



## ANNUAL NEWSLETTER

### INTRODUCTION by the Scientific Coordinator



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Welcome to the first Newsletter of SABYNA. SABYNA is a project that has been funded by the European Commission (EC) under the H2020 call topic NMBP-15-2019: “Safe by design, from science to regulation: metrics and main sectors”. The official starting date of the project was 1st of March 2020 and it will be running until the end of February 2024.

Safe by design (SbD) is not a new concept, it has been used for years in industry, anticipating

safety impacts of materials or products, and incorporating management measures into the design and production phases of their innovation processes. In the context of Nanotechnology, **implementation of the SbD concept requires** a good understanding of the properties influencing nanoforms (NF) or nano-enabled products (NEP) safety as well as **technical functionality** (performance-oriented properties), and a **comprehensive guidance on how to exploit this knowledge into SbD opportunities** during the innovation process. Therefore, the proposed SbD strategies will have to ensure a balance between safety and functionality aspects, always considering implementation cost-effectiveness at all the stages of the product’s life cycle. **SABYNA will provide an interactive and integrative web-based Guidance Platform for the implementation of SbD concept into the development of safer and sustainable NF and NEP.**



## First Year Progress

### Developing hazard and exposure strategies that help to inform SbD decisions

- Development of criteria to select hazard and exposure assessment resources (models, databases, tools and methods) that can be improved for SbD purposes
- Selection of resources for assessing human and environmental hazard and exposure for the purpose of SbD: we decided to move forward with the GUIDEnano tool and improve the different modules to include SbD options.

For the hazard strategy, this means that use of in vitro data and grouping approaches will be included to allow hazard assessment based on limited or even without in vivo data. For the exposure strategy, existing human exposure and environmental release, fate and exposure will be optimized, improving their usability, as well as including approaches to link models directly to relevant data libraries and integrate into GUIDEnano model components to support the prediction of releases and exposures needed to support SbD decisions.

- Acknowledging the importance of including the life cycle: Experimental work on testing NFs throughout the life cycle to understand how transformations in the NF will affect their toxicological and/or exposure profile.

Initial experiments are currently being performed for exposure and hazard in the 3D printing case study. Experimental work concerning exposure and hazard in the paints sector will commence soon.

### Towards Safer nanoforms (NF), nano-enabled products (NEP) and nanoprocesses: Managing risks along the NF/NEP life cycle applying SbD strategies and other risk management measures (RMM)

The state-of-the-art on safe-by-design strategies towards safer products (NF/ NEP) was provided by analyzing more than 100 sources (i.e., research articles, guidelines, projects' outcomes). From this analysis, we were able to identify some strategies for SbD as basis for developing the module of the SAbyNA platform in which the user will be guided to solutions that will i) minimize risks, and ii) preserve the function of the nano-enabled product. Furthermore, we have extracted a list of physical-chemical drivers of nano-risks. Several SbD strategies targeting these drivers are available, the SAbyNA Platform will suggest those ones that preserve the best the intended use of the nano-enabled product. An important task of this work will be the assessment of the cost-effective implementation of the proposed SbD strategies in an industrial context.

The SAbyNA platform will also include a guidance on how to manage the risks of nanoprocesses along the product life cycle from an early stage of the innovation process. The work on this area was focused on the compilation and analysis of available resources (guidance documents, databases, standard procedures, frameworks) that are currently used for the design and safe operation of nanoprocesses. The next step in the analysis of these resources is to adapt and improve their usability to guide industry in the identification of safety issues to be consider in their processes as early as possible in their innovation strategy.



### SABYNA Guidance Platform general structure

The main structure of the Guidance platform was generated, and it is envisaged to consist of two parts:

**PART 1-** Identification of the main aspects for concern in the case under evaluation and alert the user offering a potential exit point with SbD suggestions or directing the user to a more detailed assessment, and the most suitable scope for it

**PART 2-** suggests a workflow which includes guidance on when/how to use different types of external resources (existing methodologies, models, and tools for exposure, hazard, and risk assessment). It also includes the library of categorized SbD strategies (towards safer NF/ NEP and nanoproceses) from which relevant resources will be presented to the user depending on the case under evaluation.

The platform will also integrate sustainability and costs resources to evaluate potential impacts and cost implications from a global point of view. The strategy selected aims for a balance between low data demand, low expertise required and acceptable level of uncertainty, to providing a basis to support decision making even at early stages of the NEP development process.

### Stakeholder Engagement Activities

SABYNA successfully initiated the interactions with stakeholders at an early stage of the project to involve them already in defining the structure of the SABYNA Guidance Platform: refining the scope and specifications by selecting the expected workflows along the guidance. The consultation was done in two ways: via one-to-one interviews with selected stakeholders and via an online questionnaire open to all the stakeholders. The online questionnaire was generated jointly with the other projects funded under the same call topic (ASINA & SbD4Nano). The analysis of the feedback received will be used for the refinement of the scope and structure of the SABYNA Guidance Platform.

### Identification of sector-specific (paints and 3D printing) practices and relevant nanosafety alerts

Sector-specific (3D printing and paints) typical activities that can be associated to relevant releases of nanoforms (NFs) to the environment or to direct human exposure for the paint and 3D printing sectors were identified described by industrial partners working in these sectors. Additionally, a literature review has been performed for the paints and 3D printing sectors to identify sector-specific activities and releases of associated nanoforms. The information extracted from this review was on: The list of activities commonly taking place for the paint and 3D printing sectors along with information on their release potential, key release determinant factors and existing data on on-site measurements. Furthermore, for these two sectors, a list of commonly used nanoforms, matrices and standards have also been compiled. The literature database from this deliverable for the two sectors will be updated during the project for its use to tailor the SABYNA Guidance Platform for these two sectors.



## Identification of typical Stage -Gate processes in the selected industrial sectors

SABYNA industrial partners provided the description on typical Stage-to-Gate processes used by these companies active along the value chain of the two selected sectors (additive manufacturing and paints). SABYNA industrial partners (IPs) were interviewed in order to acquire sector-specific information regarding the different stages of innovation process (Idea/Scope, Research & Development, Scale-up/Testing & Validation, Market Launch) where safety issues (occupational, consumer, environmental) may arise. Specific qualitative data on the resources used, priorities during decision-making and risk management practices were collected. Ten external stakeholders were also engaged to input information with expanded scope but similar focus. This analysis is critical to support the selection of the optimal Safe-by Design (SbD) approaches in each case, to generate a guidance platform suitable for these industrial sectors, and to ensure the applicability and feasibility of the potential SbD strategies proposed.

## SABYNA case studies from 3D printing and paints sectors

A list of case study materials and products were selected and some of the materials were already delivered to initiate the experimental work (characterization and exposure monitoring). Industrial partners provided the first batches of case study materials to RTD partners. In addition, the production of nano-enabled products is in progress to distribute them to partners that will start the monitoring of hazard and exposure at later stages of the life cycle (use and end-of-life stages). Dedicated meetings have been organized to facilitate communication between partners (industrial partners and experimentalists).

## Data Management Plan

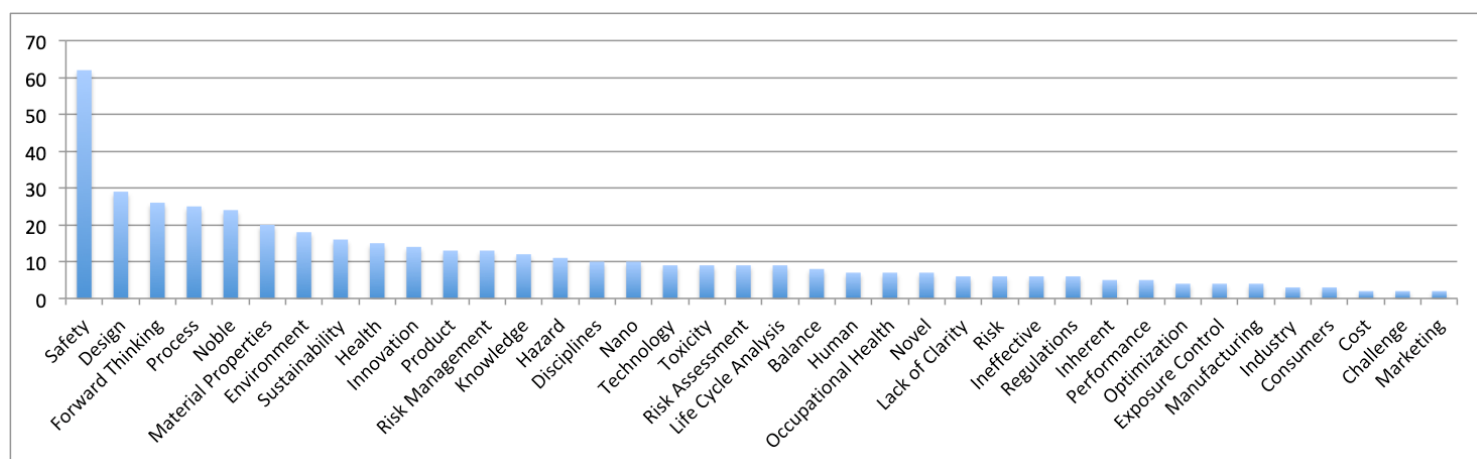
The NanoCommons data warehouse is offered as a service to projects and individual researchers to store, manage and share their data based on the FAIR principles. In SABYNA, we followed the procedure to apply for this service (TA application was submitted via the online system provided by NanoCommons), which consist of a training on how to make use of the NanoCommons data warehouse platform. Representatives from several WPs in SABYNA (selected people that has previous experiences in data management and/ or building different database structures) are the direct link with representatives from NanoCommons platform and were trained on how to make use of all their services. Then, these representatives from SABYNA transferred internally (to all the partners generating data in the consortium) the different procedures to be followed to be able to correctly report and store SABYNA's data. In this way we will ensure that all the experimental data produce in SABYNA and that reported in literature and used for SABYNA purposes, as well as the methodologies/ protocols will be successfully integrated in the NanoCommons data Warehouse.

## RRI Activities



What do we really mean when we talk about “Safe(r)-by-Design” (SbD)? Horizon 2020’s NMBP-15 projects focus extensive resources on developing SbD platforms for widespread industry use. There is a need to ensure that these deliveries correspond to industry needs, priorities and capabilities for adaptation. Thus the projects all include some form of stakeholder partnership, consultation and collaboration.

Project SAByNA goes even further, to understand underlying responses to and conceptions of SbD. The Responsible Research and Innovation (RRI) Team of SAByNA ask ourselves the following question: when individuals from different areas of the sustainable nanotech universe evoke “Safe-By-Design”, do they conceive of the same thing? Our initial findings from a 2-minute online survey (open Feb-March 2021) gathers responses from 133 respondents across the globe. With over 400 individual data points, we can say pretty confidently that most times, they don’t! As seen in **Figure 1**, these data points can be sorted into 38 discrete categories that span core concepts such as “sustainability”, “cost”, “innovation” and more.



**Figure 1:** Preliminary categorization of mini-survey responses into 38 discrete categories.

### Dissemination Highlights

During this last year, the SAByNA project has sought to adapt to the COVID situation in order to disseminate the project as much as possible.

It has been a bad year for fairs and dissemination events, but despite this, SAByNA has managed to move forward with different posters, presentations and all kinds of online events.

We would have liked to be present in many more places, but we are satisfied with everything that has been done. We value the work carried out by the coordination of the project to be able to be present in as many places as possible and also to all those who have given support to disseminate SAByNA in this strange year.

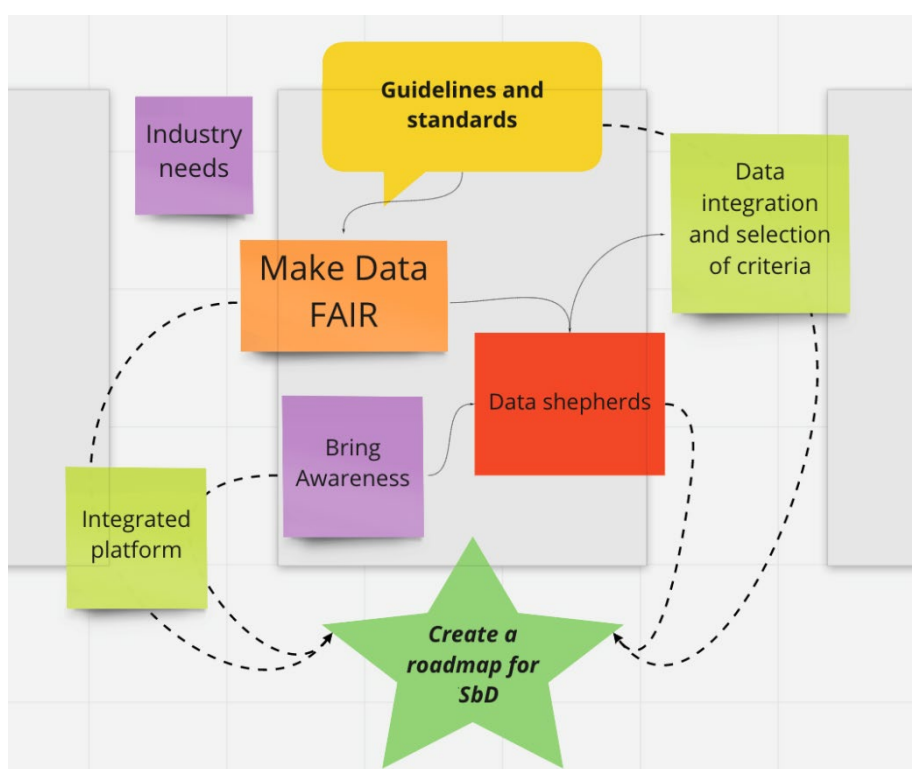
Those are examples of the spread of SAByNA:

- *Annual Conference of The European Masterbatchers and Compounders Association (EuMBC) (May 2021)- [Oral presentation](#)*
- *Nanosafety Training School, which took place on 21st-25th June 2021*



At this year's online Nanosafety Training School, the Responsible Research and Innovation (RRI) team of H2020 SAByNA hosted an interactive session entitled "RRI Roleplay Workshop: Safe-by-Design Sustainability Forum". The session offered an opportunity for 40 young career researchers across nanoscience disciplines to come together and discuss questions surrounding Safe/r/ty-by-Design. The twist? Participants were invited to roleplay as members of various stakeholder groups (industry, academia, regulators, elected officials, and consumers) participating in a UN Sustainability Summit. Their mission? To provide the Committee with recommendations to help answer the following (nonexhaustive) list of questions: How do we know a nanoparticle or product is "Safe-by-Design"? What are the criteria to say that something is SbD? Is "safety by design" already being achieved?

The groups brought back presentations (**Figure 2**) from their breakouts to present in plenary from their stakeholder viewpoint. The workshop concluded with participants reflecting on the origins of their own conceptions of SbD and to what extent these were aligned or misaligned with their assigned role. SAByNA will be conducting further workshops with the larger nanosafety community to help us all delve into the divergent multiplicity of meanings of our everyday terminologies. If you're interested in learning more about our work, helping us shape an upcoming large-scale survey, or participating in similar workshops, please contact us at [rri.sabyna@gmail.com](mailto:rri.sabyna@gmail.com).

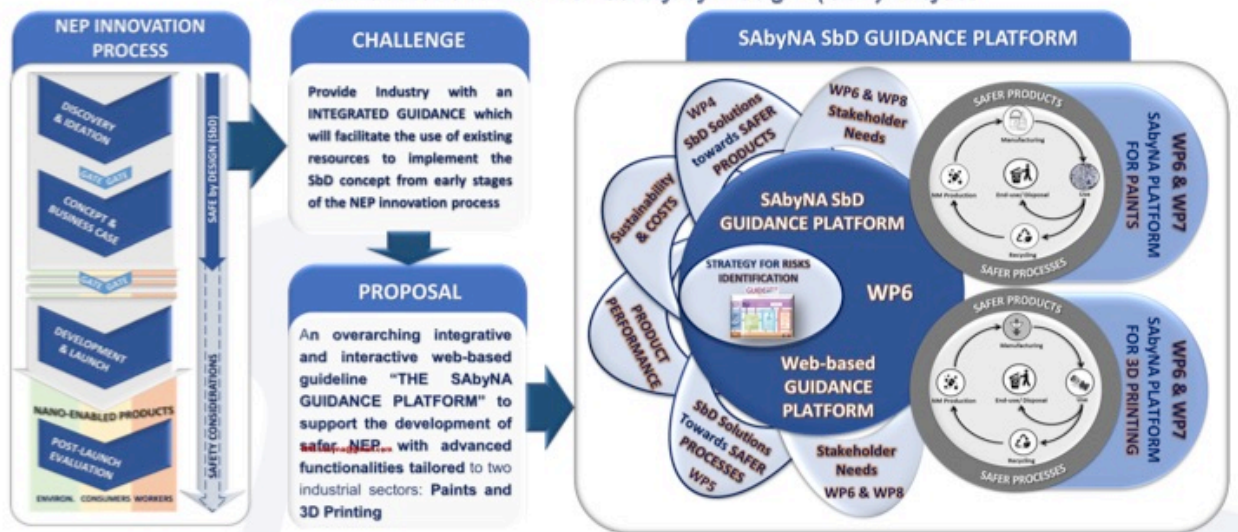


**Figure 2:** A sample workshop participant group presentation.



## SABYNA Guidance Platform: Guiding Industry in the Design and Development of Safer Nanomaterials and Nano-Enabled Products (NEP)

A Horizon 2020 NMBP-15 "Safety by Design" (SbD) Project



We invite stakeholder input as we build the platform:

- Industry interviews, workshops
- Responsible Research and Innovation (RRI) survey and workshops

Watch our video on this booth!

Join a workshop:



[RRI.sabyna@gmail.com](mailto:RRI.sabyna@gmail.com)

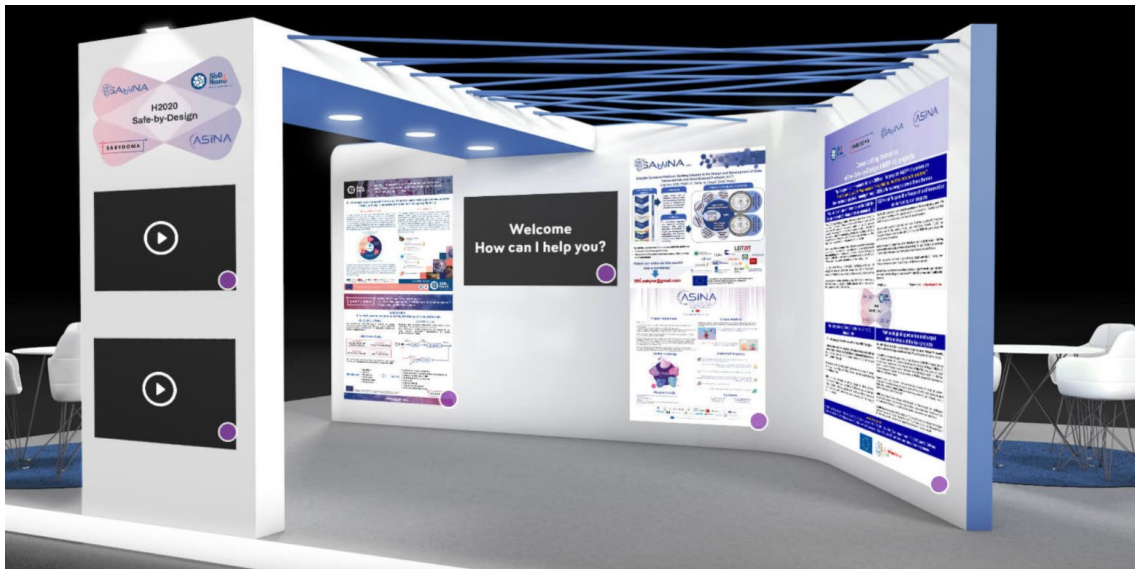


This project has received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement N° 862419.

- [EuroNanoForum \(May 2021\)- Poster and Booth](#)

Figure 3: Poster for SABYNA as part of the NMBP-15 Booth.





**Figure 4:** A participant view of the NMBP-15 Booth. Videos linked to 1) an introductory video presenting all of the projects and 2) a video presenting SAByNA’s RRI work.



## Cross-cutting thematic of the Safe-by-Design NMBP-15 projects

The European Commission's Horizon 2020 call for projects NMBP-15 centers on *"Safe by design (SbD), from science to regulation: metrics and main sectors"*. The four funded projects, running through 2024, offer coverage across these themes:

<p><b>Regulatory and governance issues for Safe by Design in nanotech - from safety to sustainability</b></p> <p>The <b>EU Chemicals Strategy for Sustainability</b> towards a toxic-free environment is a step towards the European Green Deal zero-emissions target for a pollution-free environment. The strategy promotes innovative solutions for safe and sustainable chemicals, minimizing environmental footprints, and increasing protection of people and the environment. <b>NMBP-15 projects directly contribute to the strategy</b> and ongoing international activities towards a more sustainable development, addressing also criteria beyond safety (e.g. environmental, circular, economic and social aspects).</p> <p>NMBP-15 projects <b>facilitate implementation of SbD in the nanotech innovation chain</b>, and enable the safe(r) development and application of nano by <b>advancing scientific knowledge of the potential impact</b> on human health and the environment - then provide <b>tools for real-life relevant risk prediction &amp; assessment</b> along the entire life cycle. These will support risk governance on both the regulatory and the industrial side.</p> <p><i>The four projects will deliver proper surface engineering approaches, risk management measures' performance models, new data on functionality-material relationships and tools for rapid tox screening during online production.</i></p> <p>Active dialogue with regulatory stakeholders and the NMBP-13 projects establishing a Nano Risk Governance Council will help to <b>facilitate acceptance</b> of newly developed SbD tools and predictive models for risk assessment.</p>	<p><b>ELSA and Responsible Research and Innovation are served by our projects</b></p> <p>The <b>NMBP-15 consortia have a direct experience of transdisciplinary work!</b> We gather experts from release, fate, exposure, hazard, risk assessment, materials scientists and IT developers, as well as end-users from industry and regulation.</p> <p>Obviously safer nanotech is not just a tech issue. Achieving sustainability means our solutions have to also address Ethical, Legal and Social Aspects (ELSA) and Responsible Research and Innovation (RRI). For that, the NMBP-15 teams include the social sciences and humanities.</p> <p>While <b>"Safe/rty by Design"</b> are terms often heard, our projects reveal that they cover <b>multiple and possibly contradictory meanings</b>. Our aim is to help end-users get a handle on these dimensions and make solutions more feasible &amp; cost-effective.</p> <p>So far, our projects have held a groundbreaking <b>Legal Workshop*</b>, hearing from medicine, pharma, and bigtech across Europe, North America and Asia.</p> <p>Whether you are a producer, consultant, academic or just interested, participate in our surveys and workshops to have a voice** in detailing views and priorities that shape SbD.</p> <p>*SABYDOMA <span style="float: right;">** Register here: <a href="mailto:rri.sabyna@gmail.com">rri.sabyna@gmail.com</a></span></p>
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<p><b>Industry case applications for realism and adaptability</b></p> <p>Case studies play an important role within all four NMBP-15 projects.</p> <p>In total, <b>22 case studies will implement and evaluate developed tools and infrastructures</b> to facilitate the safe(r) design of engineered nanomaterials. The use cases progress up the TRL ladder, starting at TRL4 and achieving TRL6 at the end of the project.</p> <p>All studies are performed with <b>industrial partners</b> from a range of relevant sectors: <i>paints &amp; coatings, 3D printing, cosmetics</i> as well as <i>pharmaceutical and health technology</i>.</p> <p>SMEs and large enterprises are actively engaged to identify benefits, shortcomings and limitations of the SbD approaches under realistic scenarios of use, to select cost-effective approaches, to test the user-friendliness of the support sequence, and to derive guidelines on integrating SbD into industry's innovation process.</p>	<p><b>Methodological approaches and output platforms/tools of the four projects</b></p> <p>The NMBP-15 call is explicit about using existing resources: <i>Making frameworks, models, tools and strategies available for YOU</i>. We work together to improve access.</p> <p>The <b>ASINA</b> SbD management system offers a 5-step Roadmap: 1) <b>DEFINE</b>, imagine products and processes consistent with customer demands and the enterprise strategy; 2) <b>MEASURE</b>, testing strategy to measure quality and safety attributes; 3) <b>ANALYZE</b>, data curation and expert system to generate response functions and identify the best design solution; 4) <b>DESIGN</b>, testbeds to develop and optimize the design solutions; 5) <b>VERIFY</b>, pilot plants to implement and validate the best design solutions.</p> <p><b>SABYNA</b> supports safe innovation and manufacturing processes by small and medium enterprises. A web-based platform will integrate and streamline existing tools. <b>SMEs can input limited data to obtain tailored guidance</b> on identifying, assessing and mitigating risks to workers, consumers and the environment.</p> <p><b>SbD4Nano</b> develops a novel software "e-infrastructure" to foster dialogue and collaboration between actors along the nanotechnology supply chain for a knowledge-driven definition of Safe-by-Design approaches based on hazard, exposure, product performance and cost criteria.</p> <p><b>SABYDOMA</b> is developing two demonstrators at TRL6 as specific safety-by-design technologies. During the development process through the SABYDOMA case studies, the demonstration of these technologies within the other three projects' programmes will be encouraged.</p>
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**Figure 5:** One of the NMBP-15 project posters which utilized cross-project collaboration to identify key thematic linkages across sister projects ASINA, SABYDOMA & SbD4Nano.

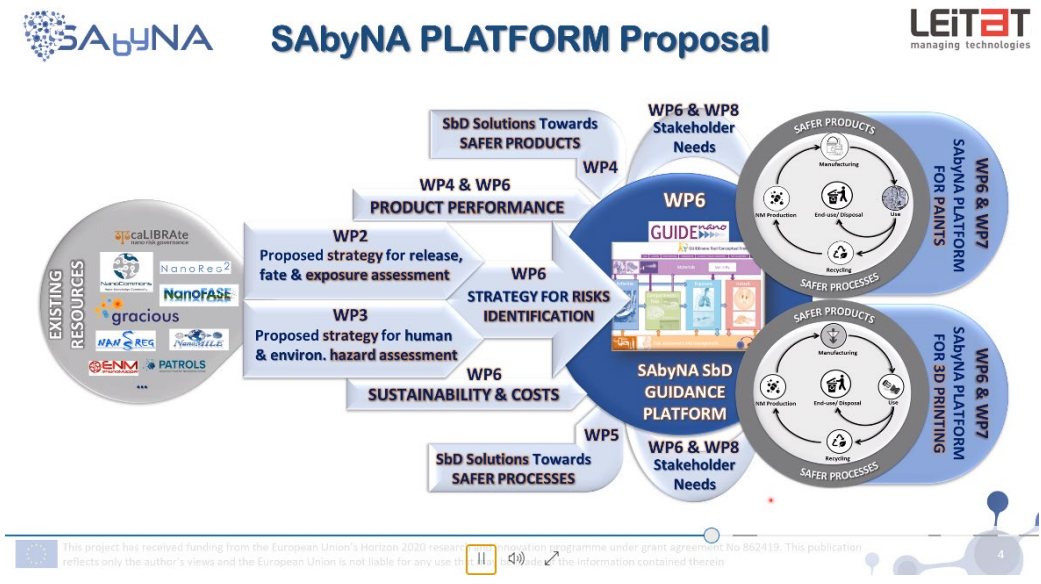


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- Nanotox Conference (April 2021)- Poster



- NanoSafety Cluster Education Day within the NANOSAFE Conference (Nov 2020)- Organizer of the session on: “Elements of Safe-by-design for sustainable development and innovation of Nanomaterials” and of the session on: “Science Diplomacy: A New Way to Think About Your Role in a Community of Research”- Oral presentations



- 1st Meeting with SABYNA's Advisory Board (October 2020)- Oral presentation & discussion session

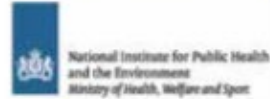


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Coordinator



PARTNERS



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