framework for the safety assessment of Nanomaterials (EC Policy Report)
NanoFASE Nanomaterial FAte and Speciation in the Environment	Exposure Assessment Framework Factsheets
NANoREG A common European approach to the regulatory testing of nanomaterials	NANoREG Deliverable D 5.8 - Decision tree for risk assessment of MNMs Towards a nanospecific approach for risk assessment NanoReg framework for the safety assessment of Nanomaterials (Policy Report) D6.1 Proposal to monitor innovations in new nanomaterials and their applications D6.2 Inventory of safety assessment issues and new approaches to research and governance D6.3 Comparison on toxicity testing in drug development and in present MNMs safety testing Factsheets
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Report on integrated safety assessment framework
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Framework (in progress; project started January 2019 and ends February 2023)
SmartNanoTox Smart Tools for Gauging Nano Hazards	PMFs and binding free energies for interaction of NM with building blocks of biomolecules

Project Name and Link to EU Factsheet	Documents Output
SUN Sustainable Nanotechnologies	Basic framework for the tiered SUN qualitative to quantitative modelling-based assessment of consumer and worker inhalation, dermal and dermal-to-oral exposure to NOAA

6.3.7 *Databases*

Links to e-mappers from the different projects. Furthermore, links to models and reports are given to show how the databases were developed.

Table 17 Results of projects with databases

Project Name and Link to EU Factsheet	Documents Output
EU-ToxRisk An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century	Additional file 2: Table S1. of Comparison of a teratogenic transcriptome-based predictive test based on human embryonic versus inducible pluripotent stem cells Additional file 2: Table S1. Comparison of a teratogenic transcriptome-based predictive test based on human embryonic versus inducible pluripotent stem cells Comparison of a teratogenic transcriptome-based predictive test based on human embryonic versus inducible pluripotent stem cells Additional file 1: Figure S1. of Comparison of a teratogenic transcriptome-based predictive test based on human embryonic versus inducible pluripotent stem cells
GoNano Governing Nanotechnologies through societal engagement	The GoNano Knowledge Database
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	H2020 GRACIOUS Database (e-nanomapper)

Project Name and Link to EU Factsheet	Documents Output
NANoREG A common European approach to the regulatory testing of nanomaterials	NANoREG - eNanoMapper database
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Database/structural model and report describing the relationships between functionality, physicochemical properties and hazard, and allowing for integration in the safe innovation approach Report on the defined ISA-TAB nano templates
PROSAFE Promoting the Implementation of Safe by Design	Landscape of databases useful to EHS assessment of nanomaterials - Gaps and overlaps review ISA-TAB-NANO database system established and adopted within the Nanosafety Cluster Minimal ontology and naming convention for nanosafety data Report on available database linking tools
SbD4Nano Computing infrastructure for the definition, performance testing and implementation of SbD approaches in nanotechnology supply chains	Database on e-Mapper (In progress, project started in April 2020 and will end March 2024)
SUN Sustainable Nanotechnologies	SUN Project Database

6.3.8 *Networking platform*

Links to several platforms which connect people. These networking platforms can either be operational or ongoing.

Table 18 Results of projects with a networking platform to connect stakeholders.

Project Name and Link to EU Factsheet	Documents Output
BioNanoMet	BioNanoNet is an Austrian network in the Key Enabling Technologies (KETs) of bio- and nanotechnology with international visibility in three scientific areas.
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies	Initial and Final Report on the EC4SafeNano networks Initial and final Proposition for a structure and its governance Report on mechanisms to overcome barriers to collect and make available the data Mechanisms to keep the service provision up-to-date Initial and final Description of current needs of Member States, European Commission & EU Agencies, private stakeholders and NGOs Initial and final Commented inventory of the competences, equipment and services Economic legal entity mapping and Legal structure possibilities identification Ranked list of questions from the three targeted stakeholder groups A survey on the state of nanosafety research in the European Union and the United States
ENF2015 EuroNanoForum 2015 ENF2017 EuroNanoForum 2017 EFN2019 EuroNanoForum 2019	Conference website 2017 Conference website 2019

Project Name and Link to EU Factsheet	Documents Output
GoNano Governing Nanotechnologies through societal engagement	Adapted co-creation platform made public D4.3- Evaluation report on the outcomes of the Mobilisation and Mutual Learning platform* External evaluation report I
NanoFabNet International Hub for sustainable industrial-scale Nanofabrication	NanoFabNet hub Still under construction (project started March 2020 and ends February 2022)
NanoSafetyCluster Strategic Directions Enhancing Synergies (not an H2020 project)	Platform
SweNanoSafe (not an H2020 project) The national platform for nanosafety (this project is in Swedish; Google Translate was used)	About the Project Workshops on the project and Reports of activities of the Platform

6.3.9 *Platform for tools*

Links to several platforms with tools or e-platforms either operational ongoing.

Table 19 Results of projects that have created a platform for tools.

Project Name and Link to EU Factsheet	Documents Output
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	NanoSafety Governance Portal (NSGP) (ongoing; project started January 2019 and ends December 2022)
GRACIOUS Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products	Platform (ongoing; project ends June 2021)
NanoCommons The European Nanotechnology Community Informatics Platform:	Knowledge Portal (only for account members)

Project Name and Link to EU Factsheet	Documents Output
Bridging data and disciplinary gaps for industry and regulators	
NanoInformaTIX Development and Implementation of a Sustainable Modelling Platform for NanoInformatics.	Platform (ongoing; project started January 2019 and ends February 2023)
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	SbD Implementation Platform
NanoSolveIT Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT)	NanoSolveIT e-platform (ongoing; project started January 2019 ends February 2023)
OpenRiskNet Open e-Infrastructure to Support Data Sharing, Knowledge Integration and in silico Analysis and Modelling in Risk Assessment	Initial API version provided to providers of services Report on deployment of virtual infrastructures with service discovery and container orchestration Fully functional support infrastructure Reference OpenRiskNet system available online Final API available for internal and external service providers Development infrastructure online Dissemination & Training Activities (Final Report) First report on the management process Report on Service Integration with OpenRiskNet (Final Report) Report on requirement analysis and recommendations for WP2-4 including Data Management Plan Final report on the management process Report on Service Integration with OpenRiskNet (Intermediate Report)

Project Name and Link to EU Factsheet	Documents Output
	Data management, maintenance and sustainability plan Report on Service Integration with OpenRiskNet (Initial Deployment) First documentation of the core e-infrastructure Report on Re-Identification Risks and Private by Design Risk Management Report on the results of the Implementation Challenge Dissemination & Training Activities (Intermediate Report) Case studies on how to use the platform Final definition of case studies e-Infrastructure Platform Multiple available services such as real-world applications like systems biology approaches for grouping compounds and read-across applications using chemical and biological similarity.
SbD4Nano Computing infrastructure for the definition, performance testing and implementation of SbD approaches in nanotechnology supply chains	E-infrastructure (ongoing; project started in April 2020 and will end March 2024)

6.3.10 *Foresights*

Links to outlooks, emerging topics such as risks, and solutions to possible barriers from the projects.

Table 20 Results of projects that have created outlook and foresight

Project Name and Link to EU Factsheet	**Documents Output**
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Document on outlook after TRL 5-6 and how it can be dealt with in the Safe Innovation Approach Final Report addressing the barriers to the application of grouping and Safety-by-Design Concepts. Overview of barriers and possible solutions for implementation of the Safe Innovations Approach
PROSAFE Promoting the Implementation of Safe by Design	Foresight Exercise WP2: Exploiting Synergies (Deliverables)

6.3.11 *Datasets*

Links to all datasets such as nanomaterial safety data sheets or specific physico-chemical data obtained in each project.

Table 21 Results of projects with datasets on nanosafety or physico-chemical data

Project Name and Link to EU Factsheet	**Documents Output**
MARINA Managing Risks of Nanoparticles	Data sets from the Cordis website
NanoFASE Nanomaterial FAte and Speciation in the Environment	DPMFA_EU_ENM_2000-2020: Dynamic Probabilistic Material Flows of Engineered Nanomaterials from 2000 to 2020 - Raw results
NANOSOLUTIONS Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM): Systems Biology Approaches to Understand Interactions of ENM with Living Organisms and the Environment	MVDA: a multi-view genomic data integration methodology

Project Name and Link to EU Factsheet	**Documents Output**
NanoSteeM NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing	A list of nanomaterials currently used in the semiconductor sector to be considered within NANOSTREEM Comparison of occupational exposure values For nanomaterials listed in D1.1, a list of associated tasks, activities and operations where exposure might occur. A set of typical relevant exposure scenarios for nanoparticles in semiconductor industry (dataset) A list of nanomaterials of strategic importance for the semiconductor sector in the future Nanostreem Task 1 3 exposure scenarios v2.3 – public NanoStreeM D1 5 update Future NM table 181213 WP3 Task31 Inventory safety evaluation methods v21
NANOVALID Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials	Data sets from the Cordis website
PATROLS Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment	Critical toxicity data for IVIVE based on existing *in vivo* sub-acute and (sub)chronic oral and inhalation studies Materials acquisition, physicochemical intrinsic properties and endotoxin evaluation on Tier 1 and 2 ENM An inflamed human alveolar model for testing the efficiency of anti-inflammatory drugs *in vitro*

6.4 Pillar 4 – Strategic positioning

The Strategic Positioning pillar for SbD applies to the national and international positioning of SbD as a concept, its goals and methodology, and its positioning on the agenda. This includes practical examples and to connecting it to other (policy) developments in such a way that this contributes to the long-term goal of a clean and safe living environment. It is important to note that some of the projects have relevant results in multiple pillars.

Table 1, the 'overview of projects' shows the general information on each project in alphabetical order. It shows the abbreviation and full name of the project (with link to the (CORDIS) website), the pillar(s) in which this project obtained results, the discipline in which the project was active, the outcome in short, the SbD aspect in one or two sentences, and a short description. The following tables show the projects and links to the results of the projects sub-divided in different topics. Results in the strategic positioning pillar are sub-divided into international support, stakeholder support, creating awareness, and projects that have put SbD on the strategic agenda.

6.4.1 *Overview of projects*

Table 22 Overview of projects with results in the strategic positioning pillar

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
GoNano Governing Nanotechnologies through societal engagement	Education, Strategic Positioning, Industry	Multidisciplinary, Nano	Workshops, Guidelines (white paper), Platform, knowledge database, concept development and stakeholder support	Develop a pilot project in each of the nanotechnology areas (Health, Energy, and Food) which should engage citizens with researchers, professional users, societal organisations, industry, and policy makers to co-create concrete suggestions for future nanotechnologies on several aspects such as safety.	Nanotechnologies – the purposeful engineering of matter on the atomic or molecular scale – have given rise to great expectations in recent years, unlocking new research opportunities in areas as diverse as energy, healthcare, electronics, food, and construction. At the same time, concerns have been raised about possible unintended consequences of the use of nanomaterials. The EU-funded GoNano project enables co-creation between citizens, researchers, industry, societal organisations, and policy makers across Europe to align future nanotechnologies with societal needs and concerns.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Scientific publications, Training school, Nano risk governance model, nano risk governance council	Develop a nano risk governance council (NRGC) that will support SbD practices. It will explore upcoming tools and approaches such as Findable, Accessible, Interoperable and Re-usable (FAIR) databases and blockchain technology.	The Gov4Nano project will develop the first implementation of a future-proof operational Nano Risk Governance Model (NRGM) that addresses the needs of the transdisciplinary field and innovative (and key enabling) character of nanotechnology. The Gov4Nano project will design and establish a Nanotechnology Risk Governance Council (NRGC), to create a trustworthy and objective international umbrella for the risk governance of nanotechnologies.
HISENTS High level Integrated SEnsor for NanoToxicity Screening The follow up of HISENTS is SABYDOMA	Research, Industry, Strategic Positioning	Multidisciplinary / Nano (and Nano-medicine)	Framework, New test methods, Scientific Publications	Create a platform capable of nanosafety assessment using high-throughput screening and SbD concept development.	HISENTS aims to deliver an advanced nanosafety platform capable of providing high-throughput toxicity screening for the risk assessment of novel nanomaterials. The platform will be made up of an integrated set of miniaturised modules each representing critical human physiological functions from molecular interactions through to cell, organ and organism effects.
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	Education, Research, Industry, Strategic Positioning	Bionanomaterials / Medicine	SbD training, guidelines, bringing networks together, Scientific Publications	Bring together research groups to create novel bioactive nanomaterials for medical application.	The aim of the project is to design, develop, produce and characterise novel nanostructured bioactive materials for biomedical applications. The idea is to bring together research groups specialised in material science and experts in bio-active materials and review the nanomaterials' application in medicine.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NanoHarmony Towards harmonised test methods for nanomaterials	Industry, Strategic positioning	Multidisciplinary, Nano	No results yet (Started in April 2020 and end in March 2023) Expected: eight test guidelines (OECD)	Develop test guidelines and guidance documents for eight endpoints where nanomaterial-adapted test methods have been identified as a regulatory priority, which will support SbD applicability.	NanoHarmony will focus on OECD TGs and GDs for eight nanomaterial test endpoints prioritised with the help of ECHA, NMEG, Industry and the Malta Initiative, and the OECD WPMN priority recommendations. NanoHarmony will coordinate the collection and use of available data and information to support the finalisation of test method development. It will also develop a sustainable international network of experts for data analysis and recommendations for test method maturation, plus future regulatory pathways. NanoHarmony will also analyse processes in test method developments to set up a framework structure for seamless and smooth cooperation between all stakeholders for the timely development of test methods ready for regulation.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANoREG A common European approach to the regulatory testing of nanomaterials	Education, Research, Industry, Strategic Positioning	Multidisciplinary / Nano	Workshop, Scientific Publications, Toolbox, Guidelines, Case Studies, Framework, e-Nanomapper, Policy and legislation/ regulation relevance	A risk assessment framework suitable for SbD applicability.	The innovative and economic potential of Manufactured Nano Materials (MNMs) is threatened by a limited understanding of the related environment, health, and safety (EHS) issues. While toxicity data are increasingly available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM is driving the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods.
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Education, Research, Industry, Strategic Positioning	Multidisciplinary / Nano	Workshops, Scientific Publications, Tools, Guidelines, Case Studies, Framework, Databases, Foresights, Stakeholder Support, International Support, Creating Awareness	Development of the Safe Innovation Approach (SbD, regulatory preparedness, trusted environments)	The NanoReg2 project, built around the challenge of coupling SbD to the regulatory process, will demonstrate and establish new principles and ideas based on data from value chain implementation studies to establish SbD as a fundamental pillar in the validation of novel manufactured nanomaterials (MNM). Grouping concepts developed by NanoReg2 can be regarded as a major innovation, as guidance documents on NM grouping will not only support industries or regulatory agencies but will also strongly support the commercial launch of a new NM.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Education, Research, Industry, Strategic Positioning	Multidisciplinary / Nano	Training, Scientific Publications, Nano risk governance framework, Nano risk governance council	Develop a nano risk governance council (NRGC). The ultimate aim of NANORIGO is to deliver a Risk Governance Framework for the safety of nanomaterials, for risk assessment, hazard and exposure, human health and environment, and risk mitigation including regulatory aspects of SbD.	NANOtechnology RIsk GOvernance aims to develop and implement a transparent, transdisciplinary Nanotechnology Risk Governance Framework and a related Risk Governance Council to guide all stakeholders in the sustainable development of nanotechnologies in Europe. NANORIGO will collaborate on this with RiskGone and Gov4Nano (also funded under the NMBP13-2018 Call).

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
PROSAFE Promoting the Implementation of Safe by Design	Industry, Strategic Positioning	Multidisciplinary, Nano	White paper, International support, guidelines, Foresight Exercise, OECD workshop	Recommendations for policymakers and regulators aimed at a more effective and cost-efficient assessment of nanomaterials in a regulatory context and for application for SbD.	In ProSafe, twelve organisations from nine EU member and associated states collaborated to evaluate the results of a wide range of EU projects on Environment, Health and Safety research in the field of nanotechnology. The main outcome of the ProSafe project was the white paper, which integrates and analyses the results of the EU funded projects NANoREG, ProSafe and numerous other nanosafety projects, and translates the findings into 15 recommendations for policy makers and regulators. Deliverables were developed under the umbrella of the ProSafe project and include the report on the OECD-ProSafe Joint Scientific Conference in Paris 2016, the Joint Document and the White Paper.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
REFINE Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	Research, Industry, Strategic Positioning	Bionanomaterials	Regulatory science framework, guidelines (white paper), Knowledge exchange conferences, thesis dissertation	Regulatory Science Framework for Nano(bio)material-based community which facilitates SbD.	REFINE will gather a wide community of stakeholders in regulation, industry, science, technology development, patients, and end-users, into a Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicine. Aims: to set up/ build a Regulatory Science framework to close the gap on the existing development of nanomedicine products. We will set a sustained forum that enables regulators, scientist, and developers to liase and develop: -a clear overview of current and anticipated regulatory concerns, including harmonisation, -a gap analysis where regulatory concerns and scientific evidence do not match up. - a heuristic to transfer new scientific evidence into regulatory strategies, and to translate regulatory concerns into hot spots in the standard testing cascades.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
RISKGONE Risk Governance of Nanotechnology	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Webinars, Scientific publications, OECD guidelines, Nano risk governance council.	Develop a nano risk governance council (NRGC) that will help SbD practices. Develop tools to identify the environmental and human health impacts of nanomaterials for SbD applicability.	RISKGONE (Science-based Risk Governance of Nano-Technology) is an EU H2020 project aiming at providing solid procedures for consistent risk governance of engineered nanomaterials.The project will develop new tools or modify existing ones to identify the environmental and human health impacts of a number of nanomaterials with greater certainty. These tools and the results of tests using them will then be integrated into the work of a European Risk Governance Council (ERGC), a group of individuals with different areas of expertise on nanomaterials tasked to provide governance decisions on the safety of the specific materials. A risk governance framework consisting of the tools and the ERGC will be developed to address nanomaterial safety governance in a coherent and scientifically robust way.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
SeeingNano Developing and Enabling Nanotechnology Awareness-Building through the Creation and Exchange of enhanced Communication and Visualisation Tools and Guidance for 'Seeing at the Nanoscale'	Strategic Positioning	Multidisciplinary, Nano	Mobile app (however, it is no longer available in the google play store or the apple store)	Create awareness of nanomaterials in citizens by developing a mobile app which allows using augmented reality to visualise nanomaterials in real life.	The SeeingNano Project will create a Novel Visualisation Tools for Enhanced Nanotechnology Awareness to provide the public with an ability to 'see at the nanoscale', providing understanding and awareness of the breadth of nanotechnologies and the uncertainties and potential risks connected to them. Once fully developed, the SeeingNano Visualisation Tools will be made available to the wider community on an online platform where the tools and guidance documents will be available for download.
SUN Sustainable Nanotechnologies	Education, Research, Industry, Strategic Positioning	Multidisciplinary, Nano	Workshops, Scientific Publications, Case studies on SbD and Safety, Framework and Guidelines, International Support, Tools	An integrated approach addressing the complete product lifecycle to assess health and environmental risks for SbD applicability within nanotechnology.	The Sustainable Nanotechnologies (SUN) project is based on the idea that current knowledge on environmental and health risks of nanomaterials – while limited – can nevertheless guide nanomanufacturing to avoid liabilities if an integrated approach addressing the complete product lifecycle is applied.

Project Name and Link to EU Factsheet	Pillar(s)	Discipline	Outcome	SbD Aspect	Short Description
The European Commission, DG Environment (not a H2020 project)	Strategic Positioning	Policy view	International support	Report on the current state of the art research on nanosafety and the link to policy.	The aim of this In-Depth Report is to present the most promising strategies and most significant challenges of nanomaterial characterisation, exposure, fate and behaviour, and ecotoxicological hazard and risk assessment. It presents examples and case studies of both scientific developments and knowledge gaps.

6.4.2 *International support*

Links to policy, legislation, regulation, and liaison impact on international (mostly EU) level.

Table 23 Results of projects with links to international support

Project Name and Link to EU Factsheet	**Documents Output**
Gov4Nano Implementation of Risk Governance: meeting the needs of nanotechnology	European Nano risk governance council operational Nano Risk Governance Model (NRGM) (ongoing, project started January 2019 and ends December 2022)
NANoREG A common European approach to the regulatory testing of nanomaterials	Policy and legislation/regulation (White paper ProSafe)
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Impact of the NANoREG II liaisons
NANORIGO Establishing a Nanotechnology Risk Governance Framework	Nano risk governance Framework and Nano risk governance Council (ongoing; project started January 2019 and ends February 2023)
PROSAFE Promoting the Implementation of Safe by Design	White Paper
REFINE Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices	Knowledge Exchange Conferences
RISKGONE Risk Governance of Nanotechnology	Nano risk governance council and OECD guidelines (ongoing; project started January 2019 and ends February 2023)
SUN Sustainable Nanotechnologies	Society for Risk Analysis Roundtable with the EU NanoSafety Cluster
The European Commission, DG Environment (not a H2020 project)	Report from EU on different projects up to 2017 Assessing the environmental safety of manufactured nanomaterials

6.4.3 *Stakeholder support*

Links to networks, platforms, knowledge databases and reports bringing stakeholders together to support common interests and induce communication between them.

Table 24 Results of projects with links to stakeholder support

Project Name and Link to EU Factsheet	**Documents Output**
GoNano Governing Nanotechnologies through societal engagement	Report on the role of values and culture in societal debates, and design requirement arising from differing culture and communication traditions as well as from gender concerns D1.3- Nanotech in food, energy and health: what areas and issues for a dialogue? D3.2- Briefing report on citizen needs and values in relation to nanotechnology in food, energy and health D1.1- Building on the State-of-the-art: ex-post evaluation on mutual learning D1.2- Understanding the role of culture, gender and communication traditions, and their implications for GoNano engagement methodologies Working paper with summary of the interview findings, definitions, and description of product examples for the pilot studies First briefing report on the nanotechnology R&I policy context as input to method developments and background material for the pilot studies R&I background production for pilot studies, including standard materials in English, and all the translated materials from the hosts of the pilot studies D3.3- Briefing report on the outcomes of the online consultation Methods and manual for the pilot studies D2.1- Towards a GoNano co-creation approach Communication and branding plan Report on lessons learned from previous MML projects on multi-stakeholder co-creation and public engagement D5.1- Risk governance and research & innovation priorities in Nanotechnologies

Project Name and Link to EU Factsheet	Documents Output
NanoBioMat Nanostructured Biocompatible/Bioactive Materials	Links to other international networks SIINN ERA-NET (under construction) The SIINN ERA-NET promotes the safe and rapid transfer of European research results in nanoscience and nanotechnology (N&N) into industrial applications. European initiative for sustainable development by Nanotechnologies (nanofutures) Nanotechnology is the basis for the next industrial revolution. We have several samples of successful business cases e.g., the chemical industry. OSHwiki OSHwiki has been developed by EU-OSHA to enable the sharing of occupational safety and health (O.SH) knowledge, information, and best practices. This in order to support government, industry and employee organisations in ensuring safety and health at the workplace.
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	Report on PPPs (Report on public private partnerships)

6.4.4 *Creating awareness*

Links to movies and apps to create awareness on SbD and nanosafety.

Table 25 Results of projects that create awareness

Project Name and Link to EU Factsheet	Documents Output
GoNano Governing Nanotechnologies through societal engagement	The GoNano YouTube channel Website for citizens
NanoReg2 Development and implementation of Grouping and SbD approaches within regulatory frameworks	NanoReg2: Safe Innovation Approach (A YouTube video)
SeeingNano	Documents that led to the creation of the mobile app

Developing and Enabling Nanotechnology Awareness-Building through the Creation and Exchange of enhanced Communication and Visualisation Tools and Guidance for 'Seeing at the Nanoscale'	Video explaining 'seeing nano'

6.4.5 *Projects that have put SbD on a national or EU strategic agenda*

A small number of projects have specifically worked towards putting SbD on the political agenda. These are NANoREG, NanoReg2, and PROSAFE. These projects actively collaborated by participating in several meetings such as the NanoSafety Cluster (NSC), OECD, ECHA, Nanomaterials Working Group (NMWG) and CASG Nano. Moreover, important connections were continued with potential partners on a global scale.

7 Appendix

7.1 AceNANO

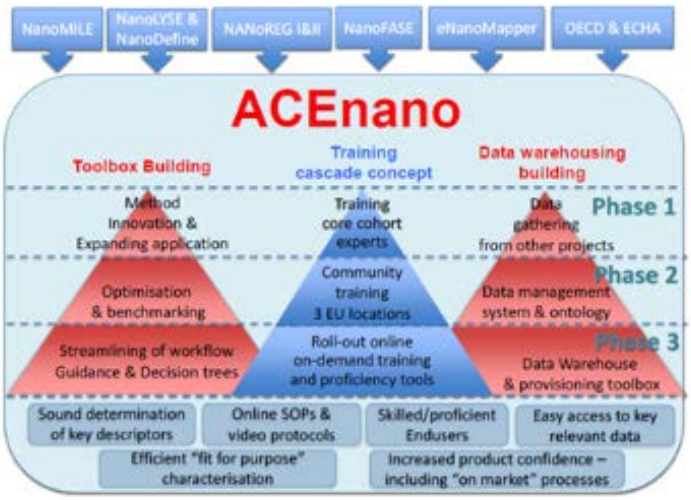
Analytical and Characterisation Excellence in nanomaterial risk assessment: A tiered approach

Description
ACEnano will introduce confidence, adaptability and clarity into nanomaterial risk assessment by developing a widely implementable and robust tiered approach to **nanomaterials physicochemical characterisation** that will simplify and facilitate contextual (hazard or exposure) description and its transcription into a reliable nanomaterials grouping framework.

This will be achieved by the creation of a "conceptual toolbox" including a tiered approach to cost efficient nanomaterials analysis that will facilitate decision-making in choice of techniques and SOPs, linked to a characterisation ontology framework for grouping and risk assessment.

ACEnano will initiate activities to support data collection, management, interpretation and delivery to a data warehouse for safe use & storage. It will thus underpin the future of nanomaterial quality control, labelling and anti-counterfeiting.

Strategy



Discipline
Multidisciplinary/Nano

Pillar(s)
Education, Research, Industry

SbD aspects
Nano decision tool for facilitating decision-making in choice of techniques and SOPs

http://www.acenano-project.eu/about-acenano/nano-size

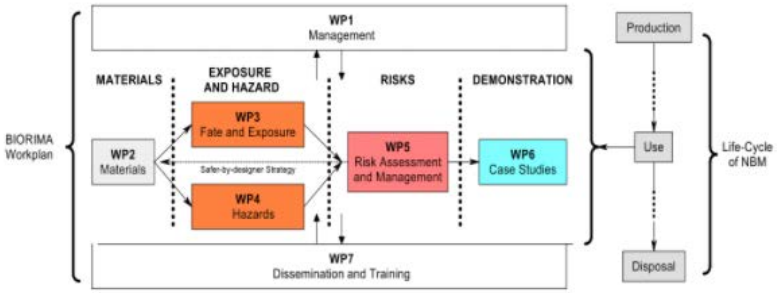
Expected Impacts and Outcomes
- Enable the identification of key descriptors that can be used to reveal correlations associated with health & environmental impacts and meaningful basis for grouping, read-across and QSARs purposes
- Increased confidence in nanosafety studies and findings through sound physico-chemical characterisation methods and standard operating procedures
- Reduced costs related to the physico-chemical characterisation of nanomaterials in relevant environments
- On top of safety related objectives, proposals should seek synergies with applications of the methods in other areas such as quality control, product traceability, labelling and counterfeiting

7.2 BIORIMA

Biomaterial Risk Management.

Description
BIORIMA aims to develop an Integrated Risk Management (IRM) framework for NBM used in ATMP and MD. The BIORIMA IRM framework is a structure upon which the validated tools and methods for materials, exposure, hazard and risk identification/assessment and management are allocated plus a rationale for selecting and using them to manage and reduce the risk for specific NBM used in ATMP and MD.

Strategy



Discipline
Medicine, bionanomaterials

Pillar(s)
Education, Research, Industry

SbD aspects
Framework for allocating validated tools and methods for materials, exposure, hazard and risk identification/assessment and manage and reduce the risk for specific nanobiomaterials.

https://www.biorima.eu/project/index.php

Expected Impacts and Outcomes
A key work during this first period was promoting the NBM selection, production and distribution. This allowed the partner to have the target NBM and to start the experimental activity. The widespread characterisation action supported provided new and extensive physicochemical descriptors to be used in WP 3-5 to promote the correlation and get information on real in vitro dose and fate, in complex biological system. Strong participation of the companies to production and distribution of NBM offered a key tool to the project, in terms of availability of NBM at high TRL with a clear regulation pathway and of robust information ready to be exploited. Work on hazard assessment is comprehensive and deals both with human health and environmental impacts. We have addressed both acute and chronic or long-term effects and this is something that we will continue to work on in WP4 in order to develop robust test methods for both acute and chronic effects. Some of the work is already being utilised towards the development of new test standards and this is something will continue to emphasise as we move forward; it is not sufficient to generate data sets across multiple different model systems, but we also need to ensure contributing to the development or validation of robust test methods for nanobiomaterials that are manufactured for medical products or devices. The BIORIMA IRM framework validation strategy reflects the commitment to bring the achieved results to the NBMs value chain, from production and use, to end-of-life treatments in both industrial facilities and hospitals. Our dissemination strategy reflects the commitment to bring the achieved results to the global community in general and to interested stakeholder groups. Public Training Schools open to everyone support this strategy

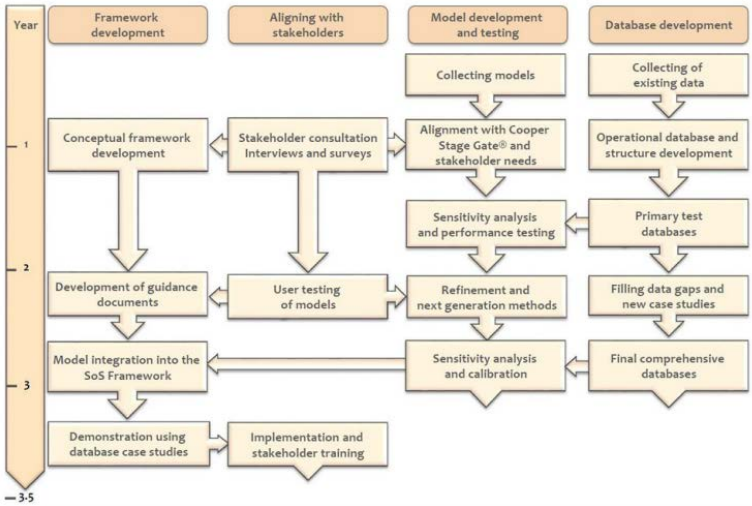
7.3 caLIBRAte

Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials

Description
Currently, none of the existing REACH compliance models are suited or validated for risk assessment of manufactured nanomaterials, and many existing exposure limits are not suitable for nanomaterials.

caLIBRAte will address this by developing a 'system of systems', based on a suite of tested and calibrated manufactured nano-specific risk prioritisation and control banding tools. Our work will leverage more than a decade of nanosafety research and resources to develop models for next generation nano-risk governance framework.

Strategy



http://www.nanocalibrate.eu/sites/default/files/caLIBRAte%20flyer.pdf

Discipline
Multidisciplinary/Nano

Pillar(s)
Education, Research, Industry

SbD aspects
Developing a nanotool and framework based on a suite of tested and calibrated manufactured nano-specific risk prioritisation.

http://www.nanocalibrate.eu/home

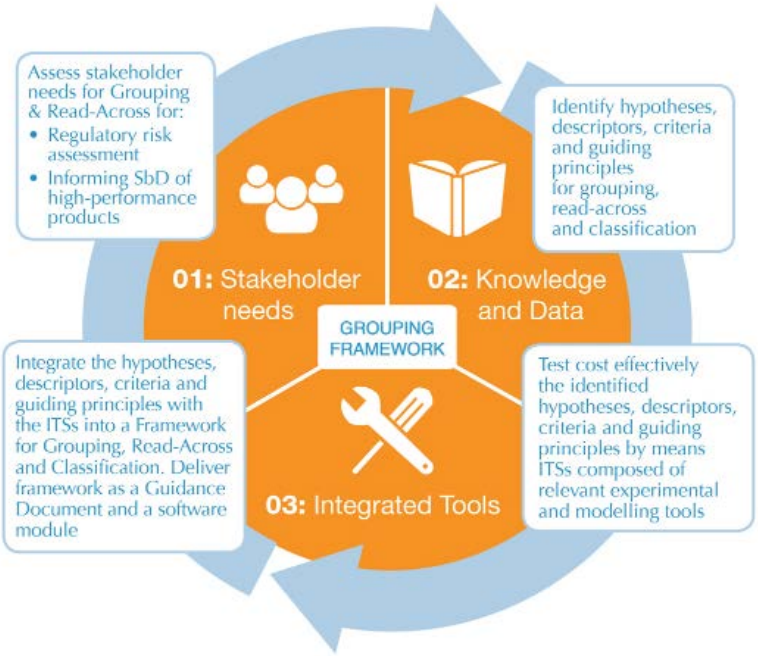
Expected Impacts and Outcomes
The caLIBRAte Nano-risk Governance Framework and Portal help its users to find nanosafety information and guidance for identifying NMs, assessing and managing risks, workplace monitoring, and decision making. The portal also includes case studies, hazard and exposure measurement data, and best practices in NM development.

7.4 GRACIOUS

Grouping, Read-Across, CharacterIsation and classificatiOn framework for regUlatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products

Description
The GRACIOUS project will develop a highly innovative science-based framework that supports the assessment of risk posed by the ever increasing array of nanomaterials on the market and under development. The framework will streamline the process for assessing their risk by logically grouping nanomaterials thereby allowing extrapolation between (read-across) nanomaterials and reducing the need to assess exposure to and toxicity on a case by case basis.

Strategy



Discipline
Multidisciplinary/Nano

Pillar(s)
Education, Research, Industry

SbD aspects
Development of a framework with a guidance, database on e-nanomapper and tools for logically grouping nanomaterials.

https://www.h2020gracious.eu/

Expected Impacts and Outcomes
Application of the Framework will allow movement away from the case-by-case risk assessment paradigm, thereby improving the efficiency of risk analysis and decision making for safer design of quality nano-enabled products.

The Framework and its Intelligent Testing Strategies (ITSs) will be delivered as:
- E-tool fit-for-purpose for various key stakeholders (regulatory and industrial)
- Guidance Document

Both the E-tool and the Guidance document will be designed for practical application to:
- Help industries and regulators assess environmental and human health risks of existing NMs/NFs cost-effectively
- Facilitate business decisions concerned with developing new nano-enabled products (NEPs)

- To inform Safety-by-Design (SbD) practices

7.5 HISENTS

High level Integrated SEnsor for NanoToxicity Screening

Description
HISENTS aims to deliver an advanced nanosafety platform capable of providing high-throughput toxicity screening for the risk assessment of novel nanomaterials.

The platform will be made up of an integrated set of miniaturised modules each representing critical human physiological functions from molecular interactions, through to cell, organ and organism effects.

To achieve this, the project will take a multidisciplinary approach drawing on experts from industry and research in the fields of nanotechnology, chemistry, cell biology, toxicology, engineering, electronics, computer modelling and material science.

Strategy
WP1: Nanomaterial synthesis and characterisation (Victor Puntes, ICN2)
WP2: High throughput screening smart instrumentation and integration (Vladimir Ogurtsov, Tyndall UCC)
WP3: High content analysis toxicogenomics (Eckart Meese, Universität des Saarlandes)
WP4: in vitro sensing modules (Peter Ertl, TU Wien)
WP5: Modelling mechanisms, pathways and effects (Peter Šimon, STUBA)
WP6: Calibration, standardisation, performance and validation (Andrew Nelson, University of Leeds)
WP7: Dissemination and exploitation (Mick Karol, Blueprint Product Design)
WP8: Project management and coordination (Andrew Nelson, University of Leeds)
WP9: Ethic requirements (Andrew Nelson, University of Leeds)

Discipline
Multidisciplinary/Nano and Nanomedicine

Pillar(s)
Research, Industry

SbD aspects
Creating a platform capable of nanosafety assessment using high-throughput screening and SbD concept development.

https://hisents.eu/

Expected Impacts and Outcomes
- The project will generate a new screening tool to speed up the profiling of nanomaterial hazards
- It will allow faster characterisation of the mechanisms by which nanomaterials can cause toxicity

- Allow 'safer by design' approaches whereby the data generated by the project on nanomaterial safety can be used to design future nanomaterials that avoid any toxicity issues
- Generate data on nanomaterial safety that can be used beyond the lifetime of the project
- It will contribute to the wider conversation of nanosafety and nanoregulation in Europe. As part of this, the project will be an active member of the Nano Safety Cluster

7.6 NanoBioMat

Nanostructured Biocompatible/Bioactive Materials

Description
The aim of the Project is to design, develop, fabricate and characterise novel nanostructured bioactive materials (NSBM) for biomedical applications. The Project concept is to bring together research groups specialised in material science and experts in bio-active materials and their application in medicine. Project concept is based on combination of fundamental researches (studying interfacial phenomena and the structure-property relationships) and applied problems in the development of new bionanomaterials.

Strategy

Discipline
Bionanomaterials, medicine

Pillar(s)
Education, Research, Industry, Strategic Positioning

SbD aspects
Bringing together research groups to create novel bioactive nanomaterials for medical application.

https://gonanobiomat.eu/

Expected Impacts and Outcomes
The objectives of the project were based on the principle of interdisciplinary research. The main research objectives of the 4-year joint programme are: to elaborate novel drug-delivery systems based on nanoporous or nanoparticulate oxides, synthetic polymers and biopolymers; to synthesise and characterise NSBM with immobilised metal and metal oxide nanoparticles with bactericidal properties; to expand the modification of NSBM to improve their biocompatibility, to develop porous polymeric monoliths and disperse materials for pollutant and biotoxins removal from liquid media under static and dynamic regimes; to develop new NSBM based on semi-interpenetrating polymer networks (IPN) filled with metal, oxide and carbon nanoparticles for medical applications and optimise their physicochemical and mechanical properties; to elucidate the mechanisms of adsorption of bioactive compounds from aqueous solutions and biological media on NSBM; to study the structure-property relationships and a role of interfacial phenomena in performance of NSBM.

7.7 NanoCommons

The European Nanotechnology Community Informatics Platform: Bridging data and disciplinary gaps for industry and regulators

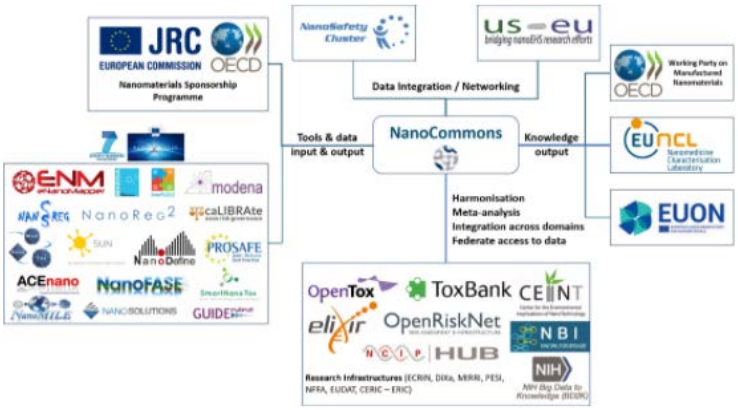
Description
Read-across approaches, which are currently absent for NMs, in large part as a result of data fragmentation and inaccessibility, would reduce the cost of nanosafety research and regulation dramatically by removing the need for extensive laboratory and animal testing.

The availability of a nanosafety knowledge infrastructure, that organises and visualises data and data relationships, makes it accessible, integrates computational tools for risk assessment and decision support, enables their validation and facilitates the necessary grouping will be a critical factor in reducing regulatory costs.

The H2020 Infrastructures project, NanoCommons, addresses this gap by creating a community framework and infrastructure for reproducible science, and in particular for in silico workflows for nanomaterials safety assessment and beyond, by:

1. integration and federation of existing NMs characterisation and interaction mechanisms knowledge, protocols and data (beyond simple toxicity), along with quality assurance criteria and underpinning ontologies
2. compilation and development of a user-friendly interface for a suite of computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and bench-marking of their predictive power; and
3. provision of (typically remote) access to its KnowledgeBase, modelling toolbox (predictive, grouping, risk assessment) and workflow optimisation, and the supporting expertise, to the broader user community.

Strategy



Discipline
Multidisciplinary/ Nano

Pillar(s)
Research, Industry

SbD aspects
Creating a platform with computational tools for mechanistic and statistical modelling, read-across, grouping, SbD and life cycle assessment, and bench-marking of their predictive power, user friendly for all stakeholders (regulators and industry).

https://www.nanocommons.eu/

Expected Impacts and Outcomes
NanoCommons has the unique potential to deliver a step-changing impact for the emerging nanoinformatics in nanosafety community. It will remove barriers from nanosafety-related regulatory & industry processes by revolutionising data capture, management & sharing. NanoCommons will achieve this through:

1. Its integration of disparate datasets, tools and modelling approaches from across the 60+ projects related to nanosafety-funded across FP6, FP7 and H2020 (NA),
2. Its development of an integrated KnowledgeBase to facilitate development and application of regulatory tools such as QSARs, grouping and read-across (JRA); and
3. Its efforts to support Users (all stakeholders: academia, industry, regulators etc.) in their utilisation of the appropriate tools and supporting expertise to address their data and research needs (TA).

7.8 NanoFASE

Nanomaterial FAte and Speciation in the Environment

Description
Progress is needed in the prediction of environmental distribution, concentration and form (speciation) of nanomaterials, to allow early assessment of potential environmental and human exposure and risks,

to facilitate safe product design and to include these aspects in nano regulation.

The overarching objective of NanoFASE is to deliver an integrated Exposure Assessment Framework (protocols, models, parameter values, guidance ...) that:

- Allows all stakeholders to assess the environmental fate of nano releases from industrial nano-enabled products,
- Is acceptable in regulatory registrations and can be integrated into the EUSES model for REACH assessment,
- Allows industry a cost-effective product-to-market process, and
- Delivers the understanding at all levels to support dialogue with public and consumers.

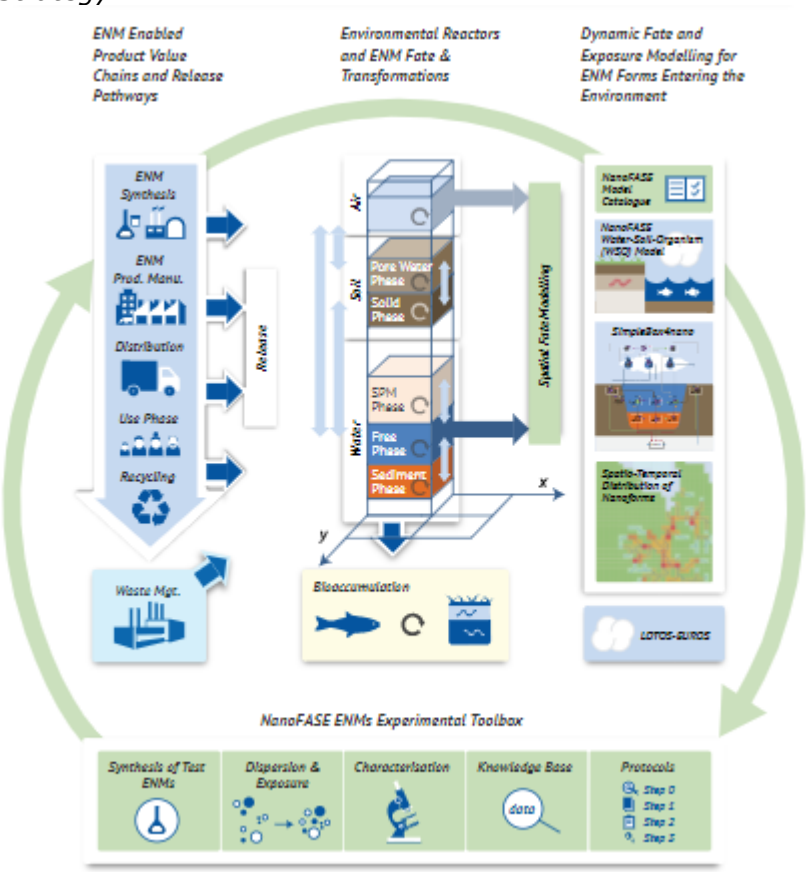
The ambition is to reach a level of ENM Fate and exposure assessment at least comparable with that for conventional chemicals.

For that, NanoFASE will develop a set of novel concepts and approaches to underpin the Framework, developed as common themes linking the research, exploitation and dissemination throughout the project.

Our vision is to move from the current mainly mass-based lifecycle and release flow approaches towards systems that can account for spatial and temporal variability of ENM release, environmental transport and fate. The framework, supported by standard operating procedures (SOPs), parameter values, models and guidance, will incorporate:

1. the behaviour of the actual relevant ENM forms released from ENM products (a distribution of composite bound and free particles);
2. how reactions in waste management and environmental compartments (or "reactors") transform such release-relevant ENMs (integrating environmental speciation with ENM properties); and
3. the consequences of these transformations for transport and fate and among the different environmental compartments including organism uptake and local accumulation of ENMs in some environmental compartments ("environmental sinks" and hot spots).

Strategy



Discipline
Multidisciplinary/Nano

Pillar(s)
Education, Research, Industry

SbD aspects
Developing a set of concepts and approaches to underpin the Exposure Assessment Framework.

http://www.nanofase.eu/

Expected Impacts and Outcomes
NanoFASE aims to specifically address the need for regulatory development for nanotechnology by reducing uncertainties in the "fate" related aspects of risk assessment as a key link in the delivery of objectives for nanosafety. The project will support the development of innovative solutions to support better standardisation of risk assessment approaches, thereby helping to bring sustainable innovative nanotechnology products and services into the market. Combined with research initiatives on the other component of "hazard" assessment for health and the environment (e.g. OECD Sponsorship Program), risk assessment (e.g. NANoREG), and SbD (e.g. NanoReg2), NanoFASE will bring a significant improvement in exposure assessment and reduction

of risks related to ENMs over their life cycle (production, transport, use and disposal). NanoFASE specifically addresses the following impacts:

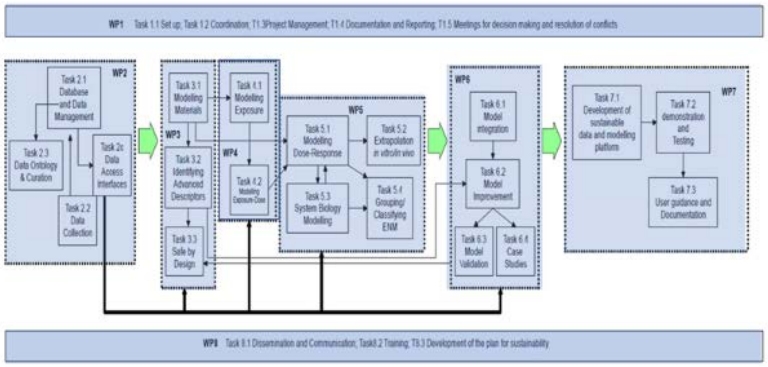
1. improve innovation capacity and integrate new knowledge to provide significant economic and commercial impact;
2. inform policy by enhanced EMN risk assessment in REACH and other regulatory regimes;
3. input to future cultural and societal impacts for nanotechnology/nanosafety.

7.9 NanoInformaTIX

Development and Implementation of a Sustainable Modelling Platform for NanoInformatics.

Description
NanoInformaTIX develops a web-based Sustainable Nanoinformatics Framework (SNF) platform for risk management of engineered nanomaterials (ENM) in industrial manufacturing. The tool will be based on the significant amounts of data on physico-chemical and toxicological and ecotoxicological properties of ENM generated over the last decades, as well as new data coming from research.

Strategy



Discipline
Multidisciplinary/Nano

Pillar(s)
Industry

SbD aspects
Creating an online platform based on predictive toxicology knowledge.

https://www.nanoinformatix.eu/

Expected Impacts and Outcomes
The online NanoInformaTIX SNF platform aims to help shortening the path from lab bench to the market, by providing:

> a global hub for ENM SbD,

> a portal for manufacturers and scientists , for information on materials.

It will be based on predictive toxicology knowledge, thus enabling sustainable production of engineered nanomaterials (ENM) through:

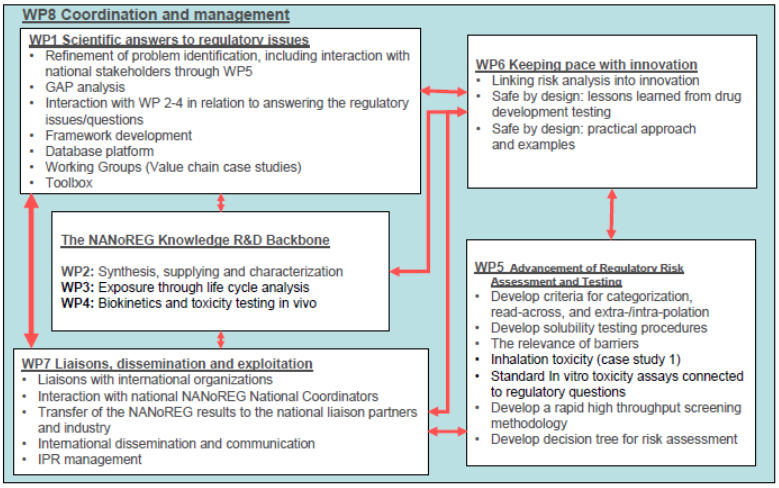
- Reduction of animal experimentation
- SbD
- Grouping/classifying ENM for risk assessment

7.10 NANoREG

A common European approach to the regulatory testing of nanomaterials

Description
The innovative and economic potential of Manufactured Nano Materials (MNMs) is threatened by a limited understanding of the related EHS issues. While toxicity data is continuously becoming available, the relevance to regulators is often unclear or unproven. The shrinking time to market of new MNM drives the need for urgent action by regulators. NANoREG is the first FP7 project to deliver the answers needed by regulators and legislators on EHS by linking them to a scientific evaluation of data and test methods.

Strategy



Discipline
Multidisciplinary/Nano

Pillar(s)
Education, Research, Industry, Strategic Positioning

SbD aspects
A risk assessment framework suitable for SbD applicability.

https://www.rivm.nl/en/about-rivm/mission-and-strategy/international-affairs/international-projects/nanoreg

Expected Impacts and Outcomes
The NANoREG consortium has proven that it is feasible to come to a concerted action regarding the materials to be tested, test methods and cell lines to be applied, quality checks, etc. Such concerted action is an

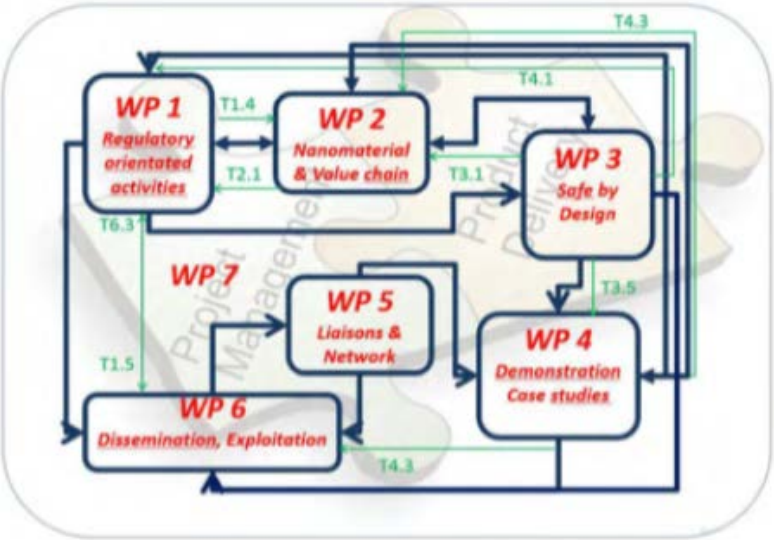
absolute must for generating meaningful data. The project also has proven that the basic willingness of partners to collaborate can be used to come to an agreement (possibly for the first time) to make data and deliverables publically available. This makes it possible for other projects to build on the results of NANoREG. In this context, it can be noted that NanoReg2 and caLIBRAte will further elaborate on the data generated in the project. It would be a major step forward if other nanosafety projects would copy the example NANoREG has set, with respect to opening up the results. All NANoREG results are available in the NANoREG Results Repository.

7.11 NanoReg2

Development and implementation of Grouping and SbD approaches within regulatory frameworks

Description
The NanoReg2 project, built around the challenge of coupling SbD to the regulatory process, will demonstrate and establish new principles and ideas based on data from value chain implementation studies to establish SbD as a fundamental pillar in the validation of a novel manufactured nanomaterials (MNM). It is widely recognised by industries as well as by regulatory agencies that grouping strategies for NM are urgently needed. ECETOC has formed a task force on NM grouping and also within the OECD WPMN a group works on NM categorisation. However, so far no reliable and regulatory accepted grouping concepts could be established. Grouping concepts developed by NanoReg2 can be regarded as a major innovation therefore as guidance documents on NM grouping will not only support industries or regulatory agencies but would also strongly support commercial launch of a new NM.

Strategy



Discipline
Multidisciplinary/Nano

Pillar(s)
Education/Research/Industry/Strategic Positioning

SbD aspects
Development of the Safe Innovation Approach (SbD, regulatory preparedness, trusted environments)

http://www.nanoreg2.eu/

Expected Impacts and Outcomes

For industry:
Safer products, less uncertainties, overall saving of time and money us well us faster time to market thanks to timely identification of uncertainties and risks to manage them, finding alternative solutions as early as possible

For regulators:
Be prepared for up-coming innovations & respective products thanks to insight into the innovation processes, dossier compatible data along the development process, regulation oriented tools and SOPs, etc.

For R&D community:
Strengthening R&D and inno-vation process through the SbD concept thanks to being well connected to the development and implementation of regulatory driven tools, SOPs, data bases, etc.

For the society:
Transparent and traceable information on the safety of MNMs and nano inspired products but also the capability to understand and compare products on the market

7.12 NANORIGO

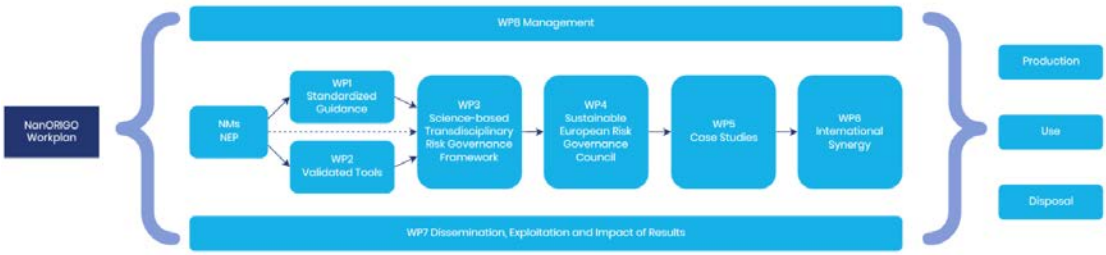
Establishing a Nanotechnology Risk Governance Framework

Description
NANOtechnology RIsk GOvernance aims to develop and implement a transparent, transdisciplinary Nanotechnology Risk Governance Framework and a related Risk Governance Council.

The Main goal is to develop a Risk Governance Framework (RGF) and a Risk Governance Council (RGC) to guide all stakeholders in the sustainable development of nanotechnologies in Europe.

NANORIGO will collaborate on this with RiskGone and Gov4Nano (also funded under the NMBP13-2018 Call).

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Education, Industry, Research, Strategic Positioning

SbD aspects
Develop a nano risk governance council (NRGC). The ultimate aim of NANORIGO is to deliver a Risk Governance Framework for the safety of nanomaterials, for risk assessment, hazard and exposure, human health and environment, and risk mitigation including regulatory aspects of SbD.

https://nanorigo.eu/

Expected Impacts and Outcomes

- A transparent, self-sustained and science-based
- European Nanotechnology Risk Governance Council (RGC)
- Transparent Risk Governance Framework (RGF) tools for managing possible nanotechnologies risks
- Availability of high quality data for decision making
- Consistency of approaches in all EU Member States and internationally

7.13 NANOSOLUTIONS

Biological Foundation for the Safety Classification of Engineered Nanomaterials (ENM): Systems Biology Approaches to Understand Interactions of ENM with Living Organisms and the Environment

Description
The overarching aim of the NANOSOLUTIONS consortium is to provide a means to develop a safety classification for engineered nanomaterials (ENM) based on an understanding of their interactions with living organisms at molecular, cellular and organism levels.

The objective is to determine the "biological identity" of ENM, and subsequently develop a computer program that can predict from the properties of ENM their ability to cause health or environmental hazards. New innovative methods are needed for the ENM risk assessment of ENM safety, i.e. ENM SAFETY CLASSIFIER.

This will allow for the crucial transition from descriptive toxicology to predictive toxicology

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research
SbD aspects
Developing tools for safety classifications for engineered NM.

http://nanosolutionsfp7.com/

Expected Impacts and Outcomes
Thirty-five partners with extensive expertise in omics research (transcriptomics, proteomics and epigenomics) are identifying the characteristics of ENMs that determine their biological hazard potential with EU funding of the project NANOSOLUTIONS. The consortium plans to establish biomarkers of ENM toxicity to be used in assessments of safety and toxicity across species. The overarching goal is to provide the tools to develop an ENM safety classifier based on materials characteristics. The resulting classifier will do for ENM what the material safety data sheets do for chemicals.

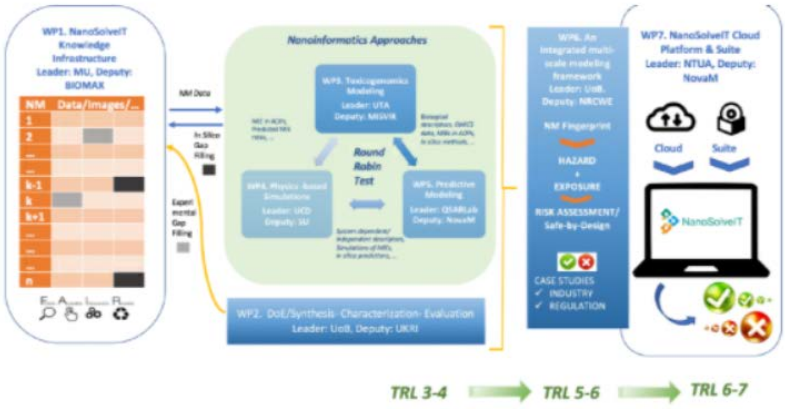
7.14 NanoSolveIT

Innovative Nanoinformatics models and tools: towards a Solid, verified and Integrated Approach to Predictive (eco)Toxicology (NanoSolveIT)

Description
NanoSolveIT's ambition is to advance nanoinformatics well beyond the state-of-the art by developing and implementing innovative modelling techniques and tools that will be integrated within NanoSolveIT IATA and then incorporated into a sustainable interoperable product, the NanoSolveIT e-platform, which will become an essential element for supporting industrial and regulatory nano-risk governance and the anticipated nano-risk governance council established in the EU H2020 NMBP-13-2018 call.

NanoSolveIT will develop a validated tiered IATA to identify the critical characteristics of nanomaterials responsible for their adverse effects on human health and the environment or for their functionalities in high-tech applications, and will implement a nanoinformatics-driven decision-support strategy based on innovative in silico methods, models and tools. An important novel concept is the nanomaterial fingerprint – a set of descriptors and properties that can be predictively linked to nanomaterials properties, functionality and hazard by the development and integration of advanced nanoinformatics methods and tools.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research, Industry

SbD aspects
NanoSolveIT aspires to introduce an in silico Integrated Approach to Testing and Assessment (IATA) for the environmental health and safety of nanomaterials (ENM), implemented through a decision support system packaged as both a stand-alone open software and via a Cloud platform.

https://nanosolveit.eu/

Expected Impacts and Outcomes
NanoSolveIT has the unique potential to deliver a step-changing impact for nanotechnology. It will remove barriers from nanosafety-related regulatory and industrial processes by revolutionising modelling across scales and model types, integrating multi-scale physics-based and data-driven (AI) approaches. The expected impacts from NanoSolveIT can be summarised as follows:

- Nanoinformatics models, recognised for their predictive power and reliability, are widely utilised by stakeholders
- Nanoinformatics models and the IATA are available in an accessible and user-friendly platform
- Data are delivered into the IATA in model friendly formats to maximise applicability and predictivity of models
- Community/stakeholder acceptance of models and IATA is high based on SOPs, benchmarking and case studies
- Industry and regulatory acceptance of the one-stop complete IATA system leads to a direct reduction in animal testing, and the cost and time needed for risk assessment of NMs.

7.15 NanoSteeM

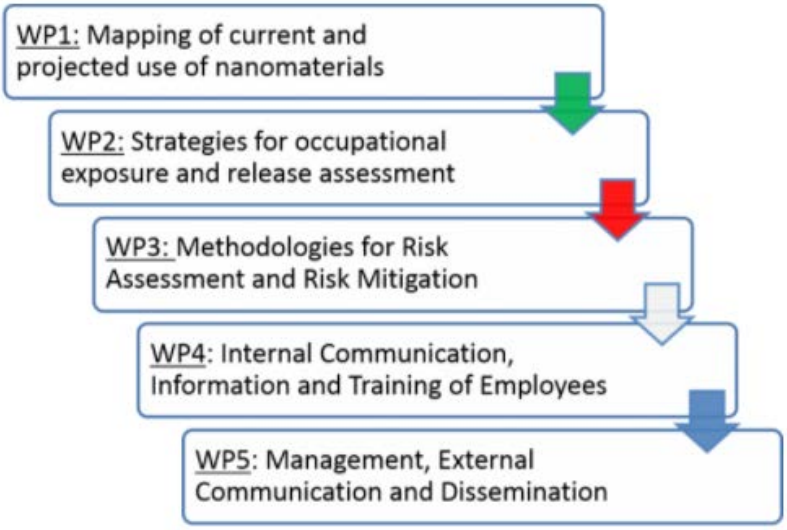
NANOmaterials: STRategies for Safety Assessments in advanced Integrated Circuits Manufacturing

Description
Nanoelectronics relies on multiple semiconductor processes resulting in pattering of macroscopic objects (silicon wafers) at nanoscale level. Advanced technologies developed by semiconductor manufacturers offer unprecedented control of the properties of the finished product in large volumes. The rapid pace of progress in the semiconductor manufacturing dictated by the Moore's economic law also introduces a variety of novel nano-structured materials having poorly understood hazardous properties.

The NanoStreeM consortium has taken up the challenge in defining a road map of Safety of nanomaterials in nanoelectronics where we identify the existing gaps in our knowledge and a number of recommendations for their mitigation.

The goal of the NanoStreeM project is to promote good practices by identifying and implementing standards, identify gaps in methodologies and directions for further investigations in order to support governance of the occupational risk induced by the use of nanomaterials in semiconductor industry. The NanoStreeM consortium combines unique expertise throughout the research and development chain: from the academic labs via technology development through semiconductor application side. We aim to identify all cases of concern and *propose* a systematic strategy of prioritisation and management of risk. The consortium combines the expertise of the industry and research organisations in material science, toxicology, environmental science and occupational medicine, providing a critical mass for a coordinated action on a European scale.

Strategy



Discipline
Chemistry, Physics, Nano

Pillar(s)
Industry/Research/ Strategic Positioning

SbD aspects
Identifying all safety risks from the labs via technology development up to the application of nanoelectronics.

http://www.nanostreem.eu/

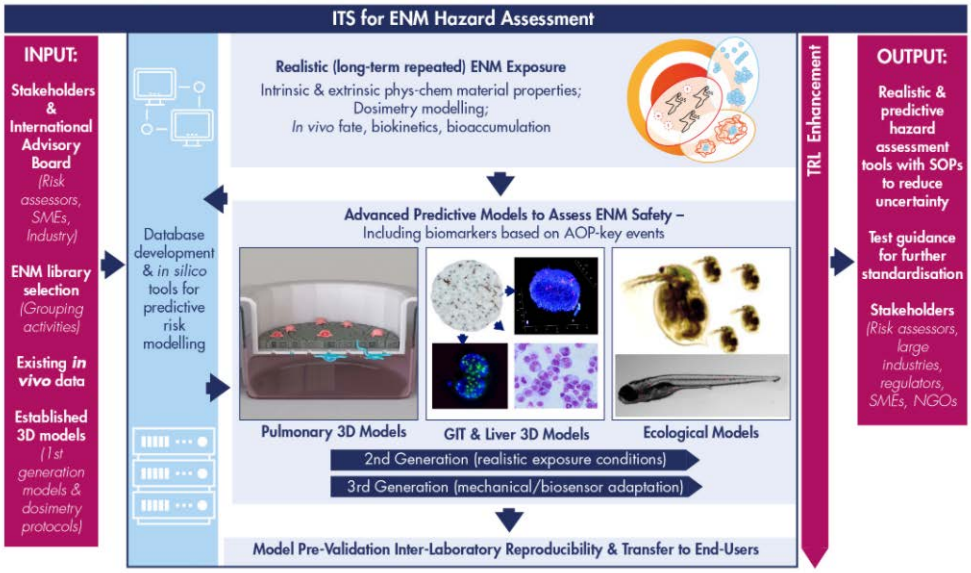
Expected Impacts and Outcomes
- better understanding the occupational hazards related to the use of nanomaterials
- improvement of the assessment of the potential impact of nano-materials on workers and environment during semiconductor fabrication
- Intensification of international cooperation with USA and Asia in the areas of standardisation
- sharing of information with other industries facing similar issues in understanding properties and controlling nanohazards

7.16 PATROLS

Physiologically Anchored Tools for Realistic nanOmateriaL hazard aSsessment

Description
PATROLS is an international project combining a team of academics, industrial scientists, government officials and risk assessors to deliver advanced and realistic tools and methods for nanomaterial safety assessment. PATROLS will provide an innovative and effective set of laboratory techniques and computational tools to more reliably predict potential human and environmental hazards resulting from engineered nanomaterial (ENM) exposures. These tools will minimise the necessity of animal testing and will support future categorisation of ENMs in order to support safety frameworks.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research, Industry

SbD aspects
Developing tools and methods (3D tissue models for lung, gastrointestinal and liver) to minimise animal testing and categorise engineered nanomaterials.

https://www.patrols-h2020.eu/

Expected Impacts and Outcomes
Produce realistic test systems for nanosafety evaluation including:
- 3D human liver, gut and lung cell culture models
- Advanced Ecological test systems relevant to a range of species or organisms

Create robust computational models for hazard prediction:
- Development of tools for predictive risk modelling providing a rapid and cost effective approach for assessing engineered nano material safety

Develop test method guidance to support risk assessment frameworks:
- To provide input into ongoing regulatory nanosafety policy development.

Support the reduction of animal testing in nanosafety:
- The cutting-edge, physiologically relevant, test systems produced through PATROLS will serve to reduce and replace the current animal test methods

7.17 PRISMA

Piloting RRI in Industry: a roadmap for tranSforMAtive technologies

Description
The overarching goal of the PRISMA project is:
- to help companies to implement Responsible Research and Innovation (RRI) in their innovation and social responsibility strategies,
- to provide evidence on how RRI can improve innovation processes and products
- to show how RRI leads to trust from society (thus strengthening the market position of companies).

The project has develop a roadmap, consisting of 6 steps, to formulate a roadmap including a template. In addition, the project has developed a list of KPIs companies can use to formulate or to measure (intended) impact.

Strategy

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research, Education

SbD aspects
Developing a practical guideline and standards for companies aiming at developing a strategy for Responsible Research and Innovation (RRI) which includes SbD.

https://www.rri-prisma.eu/

Expected Impacts and Outcomes
Based on the experience in eight pilots with companies active in different sectors and technologies, PRISMA developed a practical guideline / roadmap for companies aiming to strengthen consideration of ethical, legal and social impacts (ELSI) aspects in their technology and product development. The PRISMA exemplary roadmap is structured on a set of acknowledged RRI principles, that are operationalized based on three key actions:

- Integrate analysis of ethical, legal and social impacts since the early stages of product development (Reflection and Anticipation)
- Perform stakeholder engagement to inform all phases of product development (Inclusiveness)
- Integrate monitoring, learning and adaptive mechanisms to address public and social values and normative principles in product development (Responsiveness).

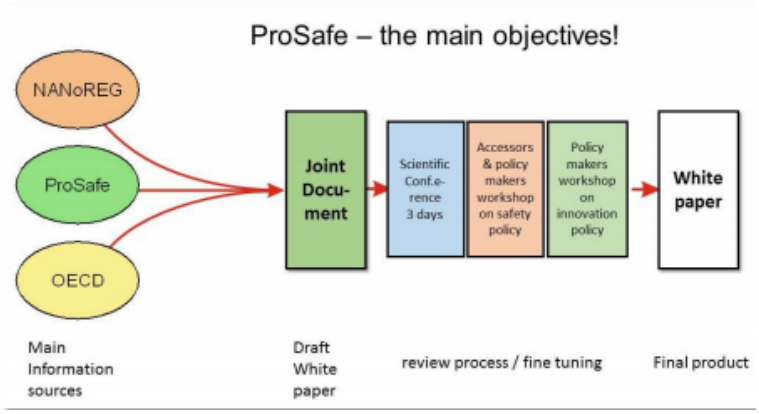
7.18 PROSAFE

Promoting the Implementation of Safe by Design

Description
The capitalisation of the innovative and economic potential of nanotechnology is hampered by the uncertainty regarding the EHS aspects of nanomaterials and –linked to that-the regulation of these aspects. A number of nanosafety projects try to limit these uncertainties by developing methods for testing and assessing the effects and risks of nanomaterials in a regulatory context. In addition to this several projects try to develop the concept of Safe by Design as a way to incorporate the EHS aspects in an early stage of the innovation process.

The H2020 Coordination and Support Action ProSafe that was launched on 1 February 2015 evaluates and integrated the results of these projects among which the FP7 NANoREG project and the OECD Sponsor Programme. The results of the evaluation and integration will be laid down in a Joint Document that will be discussed during a three days scientific conference that will be co-organised with the OECD in November 2016. The results of the conference will be input for a more policy oriented White Paper. This White Paper will provide building blocks for regulators and industry to cover EHS aspects of MNMs including evaluated methods for testing and assessing risks of nanomaterials. It will also addresses the innovation policy in relation to nanosafety. To this end the results of the NANoREG and ProSafe project regarding SbD, a study on novel risks, a standardised way of data management as well as the preliminary results of the H2020 project NANoREG II will be combined with the results of the Scientific Workshop and underlying Joint Document. The creation of the White Paper and the preceding Joint Document with scientific information, will be an interactive process in which Member States, associated States and Industry representatives will be strongly involved.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry

SbD aspects
Recommendations for policymakers and regulators aimed at a more effective and cost-efficient assessment of nanomaterials in a regulatory context and for application for SbD.

https://www.rivm.nl/en/about-rivm/mission-and-strategy/international-affairs/international-projects/prosafe

Expected Impacts and Outcomes
ProSafe is designed to have a major impact on the outcome of the NANoREG project and other nanosafety projects. It will:

- Strengthen and support the aims of NANoREG.
- Exploit synergy, mainly within all MS and AS but also world-wide, with activities aiming to support the implementation of SbD approaches to regulation. The action will lead to joint projects, twinned projects and global networks facilitating the goal of risk management and incorporating risk assessment in the early stages of material,
- product and process design.
- Combine efforts with those of the NANoREG project so that the expected datasets from the latter can be complemented and cross validated with similar datasets from other projects running globally in order to reach OECD - MAD (Mutually Accepted Data) status identifying and eradicating any inconsistencies.
- Evaluate and combine results and present them in such a way that they can be used as building blocks for a standardised approach of testing and assessing the EHS aspect of MNMs in a regulatory context

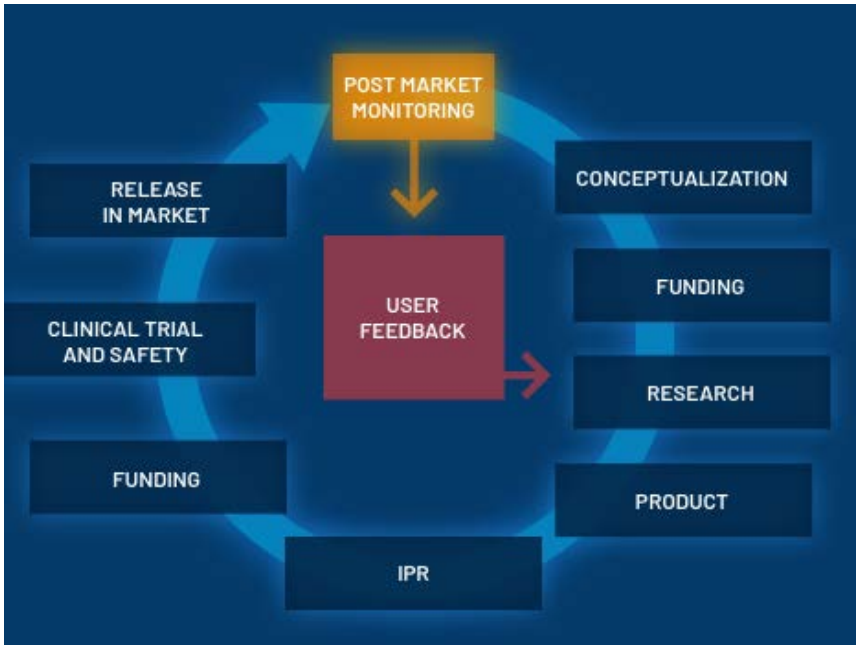
7.19 REFINE

Regulatory Science Framework for Nano(bio)material-based Medical Products and Devices

Description
REFINE will gather a wide community of stakeholders in regulation, industry, science, technology development, patients, and end-users, into a Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicine.
To set up/ build a Regulatory Science framework to close the gap presently on the existing development of nanomedicine products. We aim to set in motion a sustained forum that liaises regulators, scientist, and developers in the task to develop:

- A clear overview of current and anticipated regulatory concerns, including harmonisation,
- A gap analysis where regulatory concerns and scientific evidence don’t seem to match up.
- A heuristic to transfer new scientific evidence into regulatory strategies, and to translate regulatory concerns into hot spots in the standard testing cascades

Strategy



Discipline
Nanobiomaterials

Pillar(s)
Research, Industry, Strategic Positioning

SbD aspects
Regulatory Science Framework for Nano(bio)material-based which facilitates SbD.

http://refine-nanomed.eu/

Expected Impacts and Outcomes

- REFINE will help to establish a European Consortium for the Advancement of Regulatory Science in Biomaterials and Nanomedicines with representation from all the stakeholder communities.
- REFINE will identify critical issues for innovative products and establishment of an action plan for further studies.
- REFINE will deepen existing and establish with existing European Infrastructures along with relevant European Research Networks;
- Within REFINE we will elaborate an action plan for a better integration of the European Union with other regions of the world.
- REFINE will help to reduce the cost of preclinical and clinical development of NBMs.
- REFINE will help to reduce the time for innovations to reach the patients.
- REFINE will provide tools for more informed risk assessment and decision-making.
- REFINE will help to improve standardisation of regulatory practice at the European and international level.

- REFINE will foster close collaboration with the stakeholders community

7.20 SAF€RA

Coordination of European Research on Industrial Safety towards Smart and Sustainable Growth

Description
The scope of SAF€RA includes research on the prevention of major accidents, with off-site consequences and risks to the environment and society, and in particular the economic benefits of industrial safety solutions, safe innovative processes, preparedness and response as well as protection of the environment, new methods to enhance the creation of a safety culture and prudent attitudes, risk reduction strategies, reference technologies for life extension of aged and repaired structures, as well as products and systems required to improve industrial safety.

Discipline
Engineering

Pillar(s)
Industry, Research (engineering for safer processes)

SbD aspects
Tools and partnership for safer processes.

https://www.safera.eu/

Expected Impacts and Outcomes
Potential Impact:
The activities carried out during the SAF€RA project, as well as further actions to be undertaken after the end of the project, will have either a direct or an indirect impact on a number of issues related to industrial safety. The project was expected to have a direct impact on the following issues:

- Reinforcement of the European Research Area on industrial safety
- Identification of the future challenges related to industrial safety in the EU
- Creation of a durable European research network related to industrial safety
- Publication of European and national strategies and research priorities related to industrial safety
- Establishing effective dissemination and promotion to implement industrial safety in the EU

The main results of the SAF€RA project were:

- Trust and cooperation beyond national level improved between the national and regional research programme owners and managers
- Network, operating model and tools set up for future collaboration
- Common vision and joint strategy, beyond the project, agreed and priority topics identified

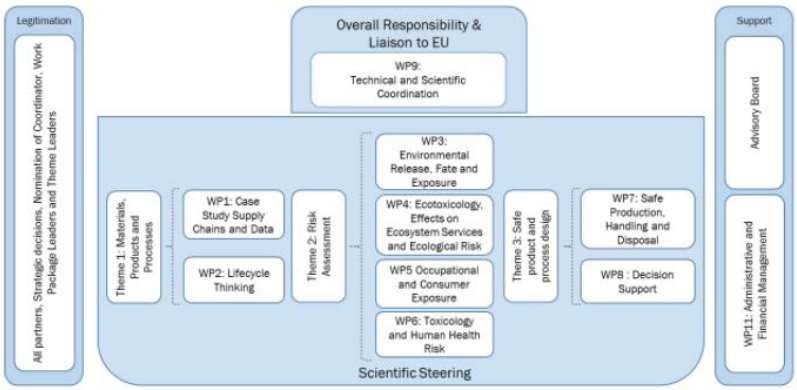
- Coordinated joint activities carried out with two successful joint calls for project proposals (2013, 2014)
- New opportunities offered for industrial safety research, and a significant number of new transnational European projects funded
- Visibility gained for industrial safety as a topic, e.g. through annual SAF€RA Symposia and various other networking and promotion activities, in cooperation with ETPIS
- Cooperation continued beyond the project in the context of ETPIS, commitment of members

7.21 SUN

Sustainable Nanotechnologies

Description
Our understanding of the environmental and health risks from nanotechnologies is still limited, which may result in stagnation of innovation and economic growth. Nano-enabled products that show ecological or health effects after their market introduction can cause significant costs for society and the enterprises in the form of over-balancing regulations and demolished consumer confidence.

The Sustainable Nanotechnologies (SUN) project is based on the idea that the current knowledge on environmental and health risks of nanomaterials – while limited – can nevertheless guide nanomanufacturing to avoid liabilities if an integrated approach addressing the complete product lifecycle is applied.
Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Education, Research, Industry, Strategic Positioning

SbD aspects
An integrated approach addressing the complete product lifecycle to assess health and environmental risks for SbD applicability within nanotechnology.

http://www.sun-fp7.eu/

Expected Impacts and Outcomes
One of the key conclusions is that to benefit the environment the future nanotechnology applications should have a combination of following characteristics:

- Using nanomaterials as additives leading to better functionality of the nano-enabled product.
- Environmental benefit in the use phase (higher resource and/or energy efficiency).
- Long-life (persistent) product.
- Nanomaterials integrated in the productmatrix (low release).

Summary Booklet of SUN Results

7.22 RISKGONE

Risk Governance of Nanotechnology

Description
RiskGONE (Science-based Risk Governance of Nano-Technology) is an EU H2020 project aiming at providing solid procedures for consistent risk governance of engineered nanomaterials.

The project began on 1st January 2019 and will end on 28 February 2023. In that time the project partners will develop new tools or modify existing ones to identify with better certainty the environmental and human health impacts of a number of nanomaterials. These tools and the results of tests using them will then be integrated into the work of a European Risk Governance Council (ERGC), a group of individuals with different areas of expertise on nanomaterials tasked to provide governance decisions on the safety of the specific materials. A risk governance framework, made up of the tools and the ERGC, will be developed to address nanomaterial safety governance in a coherent and scientifically robust way. The project has a budget of € 5 Million.

Discipline
Multidisciplinary, Nano

Pillar(s)
Education, Research, Industry, Strategic Positioning

SbD aspects
Develop a nano risk governance council (NRGC) that will help SbD practices. Develop tools to identify the environmental and human health impacts of nanomaterials for SbD applicability.

https://riskgone.eu/

Expected Impacts and Outcomes
The project's activities are balanced between experimental and theoretical work. RiskGONE will focus on:

- A risk governance framework and council
- Risk-benefit assessment
- Characterisation in vitro dosimetry and environmental fate
- Human hazard assessment

- Eco-toxicological hazard assessment
- Ethical issues

7.23 Gov4Nano

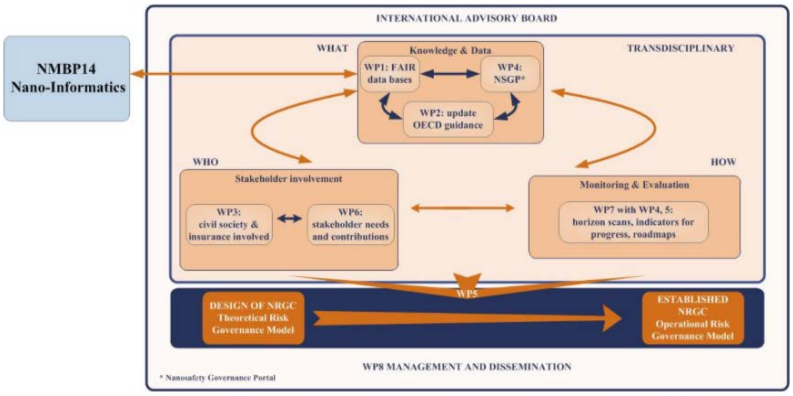
Implementation of Risk Governance: meeting the needs of nanotechnology

Description
The Gov4Nano project will develop the first implementation of a future-proof operational Nano Risk Governance Model (NRGM) that addresses the needs of the transdisciplinary field and innovative (and key enabling) character of nanotechnology.

Gov4Nano will take into account the particulars of different generations of nano-technologies and risk/benefits/public concerns to develop an integrated approach connecting the scientific, regulatory and market layers and the different actors involved from generation of data and knowledge to application in legislation and standards, and propose the basis for efficient and effective risk governance of nanotechnologies. The Gov4Nano project will design and establish a Nanotechnology Risk Governance Council (NRGC), to create a trustworthy and objective international umbrella for the risk governance of nanotechnologies.

The Gov4Nano consortium will work closely with the two other risk governance projects funded under the same NMBP-13-2018 call: RiskGONE and NANORIGO, that are addressing the same goal, to ultimately ensure a sustainable and equitable RGF and RGC developed for nanotechnology in Europe.

Strategy



Discipline
Multidiciplinary

Pillar(s)
Industry, Research, Strategic Positioning
SbD aspects
Develop a nano risk governance council (NRGC) that will help SbD practices. Exploring upcoming tools and approaches such as Findable, Accessible, Interoperable and Re-usable (FAIR) databases and blockchain technology.

https://www.gov4nano.eu/

Expected Impacts and Outcomes

- It will explore the potential added value of upcoming tools and approaches such as Findable, Accessible Interoperable and Re-usable (FAIR) databases, data-hackathons, blockchain technology and implementation of SbD to achieve adaptive and resilient risk governance.
- It will support consensus building, prioritisation and harmonisation of practices amongst stakeholders, with a focus on key aspects for risk governance of nanotechnologies, including risk assessment, risk management, risk perception and risk communication, risk-benefit evaluation, and risk-transfer and the societal desirability of nanotechnology applications.
- It will include knowledge management and data management, efficiently executed through stakeholder involvement.

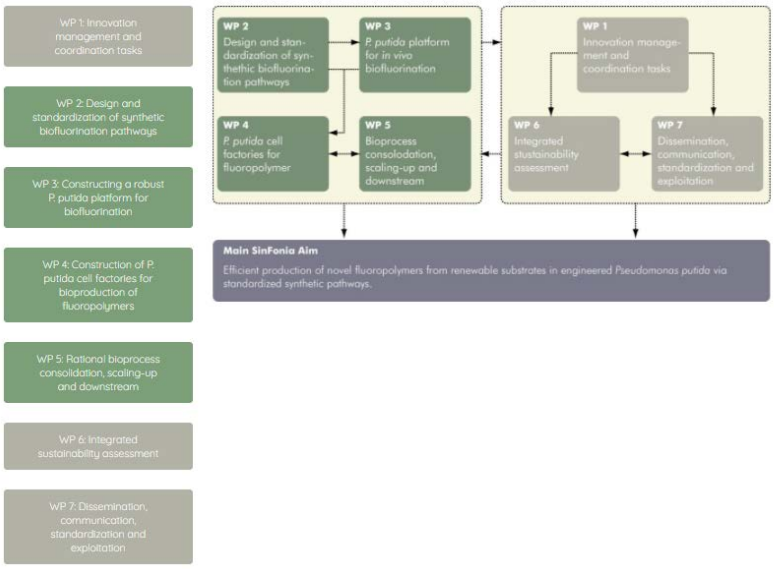
7.24 SinFonia

Synthetic biology-guided engineering of Pseudomonas putida for biofluorination

Description

SinFonia aims to produce novel fluorochemicals in a biological way. Materials containing the element fluorine (F) are extremely important in our modern world, with applications in electronics, healthcare, automotive and wearables. Currently these fluorochemicals are exclusively synthesised using chemical methods, something SinFonia wants to change.

Strategy



Discipline

Biotechnology

Pillar(s)

Research

SbD aspects
Building sustainable and safe process alternatives for fluorinating agents by using bacteria and enzymes.

https://www.sinfoniabiotec.eu/

Expected Impacts and Outcomes
The ambition of SinFonia is to set the stage for a future economically, ecologically and societally sustainable value chain for the production of novel, bio-based fluoropolymers from renewable substrates. The innovation potential of SinFonia is high: we have set several ground-breaking objectives that include cutting-edge synthetic biology, smart metabolic engineering, rational protein design, bioprocess engineering, material science and polymer chemistry. Our project will contribute concepts and approaches to these fields (including standardisation of metabolic pathways from difficult-to-manipulate organisms to ease their transfer into a formatted and robust bacterial chassis) while designing cell factories for efficient synthesis of novel fluorinated products

7.25 NANOGENTOOLS

Developing and implementation of a new generation of nanosafety assessment tools

Description
Aimed at developing new methodologies for the identification and control of hazards associated with nanomaterials, ensuring consumer and Society safety. It pursues the main objective of generating a common solid knowledge basis arising from the fruitful cross-sectorial synergy between forefront research Centers in nanosafety and industry, in a cross-fertilisation multidisciplinary approach that will provide new tests and methodologies (or improve existing ones) to assess the long term risks of nanomaterials (NMs) in a rapid and cost effective manner suitable for regulatory inclusion.

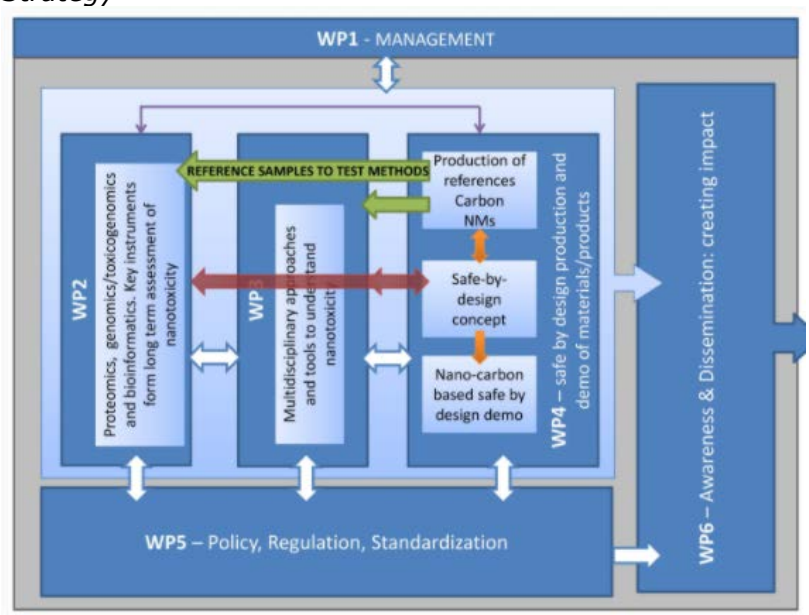
NANOGENTOOLS combines genomics (toxicogenomics), proteomics and multidisciplinary science (biophysics, molecular modelling, chemistry, bioinformatics, chemoinformatics) to develop fast in vitro high throughput (HTS) assays, with molecular based computational models for better understanding of the molecular fundamentals of nanotoxicity, and it will initiate the development of online nanosafety assays for use by SMEs during product development.

NANOGENTOOLS
The expected impacts include pre-validated tools for efficient cost-effective nanosafety assessment applicable to SMEs and suitable for incorporation into regulatory frameworks, and translation of the knowledge into a demonstration of the application of safety-by-design principles for the development of a CNT-based nanosensor.

The specific objectives of our project are:
- To provide solutions for faster and more reliable assessment of NM toxicity and propose a battery of HTS and -omics tools suitable for predicting the toxicological properties of NMs.

- To develop new bioinformatics methodologies capable of analysing -omics data and create an open database for the scientific community in collaboration with the EU Nanosafety Cluster.
- To conduct research and training on biophysical techniques and mathematical models for accurate and fast nanotoxicity prediction linked to safety-by-design concepts.
- To understand, build and improve the safe by design concept, with demonstration using carbon-based NMs and nanosensors and demonstrate translation across applications and NMs.
- To place our new knowledge in the context of present regulations and EU roadmaps.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research/Industry/Education

SbD aspects
High throughput in vitro tests for the safety assessment of nanomaterials and for the early application of SbD.

https://www3.ubu.es/nanogentools/

Expected Impacts and Outcomes
NANOGENTOOLS has contributed to bring a step further the availability of *in silico* and *in vitro* laboratory techniques for the toxicology assessment of nanomaterials. The project has worked as well in fostering the discussion on standards, methodologies and regulation for nanotechnology risks assessment, being in this regard aligned with the strategy research agenda "Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations".

One of the most important achievements of NGT has been to train scientists and SMEs with a state of the art knowledge in the area, something necessary for the future of European industry. NGT has contributed to the development of nanotechnology at EU level (a KET with an impressive potential of jobs creation), generating new knowledge related to the enhancement of workers, consumers and environmental safety.

NGT action has provided an outstanding framework for this purpose, since the actors involved in the project included some of the most relevant players in the definition and the development of nanoEHS (Environment, Health and Safety) science, and resulting policies for the aforementioned tasks

7.26 SAFEnano

Effect of water and wastewater treatment on the properties of engineered nanomaterials (ENMs) in context of their fate, toxicity and interaction with other contaminants

Description
Our research is mainly focused on fate (especially bioavailability and ecotoxicity) of different contaminants in environment as well as the development and improvement of methods to removing these contaminants from water, soil and sediments. Most recent works are focused on fate of nanoparticles in soil, sediment and sewage sludges and the effect of these materials on living organisms. We also investigate the use of biochars, activated carbon and carbon nanotubes as an adsorbent for organic contaminants removal from water, soil and sewajge sludge. The important part of our research are photocatalysis for water treatment. We are also interested in all kinds of processes related to interactions between environmental compartments (soil, water, atmosphere, waste materials) and improvement of analytical procedures/techniques in environmental chemistry.

Strategy

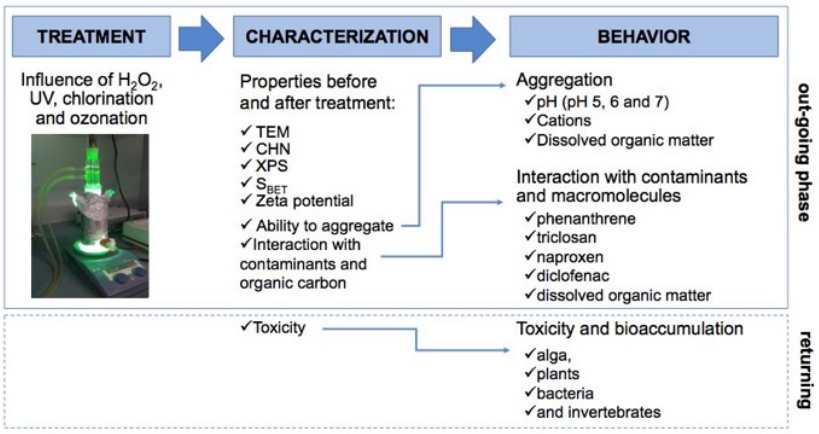


Figure 1. General outlook on the project tasks

Discipline
Multidisciplinary, Nano, Ecotoxicity

Pillar(s)
Research

SbD aspects
Investigate the fate of nanoparticles in soil, sediment and sewage slugs and the effect of these materials on living organisms. This is relevant for SbD applicability.

http://zchs.umcs.lublin.pl/Webside/SafeNano.html

Expected Impacts and Outcomes
The proposed project is expected to contribute significantly to the current scientific understanding of the fate and effects of ENMs on environment, which are currently poorly understood. Improving this understanding is recognised as one of the "grand challenges" that must be addressed by the European Research Area. The proposed collaboration with a world-leading institute outside Europe is the great benefit to the European community by both training the candidate to an internationally competitive level and transferring knowledge of state of the art scientific approaches to the European research community. Indeed, by allowing me to gain research experience in the highly collaborative settings of Duke, this fellowship therefore provided support for me to establish international connections with other researchers, which could form the basis of future independent collaborations. I believe that the proposed research will also result in publications in top quality scientific journals, as well as presentations at international meetings, which support the European standard for excellence in research. From point of view of socio-economic impact and the wider societal implications, the project provides many important aspects. Due to the increasing use of nanoparticles in various aspects of life (medicine, cosmetics, food), nanoparticles can pose a potential threat to living organisms, including humans. Up to date, research has mainly focused on the direct impact of nanoparticles, usually pristine (brand-new). In our research, we go further and focus on realistic conditions and changes that nanoparticles may undergo in the environment becasue these nanoparticles will have a direct impact on living organisms and the environment. Our studies have shown that as a result of water purification, the properties of nanoparticles can undergo changes that sometimes affect their environmental behaviour and, above all, interaction with other dangerous contaminants presented in water. The extension of current knowledge in the field of presence and the impact of nanoparticles on the environment will contribute to better management of engineered nanoparticles. This will affect not only the quality of the environment but also quality of human health, which is directly connected with environment contamination. The reduction of the risk will affect the quality of life at all levels of life and will also ensure a secure for future generations.

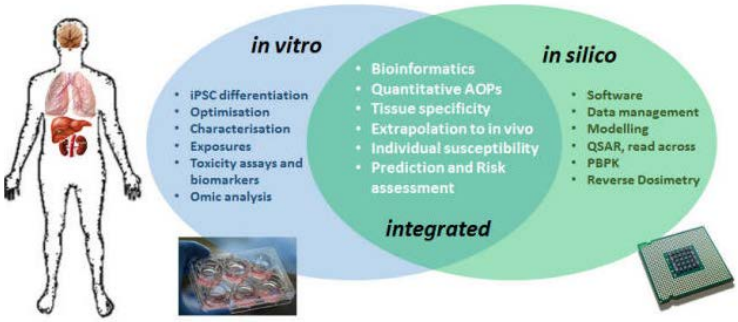
7.27 in3

An integrated interdisciplinary approach to animal-free chemical and nanomaterial safety assessment

Description
The in3 project is funded by the EU's Marie Skłodowska-Curie Action - Innovative Training Network (MSCA-ITN for short) that aims to drive the synergistic development and utilisation of *in vitro* and *in silico* tools for human chemical and nanomaterial (NM) safety assessment. The project focuses on differentiation of human induced Pluripotent Stem Cells (hiPSC) to toxicologically relevant target tissues including; brain, lung, liver and kidney. The tissues, from the same genetic backgrounds, are exposed to common compounds and the data generated and prediction tools generated will be used to develop modernised safety assessment approaches combining cheminformatics, mechanistic toxicology and biokinetics into computational models which can account for donor and tissues specific effects. The project employs 15 PhD students to carry out these activities in a coordinated and collaborative fashion.

Core scientific activities:
- Differentiation of well-characterised human iPSC into brain, lung, liver, kidney and vascular cells
- Delineation of tissue specific and donor specific effects of compound exposures (uptake, metabolism, extrusion, and mechanistic toxicity)
- Development and optimisation of quantitative adverse outcome pathways (qAOPs) for each target organ which will be unified in an organism-level model
- Optimisation of QSAR and read-across tools for safety assessment
- Ultimately to create a unified expandable integrated testing strategy for chemical and NM safety assessment

Strategy



Discipline
Chemicals

Pillar(s)
Research

SbD aspects
Through the synergistic development and utilisation of in vitro and in silico tools for human chemical and nanomaterial (NM) safety assessment, SbD can be applied.

https://estiv.org/in3/about.html

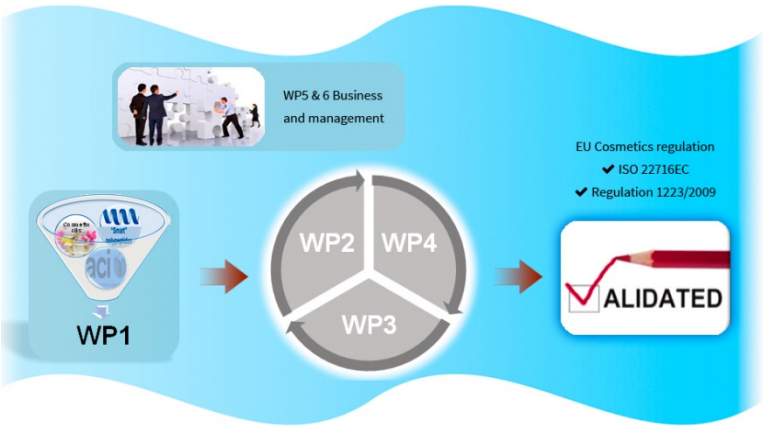
Expected Impacts and Outcomes
in3 aims to build on our collective experiences and achievements in projects such as Predict-IV, StemBANCC, eNanoMapper, NanoPUZZLES, the SEURAT1 clusters HeMiBio, COSMOS, DETECTIVE, ToxBank, and the newly launched Horizon 2020 project EU-ToxRisk. All of these projects focused to specific aspects of animal-free chemical and NM safety assessment. Here we will bring these innovations under a single training umbrella, focusing to mechanistic studies as a basis for hazard assessment, linking exposure to hazard, creating biokinetic models and integrating *in vitro* data with in silico tools.

7.28 PEPTICAPS

Design of polyPEPTIdes diblock copolymers as emulsifiers to produce safe, controlled and reliable novel stimuli-responsive nanoCAPSules for skin care applications

Description
PeptiCaps aims at producing and validating a new family of smart nanocapsules to encapsulate and protect fragile active ingredients for the treatment of skin conditions affecting wide number of people, such as irritant and allergic contact dermatitis, skin UV-damage and pigmentation. Those nanocapsules will be designed to encapsulate, either hydrophilic or lipophilic actives, and more importantly the release of those compounds will be triggered by the changes in pH and enzyme concentration characteristic of those skin conditions, ensuring its delivery at the site to be treated.

Strategy



Discipline
Cosmetics

Pillar(s)
Research

SbD aspects
To design nanocapsules for cosmetics including risk and safety assessment in the early stages of the innovation process.

http://www.pepticaps.eu/

Expected Impacts and Outcomes
COSMETICS OBJECTIVES

- Efficient action of the nanocapsules for skin recovery
- Risk and safety assessment of the nanocapsules
- Cosmetic product validation

SCIENTIFIC OBJECTIVES

- Optimisation of the nanocapsules design
- Production of nanocapsules via industrially relevant process
- Treatment of skin condition

During the project, researchers developed and validated a new family of safe, stimuli-responsive nano-capsules designed to carry such fragile and natural active ingredients as vitamins and extracts. These nano-capsules are incorporated into, for example, cosmetic creams. When the user applies the cream to their skin, the PEPTICAPS technology takes advantage of the changes induced by damaged skin (such as a change in pH and the presence of enzymes) to release the nano-capsule's active ingredients where the skin needs it most.

Not only has the project produced a solution capable of better treating common skin conditions, it also demonstrated how this solution can be produced at an industrially-relevant scale and in accordance with cosmetic and safety regulations. "In just three years, we have successfully gone from a proof-of-concept to a fully-patented product that is market-ready," says Dupin.

The consortium partners have established EMISSARY Cosmetics, a new company that will commercialise the products developed during the PEPTICAPS project. The company has the exclusive rights to commercialise the nano-capsules with actives developed during the project and a full encapsulation service. "Through EMISSARY, PEPTICAPS are expected to replace liposome technology, thus becoming the gold standard for encapsulation in the cosmetic world and offering a better product to customers," adds Dupin.

7.29 STARNANO

Spheroids as a Tool to Assess Realistic long term effects of mixtures of nanomaterials and chemicals

Description
Among the many nanomaterials (NMs), graphene-related materials (GRM) have become a subject of intensive scientific and industrial interest. The exceptional mechanical, electrical, thermal and optical properties of these materials make them tremendously attractive for a multitude of different applications. To take advantage of these promising materials without hindering their innovation processes, specific safety issues for human health and the environment have to be addressed. GRM are inevitably released into the environment where aquatic systems tend to be their ultimate sink. Because of their particular physico-chemical properties, GRM are likely to interact with existing environmental contaminants. This may lead to remarkable changes in their fate and therefore bioavailability and impact on biota. Adverse

effects of some NMs on aquatic organisms, in particular fish, have already been reported. Although conventional in vivo tests have been routinely used to assess the potential risks of NMs to fish, European regulatory bodies encourage and favor the use of alternative methods for obtaining this kind of data. Isolated rainbow trout hepatocytes maintained in 3D cellular structure mimic the tissue/organ environment, thus represent a more powerful tool to investigate the in vivo effects of NMs. The main objective of the present project was to assess the combined effects of NMs and environmentally relevant pre-existing contaminants. To achieve this goal, two specific objectives were delineated:

- Specific Objective 1. To determine the mechanisms of toxic action of individual NMs or chemicals
- Specific Objective 2. Determination of the effect of co-exposure of one NM and an organic substance on their cytotoxicity

Discipline
Nanomaterials, Graphene, Mixtures

Pillar(s)
Research

SbD aspects
Research on mixtures and importance for multicomponent advanced materials, using graphene related materials (GRM) as a case study to develop a method to measure combined effects.

Expected Impacts and Outcomes
Once released into the environment, GRM due to their unique physicochemical properties, are likely to interact with other simultaneously present chemicals. Nevertheless, current risk assessments for regulatory purposes mainly rely on the evaluation of the effects of individual chemicals and they do not take into account the mixture toxicities. The present project addresses this issue and the information generated will have an impact on the knowledge about effects of GRM and about the combined NM-chemical effects on the organisms, which is crucial in the development of risk assessment approaches that contemplate the specificities of this kind of substances.

In addition, the generated information will facilitate the regulation and assessment processes of GRMs that are currently being produced or imported in Europe. This is strongly related with a positive economic impact of the project. At the same time, this project can have an important social impact by contributing to generate collective awareness about benefits and hazards of nanomaterials, helping therefore to an appropriate use of these substances.

7.30 NanoLabels

Labelling of engineered nanomaterials for nanosafety tracing

Description
There has been a notable rise in the development and production of engineered nanomaterials (ENMs) in recent years. However, concerns

still remains regarding their potential impact on environmental safety and human health. Despite much research effort devoted to nanosafety studies in the past 15 years, a mechanistic understanding of the action of ENMs remains limited. A particular challenge is the detection of ENMs in complex biological tissues and environmental media, and against high natural background levels of either namoparticulate matter (natural borne nanoparticles) or constituent elements (e.g. Cu, Zn, or Fe). Besides, ENMs are highly dynamic, and prone to transformation (physical or chemical) upon entering the environment or biological tissues. For example, some metal-based NMs (silver, copper, zinc oxide) may dissolve quickly or transform to structurally and/or chemically different phases. These processes further complicate the detection of ENMs.

A common solution for this problem involves the introduction of a tracer in the ENMs ("labelling"). A tracer maybe a fluorescence dye, a foreign element of low natural abundance, or a less-abundant isotope (stable or radioactive) of the same constituent element(s) of the ENM. Labeling with fluorescent dye or exogenous radioactive isotopes, however, possibly modify and change the surface chemistry of ENMs and thus alter their environmental and biological behaviour. The labels may also detach from the core ENMs and would thus not replicate the real behaviour of ENMs. Using radioisotope labelling is of more limited applicability due to the hazards involved in handling a radioactive substance. Compared with the labeling methods above, stable isotope labeling is safer and more versatile. The tracers may be detected using most commonly highly sensitive ICP-MS analysis (or other techniques that can distinguish isotopes of the same element, e.g. SIMS/nano-SIMS, thus providing very sensitive signals that could distinguish them from endogenous background elements in a variety of samples. Stable isotope labeling has no quenching issue of labels, thus is very suitable for life-cycle monitoring of various products and also conduct trophic transfer experiments.

The objective of NanoLabels is to assign "ownership" or "source" to ENMs using different labelling techniques thereby enabling tracing of them in environment. The project not only helps scientific community to understand fundamental questions in nanosafety, i.e. the biological and environmental behaviour (uptake, translocation, transformation) by improving the tracing ability, but also provide labelling strategy that can be adopted by industry to facilitate applications such as nanosafety assessments before ENMs enter the market and environment, as well as for product authentication and tracking.

Discipline
Multidisciplinary, Nano

Pillar(s)
Research

SbD aspects
Designing labels for nanomaterials to trace them in the environment which will help understand nanosafety and support the SbD concept.

Expected Impacts and Outcomes
The NanoLabels methodology succeeded at detecting the uptake of ENMs in the environment, even at a very low concentration. "The labelling methodology we developed in this project, which has been subsequently published in 'Nature Protocols', has put our 'stamp' on this developing field of research," says Valsami-Jones.

"It will also play a big part in educating the next generation of nanoscientists in using isotope labelling techniques."
Another important outcome of the project is scalability. "We expect that the scaling-up of the synthesis of stable isotope labelled ENMs could be tested, modified and standardised. It has the potential to be used in such industrial applications as the authentication of materials," Valsami-Jones explains.

Project researchers are currently developing labelling for carbon-based nanomaterials, such as carbon nanotube, graphene and microplastics. "With carbon being the most common element in the environment, the tracing of carbon-based nanomaterials is extremely difficult – so watch this space," concludes Valsami-Jones.

7.31 IZADI-NANO2INDUSTRY

Injection moulding, casting and coating PILOTS for the production of improved components with nano materials for automotive, construction and agricultural machinery.

Description
In IZADI-NANO2INDUSTRY conventional materials and injection moulding, casting and coating manufacturing processes will be improved by nanotechnology and will be combined to enable industrial scale production of new performance-enhanced components.

IZADI-NANO2INDUSTRY is built on and harvests the results of previous research projects, which include Plast4Future (FP7 FoF), EFEVE (FP7 FoF) OFIENGINE (FP6 SUSTDEV) and EXTREMAT (FP6-IP) all in TRL 5.

The project will establish the value chain for nanomaterial enabled improved performance products, and finally will validate the technologies through three components in industrial environment (TRL 7). Technologies and strategies based on nano-reinforced materials, nanotextured surfaces and nanostructured-coatings that have been developed in the frame of these previous FP6 and FP7 projects will be further implemented in real manufacturing production plants.

Strategy

Discipline
Multidisciplinary, Nano

Pillar(s)
Research, Industry

SbD aspects
Replacing toxic or hazardous substances by less hazardous or less reactive substances.

https://www.izadinano2industry.eu/

Expected Impacts and Outcomes
Izadi-Nano2Industry proposes different solutions based on KETS such as nanotechnology, advanced materials and advance manufacturing that are implemented in three innovative PILOTS (ESTCRATCH, HARDcast and TRIBOnano). Each Pilot manufacture new performance-enhance components, integrating SbD approaches into all the development stages.

In ESTCRATCH Pilot, nanoreinforced thermoplastic based on masterbatches and inserts for
injection moulds with nanotextured surfaces are used to produce innovative aesthetic parts for the automotive sector with both excellent mechanical properties and appearance, and light, weathering and scratch resistance (+50% material resistance, -20% component cost, improved recyclability, greener production process, more colour and functionality).

In HARDCAST Pilot, nano-reinforcements are added and dispersed via master-pellets. It is a new, low cost and safe gravity casting process concept to cast metallic components with improved durability and wear resistance (+15% component efficiency, -15% of power losses, +15% of wear/temperature).

In TRIBONANO Pilot, nanostructured powders for metallic cermet coatings and thermal spray technology for solid state deposition are combined to have more durable metallic parts in a more efficient way (+10% wear resistance, -20% of costs associated to the finishing of the component, -15% mechanical friction losses, -15% of material used).

7.32 NanoERA

Nanomaterials Ecological Risk Assessment: A study of the long-term effects and risks of nanoscale Iron Oxide used in plastic composites in the aquatic environment

Description
Nanomaterials are part of many consumer products, but the future of the field depends on ensuring their safe use. For example, nanoscale copper phthalocyanine (n-CuPc) is a pigment widely used in paints to enhance automobile coatings and make colours transparent and more appealing to users. This use can potentially lead to n-CuPc release and induce occupational as well as environmental risks.

Presently, very little is known about the biological interactions and the ecological risks of nanoscale Cu-Pchalocyanine. Therefore, the goal of NanoERA is to develop concepts and methods, and to generate data to predict the long-term ecological effects and risks of nanoscale Cu-Pchalocyanine in the aquatic environment and human health.

In order to achieve this, the fellow will analyse how the physicochemical properties of the nanoscale Cu-Pchalocyanine change in environmental (i.e. freshwater and sediment) and biological (cell culture) media and how these changes affect the biological interactions of these materials. The generated (eco)toxicological effects data will be used to derive dose-response relationships and to quantitatively estimate the long-term ecological risks of the nanoscale Cu-Pchalocyanine.

Strategy

Discipline
Nano safety research, (eco)toxicity

Pillar(s)
Research

SbD aspects
To develop concepts and methods, and to generate data to predict the long-term ecological effects and risks of nanoscale Cu-Pchalocyanine in the aquatic environment and human health.

http://www.ecraunit.com/nanoera/

Expected Impacts and Outcomes
This is the first report concerning the cytotoxicity of released n-CuPc from automobile coatings to macrophages. We are first to study the cross-linked, isocyanate-hardened matrix that is typical for coatings and is quite different chemistry than the soft polymer binders used in paints, epoxy or thermoplastics. We are the first to study copper-containing nanomaterial fillers, which a priori could result in quite different response than carbon nanotube (CNT) fillers or TiO2 fillers in the (few) previous studies of fragment toxicity. Further, we combined assessment of both the release of nanoparticles in realistic conditions and the evaluation of hazard of the released fragments, specifically by using a macrophage model. In a preliminary risk screening, we evaluated the human risk to workers through the whole life cycle of the product. The study is thus very important to the automobile industry since it assesses the potential risk to the workers employed in this sector.

7.33 MolNANOtox

Nanomaterial surface interactions at the molecular level and their impact on ecotoxicity

Description
Nanotechnology has revolutionised many industries. Engineered nanomaterials (ENMs), the small, nanoscale materials at the heart of this technology, have novel and unique properties that drive the nanotechnology industry. However, increasing ENM abundance and availability has led to concerns regarding the risks they may pose to the environment. Significant advances have been made towards understanding ENM core chemistry, behaviour and transport, but a knowledge gap exists regarding their surface chemistry and its evolution in the environment, and how this may impact interactions with living organisms. In particular, the dynamic, environmentally-acquired surface coating called the "eco-corona" is a new concept that has seen little exploration until recently. The coating formed may be composed of entities right from small ions or molecules to large macromolecular material such as natural organic matter, and may have different attachment modes and strengths. Since ENMs have a high specific surface area and surfaces play a major role in ENM interactions and reactivity, understanding their surface chemistry is important in a comprehensive assessment of ENM fate and impact.

The overall objective of the project was to characterise the fundamental interactions occurring at the surface of ENM and its impact on environmental ENM chemistry and bio-nano interactions with a range of analytical and imaging techniques. The project focused on the exploration of Raman spectroscopy and surface-enhanced Raman spectroscopy (SERS) as a novel application to probe the surface

chemistry of ENMs in the context of eco-corona formation, as well as the application of a multimodal approach to imaging the bio-nano interactions.

Discipline
Nano safety research, (eco)toxicity

Pillar(s)
Research

SbD aspects
Using spectroscopy to characterise the surface coating of engineered nanomaterials (ENM) to understand the bio-nano interactions and impact on the environment.

https://www.ceh.ac.uk/our-science/science-areas/pollution

Expected Impacts and Outcomes
Our understanding of the environmentally acquired coatings on ENMs is still in its infant stages. The data in the first Task Set enables us to recognise that Raman spectroscopy and SERS can be utilised to probe ENM surface interactions that may affect their stability in environmental systems. It also confirmed the role of chloride in Ag-NP dissolution and the protective role humic acids can play. Therefore, while there are limitations, this is one of the few techniques that are able to gain chemical data selectively from the surface and is likely to be important for investigating Ag-NPs and other ENMs in an ecotoxicological context.

The impact of these coatings, or the "eco-corona", on the ENM interactions with biota is also an emerging research area. The advantage of Raman spectroscopy where one can analyse ENMs in water makes it a highly promising method to explore in environmental nano(eco)toxicology. Combined with the multimodal imaging approach demonstrated in the second Task Set, we will be able to examine the potential effect of the surface chemistry on environmental bio-nano interactions. These capabilities will contribute directly to understanding the overall impact of ENMs in the environment and, in the future, towards engineering their properties for safe and beneficial use for the environment and society. During the project collaborations with larger EU H2020 projects on environmental fate (NanoFASE) and advanced characterisation (ACEnano) have let the findings of this fellowship flow directly into initiatives that will develop robust and more affordable analytical techniques and equipment to inform us on the fate of ENMs in the environment to help deliver safe industrial progress and new products benefitting society economically and functionally.

7.34 BASMATI

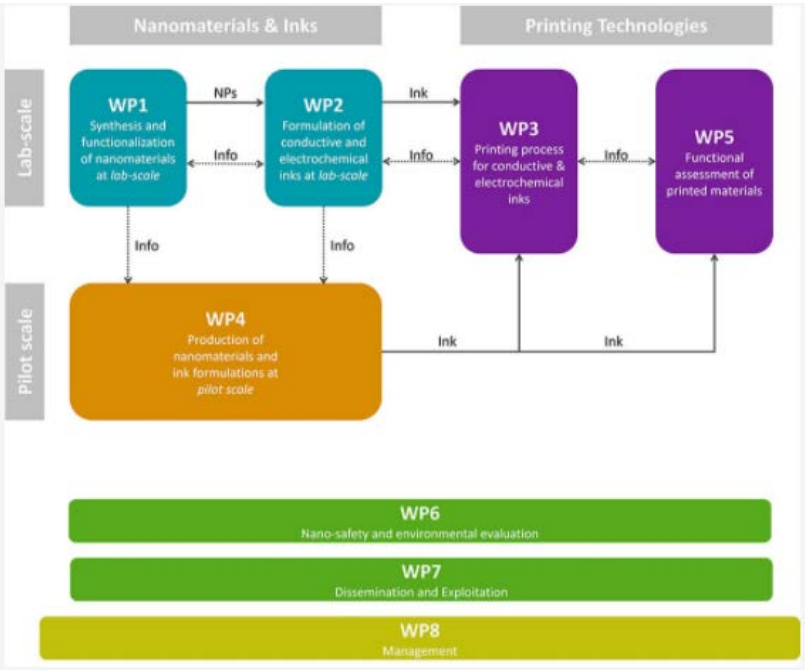
Bringing innovAtion by Scaling up nanoMATerials and Inks for printing

Description
BASMATI addresses the development of active nanomaterials and their formulation in conductive and electrochemical inks for screen and inkjet printing. As a case study, these functional inks will be applied in a

printed thin film battery. BASMATI's general objective is to develop pilot lines for material synthesis and ink formulation, ensuring large volume fabrication of new products with improved properties for printing. Furthermore, the project investigates new sources of nanomaterials for conductive and electrochemical inks. Nanosafety issues concerning these novel active materials are carefully considered in BASMATI.

With the knowledge achieved by the research groups and its transfer to pilot lines by SMEs and industrial partners, BASMATI will pave the way for the industrial production of functional inks for mass applications such as printed electronics.

Strategy



Discipline
Battery research, Nano

Pillar(s)
Research, Industry

SbD aspects
Recommendation of best practices and safe design of active nanomaterials in conductive and electrochemical inks for screen and inkjet printing.

http://www.basmati-project.com/

Expected Impacts and Outcomes
The project will overcome technological and economic barriers inherent to the availability of inks for printed electronics:

- Supply of low cost conductive inks: reduction of 50% compared with current silver based inks

- High availability: production of relevant quantities of electrochemical (150 kg/batch) and conductive inks (350 kg/batch)
- Compatibility with high definition printing processes: different inks will be developed both for high throughput (screen printing) and for high resolution (inkjet printing) printing technologies
- Nanosafety guidance will be carefully applied at all steps of powder synthesis and ink formulation
- Ink formulations involving water based and non-toxic solvents will be studied.

The project covers two kind of nanomaterials inks:
- Conductive inks based on Cu and Ni will be suitable as a low cost alternative to silver for a large range of applications (RFID, photovoltaic, sensors, vehicles, smart packages).
- Electrochemical inks will be targeting printed energy storage applications (printed electrodes, thin-film printed batteries).

The project consortium brings together the whole industrial value chain covering nanomaterials inks formulation and upscale (nanomaterials synthesis, ink formulation, ink production, printing equipment manufacturing and end-user). Collaboration between all stakeholders in the value chain will enable a better integration of the different technologies developed in the project facilitating the industrial take-up of ink productions in printed device applications.

7.35 ToxEcoGraphene

Assessment of ecocorona acquired by Graphene Family Nanomaterials during exposure to biofilms and fate following uptake

Description
The increasing integration of high-performance advanced materials and nanotechnology in everyday life applications imposes a pressing need to shed light not only on the fundamental nanomaterial features and properties, but also on the environmental processes that will determine their distribution and fate in the environment. Graphene Family Nanomaterials (GFN) are undoubtedly some of the most promising nanomaterials developed to date, combining unique features and physicochemical properties that can be exploited in a plethora of applications. Given the serious concerns raised over the potential impact of GFN on the environment, and in order for GFN nanotechnology to develop in a sustainable manner, it is crucial to ensure that development of GFN takes place alongside research focused on its consequences for public health and potential environmental impacts. One major objective of the project was to develop, characterise and utilise GFN-oriented protocols and methods to facilitate investigation of fate and transport in natural complex media. Various physicochemical properties were studied, including the flake dimensions, particulate state, surface chemistry etc. Investigation of GFN fate in natural media has been conducted by focusing on the aggregation kinetics and stability of GFN in aquatic environments. The evaluation of GFN toxicity to biofilms was another objective, by focusing on hetero-aggregation and eco-corona growth on GFN surface and assessing changes in community structures

as a function of exposure concentrations and durations. Aquatic systems include a complex heterogeneous plethora of several types of organic molecules, ranging from humic substances to polysaccharides and proteins, briefly described as natural organic matters. Thus, GFN environmental fate, including transport, stability, dissolution, bioavailability, and ecotoxicity is strongly depended on the interaction between them. Another main objective was the implementation of the main research conclusions in order to mitigate identified environmental impact and design-out potential hazards related to GFN technology and applications. Graphene family nanomaterials have a great potential to become a key solution for advanced composite materials with enhanced properties and applicability in a wide range of application sectors. Several crucial aspects related to the impact of GFN and nanomaterials in general need to be addressed through European Union policies and a coherent regulatory framework supported by effective standards.

Discipline
Multidisciplinary, Nano, Graphene

Pillar(s)
Research

SbD aspects
Evaluation of environmental fate of graphene for SbD applicability.

Expected Impacts and Outcomes
Graphene nanomaterials have a great potential to become a key solution for advanced composite materials with enhanced properties and applicability in a wide range of industrial sectors and commercial products. The project aimed to address many theoretical and experimental issues related to the research on the nanoecotoxicological impacts of GFN and tried to place emphasis on environmentally relevant species and conditions The project's impact involves the importance of the environmental transformation processes in order to assess the risks. By conducting interdisciplinary research simultaneously the project offered novel insights and advanced the state-of-the art in the field of nanoecotoxicology of GFN. This was achieved through the adoption of a theoretical and analytical approach covering aspects of materials science, nanotechnology, ecotoxicity. The project outcomes have the potential to advance our understanding in GFN ecotoxicological impacts. Overall, the project aimed to provide to EU nanotechnology-related industry and other stakeholders with valuable knowledge and datasets to support related regulations. Also, the protein-corona investigation can provide important hints in the nanomedicine applications of GFN. Knowledge obtained in this project, can lead to SbD tailoring of the physicochemical properties of GFN and can therefore increase their applications potentials and reduce environmental impact.

7.36 NanoBBB

Transport of Engineered Nanomaterials across the blood-brain-barrier

Description
This project will allow us to systematically understand the behaviour and fate of certain engineered nanomaterials (ENMs) in brain and contribute to safer design of ENMs. Nano blood brain barrier (BBB) also offers placements in industry for the on-a-chip technology development and an NGO to host the in-vivo experiments enabling validation of the model.

Discipline
Multidisciplinary, Nano

Pillar(s)
Research

SbD aspects
Understanding the behaviour and fate of ENMs in the brain and contribution to safer design of ENM.

7.37 EU-ToxRisk

An Integrated European 'Flagship' Program Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st Century

Description
The vision of EU-ToxRisk is to drive the required paradigm shift in toxicological testing away from 'black box' animal testing towards a toxicological assessment based on human cell responses and a comprehensive mechanistic understanding of cause-consequence relationships of chemical adverse effects. EU-ToxRisk will integrate advancements in cell biology, omics technologies, systems biology and computational modelling to define the complex chains of events that link chemical exposure to toxic outcome. The consortium will provide proof of concept for such a mechanism-based chemical safety testing strategy. The focus of this project is on two areas: repeated dose systemic toxicity, using the lung, kidney, liver and nervous system as examples of potential target organs; and developmental and reproductive toxicity. It will also provide guidance for its universal application, allowing to push the entire field forward in an integrated manner. The ultimate goal is to deliver testing strategies to enable reliable, animal-free hazard and risk assessment of chemicals.

Strategy
The EU-ToxRisk work plan is structured along a broad spectrum of case studies, driven by the cosmetics, (agro)-chemical, and pharma industry together with regulators and specialists from academia. Different human tiered test systems are integrated to balance speed, cost and biological complexity. The project's methodology can be summarised under the four following themes, which the Work Packages (WPs) – that make up the project – respectively feed into:

1. Datababase requirements & design: The project combines in silico tools and in vitro assays by computational modelling approaches to provide quantitative data on the activation of Key Events (KE) of Alternative Outcome Pathways (AOPs). This information, together with detailed toxicokinetics data, and in

vitro-in vivo extrapolation algorithms forms the basis for improved hazard and risk assessment.

2. Systems toxicology/biology, AOPs: EU-ToxRisk extensively integrates the AOP-based toxicity testing concept, by identifying and quantitatively describing the AOPs which link the effects of EU-ToxRisk test compounds to apical endpoints and to adverse effects in humans. Established and novel assays will generate concentration and time course responses for all project chemicals to ultimately derive the Point of Departure (PoD). The in vitro data obtained in WP5-WP9 will provide WP11 (see below) with AOP-based thresholds and/or PoDs for individual chemicals.
3. Test system evaluations: Advanced technologies, including high-throughput transcriptomics, RNA interference, and High Content Imaging, will provide quantitative and mechanistic underpinning of AOPs and KE. The approach involves iterating training, testing, optimisation and validation phases to establish fit-for-purpose integrated approaches to testing and assessment with key EU-ToxRisk methodologies.
4. Risk assessment and uncertainties: The project integrates input from relevant stakeholders (i.e. risk assessors working in different regulatory contexts like cosmetics, pesticides, drugs and chemicals) so as to evolve modern theoretical concepts underpinning the approach for risk assessment in order to achieve practical applications fit for risk assessment. Hazard assessment will be performed by the use of Integrated Approaches to Testing and Assessment (IATAs) comprising in silico and in vitro methods.

Discipline
Toxicity

Pillar(s)
Research, Industry

SbD aspects
EU-ToxRisk will integrate advancements in cell biology, omics technologies, systems biology and computational modelling to define the complex chains of events that link chemical exposure to toxic outcome. This can be useful to apply SbD in the future.

http://www.eu-toxrisk.eu/

Expected Impacts and Outcomes
EU-ToxRisk aims to instigate a paradigm shift in human safety evaluation of chemicals. Five distinct impacts were identified to reach this objective. Impact 1: more effective, faster, and cheaper toxicological testing to predict human risks and meet regulatory needs. The consortium planned to achieve this by developing an Integrated Approach to Testing and Assessment (IATA) based on a systems toxicology approach. Work from CSs has informed a key publication that will detail the strategy for improved read across assessment by incorporating data from in vitro and in silico methods. Close collaboration with the RAB will ensure that EU-ToxRisk strategies are in line with regulatory needs. A read-across workshop assessing several

CSs and their regulatory relevance in depth will take place in collaboration with international regulatory agencies, including ECHA, EFSA, OECD, US-EPA and US-NTP. This will culminate in a guidance document and web-based toolkit for NAM-based safety assessment. Impact 2: improved toxicological knowledge to encourage and improve read-across procedures. The initial set of CSs focused on read-across procedures supported by NAMs. CSs have generated a wealth of data utilised in "mock" submissions, where a read-across argument was prepared according to guidance by the RAB. These mock submissions are under assessment for regulatory acceptance by RAB members. The generation of more than 15 novel AOPs has supported CS read-across procedures. Impact 3: commercial exploitation of the developed toxicological tests, tools and services. The EU-ToxRisk battery of in vitro methods was defined and is currently undergoing systematic comparative testing. Testing of all project methodologies and the use of RNA sequencing has generated a deeper understanding of the test systems and their utility. These tests are now being applied in a CS funded entirely through industry, thus making a big step towards commercial exploitation of EU-ToxRisk project outcomes. Impact 4: advancement of international co-operation in the field of toxicology and safety testing. The EU-ToxRisk consortium has continued working with the US Tox21 group, and has signed a formal collaboration agreement with the European Commission's JRC. In addition, EU-ToxRisk started to interact with the US FDA and will collaborate on state-of-the-art high-throughput transcriptomics technologies involving the US EPA as well as Tox21. Impact 5: reduced use of laboratory animals in safety testing. While first steps were made to implement animal-free hazard assessment strategies for RDT and DART, improved read-across procedures or IATAs for RDT and DART are expected to help companies fulfilling some of their regulatory requirements without additional animal experiments.

7.38 SOS-Nano

Structure – Oxidative Stress relationships of metal oxide nanoparticles in the aquatic environment

Description

The SOS-Nano project addressed one of the most pressing cutting-edge issues of econanotoxicology: to find a structural property of nanoparticles (NPs) to predict their potential toxicity in marine aquatic environments. By using an in vivo exposure system, the SOS-Nano project tested the suitability of two paradigms for ranking the hazard of metal oxide NPs: 1) NPs physical-electrochemical properties (i.e. bandgap energy and dissolution) for predicting oxidative stress potential, and 2) oxidative stress generation for predicting biological impact.

The specific goals during the project to reach the main objective were:

- To screen the validity of Bandgap-Dissolution Paradigms over a set of model- metal oxide NPs;
- To assess the influence of natural organic matter (NOM) on the potential for metal oxide NPs to promote oxidative stress in aquatic environments;

- To explore the influence of salinity on the potential for metal oxide NPs to generate oxidative stress in aquatic environments.
- To estimate the longer-term hazard of metal oxide NPs in aquatic environment under realistic scenarios.

The results obtained by SOS-Nano are of high impact for the European Union policy and the overall society. Nanotechnology is one of the six EU Key Enabling Technologies selected by the EU Commission to address the industrial-economic competitiveness and the grand societal challenges in Europe by 2020. The SOS-Nano results add important new information to enable the establishment of a suitable risk assessment of these nanomaterials in the natural environment.

Discipline
Ecotoxicology

Pillar(s)
Research

SbD aspects
Investigating the Structure – Oxidative Stress relationships of metal oxide nanoparticles in the aquatic environment.

https://www.exeter.ac.uk/research/marine/

Expected Impacts and Outcomes
The relevant research outcome of the SOS-Nano project responded to some of the most pressing scientific needs to achieve appropriate NPs risk assessment, a fundamental goal of the EU policies toward the safe development of nanotechnology. The specific impact of each result on economical-regulatory aspects of EU policies is detailed below.

- Mechanistic understanding of metal oxide NPs hazard in real aquatic environments. This can support the prediction of the toxicological impact of other metal oxide NPs sharing some proprieties found as pivotal for the actual toxicological activity in seawater. Furthermore, it can support the design a future generation of nanomaterials whose intrinsic structure guarantees the missing of their toxicological potential once in the environment.
- Novel paradigms for predicting the toxicological impact of metal oxide NPs in the environment. The research evidence obtained for the bandgap model NPs calls for the reappraisal of this paradigm within the scope of the environmental risk assessment. The mechanistic understanding of the role of the sorption capacity on the overall oxidation potential of NPs can lead the formulation of a new paradigm or to the correction of the bandgap paradigm when specifically applied to the marine environment.
- Experimental data on NPs behaviour, fate and impact under realistic scenarios. The SOS-Nano project collected a comprehensive database crossing the primary physico-chemical proprieties of three NPs with 1) their secondary proprieties and oxidation activity in seawater, 2) their actual ingestion and cellular internalization, and 3) their toxicological effects in oyster

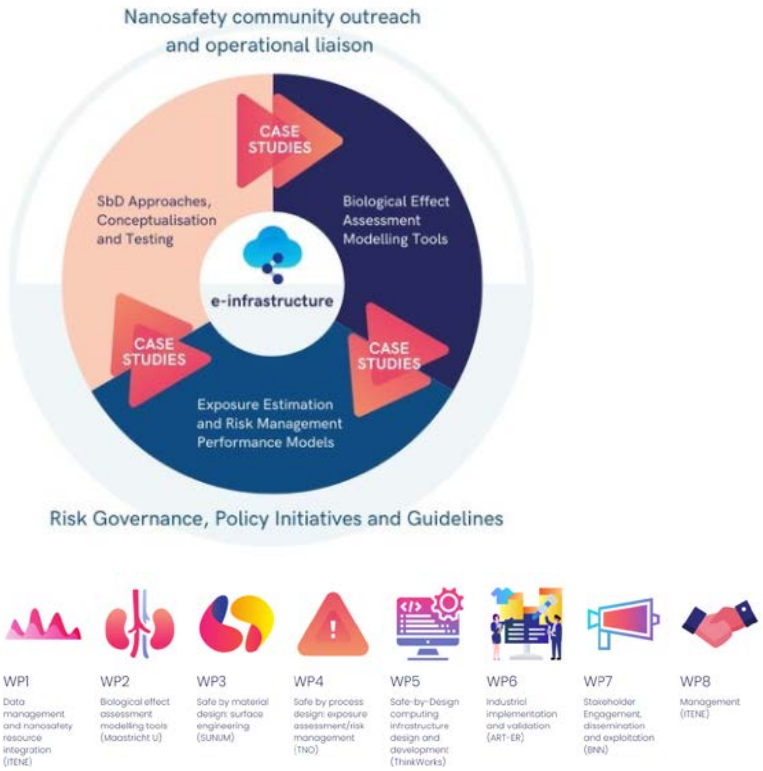
embryo-larvae. This inclusive database is available to the research and regulatory community for all purposes (including modelling).
- Innovative multi-tier testing strategy for ranking NPs hazard. The multi-tier testing strategy set by the SOS-Nano project is available to the research and regulatory communities for use. Thanks to its flexible structure, it allows for future improvement and/or tailoring toward more specific toxicological responses.
- High-throughput exposure designs for screening NPs toxic potential in vivo. The SOS-Nano highlighted high potential for NPs exposure and a remarkable sensitivity of oyster embryo-larvae, making this model a valuable candidate for regulatory testing.

7.39 SbD4Nano

Computing infrastructure for the definition, performance testing and implementation of SbD approaches in nanotechnology supply chains

Description
A major challenge for the global nanotechnology sector is the development of safe and functional engineered nanomaterials (ENMs) and nano-enabled products (NEPs). SbD4Nano addresses that problem by creating a comprehensive new e-infrastructure to foster dialogue and collaboration between all actors in the supply chain for a knowledge-driven definition of SbD setups that minimise hazards while optimising technical performances and economic costs.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry

SbD aspects
Creating an infrastructure to foster dialogue on SbD setups between all actors in the supply chain.

https://www.sbd4nano.eu/

Expected Impacts and Outcomes
- SbD approaches and tools at an early stage of the nanomaterial development process
- Quality workplaces that ensure maximum technical and economic performance in line with acceptable risk levels
- Control and mitigate exposure after release of NMs from products
- Develop and validate low-cost techniques for delivering an integrated exposure driven risk assessment and the associated design of the required post-use monitoring
- Increased innovation capacity and industrial competitiveness
- Foster international cooperation and open science
- Positive impact on human health, environment and EU policy

7.40 MODCOMP

Modified cost effective fibre based structures with improved multi-functionality and performance

Description
MODCOMP aims to develop novel engineered fibre-based materials for technical, high value, high performance products for non-clothing applications at realistic cost, with improved functionality and safety. Demonstrators will be designed to fulfil scalability towards industrial needs and focus on TRL5/TRL6. End users from a wide range of industrial sectors (transport, construction, leisure and electronics) will adapt the knowledge gained from the project and test the innovative high added value demonstrators.

Strategy

Discipline
Chemistry

Pillar(s)
Research, Industry

SbD aspects
Developing fibre-based materials with improved safety and functionality.

http://modcomp-project.eu/index.html

Expected Impacts and Outcomes
Current technological demands are increasingly stretching the properties of traditional materials to expand their applications to more severe or extreme conditions, whilst simultaneously seeking cost-effective production processes and final products. The aim of this project is to demonstrate the influence of different surface enhancing and modification techniques on carbon fibre (CF)-based materials for high value and high performance applications. These materials are a route to further exploiting advanced materials, using enabling technologies for additional functionalities, without compromising structural integrity. CF based materials have particular advantages due to their lightweight, good mechanical, electrical and thermal properties. Current generation CFs have extensively been used in a multitude of applications, taking advantage of their valuable properties to provide solutions in complex

problems of materials science and technology. The limits of the current capability of such materials, however, have now been reached. MODCOMP will develop the next generation of CF-based materials for structural and electronics applications. The benefits of fibre-based materials have clearly been shown in aerospace applications which require lightweight, high strength, high stiffness, and high fatigue-resistant materials.

7.41 LEE-BED

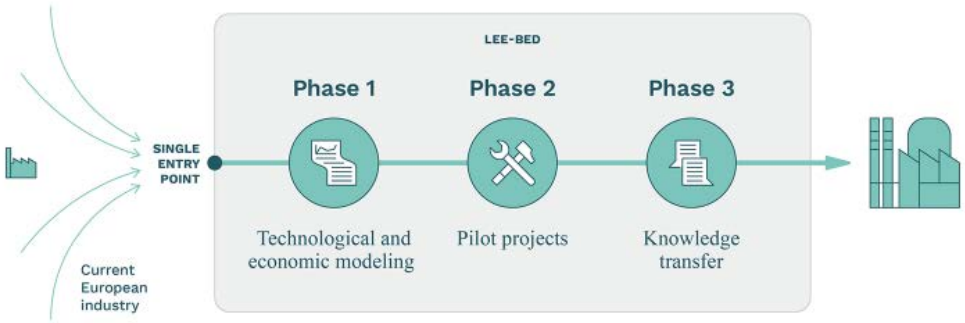
Innovation test bed for development and production of nanomaterials for lightweight embedded electronics

Description
The concept of the test bed is depicted in the image below. At the single entry point stakeholders receive a techno/economic and safety assessment, in order to determine the benefits of bringing novel nanomaterials for embedded electronics into their products and production lines. If the assessment is positive, stakeholders have the opportunity to perform a pilot project in phase II.

Phase II is represented mainly by well-established large RTOs. These RTOs will provide infrastructure to make pilot projects based on phase I modeling and assessments.

Finally, successful pilot projects will go through phase III and receive a final knowledge transfer, consisting of IPR discussions and final business plan check.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research

SbD aspects
Establish an Open Innovation Test Bed to de-risk and accelerate the development and manufacturing of nanomaterials and lightweight embedded electronics for the benefit of European industry.

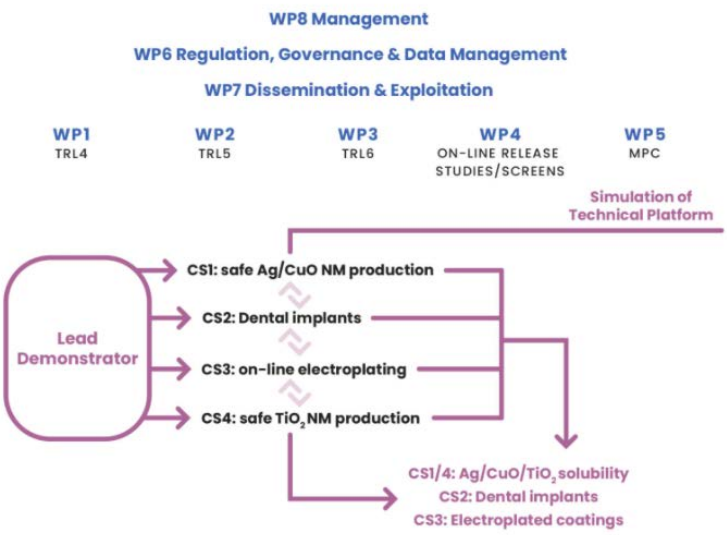
https://www.dti.dk/specialists/innovation-test-bed-for-development-and-production-of-nanomaterials-for-lightweight-embedded-electronics-lee-bed/38965

7.42 SABYDOMA

Safety BY Design Of nanoMaterials - From Lab Manufacture to Governance and Communication: Progressing Up the TRL Ladder

Description
High-performance engineered nanomaterials hold great promise for a variety of fields including medicine, electronics and energy. To achieve scalable quantities of nanomaterials that are safe to use, new methodologies for nanomaterial synthesis need to be explored, which will investigate the impact of nanomaterials on humans and the environment at the start of the process. One of the main goals of the EU-funded SABYDOMA project is to build high-throughput online platforms where nanomaterials are manufactured and screened at the point of production. Another goal is to extend the impact of SbD nanomaterials to real-world situations. The project will examine four industrial case studies set up by four industrial partners to advance the technology readiness level from 4 to 6.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry/Strategic Positioning

SbD aspects
Building a high-throughput online platforms where nanomaterials are manufactured and screened at the point of production.

https://www.sabydoma.eu/

Expected Impacts and Outcomes

1. To model all SbD protocols using the systems control and optimisation protocol with the MPC concept. To underwrite the new platform technologies with in silico modelling procedures which use data from screening and release studies to redesign the production process. In silico technology is already developed in nanosafety, and this objective aims to combine the in silico with the experimental technology to give a single platform in the production line
2. To design high throughput platform technologies which progress from TRL4 to 6 moving from the lab to the pilot line to apply the principles of SbD in the production of novel materials. The technologies at the lab level are designed according to a modelling protocol where results from high throughput screening and release studies feed back into the production line to manufacture NM with lower toxicity without impeding function. Screens will use an online platform with in vitro targets of increasing complexity from the 2D biomembrane to multiple cell-line and in vitro targets developed in current H2020 projects HISENTS and PATROLS respectively.
3. To design innovative technology to carry out short and long term release studies on NM and NM derived materials matching the theme of online flow through platforms.
4. To develop SbD technologies within the context of four specific industrial case studies involving the production, use and function of engineered nanomaterials (NM). These four case studies (CS) are:
   - Case Study 1: Coupling the HISENTS biomembrane screening model and other screening technologies direct to CuO and Ag production facilities to enable safe NM at output (Applied Nanoparticles SL);
   - Case Study 2: Production of chitosan-silicate coatings6 on in situ titanium dental implants. Release studies and high throughput in vitro screening results to feed back to and moderate implant production (RESCOLL);
   - Case Study 3: Electroplating of Ni / SiC and TiO2 composite coatings. Closed circuit electrolyte recirculation systems to allow electrolyte screening. Release studies on finished coating: results to feed back to coating formulation and production (Creative Nano PC); and,
   - Case Study 4: Flow-through synthesis of TiO2 NM (Nanotechcenter LLC).
5. To redesign the production lines in CS3 to an online high throughput mode to speed up the production process, to minimise volumes used, to lower costs and minimise waste contributing to a circular economy.
6. To maintain continuing communication with regulators and management, ensuring that SbD procedures are compliant and feed back to governance decisions within the aegis of the Stage-Gate process.

7.43 NanoQSAR

Structure-activity relationship modelling of REACH-relevant endpoints to predict the toxicity of engineered nanomaterials

Description
On the basis of the concept of the project, the main objective of the Nano-QSAR project is to develop new scientifically validated QSARs models to predict REACH relevant toxicological, ecotoxicological and environmental endpoints of a priority list of ENMs such as Metal Oxide Nanoparticles (MOx) and Quantum Dots (QD) on the basis of available literature and own experimental data.

Discipline
Toxicology

Pillar(s)
Industry

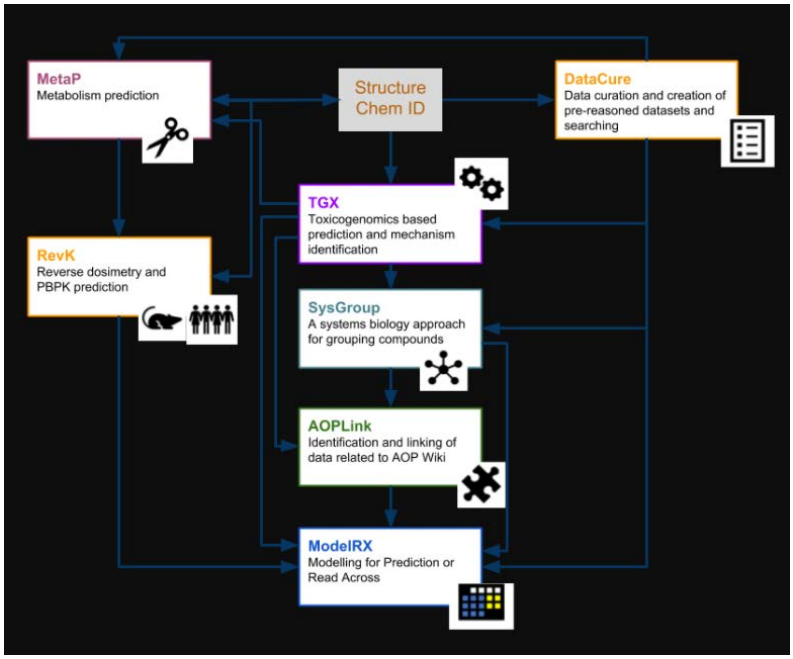
SbD aspects
Structure-activity relationship modelling to predict the toxicity of engineered nanomaterials for future SbD applicability.

7.44 OpenRiskNet

Open e-Infrastructure to Support Data Sharing, Knowledge Integration and in silico Analysis and Modelling in Risk Assessment

Description
OpenRiskNet is a 3 year project with the main objective to develop an open e-Infrastructure providing resources and services to a variety of communities requiring risk assessment, including chemicals, cosmetic ingredients, therapeutic agents and nanomaterials. OpenRiskNet is working with a network of partners, organised within an Associated Partners Programme.

Strategy



Discipline
Multidisciplinary

Pillar(s)
Research, Industry

SbD aspects
Providing an open e-Infrastructure resources and services to a variety of communities requiring chemical risk assessment, including chemicals, cosmetic ingredients, therapeutic agents, and nanomaterials, needed for SbD applicability.

https://openrisknet.org/

Expected Impacts and Outcomes
OpenRiskNet played an important role and has an impact in five main areas: developing an innovation-driven knowledge infrastructure, enabling the access to data and modelling tools, support scientific advancements in risk assessment, community impact and impact of standards and ontologies.

The OpenRiskNet knowledge base and systems modelling platform provides users with the necessary tools to develop, curate, analyse and compare systems-level toxicological models for human and animal systems. The focus of the project has been to offer users simple means to instantiate and maintain VEs on cloud-agnostic infrastructures, the standards and middleware to enable and sustain interoperable deployment of data and services and at the same time reducing the technical complexity for performing these deployment operations and adhering to state-of-the-art open standards and technical concepts.

OpenRisknet enabled easier access and sharing of integrated approaches in the form of workflows all the way from data collection to reporting opens up new opportunities by advancing our knowledge of the relationship between toxicity, architecture, function and risk. The OpenRiskNet infrastructure is optimally suited to support the scientific advancements in risk assessment, as demonstrated in the case studies by providing a platform and solid foundation for toxicology and risk assessment based on a refined theory of Heterogeneous Evidence including effects, interactions, kinetics, scales, dynamics and uncertainty implemented into our practical framework.

Our community impact activities were targeting into two directions: to strengthen the interdisciplinary community of practice focusing on data and in silico aspects of predictive toxicology and chemical/nanomaterial risk assessment and to establish toxicology as one of the important communities in the pan-European e-infrastructure landscape by collaborating with the major infrastructure activities like EOSC and providing services on these platforms.

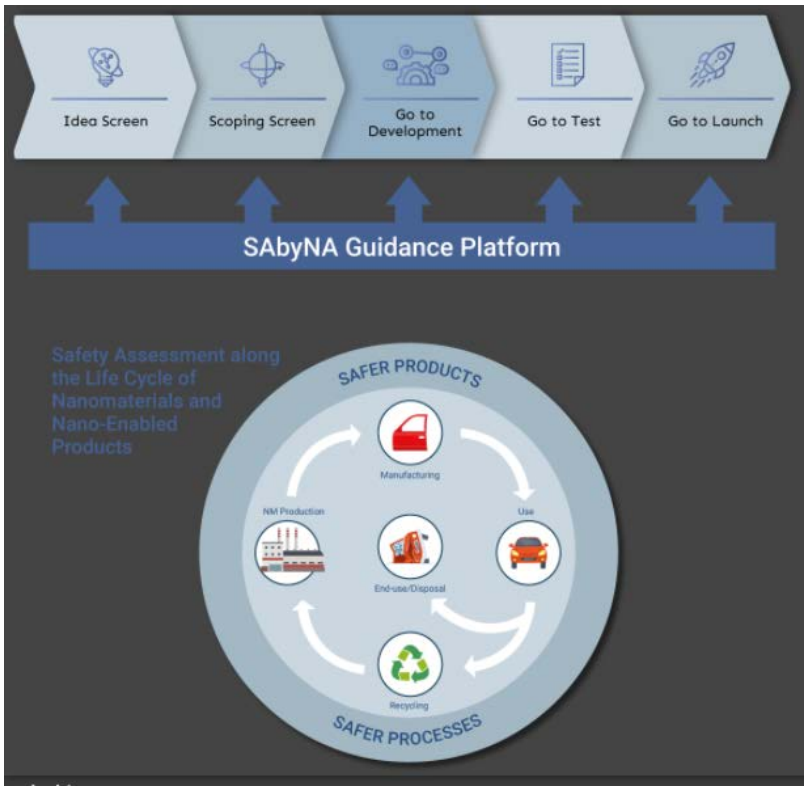
OpenRiskNet data resources and software services are aligned with the activities of international projects leading the development of open standards for predictive toxicology resources like the EU NanoSafety Cluster, OpenTox, NanoCommons and the US Nano Working Group and at a larger scale with ELIXIR and EOSC. The exchange with these groups ensures that OpenRiskNet reuses standards wherever possible and that OpenRiskNet also contributes to standards by putting forward project results to the most suitable international bodies.

7.45 SAbyNA

Simple, robust and cost-effective approaches to guide industry in the development of safer nanomaterials and nano-enabled products

Description
SAbyNA aims to provide the industry with a user-friendly, customised and integrative guidance platform to support the development of SbD nanomaterials and nano-enabled products. The SAbyNA guidance platform will integrate various available resources such as methods, models, frameworks and tools to reduce complexity and costs. Users will be able to identify the potential risks, be able to establish optimal workflows and find solutions to reduce or mitigate the risks associated to their innovation process.

Strategy



Discipline
Multidisciplinary

Pillar(s)
Industry/Strategic Positioning

SbD aspects
Making a platform which will allow users to identify potential risks in their innovation process

https://www.sabyna.eu/

Expected Impacts and Outcomes

1. Map and establish hierarchies of the most relevant existing resources that can support safe by design of nanotechnology
2. Establish simple, robust and cost-effective human and environmental hazard, exposure, and risk assessment strategies
3. Improve usability of existing tools for risk identification and risk assessment (i.e. GUIDEnano)
4. Propose safe by design strategies to eliminate or reduce risks at the design stage of a product or production process
5. Develop SAbyNA guidance platform integrating selected resources to propose safe by design strategies to maximise safety while maintaining functionality
6. Implement and validate the applicability of the SAbyNA guidance platform in 3D printing and paints

7.46 PRORISK

Best chemical risk assessment professionals for maximum Ecosystem Services benefit

Description
Once based on simplified descriptive laboratory tests, environmental risk assessment now incorporates mechanistic, ecological and socioeconomic process information. This is making it more comprehensive, realistic and relevant. The EU-funded PRORISK project will create a platform for training a network of early-stage researchers in this field. As future experts, the researchers will be trained to address the challenges of the risk assessment paradigm shift. Specifically, the project will develop and integrate mechanistic understanding, in-depth analyses of chemical-biological interactions and exposure, and functioning of ecosystems. The goal will be to empower the researchers to develop new regulatory missions protecting ecosystem services.

Discipline
Multidisciplinary

Pillar(s)
Education, Industry

SbD aspects
Training in advanced environmental risk assessment for future SbD application.

7.47 SeeingNano

Developing and Enabling Nanotechnology Awareness-Building through the Creation and Exchange of enhanced Communication and Visualisation Tools and Guidance for 'Seeing at the Nanoscale'

Description
The SeeingNano Project is creating Novel Visualisation Tools for Enhanced Nanotechnology Awareness to provide the public with an ability to 'seeing at the nanoscale', and an understanding and awareness for the breadth of nanotechnologies, and the uncertainties and potential risks connected to them.

Once fully developed, the SeeingNano Visualisation Tools will be made available to the wider community on an online platform where the tools and guidance documents will be available for download.

Discipline
Multidisciplinary, Nano

Pillar(s)
Strategic positioning

SbD aspects
Creating awareness of nanomaterials in citizens by creating a mobile app which allows using augmented reality to visualise nanomaterials in real life.

http://www.seeingnano.eu/

Expected Impacts and Outcomes
SeeingNano has contributed to raising the awareness of European citizens on nanotechnology and enhanced their understanding through publicly available material. The tools generated during the project are available for people to download and can be readily used in different settings for nanotechnology teaching and education.

The tools developed in the project apply novel techniques such as augmented reality for users to 'see at the nanoscale'. By simply pointing an Android or Apple mobile device to a marker and moving forward, the user is invited to dive into three dimensional models and microscope images of three different modules. For those who want to dig further, each module of the application is supported by an explanation of the science behind it.

SeeingNano also contributed to supporting the good governance of nanotechnology as the Profiler, the Explanimation and the background information provided to support the science behind SeeingNano (the Lexicon and the Glossary) are the tools that highlight the good governance in nanotechnology. The Explanimation explains the risks and hazards associated with nanotechnology and the ways in which scientists are addressing them.

Finally, the project helped and will continue helping with communicating nanotechnology. It can be used as a teaching aid in a number of settings, including classrooms, museum exhibitions or as a stand-alone web accessed toolset for self-education

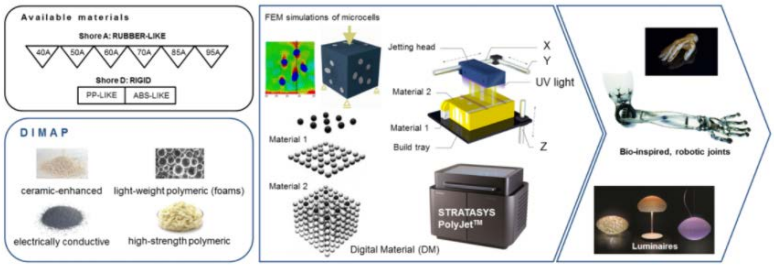
7.48 DIMAP

Novel nanoparticle enhanced Digital Materials for 3D Printing and their application shown for the robotic and electronic industry

Description
The DIMAP project focuses on the development of novel ink materials for 3D multi-material printing by PolyJet technology. We will advance the state-of-the art of AM through modifications of their fundamental material properties by mainly using nanoscale material enhanced inks. This widens the range of current available AM materials and implements functionalities in final objects. Therefore applications will not be limited to rapid prototyping but can be used directly in production processes. DIMAP will show this transition in two selected application fields: the production soft robotic arms/ joints and customised luminaires. In order to cope with these new material classes the existing PolyJet technology is further developed and therefore improved. The DIMAP project targets at the following objectives: additive manufactured joints, additive manufactured luminaires, ceramic enhanced materials, electrically conducting materials, light-weight polymeric materials, high-strength polymeric materials, novel multi-material 3D-printer and safe by design. With the development of novel ink materials based on nanotechnology improvement of the mechanical properties (ceramic enhanced and high strength polymeric inks), the electrical conductivity (metal enhanced

inks) and the weightiness (light weight polymeric materials) are achieved. Based on the voxel printing by PolyJet these new materials lead to a huge broadening of the range of available digital material combinations. Further focus points during the material and printer development are safe by design approaches, work place safety, risk assessment, collaboration with EU safety cluster and life cycle assessment. An established roadmap at the end of project enables the identification of future development needs in related fields order to allow Europe also in the future to compete at the forefront of the additive manufacturing revolution.

Strategy



Discipline
Multidisciplinary, Nano, 3D printing

Pillar(s)
Research, Industry

SbD aspects
Applying SbD for 3D printing

http://www.dimap-project.eu/

Expected Impacts and Outcomes
Almost unlimited customisation, increasing printing speed and growing accuracy make AM production an attractive alternative to conventional mass production, enabling new manufacturing possibilities in Europe. Consumers now expect a seamless flow between their online and offline activities, forcing companies to quickly adapt their strategy to reflect online-driven consumer behaviour or risk obsolescence. Consumers are also suffering from "search fatigue." Engaging customisation experiences will add value to mainstream shopping sites because they offer a new level of creative interaction. The business models, new customisation insights and multi-material technologies developed within DIMAP will enable SMEs as well as larger companies to offer unique custom products for high-impact electronic markets. As most products are based on more than one material, and since today this "multi-material" need is achieved by assembly, the new inks combined with the inkjet multi-material capabilities open a very large market for both functional prototypes and end used parts. DIMAP was and is contributing to European innovation capacity on the one hand with 4 patents, training of 5 PhD and several Diploma students in total, 8 scientific paper during project implementation and more to follow, protection of intellectual property, on the other hand by strengthening the European

competitiveness with the development of design-driven & user orientated 3D printed functional multi-materials goods. In addition the printed demonstrators were and will be displayed at fairs to show the capability of the new materials and PolyJet™ printing.

7.49 NanoHarmony

Towards harmonised test methods for nanomaterials

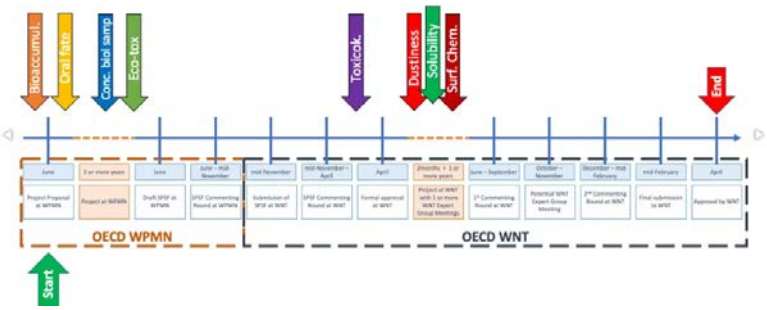
Description
Engineered nanomaterials (ENM) can pose a challenge within Test Guidelines (TG) and Guidance Documents (GD) for substance safety assessment, with complexity in lab analysis and data interpretation. The NanoHarmony project supports the development of a set of scientifically reliable test methods and good practice documents, based on the translation of existing scientific knowledge and data into a form that has regulatory relevance.

NanoHarmony will focus on OECD TGs and GDs for eight nanomaterial test endpoints that have been prioritised with the help of ECHA, NMEG, Industry and the Malta Initiative and considering the OECD WPMN priority recommendations.

NanoHarmony will coordinate the collection and use of available data and information to support the finalisation of the test method development. It will also develop a sustainable international network of experts, for data analysis and recommendations for test method maturation, plus future regulatory pathways.

NanoHarmony will also analyse processes in test method developments, to set up a framework structure for seamless and smooth cooperation between all stakeholders for timely developments of test methods ready for regulation.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Strategic Positioning

SbD aspects
Development of test guidelines and guidance documents for eight endpoints where nanomaterial-adapted test methods have been identified as a regulatory priority, which will help with SbD applicability.

https://nanoharmony.eu/

Expected Impacts and Outcomes
The three year project started on April 1, 2020 and brings together 14 expert partners from 10 European Countries and will work alongside OECD and ECHA in accelerating the development of priority Test guidelines and Guidance Documents for nanomaterials.

By identifying gaps and obstacles, and developing an adequate framework for possible implementation, e.g. in a Nano Risk Governance Council (as called for in NMBP 13), future needs for regulatory test methods will be identified and methods developed faster.

7.50 ShuttleCat

Shuttle Catalysis for Reversible Molecular Construction

Description
Homogeneous catalysis is one of the pillars of modern chemical synthesis because it enables the sustainable preparation of molecules that find applications in medicinal chemistry, agrochemistry, and materials science. However, many catalytic reactions use hazardous reagents, are unpractical on laboratory-scale or limited in scope. Moreover, while a relatively broad set of catalytic reactions are available to construct chemical bonds, methods to cleave those, which could find applications in biomass and waste valorisation, are rare.

Inspired by the synthetic power of other metal-catalysed reversible reactions, such as transfer hydrogenation and alkene metathesis, I herein describe a ground-breaking approach to homogeneous catalysis that makes use of a novel paradigm called “shuttle catalysis”, defined as the catalytic reversible transfer of chemical moieties between two molecules, to construct and deconstruct organic compounds. The first part of the proposal describes the invention of reversible catalytic functionalisation reactions of alkenes following this principle. The second part addresses the challenge of developing safer catalytic carbonylation and decarbonylation reactions that do not use nor release toxic carbon monoxide gas. Finally, the last part proposes to apply the shuttle catalysis concept to the invention of unprecedented C–X (X = P, O, S, N) bond metathesis reactions.

Discipline
Chemistry

Pillar(s)
Research

SbD aspects
Designing safer catalytic reactions that do not use or release CO gas. Example of process related SbD applicability.

Expected Impacts and Outcomes
This new approach to catalysis has the potential to revolutionise the preparation, and streamline the discovery, of numerous important molecules with applications across the molecular sciences. Importantly, in order to mitigate the high risks inherent to such a ground-breaking approach, we have collected preliminary results to demonstrate the feasibility of each of the proposed subprojects.

7.51 QSAREACH

QSAR computational models' self-using platform for EC Regulation-REACH

Description
ProtoQSAR is a company founded in 2012, with corporate address in Valencia and offices located in the European Center of Innovative Enterprises (CEEI) at the Technological Park of Paterna (Valencia).

Our activity consists in the development and application of computational methods for the evaluation of physicochemical, biological and/or (eco)toxicological properties of chemicals, either of natural origin or synthesised. Our computer tools allow us to work in a “virtual” environment, which has the following advantages over traditional laboratory tests:

- Fast results: our methods reduce the time needed with in vitro and in vivo tests, thanks to its easy and immediate applicability to thousands of chemical structures, something impossible to perform experimentally.
- Saving of material and financial resources, avoiding the costs associated with experimentation, both personal and laboratory equipment.
- Limitation of animal testing (3Rs), which have to be performed only as a last resort, when no other scientifically reliable ways to demonstrate the impact of chemicals on humans and/or the ecosystem are available.
- Regulatory validity: we help to comply with European directives for the registration and labeling of compounds (REACH, CLP, cosmetics, phytosanitary, etc.) and standards such as those set out in the ICH guidelines on impurities of pharmaceutical products. European legislation not only authorises computational techniques as valid legal alternatives, but also encourages and stimulates them by the undoubted advantages they represent.

We work on very different kind of projects, because our technology can be used in different areas such as pharmacy, veterinary, cosmetic, agrochemical, functional food, etc.

Discipline
Biology/Toxology

Pillar(s)
Industry/Education/Research

SbD aspects
Creating computational methods for the evaluation of properties of chemicals or nanomaterials.

https://protoqsar.com/en/european-comission-sme-instrument/

Expected Impacts and Outcomes
Given the exclusively computerised nature of our methods, ProtoQSAR activity has a very positive social impact. First, through computation it is possible to reduce the number of laboratory animal tests, or even to replace them in some cases*. Approximately 12 million vertebrate animals are annually slaughtered in the EU for scientific or regulatory purposes (Taylor, K., & Rego, L. (2016). EU statistics on animal experiments for 2014. ALTEX, 33, 465-468). These tests are obviously ethically questionable, and their preparation and execution are also expensive and time consuming.

On the other hand, our activities are also intended to contribute to environmental improvement. We have predictive models for a large number of eco-toxicological parameters (aquatic toxicity, toxicity in different species such as bees or terrestrial organisms, etc.), which allows us to guide the development of new active substances towards those that have proven effectiveness while respecting our natural environment.

7.52 Labex Serenade

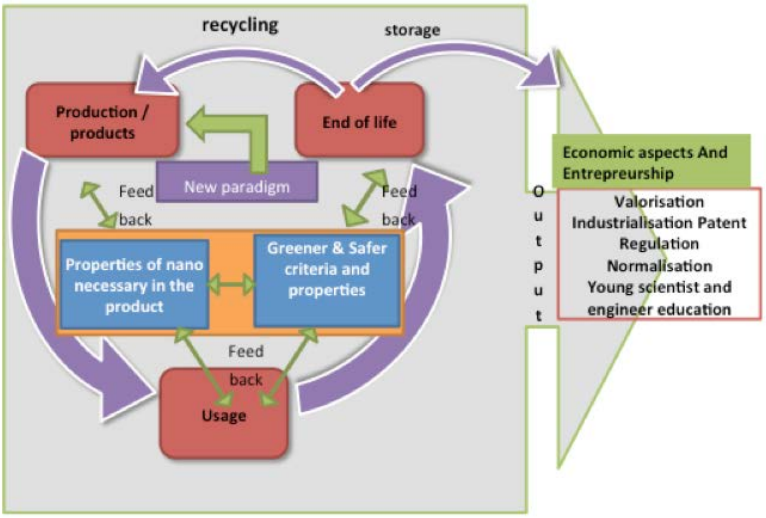
Laboratory of Excellence for Safe(r) Ecodesign Research and Education applied to NAnomaterial DEvelopment

Description
Nanomaterials are expected to be a key to innovation breakthroughs and to lead to many new applications by 2020 and further. This lead manufacturers to develop sustainable processes of production, taking account safety and acceptance considerations since first steps of the design and during the entire production of new-generation nanomaterials.

SERENADE is a Labex, i.e.and Excellence laboratory funded for 8 years by the French "Investissements d'Avenir" project. Labex SERENADE aims to build a dynamic network of academic research laboratories and industries to design tomorrow’s nanomaterials that will be safer for both humans and the environment. SERENADE is not focussed only on the design phase, but addresses nanosafety during the entire life cycle of nanoproducts, from the earliest production stages (pristine nanoparticles) to the end-of-life (recycling, disposal).

SERENADE prepares the future: it will develop lasting concepts, processes and tools and also train a new generation of scientists and skilled workers.

Strategy



Discipline
Multidisciplinary, SbD

Pillar(s)
Education

SbD aspects
Outreach on SbD to education and research.

http://www.labex-serenade.fr/
Expected Impacts and Outcomes
SERENADE LABEX (Safer(r) Ecodesign Research and Education applied for NAnomaterial Development) started the 5th of April 2012 and the kick-off meeting took place the 30th of May 2012. It creates a dynamic multidisciplinary network of 13 academic research laboratories and industries to design tomorrow's nanomaterials that are safer for both humans and the environment. SERENADE does not focus only on the design phase, but addresses nanosafety during the entire life cycle of nanoproducts.

SERENADE benefits from state-of-the-art analytical facilities (Equipex NanoID, iCeint mesocosms, Ibisa, Animex, etc).

SERENADE created a momentum that favours collaborations between partners that were fostered with the new format of the call for proposals, agreed upon by all active partners consecutive to brainstorming sessions, resulting in large(r) scale case studies that started September 2015.

SERENADE education actions targeted master students (transformation of course contents offered within Master programs) and the workforces (Action nano defi, NANoCERT, PNS – safety showroom). The network interacts with agencies such as OECD, ISO, Ministries, European Commission, for regulatory, normative purposes also proposals review

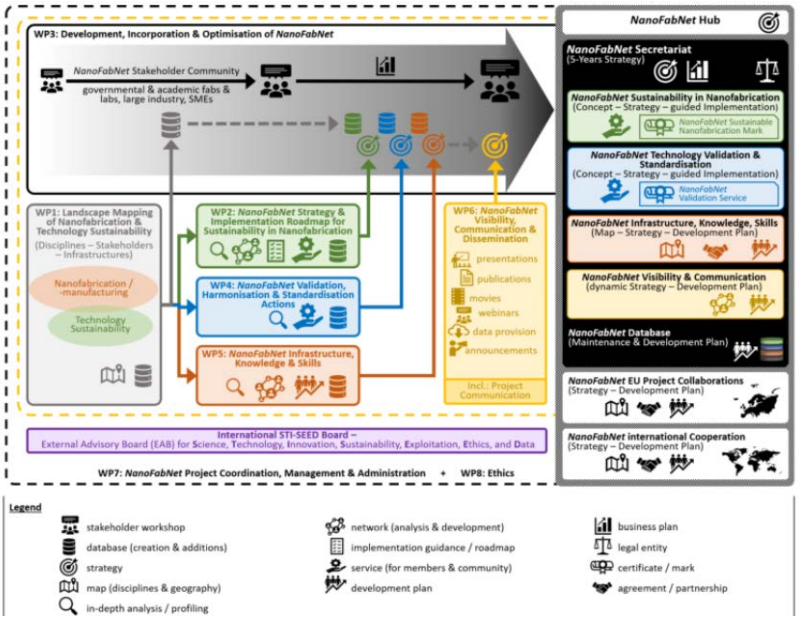
calls (ERANET SIINN...). SERENADE also developed a vigorous outreach program with various competitive clusters.

7.53 NanoFabNet

International Hub for sustainable industrial-scale Nanofabrication

Description
The EU-funded NanoFabNet Project will create a strong international network for sustainable nanofabrication, whose structure, business model and detailed strategies and action plans are designed, agreed and carried by its international stakeholders, in order to yield a self-sustaining collaboration platform: the NanoFabNet Hub. The Hub will be based upon an open structure, whose elements will be developed and validated in a stakeholder-driven approach; a secretariat at its centre will provide an accountable executive that secures its economic sustainability. It will be a one-stop-shop for sustainable nanofabrication and its successful incorporation into the high-value industries, by bringing together governmental and academic laboratories with large industries and SMEs, and thereby offering a coordination space for collaborative nanofabrication through both P2Ps and PPP.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry

SbD aspects
A guided approach to high levels of safety and sustainability, pertaining to sustainable nanofabrication.

https://nanofabnet.eu/

Expected Impacts and Outcomes
The NanoFabNet Project will create a strong international hub for sustainable nanofabrication, whose structure, business model, detailed strategies and action plans are designed, agreed and carried by its international stakeholders during the Project duration, in order to yield a self-sustaining collaboration platform: the NanoFabNet Hub, at whose centre the registered NanoFabNet Secretariat will provide an accountable, economically sustainable executive. It will be responsible for the implementation of a long-term business plan, and the provision of validation services, trainings and consultations, while collaborative and cooperative activities between actors of the wider international nanofabrication community will be fostered within the open architecture of the hub, and may be supported by membership organisation, if necessary.

7.54 NANOMET

Development and standardisation of methods for the safety testing of manufactured nanomaterials at OECD.

Description
The OEDC explores many aspects of manufactured nanomaterial safety, one of them being the need to have internationally standardised test methods to characterise nanomaterials, their physical-chemical properties, environmental fate, effects on environmental species and on human health.

Just like any other chemical substance, nanomaterials have to 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. To intensify this endeavor and support the OECD, a three-year project called NANOMET, funded by the European Union has been launched in May 2020.

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry

SbD aspects
Development of test guidelines and guidance documents for the safety assessment of nanomaterials, which can be used for SbD applicability.

http://www.oecd.org/chemicalsafety/nanomet/

7.55 NANOMICEX

Mitigation of risk and control of exposure in nanotechnology based inks and pigments

Description
The main aim of NANOMICEX project was to reduce the potential risk upon workers exposure to the engineered nanoparticles employed in the operative conditions of the inks and pigments industry, by addressing at the health and environmental consequences associated with the inclusion of nano-additives within all stages of nanotechnology based products (production, use and disposal)

Discipline
Pigments, inks, nanomaterials

Pillar(s)
Industry

SbD aspects
Health and environmental assessment in the pigment/ink industry with the inclusion of nano-additives taking into account production, use and disposal).

https://www.safenano.org/research/nanomicex/

Expected Impacts and Outcomes
The project results will involve industrial partners, providing an integrated strategy to mitigate the risk of workers dealing with nanoparticles, considering all relevant worker exposure scenarios. Furthermore, NANOMICEX will provide industrial stakeholders and the general public with appropriate knowledge on the risks of nanoparticles and nano-products, establishing synergies with the EU nano-safety infrastructure.

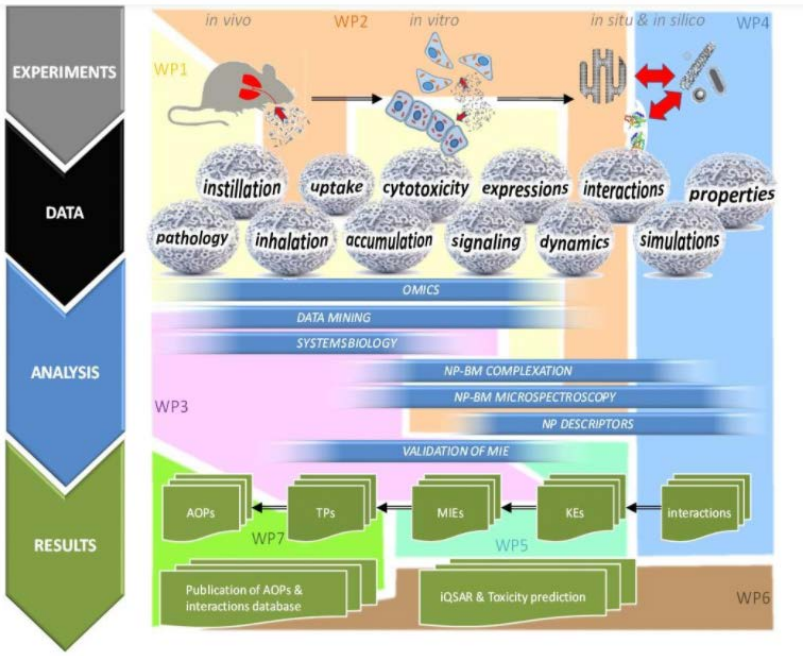
7.56 SmartNanoTox

Smart Tools for Gauging Nano Hazards

Description
A definitive conclusion about the dangers associated with human or animal exposure to a particular nanomaterial can currently be made upon complex and costly procedures including complete NM characterisation with consequent careful and well-controlled in vivo experiments. A significant progress in the ability of the robust nanotoxicity prediction can be achieved using modern approaches based on one hand on systems biology, on another hand on statistical and other computational methods of analysis. In this project, using a comprehensive self-consistent study, which includes in-vivo, in-vitro and in-silico research, we address main respiratory toxicity pathways for representative set of nanomaterials, identify the mechanistic key events of the pathways, and relate them to interactions at bionano interface via careful post-uptake nanoparticle characterisation and molecular modelling. This approach will allow us to formulate novel set of toxicological mechanism-aware end-points that can be assessed in by means of economic and straightforward tests. Using the exhaustive list of end-points and pathways for the selected nanomaterials and exposure routes, we will enable clear discrimination between different pathways and relate the toxicity pathway to the properties of the material via

intelligent QSARs. If successful, this approach will allow grouping of materials based on their ability to produce the pathway-relevant key events, identification of properties of concern for new materials, and will help to reduce the need for blanket toxicity testing and animal testing in the future.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research, Industry

SbD aspects
In vivo, in vitro and in silico research of respiratory toxicity pathways for a representative set of nanomaterials, and relate them to interactions and molecular modelling. This approach can be used for SbD applicability.

http://www.smartnanotox.eu/

Expected Impacts and Outcomes
We aim to directly address the desired impacts of both the overall NMPB Programme, and the specific call (Increasing capacity to perform nanosafety assessment):

- New screening tools to enhance the efficiency of end-rate at which NM hazard profiling can be performed. We will develop reliable in vitro and in silico tools based on the knowledge of the mechanisms of the pulmonary toxicity of NMs and bound to novel endpoints ans validate their predictive power by in vivo strength of evidence.

- Enable "safer by design" approaches, tailored to stakeholders' needs (modelers, industry and regulators) By systematically studying interactions between the NMs and all the building blocks of biomolecules, we will enable a prediction of the outcome of interaction of arbitrary key molecules with the NM and the content of NM-BM complexes for any NM with known physicochemical properties. By scanning main groups of engineered NMs, we will identify the NM properties of concern related to a particular AO, and thus should be modified or avoided. This will enable development of NMs that are safe by design.
- Data in a recognised and accessible database for use beyond the lifetime of the project We will create a bionano interactions database to classify the NM according to the type of change of the NM state and type of event each particular property can be related to. The experimental results will be made available to the community using the eNanoMapper framework.
- Solutions to the long-term challenges of nanosafety and nanoregulation We will contribute to NCBI GEO database with MIAME-compliant NM-induced gene expression profiles, contribute to OECD database with exhaustive description of new TPs (or AOPs).

7.57 R2R Biofluidics

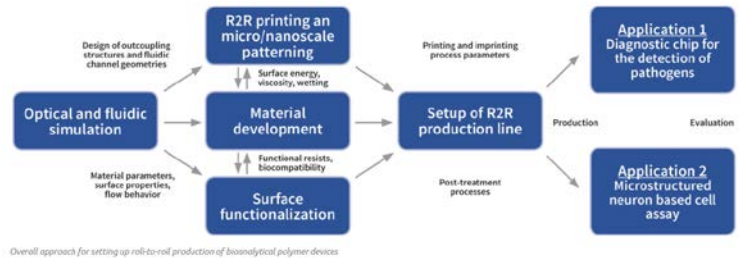
Large scale micro-and nanofabrication technologies for bioanalytical devices based on R2R imprinting

Description
R2R Biofluidics has started on February 1st, 2015. During the next 4 years it aims for the development of a complete process chain for first-time realisation of production lines for two selected bioanalytical lab-on-chip devices based on high throughput R2R nanoimprinting in combination with complementary printing and manufacturing technologies. The consortium, consisting of high qualified experts in the fields of engineering and production technology, chemistry and materials development, and biotechnology and life sciences, will fabricate two types of demonstrators by realising a complete high-volume process chain for industrial fabrication of bioanalytical lab-on-chip devices based on setting–up a roll-to-roll (R2R) production line:

Demonstrator 1: *In-vitro* diagnostic chip with imprinted microfluidic channels based on chemiluminescence detection using photodetectors; containing imprinted optical nanostructures for light coupling and thus improving device performance.

Demonstrator 2: Cell-chips containing imprinted cavities and micro- to nanoscale channels for controlled neuron culturing to be applied in high throughput drug screening.

Strategy



Overall approach for setting up roll-to-roll production of bioanalytical polymer devices

Discipline
Chemistry/Physics

Pillar(s)
Industry

SbD aspects
The SbD concept was applied in this case study using classical chemical safety assessment.

https://www.r2r-biofluidics.eu/

Expected Impacts and Outcomes
R2R Biofluidics enables a severe change within the microfluidic industry with the establishment of R2R manufacturing as an industrially viable fabrication technology. Within the project, the worldwide first R2R microarray spotter line for foil based microfluidics was established – which was an essential step on the way to a full implementation of R2R manufacturing of microfluidic devices.

R2R manufacturing will easily allow for throughputs > 5.000 chips/h and hence could lead to reduction of production costs by a factor of 5-10. R2R Biofluidics worked towards integrated production concepts for R2R manufacturing lines combining all relevant processing steps (imprinting, printing, lamination etc.) for microfluidic, bioanalytical consumables based on plastic foils. This is far beyond previous approaches that usually comprise just single R2R patterning steps.

Regarding the design and functionality of selected demonstrator applications themselves, a number of innovations were realised in the project:

Novel optical outcoupling structures were integrated into a microfluidic chip for chemiluminescence based detection of that significantly improve optical detection efficiency. A novel method for patterned functionalisation of microchannels by selective wetting contrast has been established. A new class of directly biofunctionalisable R2R UV-imprinting resist was developed, and the integration of actuators (pumps/valves) to microtiterplates has been shown, enabling cell culture device with higher degree of automation (autonomous, controlled perfusion and buffer exchange) without requiring complete robotic lab automation systems. All those advancements will further contribute to significant future impact on society and public health.

For example, bacteria that are resistant to any class of antibiotics are a very real and close threat. R2R fabricated diagnostic chips will allow to rapidly screen for such pathogens in patients entering a hospital and thus allow to isolate infected or colonised patients. Such technology will prevent superbugs from spreading throughout hospitals causing catastrophic outbreaks. Such outbreaks not only cause many deaths but also a great amount of costs that public health systems have to bear.

As another example, the project will provide a device that would allow more reliable and robust cell based assays for drug screening. Using such devices, will speed up the drug production pipeline and accelerate introduction to the market. This will have a positive influence in the availability of new promising treatments for patients.

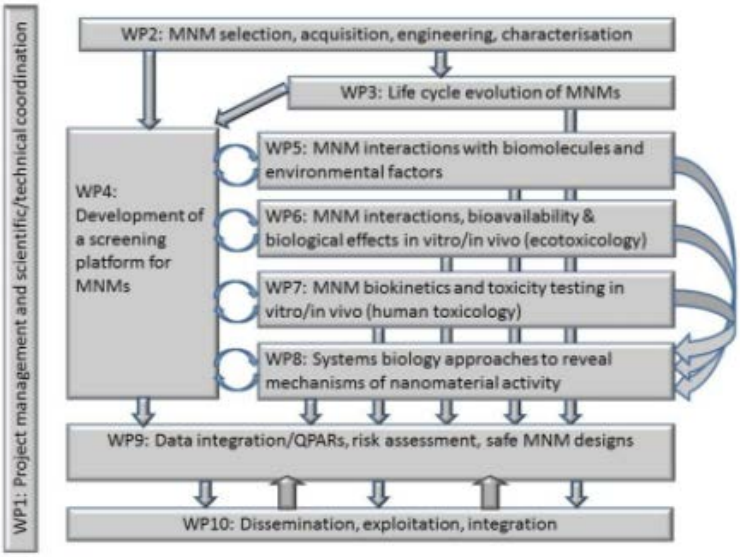
7.58 NANOMILE

Engineered nanomaterial mechanisms of interactions with living systems and the environment: a universal framework for safe nanotechnology

Description
The NanoMILE project intends to establish a fundamental understanding of the mechanisms of nanomaterial interactions with living systems and the environment, across the entire life cycle of nanomaterials and in a wide range of target species. The project will identify critical properties (physico-chemical descriptors) that confer the ability to induce harm in biological systems. This is key to allowing these features to be considered in nanomaterial production ("safety by design").

The overarching objective of NanoMILE is thus to formulate an intelligent and powerful paradigm for the mode(s) of interaction between manufactured Nanomaterials (MNMs) and organisms or the environment to allow the development of a single framework for the classification of nanomaterial safety and the creation of a universally applicable framework for nanosafety.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research

SbD aspects
To create a fundamental understanding of nanomaterial interactions with living systems for SbD applicability.

http://nanomile.eu-vri.eu/

Expected Impacts and Outcomes
The most important outcomes of NanoMILE are expected to be:

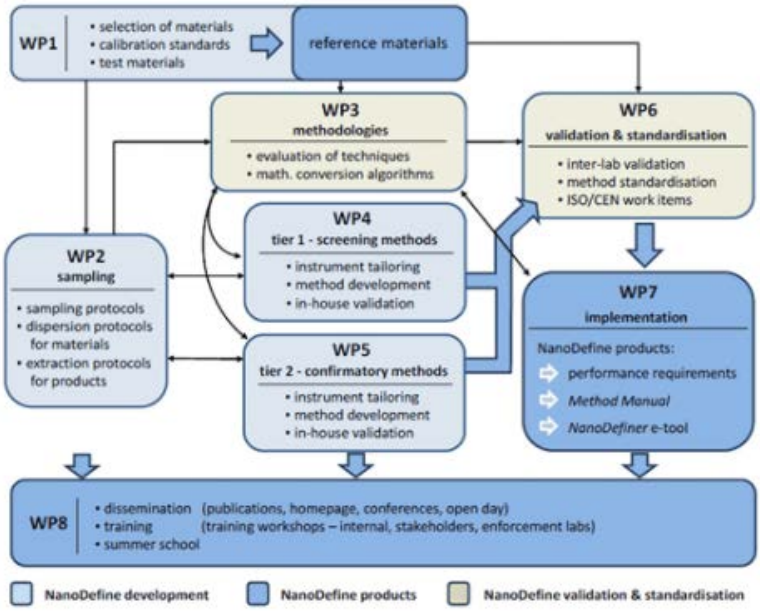
- A set of documented protocols for nanomaterials synthesis, characterisation & safety assessment, feeding into ongoing standardisation activities and building on the work of previous projects;
- MNMs libraries gathering data on structure and transformation in contact with living systems and their connection to toxicity, ecotoxicity, and fate and behaviour;
- Mechanistic and quantitative (QSAR/QPAR) descriptions of MNMs properties, and of effects of life-cycle MNMs modifications (aging, interactions with the environment);
- A source for MNMs risk-assessment (dose-response relationships for various dose metrics, target body tissues, biomarkers, biodistribution/ biopersistence);
- A framework for MNMs classification according to their biological or environmental impacts;
- A handbook of best practice (in coordination with the NanoSafety cluster).

7.59 NANODEFINE

Development of an integrated approach based on validated and standardised methods to support the implementation of the EC recommendation for a definition of nanomaterial

Description
Nanotechnology is a key enabling technology. Still, existing uncertainties concerning EHS need to be addressed to explore its full potential of this new technology. One challenge consists in the development of methods that reliably identify, characterise and quantify nanomaterials (NM) both as substance and in various products and matrices.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research

SbD aspects
Providing insight on how to define and characterising nanomaterials, which can lead to SbD applicability.

http://www.nanodefine.eu/

Expected Impacts and Outcomes
NanoDefine will explicitly address this question and support the governance challenges associated with the implementation of the nano legislation by:

- addressing the issues on the availability of suitable measuring techniques, reference material, validated methods, acceptable for all stakeholders (authorities, policies, industries),
- an integrated and interdisciplinary approach and a close international cooperation and networking between academia, concerned industries and standardisation bodies.

7.60 MARINA

Managing Risks of Nanoparticles

Description
MARINA aimed to develop specific reference methods for all the main steps in managing the potential risk of engineered nanomaterials (ENM). It addressed the four central themes in the risk management paradigm for ENM: Materials, Exposure, Hazard and Risk.

The methods developed by MARINA are based on beyond-state-of-the-art understanding of the properties, interaction and fate of ENM in relation to human health and the quality of the environment and either (newly developed or adapted from existing ones but, ultimately, they were compared/validated and harmonised/standardised as reference methods for managing the risk of ENM.

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research

SbD aspects
Development of risk management methods for nanomaterials including materials, exposure, hazard, and risk which can be used for SbD applicability. This project collaborated with NANOVALID and QUALITYNANO

https://www.safenano.org/research/marina/

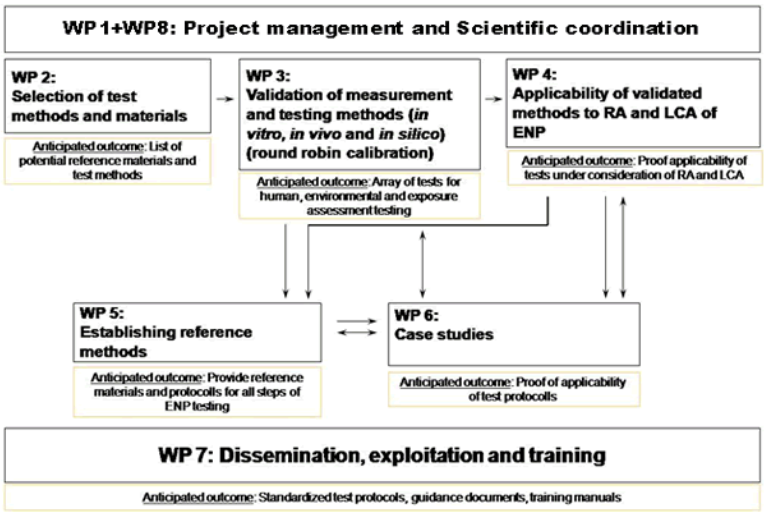
Expected Impacts and Outcomes
The MARINA consortium included SMEs in Nanotechnology such as NanoCYL and Colourobbia and SME's in research such as the IOM. The tools developed by MARINA were directly relevant and useful to industrial SMEs because these enterprises usually do not have enough funds and resources to develop the tools themselves. Furthermore, some of the materials tested in MARINA were from the SME (such as silver (Colourobbia) and multi-wall carbon nanotubes (NanoCYL)) so the tools developed by MARINA were directly relevant and useful to these enterprises. |For research, MARINA has offered the opportunity for IOM to coordinate a large research programme. This opportunity was unique for a research SME and has generated much visibility, which otherwise IOM may not have acquired. Therefore the outcomes of MARINA have made considerable impacts on all the participating SME.

7.61 NANOVALID

Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials

Description
Main objective of NanoValid is the development of new reference methods and certified reference materials, including methods for characterisation, detection/quantification, dispersion control and labelling, as well as hazard identification, exposure and risk assessment of ENs. In cooperation with other relevant projects (in particular MARINA, QNano and within the EU Nanosafety cluster), relevant standardisation and regulatory bodies, the most suitable test materials and methods will be selected and tested, and new nanomaterials synthesised, characterised and stabilised for final method validation.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research

SbD aspects
Development of risk management methods for nanomaterials including materials, exposure, hazard, and risk which can be used for SbD applicability. This project collaborated with MARINA and QUALITYNANO

http://www.nanovalid.eu/

Expected Impacts and Outcomes
In cooperation with other relevant projects, such as MARINA and QNano, and relevant standardisation bodies, such as the OECD WPMN, existing industrial or newly designed ENs will be subjected to a rigid and comprehensive inter-laboratory validation campaign that includes the currently most advanced methods and instruments for measuring and characterising of ENs, to generate accurate and reproducible material data and standardised method protocols, also for tracing and quantifying nanoparticles (NP) in complex matrices. The stability and behaviour of selected NP will be monitored and tested in a variety of relevant environmental samples and test media to derive optimum and reproducible fabrication, measurement and test conditions.
The validated characterisation methods will be used to design well-defined certified reference materials, which in turn will help to validate, adapt, modify and further develop current biological approaches (in vitro, in vivo and in silico) for assessing hazard and exposure of ENs, and associated risks to human health and the environment. Effects of chronic and accumulative exposure and of exposure under real-life conditions, where ENPs are likely to act as components of complex mixtures, will be duly taken into account.

7.62 QUALITYNANO

A pan-European infrastructure for quality in nanomaterials safety testing

Description
QualityNano is a Research Infrastructure for nanosafety assessment. QualityNano's core aim is the creation of a 'neutral' scientific & technical space in which all stakeholder groups can engage, develop, and share scientific best practice in the field.

Initially it will harness resources from across Europe and develop efficient, transparent and effective processes. Thereby it will enable provision of services to its users, and the broader community, all in the context of a best-practice ethos. This will encourage evidence-based dialogue to prosper between all stakeholders.

However, QualityNano will also pro-actively seek to drive, develop and promote the highest quality research and practices via its Joint Research Activities (JRA), Networking Activities (NA) and provision of Transnational Access (TA) functions, with a global perspective and mode of implementation

Discipline
Multidisciplinary, Nano

Pillar(s)
Research, Industry

SbD aspects
Creation of a scientific & technical space in which all stakeholder groups can engage, develop, and share scientific best practice in the field for the future of SbD. This project collaborated with MARINA and NANOVALID.

https://www.wur.nl/nl/show/qnano.htm

Expected Impacts and Outcomes
- Create a neutral ethos of excellence where all nanotechnology stakeholders can focus on concrete science-based outcomes.
- Establish a core infrastructure to address the critical issues currently hampering the industrial deployment of nanotechnologies across a range on industry sectors.
- Provide Users with a full range of services from standard nanomaterials, tuition in best practice, laboratory support and training, and a suite of protocols for all aspects of nanomaterials processing and characterisation in a biological context.
- Push beyond the state of the art in nanomaterials processing, labelling and identification and characterisation in situ.
- Develop novel analytical approaches and tools where most urgently needed to enhance understanding of health and safety issues in nanotechnology.
- Create a hub to drive the development and implementation of standards across all aspects of nanosafety evaluation and to link

with other EU actions (RTD, ERANET, Nanosafety Cluster, OECD, ISO) and international stakeholders.
- Look to the future - framed with new scientific communities, and new industry sectors, forging new (safe and responsible) applications of nanoscience and implementations of nanotechnology

7.63 ASINA

Anticipating Safety Issues at the Design Stage of NAno Product Development

Description
Although previous EU funded projects have defined tools and concepts to ensure safety of nano-enabled products through design, many hurdles still hinder the implementation of these procedures in real production processes. The EU-funded ASINA project will study the production value chains of two representative categories of nano-enabled products: coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. The project seeks to formulate design hypothesis and make design decisions by applying a SbD management methodology (the ASINA-SMM), molded on industrial six sigma practices, to ensure an easy implementation in nano-manufacturing processes. By its end, ASINA will provide a ROADMAP to generalise ASINA-SMM, and maximising the positive impacts of further products, designed to improve environmental quality and human health/wellness.

Strategy

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research, Education

SbD aspects
Application of SbD in the production value chains of coatings in environmental nanotechnology and nano-encapsulating systems in cosmetics. Develop a ROADMAP to generalise the above mentioned results.

https://www.asina-project.eu/

Expected Impacts and Outcomes
- SbD approaches and tools at an early stage of the nanomaterial development process
- ASINA-Quality-workplaces
- Quality workplaces that ensure maximum technical and economic performance in line with acceptable risk levels
- Control-and-mitigate-exposure
- Control and mitigate exposure after release of NMs from products
- Develop and validate low-cost techniques for delivering an integrated exposure driven risk assessment and the associated design of the required post-use monitoring
- Increased industrial competitiveness
- Impact on human health, environment and regulations

7.64 Nanosafety

Description
The overall objective is to increase our understanding of the fundamental connections between particle properties and human and environmental toxicology, as well as of emissions and exposure in all stages of the lifecycle of a nanomaterial. The research aims at providing the tools needed to implement Safe(r)-by-design in the development and production of novel materials.

Discipline
Multidisciplinary, Nano

Pillar(s)
Education

SbD aspects
Training on how to apply SbD

https://www.nano.lu.se/research/nanosafety

Expected Impacts and Outcomes
To promote knowledge exchange and enable network building, the course is open for PhD students and representatives from industrial and governmental sectors.

The aim of the course is to mediate knowledge of safe manufacturing and handling of engineered nanoparticles and of nanomaterials i.e. materials containing nanoparticles, in the perspective of human health and the environment. Aspects such as safety, important particle charcteristics, exposure- and emission assessment, nano-toxicology, precautionary principle, SbD, human-technology interaction, risk assessment, risk management, risk communication, life cycle analysis, legislation and ethical aspects will be covered.

7.65 SweNanoSafe

Description
SweNanoSafe - the national platform for nanosafety

"We are a forum for collaboration between academia, authorities, business and other organisations that have an interest in sharing knowledge and experiences as well as discussing, developing and influencing the implementation of nanosafety in society.

The goal is the safe handling of nanomaterials at all levels that protect human health and the environment!"

Through the regulatory letter to KemI from the Ministry of the Environment and Energy (Government Decision 2019-12-19), Karolinska Institutet is allocated funds to "further develop a platform for safe handling of nanomaterials that can contribute to achieving the environmental quality goal of a non-toxic environment and protect human health".

The assignment involves communicating and disseminating knowledge about risks with nanomaterials to academia, authorities, business and organisations and identifying any obstacles to safe handling. Furthermore, the platform can contribute with proposals for solutions and concrete measures that address obstacles, as well as work actively for improved nanosafety.

Strategy

Discipline
Multidisciplinary

Pillar(s)
Education

SbD aspects
Facilitate collaborations between research and industry and facilitate early integration of safety aspects of the innovation process (for SbD applicability).

https://swenanosafe.ki.se/ (translated by google translate)

Expected Impacts and Outcomes
"The platform's vision is to constitute an obvious national forum where academia, authorities, business and organisations can collaborate by sharing knowledge and experiences, as well as discuss, develop and influence the implementation of nanosafety in society."

The national platform for nanosafety, SweNanoSafe, was established in 2016 at the Swetox research center on behalf of the government. As of 1 January 2019, the Institute of Environmental Medicine, Karolinska Institutet , is home to the platform where it is included as an activity under the secretariat for risk assessment, research and applied work, RUT .

7.66 PANDORA

Probing safety of nano-objects by defining immune responses of environmental organisms

Description
PANDORA is a European Training Network (ETN) funded in the framework of H2020 Marie Skłodowska- Curie ITN programme. The PANDORA network aims at the education of promising young scientists who will learn how to assess the impact of engineered nano-objects (nanoparticles, NP) on the immune and defensive responses of organisms in the environment.

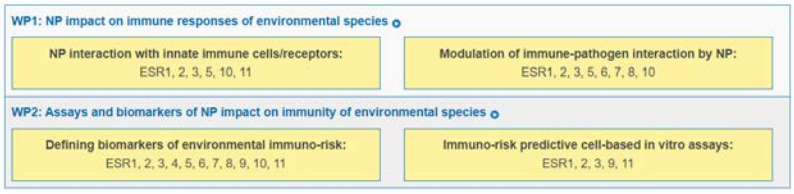
Immunity is a major mechanism for the survival and fitness of practically all living organisms, thus immunosafety of engineered NP is a key element of environmental nanosafety. PANDORA will tackle the issue of global immunological nanosafety by comparing the effects of a selected number of NP of wide application (iron, titanium and cerium oxide) on the immune response of several earth and marine organisms in parallel to human. The highly conserved system of innate immunity/stress response/inflammation will be the focus of PANDORA, as this would allow us to identify common reactivity across immune defence evolution.

The project is based on a profound interaction between the academic and industrial sectors, encompassing academic institutions, research centres, and SMEs, all with proven experience in higher education and training, and endowed with state-of-the art scientific and technical expertise and infrastructures. In this highly multidisciplinary environment, eleven Early Stage Researchers (ESR) will be trained into the issue of immuno-nanosafety. The focus on the effects of NP on the

functionality of the immune system, and consequently on the overall health protection of the target organism, will be broadened from the attention to human health to encompass a variety of environmental organisms (plants, invertebrates, marine, earth). The programme will therefore lay the basis for an integrated approach to environmental nanosafety that includes immunosafety as a key element.

By combining the beneficiaries' expertise in immunology, biochemistry, immunochemistry, cell biology, developmental biology, marine biology, microbiology, molecular biology, pharmacology, toxicology and ecotoxicology, biotechnology, chemistry and nanotechnology together with experience in project management, PANDORA will create a multidisciplinary environment where eleven young researchers will contribute at studying the effects of NP on the immune system responses of environmental organisms. This will allow them to identifying common mechanisms/markers across species that could be used for novel assays for assessing immuno-nanosafety. Concomitantly, they will acquire transferable skills which will lead them to become the new leaders of academic or industrial research.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Education, Research

SbD aspects
Creating a multidisciplinary environment where young researchers will contribute at studying the effects of NP on the immune system responses of environmental organisms, which will have future SbD applicability.

https://www.pandora-h2020.eu/

Expected Impacts and Outcomes
The development of predictive innate immunity assays for evaluating the effects of NP will allow questions about the immunological risk posed to living organisms (including human beings) to be answered in a realistic fashion, or addressed properly for the first time, a capability with significant attraction to prospective employers in academia. The exposure of fellows to different disciplines (from nanotechnology to evolution of immune responses to human immunity to safety/toxicology) and the intense exchange programme will allow them to expand the range of their scientific and technical knowledge and to learn how to work in multidisciplinary collaborations. Likewise, the industrial interest of the participating SMEs in the field of nanosafety assessment and

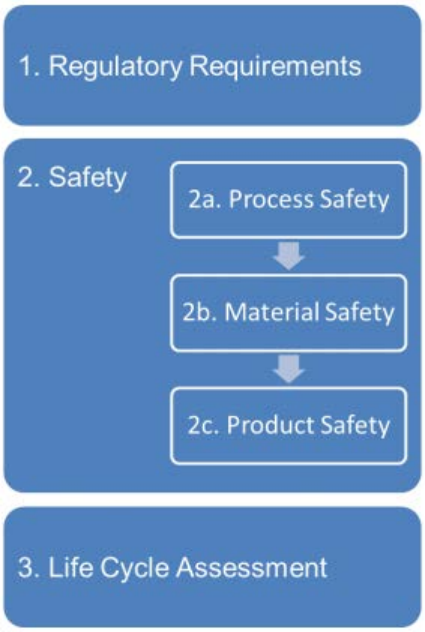
screening will provide the fellows with a technical capability that is both specialised and marketable and, with their additional experience of working at the interface between academia and industry, should enhance their career prospects in both sectors. Moreover, the transferable skill courses foreseen in PANDORA will provide the ESRs with the necessary tools to become project managers, to find funds and to communicate effectively to different stakeholders or non-scientific media. The courses will guarantee that all ESRs will receive enough knowledge on various complementary topics to foster their entrepreneurial mind-set. The intersectoriality and interdisciplinary aspects of the partnership will create a generation of scientists able to adapt to changes in global technology and that will represent an investment into the research livelihood of the European Union.

7.67 OptiNanoPro

Processing and control of novel nanomaterials in packaging, automotive and solar panel processing lines

Description
With the use of nanotechnology both in bulk and surface application, OPTINANOPRO will deliver demonstrators of packaging with improved barrier properties as well as with repellent properties resulting in easy-to-empty features that will on the one hand reduce wastes at consumer level and, on the other hand, improve their acceptability by recyclers. Likewise, self-cleaning solar panels will be provided to increase their effectiveness and extend the period between their maintenance and their lifetime by filtering UV light leading to material weathering. In the automotive sector, lightweight parts will be obtained for greater fuel efficiency.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Education, Research

SbD aspects
Introduction of nanotechnology and SbD in production lines for packaging and automotive and photovoltaic material production.

http://optinanopro.eu/

Expected Impacts and Outcomes
To demonstrate the benefits of the introduction of nanotechnology into packaging, automotive and photovoltaic materials production lines. To validate the resulting productivity and products vs. existing benchmarks in terms of performance, cost and sustainability.

The project will deliver tailored formulations of compounds and coatings for each target sector. It will also focus on the development and industrial integration of electrospray nano-deposition, online dispersion and monitoring systems to ensure a constant quality of produced materials.

7.68 ICARUS-INAS

Integrated Nanostructures Assessment-Service for the biological impact analysis of nanostructures

Description
Advances in nanotechnology over the years have led to the use of nanostructures in the research and biomedical fields. However, limited information is available on the life cycle of nanomaterials and their products. The scope of the EU-funded ICARUS-INAS project is to establish a service for assessing the biological impact and toxic effects of innovative nanostructures and record their life cycle. Using a combination of in vitro assays, omics technologies and toxicology studies, scientists will evaluate the human and environmental safety of specific nanocomposite products at all stages of their life cycle. The project will also offer the possibility to implement these methodologies at the customer's facilities upon request.

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry

SbD aspects
Looking into the life cycle of nanomaterials and their products and the impact and toxic effects of nanostructures, for future SbD applicability.

https://www3.ubu.es/iccram/icarus-inas/

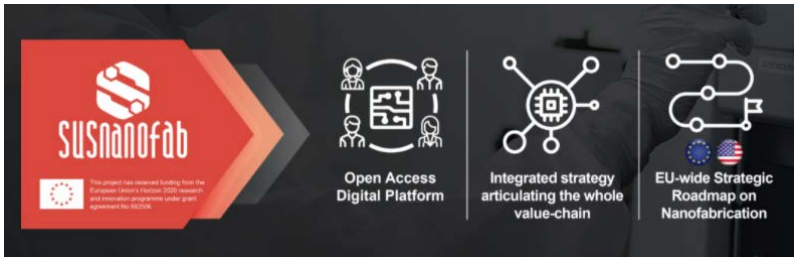
7.69 SUSNANOFAB

Integrated EU Strategy, Services and International Coordination Activities for the Promotion of Competitive and Sustainable Nanofabrication Industry

Description
Nanofabrication has the potential to address major socio-economic challenges, from better and affordable health care to cleaner energy and transports, improved consumer goods and higher living standards.

Nanofabrication enables the production of multifunctional devices with unique properties for a vast range of applications, thus having a profound impact on a multitude of industrial sectors. The vast potential of nanofabrication is undeniable, and it must be optimised.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Education

SbD aspects
A network for sustainable nanofabrication which may include SbD applicability.

https://susnanofab.eu/

Expected Impacts and Outcomes
A match-making tool for technology providers and potential customers (access to infrastructures, brockerage and training services). A centralisation and harmonisation of the available data and make it accessible to all interested parties.

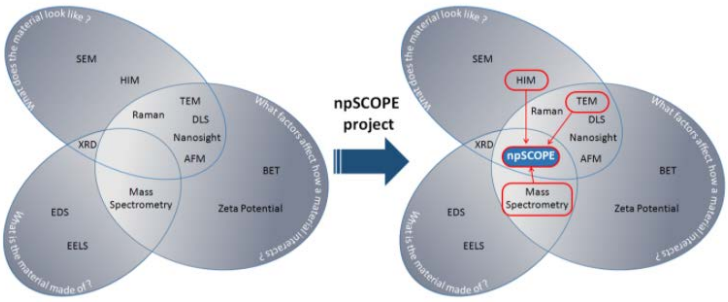
7.70 npSCOPE

The nanoparticle-scope : a new integrated instrument for accurate and reproducible physico-chemical characterisation of nanoparticles (npSCOPE)

Description
The nanoparticle-scope (npSCOPE) is a research project funded by the European Commission H2020 bringing together nine partners with the aim of developing a new integrated, optimised instrument to provide a comprehensive physico-chemical characterisation of nanoparticles both

in their original form and incorporated into complex matrices such as biological tissue.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Research

SbD aspects
Developing an instrument (electron microscope/gas field ion source) that can measure physico-chemical properties of nanomaterials both in their pristine form or embedded in complex matrices such as biological tissues which can aid in SbD applicability.

https://www.npscope.eu/

Expected Impacts and Outcomes
In the framework of the European H2020 project npSCOPE, an instrument that couples the extraordinarily high resolution of the recently commercialised helium-ion microscope with sensors for composition (a mass spectrometer) and 3D visualisation (transmitted ion detector) will be developed. The aim is to more fully characterise individual nanoparticles and their interaction with their biological environments (water, soil, body fluid, human cells and tissue, etc.) and to better understand the risks they might pose to human health or the environment.

The new integrated microscopy tool advanced from existing technologies and adapted specifically for the purpose of providing quick and concise analyses of nanoparticular material that can even be embedded in complex and biological matrices aims to provide a more efficient, comprehensive and accurate data in one to nanoparticle toxicology studies.

The development of the npSCOPE, will not only reinforce the leading position of Europe in the field of nanotechnology and in the field of advanced instrumentation, but also aims to:

- Allow an increased confidence in the determination of physico-chemical features, providing more reliable and consistent data for safety evaluation of nanomaterials. As well as quality control.

- Reduce costs and optimise time related to physico-chemical characterisation of nanomaterials, being a more accessible instrument than traditional approaches.
- Seek synergies in other areas such as quality control, product traceability, labelling and counterfeiting. For example, raising quality control in nanomedicine or detecting counterfeiting on cosmetic products.

7.71 PLATFORM

Open access pilot plants for sustainable industrial scale nanocomposites manufacturing based on buckypapers, doped veils and prepregs

Description
The three main aims H2020 PLATFORM project pursues are to develop open access environmentally friendly pilot lines for the industrial production of three cost-effective, sustainable nano-enabled products: buckypapers, CNT treated prepreg and CNT doped nonwoven veils; to create an European eco-system for testing, validation and further integration of nanocomposites and to contribute to overcome the barriers that materials are currently facing to be introduced in the market as part of advanced materials and advanced manufacturing processes in sectors such as Aeronautics and Automotive.

Discipline
Multidisciplinary

Pillar(s)
Industry

SbD aspects
A case study that applies SbD to carbon nanotube-based nano-enabled products.

Expected Impacts and Outcomes
The project has progressed in line with the initial established planning. In this 18 month period WP2 related to the analysis of the current situation for the existing pilot plans and define the specifications of the components for validation in each of the two use cases, Auto and Aero has been finished and the foreseen results have been reached.

Furthermore WP3, related to the platform business development and operation is running as planned. The construction of the technology platform is on going, with a first draft available and continuously updated with the collaboration of the partners. It will be presented during the Mid term review in September 2016. The reason to the delay in constructing the e- platform, which does not affect the course of the project, is appropriately explain within next section.

WP4, WP5 and WP6 related to the up-scale the existing line to large scale pilot lines are progressing as planned. Individual delays have been detected for the build-up of the pilot plants that do not affect the rest of the activities in a large extend and WP leaders are working together with the partners involved to overcome the problems encountered. Details

are gven in the following section. In WP7 the integration of the technologies in common composites manufacturing routes is addressed. For the Aero use case the activities are running as planned while the activities related to aero are suffering delays mainly due to the selection of materials. Partners are aware of this situation and will adapt the activities to be addressed and re-schedule the WP. WP9 is related to standarisation issues. It is running as planned eventhoug a revision of the main activities was done with the corresponding reschedule of the WP as it is explain in the next section. WP1 and WP10 related to management, exploitation and Dissemination aspects respectively have progressed adequately.

7.72 EC4SafeNano

European Centre for Risk Management and Safe Innovation in Nanomaterials Nanotechnologies

Description
A central challenge to ensure the sustainable production and use of nanotechnologies is to understand the risks for environment, health and safety associated with this technology and resulting materials and products (engineered nanomaterials), and to identify and implement practical strategies to minimise these risks. Knowledge about nanotechnology-enabled processes and products and related nanosafety issues (hazards, fate, risk...) is growing rapidly, achieved through numerous European or national programs launched over the last decade, but effective use of this knowledge for risk management by market actors is lagging behind.

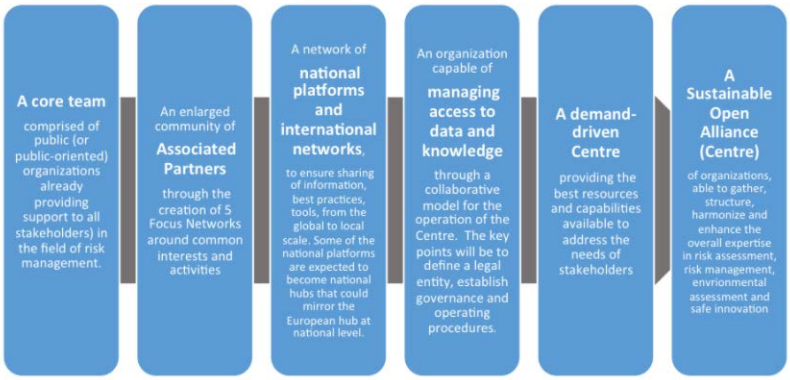
The EC4SafeNano initiative will bridge the gap between scientific knowledge and the market. It will link the nanosafety scientific community, including expert institutes/organisations active in translational research, with the wider stakeholder community. The EC4SafeNano partnership will set up a structure to integrate nanosafety services across the member states and propose them to market actors. It will thus provide an interface between the scientific community and the market actors.

EC4SafeNano seeks to develop ‘fit-for-purpose’ solutions and provide access to reliable data and experience to help solve the environment, health and safety challenges that hinder the development of safe and sustainable innovation for nanotechnology. EC4SafeNano further seeks to establish principles for safe management of nanotechnology and to assist public and private organisations and industry in the application of these principles.

Most of the EC4SafeNano core partners are national expert institutes/organisations which already provide expert support and services to industry and other private actors, public authorities and regulatory bodies. The EC4SafeNano core group invites any interested organisation to take part in the initiative as an Associated Partner, helping to design the future European Centre and to establish harmonised approaches for the proposed solutions and services. The Associated Partners will be active at the European level through their

participation in thematic Focus Networks. They will act as 'ambassadors' towards the member state where they are based.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Education

SbD aspects
Providing an independent, science-based, managed Centre (hub) linked with several networks (spokes) to act at the interface between research organisations, industry, regulatory bodies, and civil society which is necessary for SbD applicability.

http://www.ec4safenano.eu/home

Expected Impacts and Outcomes
The project will remove barriers to the ready exchange of knowledge and evidence in the field of risk analysis and nanotechnologies. It will provide a map and an analysis of the needs of the market (regulators, industry, society, research, service providers...) and of the resources available. It will propose and provide solutions such as methods, practices, standards, training or certification. The main deliverables of the EC4SafeNano project will be:

1. A robust collaborative open structure, gathering and sharing the best available resources and knowledge from across Europe and globally to promote safe innovation in nanotechnologies;
2. A set of operating procedures to operate the Centre and offer services to stakeholders along the innovation value chain, focused on removing barriers currently limiting knowledge sharing and distribution, and reducing uncertainty regarding environmental protection, safety and risk;
3. A dynamic cooperation through integration of networks, platforms and hubs connecting the nanosafety community and stakeholders to identify and solve issues related to nanotechnologies, including knowledge transfer to emerging economies and accession states;

4. ‘Pathway’ documents that identify the needs of the stakeholders and summarise the services, infrastructure and tools that the EU4SafeNano hub will provide for each stakeholder group.
5. Guidance documents setting out good practice standards relevant to market actors supporting safe innovation in nanotechnology. The final impact expected from these outcomes is to contribute to the safe and sustainable development and commercialisation of nanotechnology and so to enhance European industrial innovation and competitiveness.

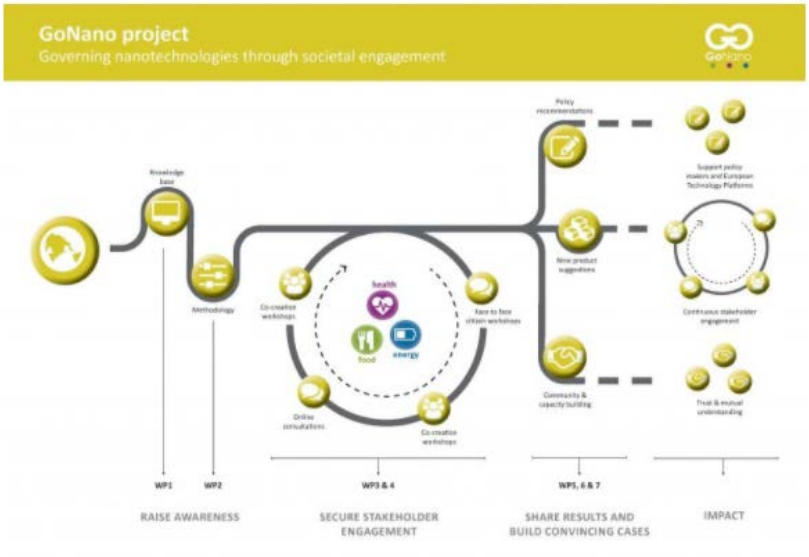
7.73 GoNano

Governing Nanotechnologies through societal engagement

Description
Nanotechnologies – the purposeful engineering of matter on the atomic or molecular scale – have given rise to great expectations in recent years, unlocking new research opportunities in areas as diverse as energy, healthcare, electronics, food, and construction. At the same time, concerns have been raised about possible unintended consequences of the use of nanomaterials.

The EU-funded GoNano project enables co-creation between citizens, researchers, industry, civil society organisations, and policy makers across Europe to align future nanotechnologies with societal needs and concerns.

Strategy



Discipline
Multidisciplinary, Nano

Pillar(s)
Strategic Positioning

SbD aspects
Develop a pilot project in each of the nanotechnology which should engage citizens with researchers, professional users, civil society organisations, industry, and policy makers to co-create concrete suggestions for future nanotechnologies on several aspects such as safety.

http://gonano-project.eu/

Expected Impacts and Outcomes

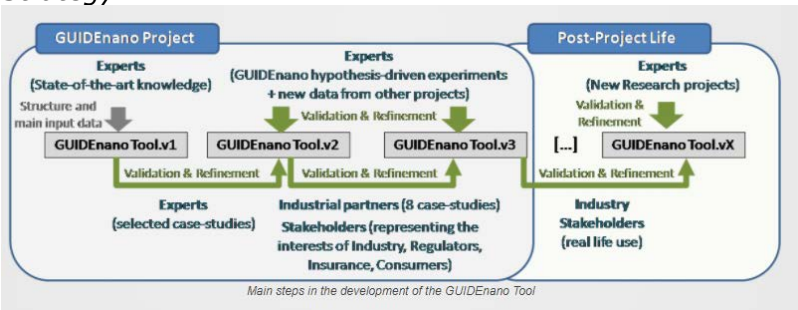
- Early and continuous engagement of all stakeholders for sustainable, desirable and acceptable innovation in nanotechnologies where R&I is aligned to the values, needs and expectations of society:
  - Knowledge base and background information to make nanotechnologies easy to understand and relatable
  - A co-creation platform and methodology for an early stage citizen and stakeholder engagement process
- Carried out the first two steps of the co-creation process
  - Feed outcomes of the project back into policy making and innovation partnerships such as European Technology Platforms, to achieve a responsive R&I system and co-production of knowledge.
  - Developed contacts for feeding information back to policy and ETPs
  - Overview of policies, regulation and risk governance frameworks for nanotechnologies
- Enhance public understanding of nanotechnology, build trust and foster mutual understanding between citizens, public and private institutions, for increased co-creation of new R&I and increased confidence of companies to invest in new technologies
  - Made information on nanotechnologies and co-creation available to all interested stakeholders including citizens.
- Project website, communication activities and social media, citizens and professional stakeholders are informed on the project and on the underlying questions of nanotechnology governance, co-creation and responsiveness in research and innovation more generally.

7.74 GUIDEnano

Assessment and mitigation of nano-enabled product risks on human and environmental health: Development of new strategies and creation of a digital guidance tool for nanotech industries

Description
The GUIDEnano project generates a risk assessment web-based tool, which incorporates as well guidance on the selection of risk management options. To reach these goals, the project is building upon the state-of-the-art on risk assessment and management by validating critical assumptions in the risk assessment process, generating new predictive models, and novel risk management solutions.

Strategy



Main steps in the development of the GUIDEnano Tool

Discipline
Multidisciplinary, Nano

Pillar(s)
Industry, Research

SbD aspects
Developing a web-based guidance tool, which will help users design nano-enabled products using SbD.

https://www.guidenano.eu/

Expected Impacts and Outcomes

- GUIDEnano will provide a Tool to be used by industry with the aim to complement existing regulations in different frameworks.
- By using this Tool, industry will be able to evaluate and efficiently mitigate possible health risks for workers, consumers and the environment associated to the use of nanotechnologies.
- The report generated by the GUIDEnano Tool will be designed to ensure transparency of the process and facilitate communication and acceptance of the Tool outcome by regulatory agencies, occupational safety and health agents, insurance companies, and consumer protection associations

RIVM

Committed to *health and sustainability* -