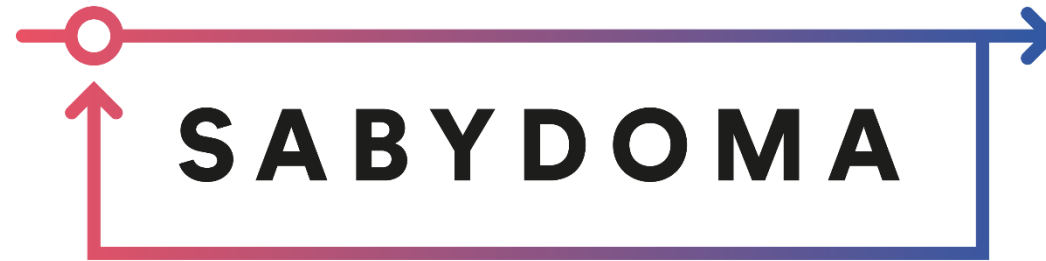


**SAfety BY Design Of nanoMAterials –
From Lab Manufacture to Governance and Communications:
Progressing Up the TRL Ladder**



*SABYDOMA project has received funding from the European Union's HORIZON 2020
Research and Innovation Programme under grant agreement no. 862296.*



SABYDOMA Workshop:

A Stakeholder's Perspective of Safe-and-Sustainable-by-Design (SSbD)

28th February 2022, GoToMeeting

Agenda

10:00 Welcome and introduction to the workshop

by Andrew Nelson (University of Leeds, UK)

10:05 1st Legal Workshop on Safe-by-Design: Summary and Output of the workshop

by Anthony Bochon (Gil Robles - San Bartolome & Partners, BE)

10:20 External opinions on Sustainability in SSbD:

Academia, Industry, Regulators, NGO, Consultancy, Other

(A 10min break is included in this session)

- Victor Puentes, Applied Nanoparticles, ES
- Mario Pansera, University of Vigo, ES
- Eva Valsami-Jones, University of Birmingham, UK
- Denis Sarigiannis, PARC project
- Jana Drbohlavová, European Commission
- Henrik Edin, ChemSec, SE
- Xenia Trier, European Environmental Agency (EEA)
- Anne Chloe Devic, European Chemical Industry Council (CEFIC), BE
- Blanca Suarez, TEMAS Solutions GmbH, CH
- Sean Kelly, Nanotechnology Industries Association, BE

12:00 Survey of SSbD moderated by Beatriz Alfaro (BNN, AT)

12:10 Break

12:15 Round Table moderated by Ignasi Gispert Pi (Applied Nanoparticles, ES)

12:55 Wrap up and end of the workshop by Anthony Bochon

Introduction to the Workshop


by Andrew Nelson, University of Leeds, UK

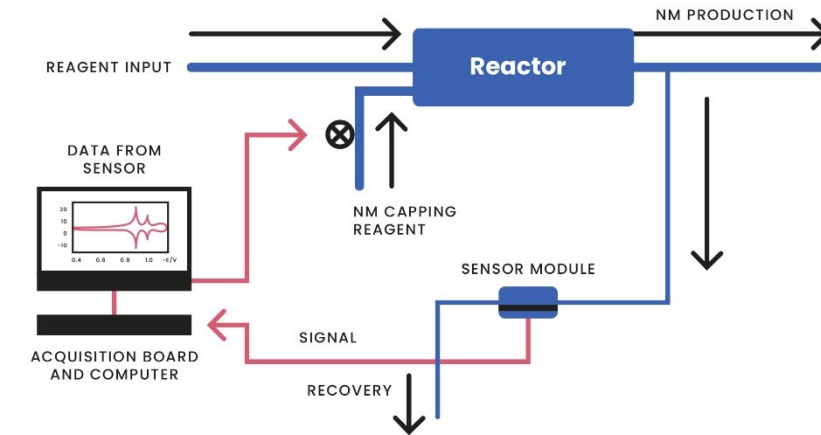
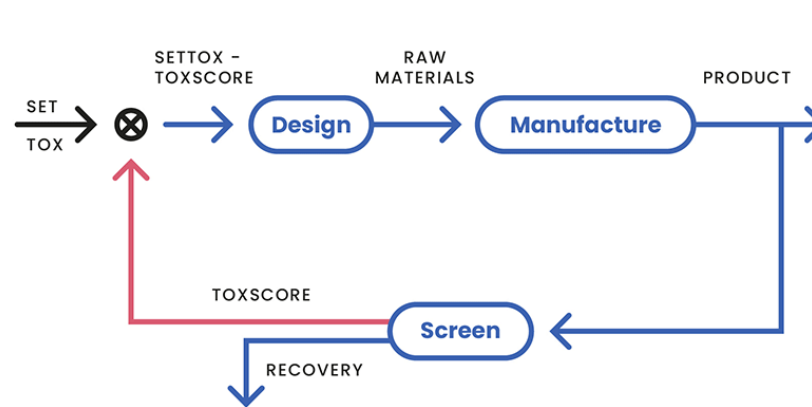
SABYDOMA: SSbD Workshop

Hi Everyone!

- Thanks for coming and welcome to the SABYDOMA SSbD workshop.
- First of all let's thank Beatriz Alfaro from BNN for organising this workshop. Many thanks Beatriz!
- Secondly, thanks to all speakers from whom we are going to hear really interesting and varied talks this morning.
- And finally, enjoy the show but before that a few introductory words.

SABYDOMA - A 3rd Generation Solution to Safe-and-Sustainable-by-Design

- Aim of  is to directly couple screening to production/release → 'Safe-by-Design'



- 'Sustainability' is implicit in SABYDOMA arising from its circular configuration and *online* micro design => 'Safe-and-Sustainable-by-Design'. SABYDOMA has global application.
- SABYDOMA is therefore contributing to this 'hot' topic area by gathering different opinions of SSbD from respective stakeholder communities from academia, industry, NGOs, etc.

1st legal Workshop on SbD

Summary and Output of the workshop

by Anthony Bochon, Gil & Robles, Belgium

Legal workshops during the project

- **Two legal workshops** during the project
 - The *first* devoted to the regulatory aspects of Safe-by-design (28th January 2021).
 - A *second workshop* (in 2023) on broader legal aspects (insurance, liability, advanced regulatory topics).
- The **first legal workshop** was based both on *interdisciplinarity* and on a *comparative law approach*.
- The *audience* of the first legal workshop included different stakeholders (scientists, industry representatives, lawyers, regulators, compliance officers, NGOs, etc).

Key findings of the first legal workshop

- Discrepancies between *regulatory approaches* of nanomaterials in different regions of the world (Asia, European Union). The EU currently has the most complex and developed regulatory framework covering nanomaterials.
- Rise of «*by-Design*» approaches in different regulatory fields: pharma, chemicals and personal data protection (privacy).
- Taking the example of the now well-established «*Privacy-by-Design*» approach, we know that such principle :
 - Only entails an obligation of means (not results)
 - Suffers from the lack of case law (judiciary interpretation of the laws)
 - Raises the question of the availability of technologies (e.g. PETs in the case of privacy by design)

Lessons from the interdisciplinary round table

- At the end of the first legal workshop, we had a *round table* with speakers skilled in different disciplines: philosophy of science, ecotoxicology, risk management, law.
- The round table highlighted that there could be no legal definition of a Safe-by-Design approach without taking into account the risk acceptance (and resilience) of the society where such principle would be established.
- Decision-making roadmaps could help with the implementation of Safe-by-Design approaches.
- There is a strong (but hidden) link between the Safe-by-Design approach and the *precautionary principle*.

External opinions on SSbD by different Stakeholders

Moderated by Beatriz Alfaro Serrano, BNN, Austria

Experts on SSbD



Mr Victor Puntos



Mr Mario Pansera



Ms Eva Valsami-Jones



Mr Denis Sarigiannis



Ms Jana Drbohlavová



Ms Xenia Trier



Ms Anne Chloe Devic



Mr Henrik Edin



Ms Blanca Suarez



Mr Sean Kelly

Representing **Academia** (ICREA):

**Victor
Puntes**

Research Professor at ICREA



Representing **Academia** (University of Vigo, Spain) :



**Mario
Pansera**

Responsible Research &
Innovation

Representing **Academia** (University of Birmingham):

Eva Valsami-Jones

Professor of Environmental
Nanoscience



Representative of starting **PARC** project:

Denis Sarigiannis

Chemical engineer, exposome,
industrial ecology, risk assessment



Representing the **European Commission**:



**Jana
Drbohlavova**

Seconded National Expert
in the European Commission

Representing the **European Environmental Agency (EEA)**:



**Xenia
Trier**

Expert on Chemicals, Environ-
ment and Human Health

Representing the **European Chemical Industry Council (CEFIC)**:



**Anne Chloe
Devic**

Senior Innovation Manager in
the European Chemical Industry
Council (Cefic)

Representing ChemSec (International Chemical Secretariat):

**Henrik
Edin**

Policy Advisor, working with
chemicals & circular economy



Representing Consultancy:

**Blanca
Suarez**

EU project manager with
a focus on SbD



Representing the **Nanotechnology Industries Association:**



**Sean
Kelly**

Responsible Senior Project
Manager at the NIA

Survey on SSbD

Moderated by Beatriz Alfaro Serrano, BNN, Austria

Definitions of SSbD by Workshop's Speakers

- 1** When one says safety and sustainability, I see health, individual health, community health, societal health, environmental health, ecological health, health at large. This forces us to always consider the full life cycle of our products and protect NPs from uncontrolled dispersion. Not only our products, but also our investigations (safe and sustainable during product design, product manufacturing, and product use, of course).
- 2** My idea of SSbD is of a deliberative democratic mechanism that enables reflections about values and purposes of its promoters as well as anticipates positive/negative consequences of its implementation.
- 3** SSbD is the identification of the various types of risks at the design stage so actions can be taken in good time. Due to functionality being linked to potential nanomaterial hazardous properties, it requires finding an acceptable balance between various factors including safety, functionality, and profitability.
- 4** The concept of Safe and Sustainable by Design for materials and chemicals is crucial for avoiding regrettable substitution. The clear definition criteria for safety and sustainability and the approaches for their assessment is the first step. The combination of risk assessment for safety and life cycle assessment for sustainability needs to be completed by other relevant aspects.
- 5** Safe and sustainable by design in materials and chemicals is the process ensuring that development of their products has embedded from the start: (1) hazard minimisation; (2) ethical sourcing of resources, and (3) operations respectful of environmental and social principles.
- 6** SSbD of chemicals and products is a design approach to prevent various types of harm to people and the planet. It starts with choosing services without the use of chemicals of concern, and designs which ensures clean material cycles, and reduces greenhouse gas emissions. This will require the development of standardized lifecycle assessments, to set minimum performance criteria for each protection goal, to develop compliance tests for final products that can be compared against overall acceptance criteria - and thereby create trust and a level playing field for products both made in, or imported into, Europe.
- 7** SSbD materials and products safeguard human health followed by environmental hazards, without compromising on major sustainability goals (minimizing GHG emissions, environmental pollution and maximizing efficiency in resource use by fostering circularity).
- 8** SSbD holds the promise to address the safety and sustainability of a material through its whole lifecycle from R&D, production, use and disposal and to do so from the very start of product development. My vision is that a definition and implementation methodology can be designed and agreed by all stakeholders before we ask companies (especially SMEs) to implement SSbD.
- 9** SSbD should concern products (chemicals and materials), all consumer products, processes and services. In the design phase, when developing those as new products, new processes... many dimensions should be taken into account at the same time. The known life cycle analysis approach (including the crucial parameter of GHG emissions), should be added to the two equally crucial dimensions of Circularity and Product safety, which means free of harmful substances from the beginning to end of life of any product, including its recycling processes. This is a process, a methodology, not a regulation. This is a complex Research & Innovation process where ideally no tradeoffs should have to be made between all these previously mentioned dimensions, and it should be considered as a journey, probably a long journey until this concept is embedded by all stakeholders along value chains, SMEs, universities, citizens...
- 10** Criteria for SSbD could be used to create a labeling system that would incentivize industry to move away from hazardous substances and strive towards greater sustainability. As hazardous chemicals are a direct threat to human health and the environment they cannot be considered as safe and sustainable.

<https://www.sabydoma.eu/wp-content/uploads/2022/02/SSbD-Definitions.pdf>

Instructions

Go to
www.menti.com

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2090 7244



Or use QR code

Round Table on SSbD

Moderated by Ignasi Gispert Pi, Applied Nanoparticles, Spain

Round Table – Moderator and Panellists



Mr Ignasi Gispert



Mr Sean Kelly



Mr Denis Sarigiannis



Ms Blanca Suarez



Mr Victor Puentes



Ms Jana Drbohlavová



Ms Anne Chloe Devic



Mr Mario Pansera



Mr Henrik Edin

Round Table – Context Question 1

- SSbD is a concept in the making. It can be understood as a complementary guidance to nano-developers (industry) within current regulation or as a potential new principle underpinning chemical regulation (that could become as influential as the Precautionary Principle) or even as the backbone of a new (understanding of) chemical regulation.
- Current chemical regulation (including NP) within the EU is based on risk (ex-post) while SSbD can be considered a pre-market approach based on “design for safety” (ex-ante).
- SSbD for NPs will require a tailored and integrated strategy aimed at promoting actively innovative SSbD NPs. Such strategy will have to include soft law mechanisms (like incentives, quality labels, NPs Innovation hubs, ECHA Guidance Documents, ISO design standards, etc) but also could include hard law mechanisms (in the form of fast-track approval procedures or other regulatory processes not based on risk evaluation of NPs but on safer process design evaluation of NPs).

Round Table – Question 1

- Where do you think SSbD concept will be in 5 years' time? Where do you would like SSbD to be in 5 years' time?

➤ Question to Jana Drbohlavová, Sean Kelly, Blanca Suarez, Anne Chloe Devic, Henrik Edin



Ms Jana Drbohlavová



Mr Sean Kelly



Ms Blanca Suarez



Ms Anne Chloe Devic



Mr Henrik Edin

Round Table – Context Question 2

- The full deployment of SSbD implies developing a “values-based” as opposed to “science-based” approach to assessment and decision making, in which the search is not just to avoid bad, but to actively pursue good, and specifically, the pursuit of sustainability objective (social, economic and environmental ones). Such an approach will require broad-based deliberative processes and to focus on the interrogation, exploration, and development of both innovation and regulatory policy, “opening up” technology appraisal and directly considering the directionality of development and decision making under conditions of scientific uncertainty. In a nutshell, a “scientifically informed” but “values-based” approach to decision making for nanomaterials.

Round Table – Question 2

- Do you consider that SSbD might become a lever for initiating a systemic change in nanoparticles governance and regulation?

➤ Question to Victor Puntos, Mario Pansera, Denis Sarigiannis



Mr Victor Puntos



Mr Mario Pansera



Mr Denis Sarigiannis

Questions?



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Questions from the audience

- What do you envisage to be the game-changing aspect of making the implementation of the *SSbD concept* (based on specified criteria) a mandatory task for any production/processing?
- The UBA-BfR report 156/2021 states "*S&SbD can lead to conflicts of targets, e.g. due to the unavoidable use a hazardous AdMat for new technology of high social benefit*". I agree. No sustainability without performance. What is your position on the relevance of enabling performance for SSbD assessment?

Thank you for your participation!

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