

Safe by Design: Fostering Interdisciplinary Dialogue

Findings, Methods, Materials
Jan 2022



#### INTRODUCTION

The Responsible Research and Innovation (RRI) team of Horizon 2020 Project SAbyNA is looking at how members and stakeholders of the **nanosafety community** can better communicate with each other regarding **Safe/r/ty-by-Design (SbD)**.

Our central hypothesis? That individuals conceive of SbD based on their disciplinary backgrounds and on their professional role. The SAbyNA RRI Team uses methods drawn from empirical social psychology to assess this hypothesis.

This brochure serves as both a brief public report of our approach and a stimulant for readers interested in leading conversations about SbD with their own colleagues or stakeholders.

#### In this brochure you will find

- 1 <u>Definitional Work</u>: What is SbD?
- 2 <u>Social Representations</u>:

  From specialist meanings to shared identity
- 3 The SAbyNA Mini Survey of SbD Representations
- 4 Exploring Meanings with Stakeholders:
  Workshop Methods and Materials
- 5 Notes

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# 1 Definitional Work



## WHAT <u>IS</u> SBD?

A single internationally accepted or standardized definition of SbD does not yet exist. Below we offer a sampler of overarching definitions of SbD, from projects and actors in the nano community today.

#### **OECD**

A working definition was provided by the OECD in December 2020 but has yet to be implemented in regulatory guidelines, thus leaving the door open to interpretation.

"14. The SbD (Safe-by-Design, Safer-by-Design, or Safety-by-Design) concept refers to identifying the risks and uncertainties concerning humans and the environment at an early phase of the innovation process so as to minimize uncertainties, potential hazard(s) and/or exposure. The SbD approach addresses the safety of the material/product and associated processes through the whole life cycle: from the Research and Development (R&D) phase to production, use, recycling and disposal.

- "15. For SbD in nanotechnology, three pillars of design can be specified:
- I. Safe(r) material/product: minimising, in the R&D phase, possible hazardous properties of the nanomaterial or nanoenabled product while maintaining function;
- II. Safe(r) production: ensuring industrial safety during the production of nanomaterials and nano-enabled products, more specifically occupational, environmental and process safety aspects; and
- III. Safe(r) use and end-of-life: minimising exposure and associated adverse effects through the entire use life, recycling and disposal of the nanomaterial or nano-enabled product. This can also support circular economy.

"16. Safety to human health and the environment is always relative rather than absolute. SbD strives for negligible human and environmental safety risks through an acceptable balance between safety, product functionality, and, as far as possible, costs, while meeting any applicable regulatory requirements for human and environmental safety and taking into account how the specific aspects of the innovative material/product may affect safety. In addition, the SbD approach helps to produce the safety-related information and data needed in order to comply with regulatory requirements and effectively communicate on any remaining risks." (OECD Dec 2020)

### **EU Chemical Strategy for Sustainability**

"Safe and sustainable-by-design can be defined as a pre-market approach to chemicals that focuses on providing a function (or service), while avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile. Overall sustainability should be ensured by minimising the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a lifecycle perspective." (European Commission Chemicals Strategy for Sustainability 2020)

#### **European Commission**

"Sustainable-by-design is an approach that aims to deliver a major change in how we make sustainable and healthy products and materials. It's a systemic approach to integrate safety, circularity and functionality of products and processes throughout their lifecycle, from design to end of life (also considering the possibility to recycle, reuse or repurpose them)." ("Advanced Materials" - Europa Online)

#### References

**OECD:** OECD Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled products (Dec 2020) Link: https://tinyurl.com/4vz9trcr

#### **European Commission Citations:**

Chemicals Strategy for Sustainability - https://tinyurl.com/6ay93289 Advanced Materials - https://tinyurl.com/ebdc5y2b

## H2020 Project SbD Definitions



#### NMBP-15 Projects

#### SAbyNA (SAfety BY design of NAnomaterials)

"SbD is about including safety at the earliest possible stage of product development, with the intention to ensure a healthy and safe living environment. Risks are identified and addressed as early as possible, and are kept low in order to ensure intrinsic safety throughout the whole life cycle." (Nanosafety Cluster Working Group E Dec 2021)

#### SbD4Nano (Safe-by-Design For Nano)

"The project explores the Safe-by-Design concept as a means to dampen human health and environmental risks, applying preventive safety measures during the design stage of a facility, process, material or product." (SbD4Nano Website)

#### SABYDOMA (SAfety BY Design Of nanoMAterials)

Reviewing literature for SABYDOMA, Ben Trump and Factor Social found that SbD is comprised of two key concepts:

- "Prevention rather than correction bringing concepts of safety to the earliest stages of development.
- "Active safety engineering out undesirable effects before they enter the marketplace."

In a <u>webinar</u> they observe that there is no one foundational publication establishing SbD in core literature, and emphasize that SbD is currently discussed as more of an aspirational philosophy than a defined process.

#### ASINA (Anticipating Safety Issues at the design stage of NAno product development)

"The Safe-by-Design concept (SbD) incorporates safety of nano-enabled product (NEP) at the design stage of the production process. SbD reverses the paradigm of downstream risk analysis and management ('is it safe?', 'can it be controlled?', 'does it transform?') and pursues the production of less hazardous nano-products affording reduced exposure, mediated by the release of nanomaterials during the life-cycle." (ASINA website)

#### NMBP-16 Projects

## SUNSHINE (Safe and Sustainable Design for Advanced Materials)

One of the new series of H2020 NMBP16 projects that focus on the enlarged concept of Safe-and Sustainable-by-Design, SUNSHINE organized a webinar presenting SSbD definitions drawn from European Commission discourse found on the previous page.

## DIAGONAL (Development and scaled Implementation of safe by design tools and guidelines for multicomponent nanomaterials and High Aspect Ratio Nanoparticles)

"Safe-by-Design principles actively eliminate or reduce risk during design development and ensures that remaining risks are effectively communicated." (DIAGONAL Website)

#### HARMLESS (Advanced High Aspect Ratio and Multicomponent materials: towards comprehensive intelLigent tEsting and Safe by design Strategies

"Safe-by-Design approaches have to predict how the multidimensional design space may affect the functionality for the intended use. [...] Potential users of Safe-by-Design suffer from the complexity and variety of testing methods." (HARMLESS Website)

#### References

SABYNA: Project Coordinator Socorro Vázquez-Campos speaking at the online Nanosafety Cluster Working Group E December 2021 Meeting SbD4Nano: https://www.yordasgroup.com/news/sbd4nano

SABYDOMA: https://www.youtube.com/watch?v=LPLe3S60ZtE
ASINA: https://www.asina-project.eu/project-objectives/
SUNSHINE Webinar: https://www.youtube.com/watch?v=bcHBbM6DFr8

DIAGONAL: https://www.diagonalproject.eu/scale-up/ HARMLESS: https://www.harmless-project.eu/project-summary/

NMBP-15 Projects:

https://tinyurl.com/jamd699 NMBP-16 Projects: https://tinyurl.com/4sdxu53s



## Definitions Summary

- SbD has a number of different working definitions,
   each with its own nuances and focuses.
- Published definitions look like guideposts and ambitions, rather than a concrete process or regulatory guidance.

SAbyNA and the other H2020 NMBP-15 and NMBP-16 projects are working to create platforms, processes and tools that can support industry in achieving safe, sustainable nano enabled products for Europe. They are all considering elements of definition to forward that goal.

As part of that, SAbyNA's Responsible Research and Innovation (RRI) team decided to look more deeply into what members of the community **say** and **think** about SbD.

We used the concept of social representations to shape our research.



## 2 Social Representations



#### SOCIAL REPRESENTATIONS

#### From specialist meanings to shared identity

The theory of **social representations** proposes that the members of a community share a fund of views, meanings, and understandings, constructed through shared practices and communication (Moscovici 2001). These views, meanings, and understandings, called social representations, form part of the fabric of group culture. Whether they remain in the unspoken background or are explicitly discussed, they help to transmit group culture. We can therefore expect to find social representations of "safe/r/ty by design" in communities dealing with the concept, and we might expect that these representations or meanings vary across communities.

## Social representations: Special to each group, with potential to be more broadly shared

Central SAbyNA stakeholders (such as industry practitioners, scientists, regulators) engineers, specialized on varied aspects of nanotechnologies. They may come from different disciplinary backgrounds, and according to their role they develop distinct ideas about nanotech and have different everyday practices (Bertoldo et al., 2015). Particular representations, information and assumptions make up part of the specialist knowledge held in each stakeholder group. Eventually, thanks to exchange of knowledge, discussion and practical activity between groups, shared representations will diffuse towards larger societal spheres (Bauer and Gaskell 2008).

Our work seeks to reveal these social representations so that they can be discussed and elaborated across the SbD communities. By identifying the aspects of SbD that are most meaningful according to different stakeholders, projects can fine-tune communications, making platforms and toolkits more attractive and accessible - in particular to the industry end users they are intended Furthermore. social to serve. representations theory suggests that by talking and thinking about SbD, the European nanosafety projects will contribute not only to providing safer, sustainable technology and products, but also in the long term to making nanotechnology part of the European cultural identity.

#### References

Martin Bauer & George Gaskell (2008). Social Representations Theory: A Progressive Research Programme for Social Psychology. Journal for the Theory of Social Behaviour. 38. 335 - 353. 1

Raquel Bertoldo, Claire Mays, Marc Poumadère, Nina Schneider, Claus Svendsen (2015). Great deeds or great risks? Scientists' social representations of nanotechnology. Journal of Risk Research. 19(6).

Serge Moscovici (2001) Why a theory of social representations? In Representations of the social, ed. K. Deaux and G. Philogène, 8-35. Oxford: Blackwell.



# 3. The SAbyNA Mini Survey of SbD Representations



#### The SAbyNA Mini Survey of SbD Representations

The SAbyNA RRI team used social representations research methods to learn about the informal definitions of SbD used by individuals working in nanotechnology. An online mini survey conducted worldwide from January to June 2021 asked: "What are the first words or ideas that come to mind when you hear the term 'Safe-by-Design'?", and also collected disciplinary background. We hypothesized that our data could show how different ideas or notions may be associated more strongly with disciplinary groups.



nat come to mind when you hear the erm 'Safe-by-Design'	2. What is your pinnary training.
Vord/Idea 1	
	Physical sciences & engineering
Vord/Idea 2	
7. 1/11. 2	Life sciences
Vord/Idea 3	
Vord/Idea 4	Social sciences and humanities

It's easy as.... 1 mini-survey 2 minutes 3 words

AHUNA





#### Global **Dissemination**

#### 164 PARTICIPANTS WORLDWIDE

**164** self-selected persons provided usable responses, with 69 describing themselves as physical scientists/engineers, 47 as life scientists, 8 as social scientists (for a total of 124 participants reporting disciplinary background). They returned a total of 462 separate responses, ranging from a single word entered into an available field, to sentence-long answers.\*

## Mini Survey Category Codebook

We developed a codebook to categorize the survey replies. Two independent coders agreed on these 23 categories after approaching the raw data respectively from the bottom up (so-called 'thematic coding') and from the top down ('content analysis', using risk governance knowledge and existing SAbyNA categories).

Frequency	Category Name	Category Abbreviation	Definition (when needed for clarity). The survey reply of "words or notions" included a clear reference to:	
44	Anticipate	Anticip	SbD as taking steps early in a design process, anticipating risks.	
37	Safe/r/ty	Safe/r/ty	"safe", "safer", "safety"	
35	LCA/Sustainability	LCA/Sust		
35	Risk_Mitigation	Risk_Mit	Risk, mitigation, reduction, control, etc.	
31	Nanoform_Properties	NF_Props	Properties, modifying properties, choosing different nanoforms	
29	Safety_Human Health	S_Human		
28	Safety_Environment	S_Envir		
25	Metaknowledge	Metaknow	Particular scientific disciplines or methodologies; data or databases; European projects by name	
23	Noble	Noble	SbD as an admirable or good thing; particular features or qualities of SbD that (also) make it positive or desirable.	
21	Innovate	Innovate		
18	Balance	Balance	SbD as implying balancing of different concerns or effects including cost; optimization	
17	Philosophy	Philo	Slogans like, "safety first"; "it's a mindset"; SbD as a conscious approach or requiring a certain attitude	
14	Process	Process	Process or selecting a safer process.	
14	Toxicity	Tox		
13	Assess	Assess	Assessment methods or targets, the need to perform assessment.	
13	Critique	Critique	Criticism, objections	
13	Product	Product		
13	Safety_Inherent	S_Inher		
10	Nano	Nano	"nano" or "nanotech" or "nanoparticles" etc.	
10	Safety_Occupational Health	S_Occu		
7	Industry	Industry		
7	Regulation	Regul		
6	Exposure	Exposure		

In qualitative work of this type, categories are not strictly exclusive. Classifying the survey responses requires interpretation and judgment. For this reason, it is useful to engage stakeholders in co-constructing results.

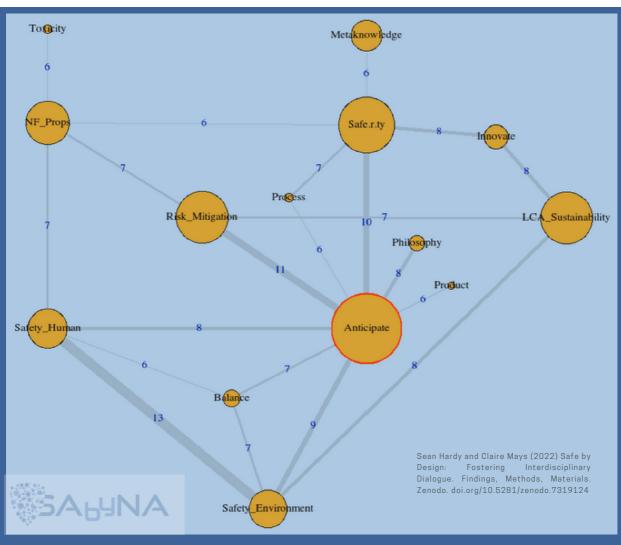
We describe in the **next pages** some of the **data presentations** we developed, and settings in which we offered the findings for **stakeholder discussion**.

## Mini Survey Data Visualization: Similitude Analysis - "Webs"

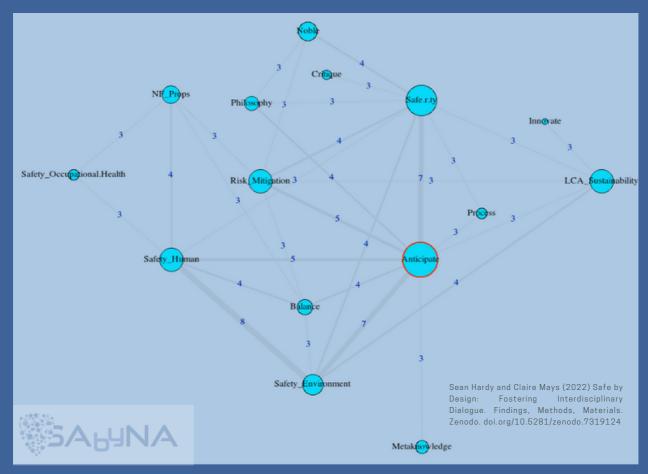
One method of analysis looks at "similitude" across survey replies. The weblike graphs on the next two pages show which ideas "go together" in the collective responses.

- Each bubble represents a particular category (larger bubbles are more frequently used categories - representing ideas or notions more frequently cited by our survey participants).
- A line joining two bubbles represents a connection between the two categories the number shows how many participants evoked both of these categories in their personal response.

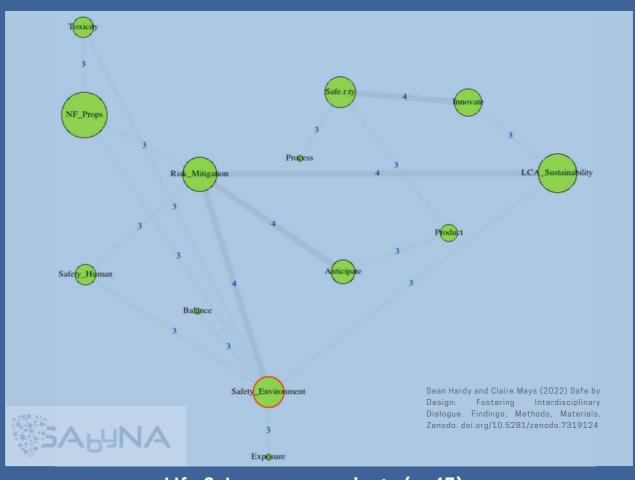
The Similitude Analysis brings out the **frequency** of these paired connections. For social representations theory, it's even more useful to pinpoint the categories that get the widest **variety of paired connections**. These are circled in red in the graphs below. Based on the frequency and variety of connections, we can determine which ideas are most central, or widely shared, across different members of the group.



All respondents (n=164), all disciplinary backgrounds
'Most connected' notions (high frequencies & paired connections)



Physical Sciences / Engineering respondents (n=69)



Life Sciences respondents (n=47)



#### Preliminary Analysis

Looking at all three graphs, we see a wide, diffuse web of ideas or categories evoked when a given group of people think of SbD.

Drilling down on the Physical Sciences / Engineering and Life Sciences groups, we see that:

- The fund of ideas about SbD remains rich and varied...
- ... and also, perhaps insufficiently defined.
- Judging in terms of <u>frequency as well as variety</u> of paired connections *our criteria for a "central" social representation* a compelling, highly shared meaning has not yet emerged in the disciplinary groups.

These results are coherent with the fact that out in the real world, standardized definitions have not yet been set. The nano community, in all its variety, is still actively discussing, debating, and developing the concepts and practices of SbD.

Still, these data are very suggestive of ideas that could come to define SbD more strongly in the shared culture of groups!

In terms of communication about SbD, what would **YOU** focus on to grab the attention of:

Physical Scientists / Engineers
Life Scientists
The General Nano Community?

Our thoughts on next page!

#### **Conceiving SbD:**

#### **Outstanding Categories and Group Distinctions**

Looking closer at the frequency nuances between graphs, we identified several key differences hinting that shared meanings, or social representations about SbD, are oriented differently for the different disciplines.

## Social Representation?

#### 'MOST CONNECTED' CATEGORY

**Full Data Set:** "Anticipate" - 8 connections **Phys / Engineer:** "Anticipate" & "Safe/r/ty" - 9

connections

Life Sciences: "Safety\_Environment" - 7
connections

Based on the preliminary returns to our Mini Survey, several communication points seem to jump out:

Physical Scientists/Engineers may engage more with "Anticipation" as a central component of SbD, while Life Scientists appear more focused on "Environmental Safety".

Physical Scientists/Engineers may highlight the process or technological dimensions of SbD, while Life Scientists may focus more on how SbD mitigates effects of nanoforms on biological and ecological systems.

## Specialized Associations

#### CATEGORY CONNECTIONS UNIQUE TO DISCIPLINE

Phys / Engineer: "Noble", "Critique", "Innovate"
Life Sciences: "Safety\_Environment",

"LCA\_Sustainability", "Risk\_Mitigation" and

"NF\_Properties"

#### **Central Concepts**

#### HIGHLY CONNECTED CATEGORIES

Full data set, all disciplinary backgrounds: 14 categories Phys / Engineer: 15 categories Life Sciences: 13 categories

#### Communication advice?

- When European projects want to send messages about SbD, and about the tools under development, they might do well to try to "speak the language" of these respective groups.
- Communities can amplify their interdisciplinary discourse: e.g. Life Scientists might articulate their main mitigation concerns to Physical Scientists who can propose chemistry or engineering processes to address them.

SAbyNA's RRI team in 2022-23 will be developing a more complex questionnaire and further consultation activities to pinpoint central SbD concepts for different stakeholder roles including industry, regulators, and consumer representatives.



## 4.

# Exploring Meanings with Stakeholders: Workshop Methods



# Analyzing the Mini Survey: LEITAT Co-Construction Workshops



We turned to co-constructing the Mini Survey results with stakeholders in order to tease out nuances that experts and practitioners found important. We organized two in-person workshops with LEITAT to explore the results with stakeholders in SAbyNA's SbD industry case study areas. Business and technical skills were represented among the participants.

- 3D Incubator LEITAT (Barcelona) Experts specialized in 3D printing, including nanoenabled components, and familiar with safety and design issues.
- LEITAT Technological center (Terrassa) Experts working in textiles and familiar with the incorporation of nano in textiles.

We share our workshop outline below. Readers can draw ideas about both:

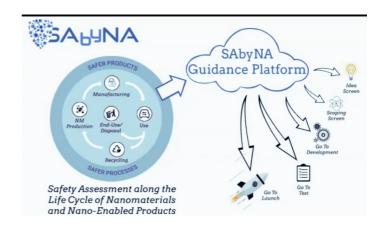
- how to organize discussion workshops (using e.g. survey materials and 'Definitional Polarities') and
- the types of reflection that emerged from this group activity.

#### **WORKSHOP OUTLINE**

We first invited participants to give their own definitions of SbD, discuss whether SbD is something already integrated in their practice, and self-identify their work within the nanosphere.

We followed up with discussion of industry demands for SbD guidance\*, relating these to our participants' own practice and needs.

Next we moved to the three Similitude Analysis "webs" presented above and invited participants to interpret these data. \*The SAbyNA SbD Guidance Platform Development Team consults industry about the areas in which support is most wanted. Follow @SAbyNA\_eu on Twitter for invitations to industry workshops to learn more about findings and to shape the SAbyNA Platform.



## Co-Construction Workshop Results: Stakeholder Interpretations

#### 3D Printing

SbD in their practice Participants said they work actively with safety in all aspects of their process without actually articulating the term SbD. Safety discussions in their context center particularly on product usage and occupational health.

#### Textiles and Consumer Products

Participants stated SbD is a European project-driven initiative that reveals a new quality of introducing safety considerations into the earliest design or proto-design phase. They explained that this differs from considering safety as an element that you evaluate as you progress along the product development life cycle.

#### Interpreting the "webs" - Hypotheses and surprises

#### 3D Printing

Looking at the Similitude Analysis

webs, these stakeholders interpreted that physical scientists appear more focused on executive, critical reasoning, while life scientists work with more hypothetical concepts. They surmised that physical scientists, more likely to work directly with nano forms, easily associate a range of technical concepts drawn from this practice. By contrast, they found that life scientists did not link outstanding categories like "Human Health" to concepts like "innovation" and "manufacturing", perhaps because they are less involved in these parts of the

Stakeholders expressed surprise that "Metaknowledge" showed low connectivity, because for them **knowledge** is the key component to ensuring safety protocols. Similarly, stakeholders were intrigued that "Exposure" was less salient, while "Sustainability" stood out.

nanosphere.

*Textiles and Consumer Products* 

These stakeholders initially

hypothesized that physical scientists would focus more on technical aspects of nanomaterials, while life scientists would be focused more on broader safety questions such as risk mitigation, human health, and the environment.

Examining the "All Respondents - All Disciplines" web. participants identified four potential types of respondents, those who focus on: "material properties", "definitions", "risk mitigation" or "social science". They predicted that physical scientists would predominantly select the "material properties" categories. However, upon looking at the two graphs isolating disciplines, they expressed surprise that all four response types actually applied to both physical/engineering and life scientists.

Overall, when comparing discussion by the two workshop groups, we see the emergence of several common themes.

- Increasing knowledge is the key to implementing SbD.
- 2. SbD offers novel perspectives on how to achieve safety.
- 3. Participants
  validated the codebook
  as appropriately
  spanning the potential
  nuances of SbD.
- 4. People intuitively know that differing social representations are at play during SbD conversations between stakeholders with different backgrounds.

Such co-constructive analysis could go deeper by adding contextual variations, discussing e.g. a manufacturing method, 'process vs. product' orientation, etc.

#### Roleplay at the 2021 Online Nanosafety Training School



At the 2021 online Nanosafety Training School, hosted by the EU NanoSafety Cluster, 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 young career researchers across nanoscience disciplines to come together in a "serious game" setting to discuss Safe/r/ty-by-Design. Forty people from a range of disciplines registered, with twenty-six attending. We outline the methodology for conducting this cross-disciplinary workshop as a blueprint for similar SbD communication activities, and also provide takeaways from student presentations on important SbD communication needs.

#### **SERIOUS GAME OUTLINE**

Participants were invited to roleplay as members of various SbD stakeholder groups (industry, academia, regulators, elected officials, and consumers) participating in a **United Nations Sustainability Summit**. Each was assigned to a stakeholder role and joined a private Zoom breakout room with their stakeholder 'peers' (organizers made sure to assign a wide variety of disciplines and profiles to each room so that each 'stakeholder group' was well mixed).

- They spent the first few minutes discussing how that stakeholder group might define and think about SbD. Then, returning to plenary, the stakeholder groups learned their task: to provide a UN Sustainability Committee with stakeholder-specific recommendations on these vital issues for SbD: "How do we know a nanoform 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 broke out again to discuss these issues, and brought back Miro boards to present in plenary from their stakeholder viewpoint.

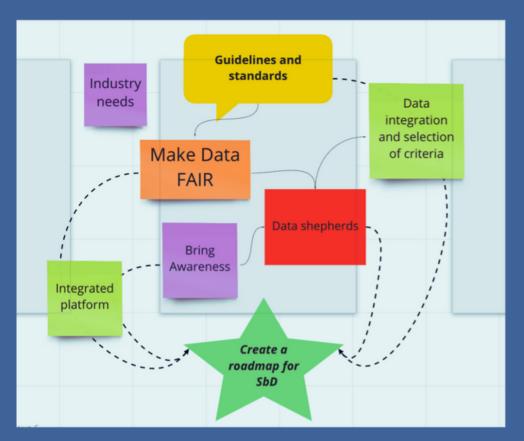
Roleplay is an interesting method to help participants reflect on definitions, representations and positions. By projecting yourself into someone else's role you can:

- Gain more insight on what they may think
- Look at your own ideas and representations differently
- Reflect on the relationships between your group and other groups/roles.

It helps to have a clearcut task, such as presenting a stakeholder opinion to an important authority like the fictional "UN Sustainability Committee"!

Here we highlight two examples of student presentations.

Both boards highlight **improved communication across stakeholder groups** as a top priority within SbD - emphasizing that knowledge today is being generated but perhaps not integrated, internalized, or actively directed to the appropriate actors.

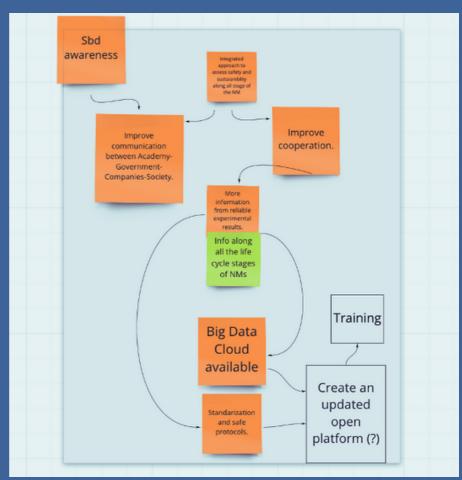


#### The First Stakeholder Opinion

"SbD data and protocols generated within academia need to be actively more 'shepherded' out across groups. At the same time, academia must listen to industry needs for cost effectiveness in order to accurately develop a roadmap."

#### The Second Stakeholder Opinion

"We imagine a big data cloud as a platform that everyone can use (not just researchers, industry, but rather all members of society). The goal would be thus to focus on training and learning such that SbD models can actively iterate and update over time."





## SbD Definitional Polarities

In addition to our global Mini Survey, we also sought to approach SbD definitional differences through a series of 14 one-on-one interviews with expert stakeholders in academia, industry, and the public sector. Interviewees were located across the world (Brazil, France, Spain, Netherlands, United Kingdom, United States) and had different disciplinary backgrounds or focus (ecotoxicology, materials science, physics, exposure).

Analyzing these interviews yielded representative quotes that can be regrouped across six "polarities" or areas of tension, demonstrating a range of views and concerns on SbD.

These polarities or tensions, printed with sample quotes on six large cards, were useful material at our co-constructive stakeholder workshops, fostering reflection and discussion. More or different statements could be added.

Knowledge of these tensions can help to orient communication of the SAbyNA Guidance Platform. Communication should seek to address these core tensions and the concerns raised by different stakeholder groups.

We offer this material for future workshops and project discussions and would be happy to see it used!

If you reproduce our material, please cite this report so that others can read up on our methods.

Sean Hardy and Claire Mays (2022) Safe by Design: Fostering Interdisciplinary Dialogue. Findings, Methods, Materials. Zenodo. doi.org/10.5281/zenodo.7319124

#### **Knowns/Unknowns**

Stakeholder interviewees across disciplines evoked needs for more concrete data in order to properly evaluate the impact of SbD for their field (e.g. industry actors pointed to cost-benefit analysis needs, environmental toxicologists called for environmental safety data, etc).

#### Unachievability/ Achievability

While some stakeholder interviewees pointed to unfeasible pressures induced by the implementation of a SbD process, others used historical references and modern-day protocol to argue that SbD is/has been already in practice.

#### Values Driven/ Rules Based

Stakeholder interviewees diverged on how SbD should be introduced throughout the product life cycle. Some emphasized the need for the process to be dictated by regulation (Rules Based), others emphasized that SbD is an independent holistic approach to nanoenabled product production (Values Driven).

- Not many people can say what they mean by Safe/r/ty-by- Design with respect to nano. They can talk glibly about modifying the surface for something, but that might make it unusable. There's a lot of naiveté there.
- Industry would like to see more work being done on commonly produced materials (vs. theoretically "interesting" compounds).
- People have to talk right at the first stage about what they're going to do in a way enabling the environmental or release safety assessors to create a conceptual model. But commercial sensitivities make that hard to talk about. If it's described in too general a fashion, then assessors can't help people.
- There has been insufficient effort to link the quantitative measures of release into the environment, exposure to the organism, and effects at every stage.

- Safe By Design I would define initially as unachievable.
- We can't predict the future. All we can do is interpret based on data we have now.
   With the best knowledge we have today, I can say to you that X is Safe/r/ty-by-Design, but new data may be found in years to come.
- And then we're worried about accidents, if you're shipping it by rail and have a train that goes off the rails and we have release into a watershed, etc., what happens?
- Safe/r/ty-by-Design is a mindset. It's not about strictly following the rules.
- It's, "I think before acting. I think about the By-Design principles". It's more than just starting early in your product or your development phase with giving attention to safety. It's also about the value of safety.
- Safe/r/ty-By-Design is more like a process than an absolute target that you need to get to, because nothing is "safe".

#### **Inherently Safe**

While certain stakeholder interviewees focused on "inherent" safety related to core properties of the nanoform, others focused on inducing safety actively at every step of the production process.

#### **Balance**

Stakeholder interviewees across disciplines evoked concepts surrounding the theme of "balance", however they differed with regard to what should be balanced. While some focused on "cost and efficacy", others honed in on "human and environmental health".

#### **Occupational Health**

Stakeholder interviewees split on whether Occupational Safety is currently implemented on a procedural level, or whether it is driven by specific individuals.

- Safe/r/ty-by-Design refers to the principle of what is called "Inherently Safe Design", meaning something will not generate damage and negative impacts on users and on the environment. At the time of design, all the barriers have been put in place and are all passive -- they do not need knowledge, or external resources, or to be activated.
- Does Safe/r/ty-by-Design mean something that's inherently safe? Because a lot of chemists would tell you that there's no such thing as a safe chemical. All chemicals are to some extent hazardous.
- If we don't manage to have an absolute level of safety, it's better to explain that there is a reasonable reduction of the risks, returning to notions that were in vogue in the 90's: ALARA & ALARP.
- We have to be careful when we say we built something that is Safe/r/ty-by-Design. People hear "safe" and think it means that there is no problem when in fact there is a residual risk.
- The challenge with a funded project is you can't give me a true cost because it's not being done on a commercial footing. You can't do a proper cost-benefit analysis because you don't have the costs, and you don't talk to me about the benefits of what this will do for me.

- The intention should be that the production process is as safe as possible given the material components such that the people who are working in production are safe.
- Our engineering manager was extraordinarily diligent in ensuring both the safety of both the operation and of all the staff. If anyone were to suggest doing less than you could possibly do, he would have them by the throat.
- My staff can wear PPE. I can overdesign their PPE. I can manage all my waste within my control. But the minute we've put the product into a bottle and sold it, there it goes. That's our real safety challenge. What happens in this material when we don't have control of it?

#### Conclusion



Throughout this deliverable report, H2020 SAbyNA's Responsible Research and Innovation (RRI) team has presented preliminary data and findings as to how the breadth of SbD definitions may be influenced by disciplinary training. We also provided a toolkit (workshop methodologies and materials) to facilitate SbD reflection and development within the nanosafety community.

We noticed a unifying factor across activities, disciplinary backgrounds, and expertise levels: participants consistently stress the link between **knowledge** and **safety**, specifically that increased knowledge (data, transparency and ease of access) leads to increased safety.

Projects should be sure to speak the language of their SbD stakeholders. More broadly, to make SbD grow as a part of nanosafety and European identity, public communication of our communities' work and results should emphasize how shared generation of knowledge about SbD may in and of itself reinforce safety.

In 2022-23, SAbyNA will be conducting further surveys (including an attention to gender analysis) and co-constructive workshops with the nanosafety community, to help us all delve into the multiplicity of meanings of our everyday terminologies, and fine-tune SbD communication.



## 5. Notes



#### Mini Survey:

#### Who filled it out? How did we process replies?

Our 2021 survey was presented online in three editions:

- i) A standalone survey disseminated via social media and direct contact.
- ii) As part of the larger "Industry survey" conducted by SAbyNA in liaison with NMBP-15 project SbD4Nano.

Disciplinary data is missing for 40 (of 73) respondents who did not go to the end of the full half-hour Industry survey. Their replies are excluded from the disciplinary subgroup analyses.

iii) As part of registration for SAbyNA's "RRI Roleplay Workshop: Safe-by-Design Sustainability Forum" held at the 2021 NanoSafety Training School.

Edition	Period Disseminated	Communication Channel	Number of Respondents
WP8 Standalone Mini Survey	Jan - April 2021	Link publicized through: Twitter (SAbyNA, personal accounts of the research team, US CoR contacts); One-On-One Interviewee direct outreach; SAbyDOMA "Legal Workshop on Safe-By-Design" chat function; NSC Newsletter 22 (March 2021); email lists and listservs: NanoFATE Young Scientists, Research Triangle Nanotechnology Network (RTNN), former members of CEINT, US-EU CORs, NCIP NanoWG.	59
NMBP-15 Industry Survey	Jan - Feb 2021	Stakeholders from SAbyNA & SABYDOMA were invited by email to fill it out. Advertised on the web pages of the four NMBP-15 projects (ASINA, SABYDOMA, SbD4Nano and SAbyNA) and in their social media. (SAbyNA T6.1 Report on the results of the stakeholders questionnaires.)	33 complete + 40 missing disciplinary data
RRI Roleplay Workshop Registration Survey	June 2021	Online registration form filled out by EU NanoSafety Cluster Training School Participants	32

We coded our Mini Survey data using **ATLASTi** 9.1 software and generated the Similitude Analysis "webs" using **IraMuTeq** 0.7a (leaving out pairings shared by few participants, to reduce noise).

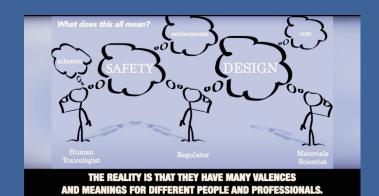
Our methodology and full findings will be reported in future peerreviewed publications, co-signed with our colleague Raquel Bertoldo (Aix-Marseille University).

#### **Methodology Video**

We invite you to watch our publicly accessible video developed for the 2021 EuroNanoForum, in which we explain our approach and reasoning as well as present a preliminary data output.

URL: https://www.youtube.com/watch?v=yXjHiTRbeE0





You are welcome to re-use our workshop methods and materials for live discussion activities if you properly credit them. Please acknowledge our work with this citation:

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