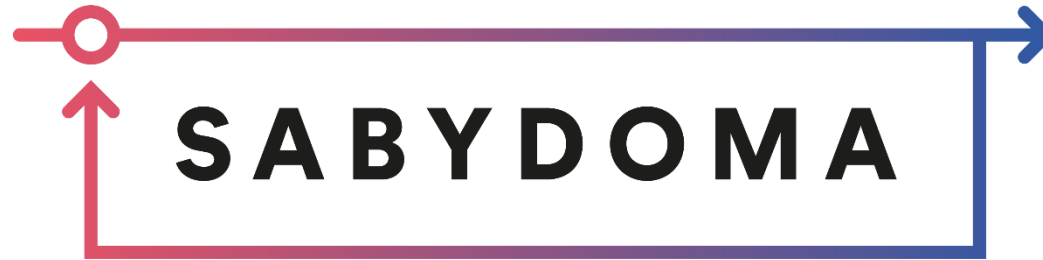


**Safety BY Design Of nanoMAterials –  
From Lab Manufacture to Governance and Communications:  
Progressing Up the TRL Ladder**



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



SABYDOMA's 2<sup>nd</sup> SSbD Workshop:

***A Stakeholder's Perspective of Safe-and-Sustainable-by-Design (SSbD) –a bigger picture!!***

*7<sup>th</sup> March 2024, ANTHOS'24 (Vienna & virtual)*

# Agenda

## A stakeholder's perspective of Safe-and-Sustainable-by-Design – a bigger picture!

**09:00**    **Introduction to the workshop – SABYDOMA's contribution to SSbD / Main project achievements**  
by Andrew Nelson (University of Leeds)

**09:05**    **Summary of SABYDOMA's legal paper & findings of SABYDOMA's two legal workshops**  
by Anthony Bochon (G&S) and Ignasi Gispert (APPNPS)

**09:35**    **Roundtable discussion**  
**Moderated** by Anthony Bochon

**Panellists:**

- Eva Valsami Jones (UoB)
- Victor Puntos (APPNPS, VHIR, ICN2)
- Sean Kelly (NIA)
- Henrik Edin (ChemSec)
- Anne Chloe Devic (Cefic)
- Denis Sarigiannis (PARC project)
- Hubert Rauscher (EC)
- Blanca Suarez Merino (NIA & TEMASOL)

**10:25**    **Conclusion and end of the workshop**  
by Anthony Bochon (G&S)

# Introduction to the Workshop

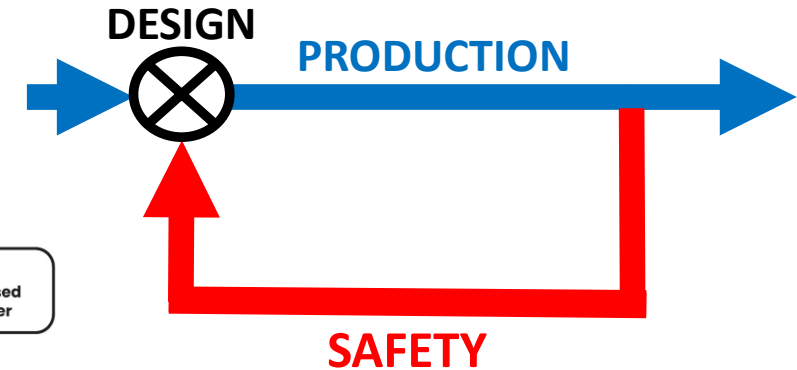
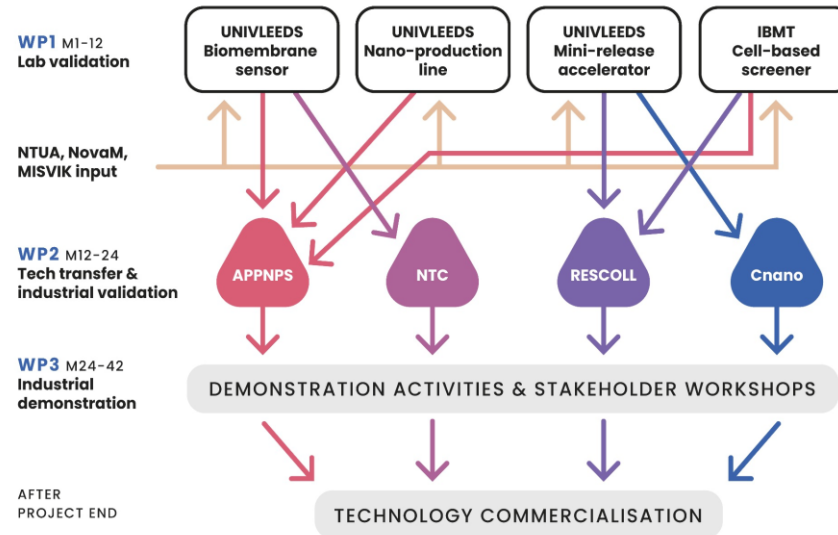
*by Andrew Nelson, University of Leeds, UK*

# SABYDOMA's contribution to SSbD

## Key contributions:

- The main technological *leitmotif*

- Exploitation strategy



- Aligning innovation with 2 legal and 2 SSbD workshops, SSbD strategies review and SSbD decision framework development

# Main project achievements

- Nanoproduction has been developed as **Lead Demonstrator**, output validated against state-of-art nanosynthetic procedures.
- Coupled Lead Demonstrator and validated Biomembrane screen have been **transferred** to APPNPS in Barcelona.
- **Cell-line flow through screening module** perfected and validated.
- **Mini-release accelerator** (MRA) validated against state-of-art release technology.
- MRA has been **transferred** to Cnano and RESCOLL and the cell-based screener **coupled** to nanoproduction line at Fraunhofer.
- Coupled lead Demonstrator with Biomembrane sensor, physical characterisation screens have been underwritten by computer simulations.
- **Two legal and two SSbD workshops** held, **SSbD strategies review paper published** and another **submitted** and **SSbD decision framework** associated with technology developed.

**Thank you for your  
attention!**

# Summary of SABYDOMA's legal paper & Findings of SABYDOMA's two legal workshops on S(S)bD

*by Anthony Bochon, Gil & Robles, Belgium*

**&**

*by Ignasi Gispert Pi, Applied Nanoparticles, Spain*



# When the project started, Sbd was a ULO (Unidentified Legal Object)

- No legal occurrence of the SbD / SSbD concept in EU legislation until the EU Recommendation of 8<sup>th</sup> December 2022 (soft law instrument)
- The initial pure textual research was not conclusive

- First occurrence of the concept of safety by design in the European Commission's Communication on future networks and the internet (SEC(2008)2507)

Paragraph 3.5 stating that « *it is clearly necessary to take steps now to make the internet of the future safe by design* »

- Second occurrence of the concept in the Commission decision of 7<sup>th</sup> March 2013 on the safety requirements to be met by European standards for certain seats for children pursuant to Directive 2001/95/EC on general product safety

Annex – Section on « General Safety Requirements » : « [...] products need to be safe by design as far as possible, and therefore labels and warnings must not replace safety by design »

# The first legal workshop (28<sup>th</sup> January 2021)

- Workshop entirely online
- Presentation of the project by Pr. Andrew Nelson
- Covered Asian (Pr. Mohammed Ershadul Karim) and EU (Anthony Bochon) regulatory aspects, as well as a presentation of a legal paper on « by design » (Dr. Mirella Miettinen)
- Current literature status (Dr. Benjamin Trump and Ignasi Gispert)
- Presentation on privacy by design (Pr. Ira Rubinstein)
- Round table (Pr. Fernand Doridot, Pr. Andrew Nelson, Prof. Maria Dusinska, Dr. Igor Linkov, Dr. Benjamin Trump and Ignasi Gispert)

# SABYDOMA contribution to the legal study : looking for the broader framework of SSbD

- Legal foundations of the concept can be found in the Treaty on the Functioning of the European Union namely with

- The precautionary principle (article 191 TFEU)

Para. 3 of the Communication from the Commission on the precautionary principle (2000)

*“The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But in practice, its scope is much wider, and specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community.”*

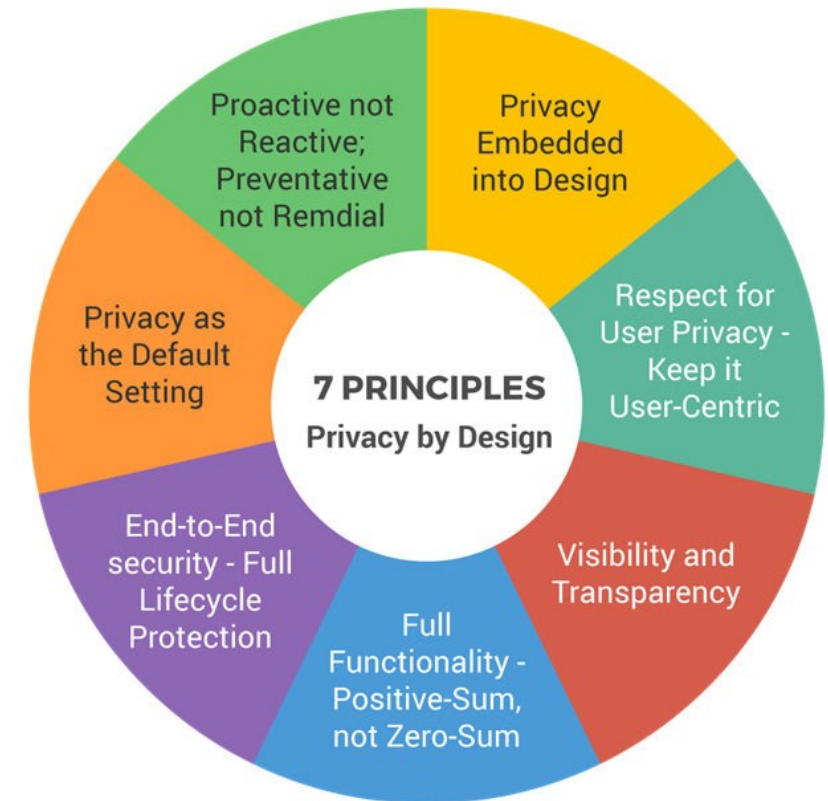
- The health policy (article 168 TFEU)
- The consumer policy (article 169 TFEU)

# SABYDOMA contribution to the legal study : looking for the broader framework of SSbD

- Relevance of the comparison with the concept of “privacy by design” which appeared in the 90’s in the privacy laws literature until its “hard law” integration in the GDPR

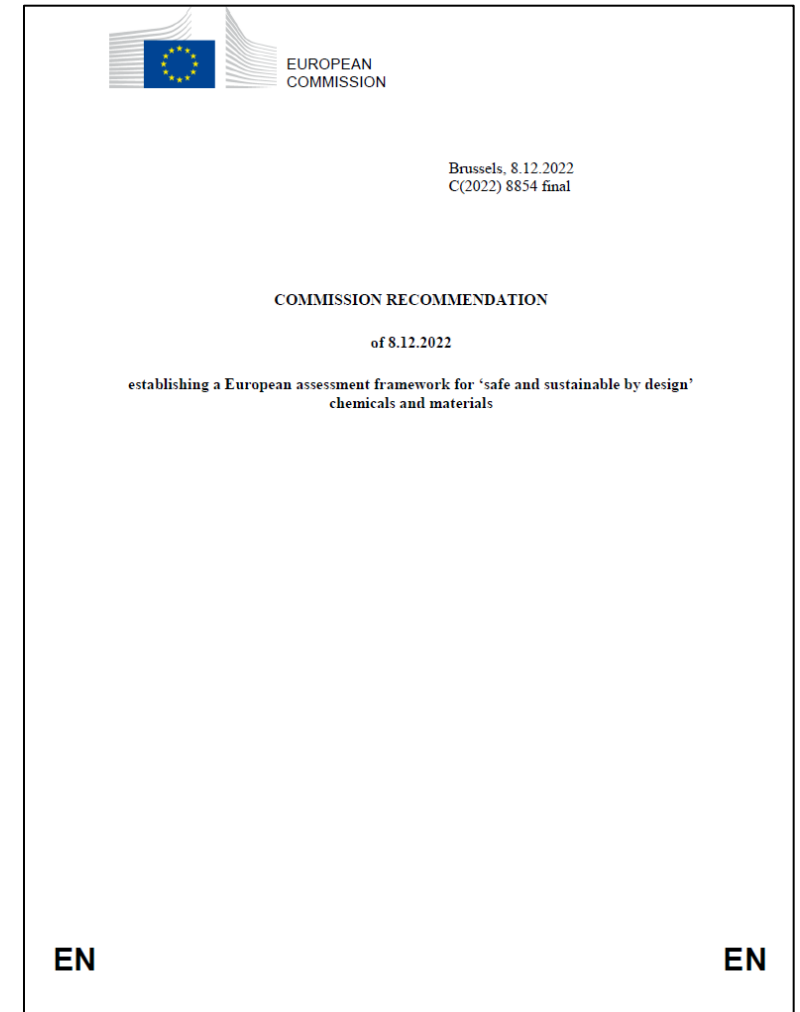
Article 25.1 provides that *“taking into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of natural persons posed by the processing, the controller shall, both at the time of the determination of the means for processing and at the time of the processing itself, implement appropriate technical and organisational measures, such as pseudonymisation, which are designed to implement data-protection principles, such as data minimisation, in an effective manner and to integrate the necessary safeguards into the processing in order to meet the requirements of this Regulation and protect the rights of data subjects.”*

- Comparison with Asian and US chemicals regulations : legal frameworks are not at the same level and there is currently no debate about the legal definition of SSbD



# SSbD : soft law integration but remaining legal challenges

- EU Commission recommendation of 8<sup>th</sup> December 2022 : a voluntary framework with references to previous policy initiatives but ...
- No legal definition of SSbD yet
- The adoption of the SSbD recommendation left open a certain number of legal challenges:
  - Adhesion to the SSbD approach : soft law instruments have no strong record of later “juridification” (see the 2008 Nano Code of Conduct)
  - Access to data Court of Justice judgment 5/03/2024 on harmonised technical standards
  - Question of the state of the art : benchmark to evaluate compliance with the methodology
  - Impact of the SSbD integration in the processes on the assessment of the liability : who did something wrong and when ? Could this person have avoided the damage caused ?

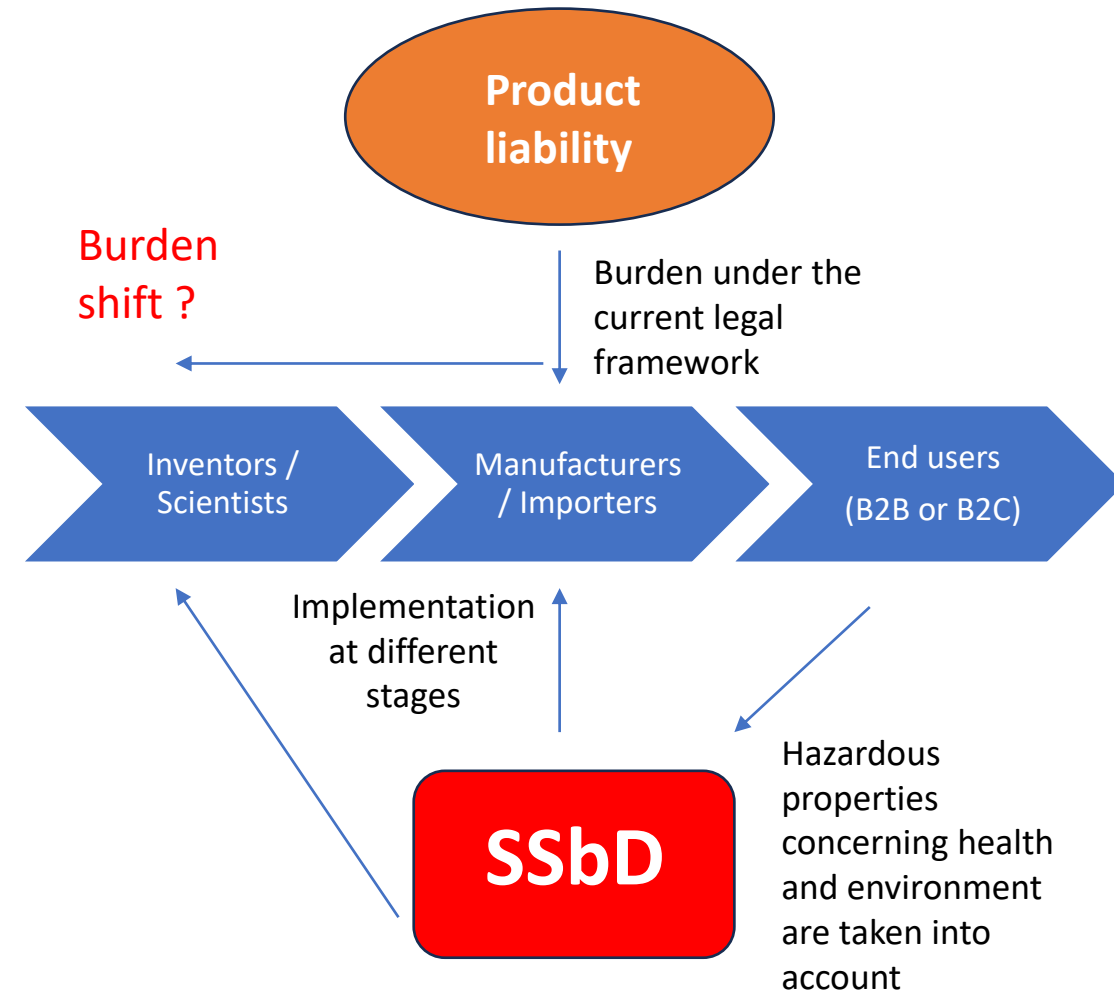


# The second legal workshop (5<sup>th</sup> June 2023)

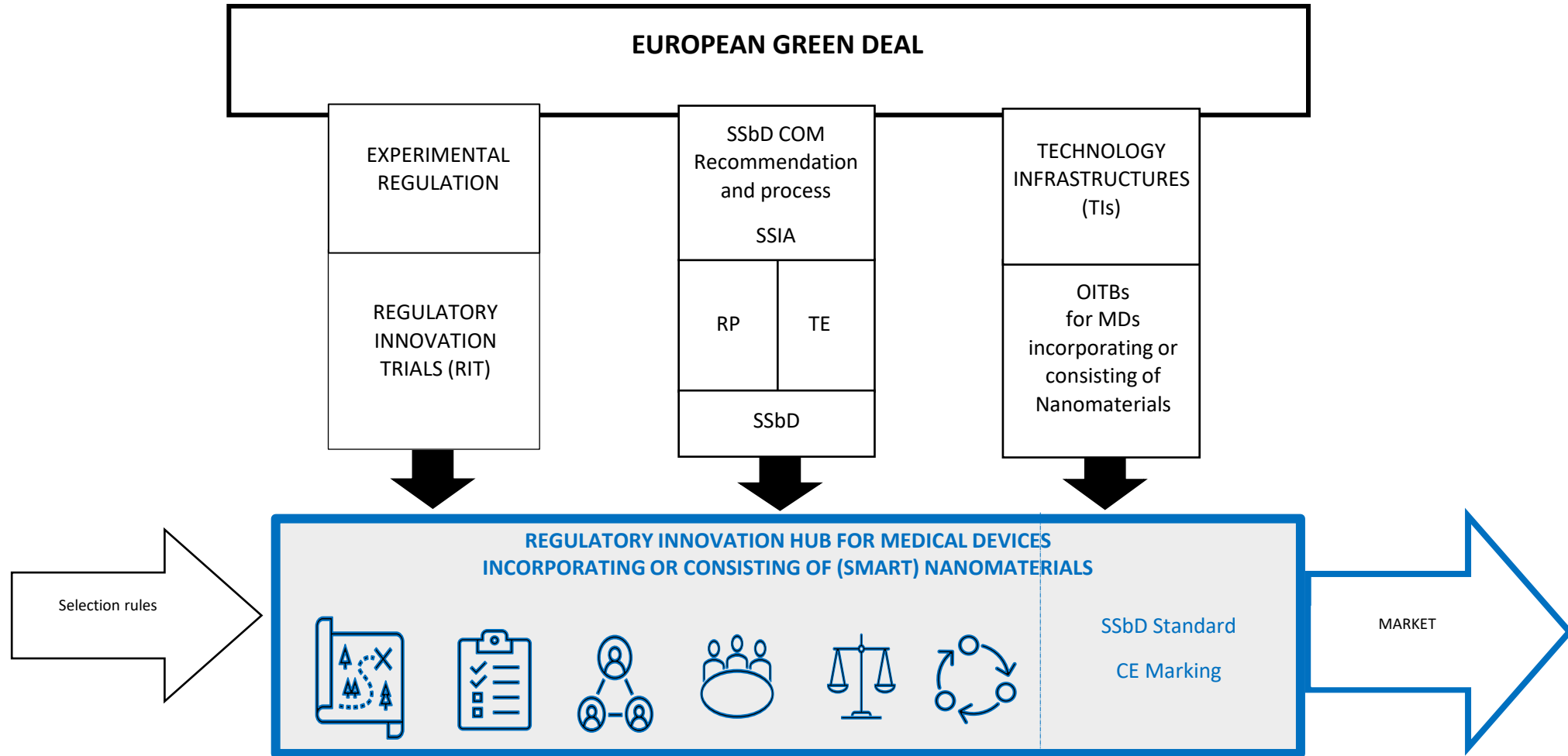
- Hybrid event
- Key findings by Prof. Andrew Nelson and Ignasi Gispert
- Presentation on the EC recommendation by Dr. Hubert Rauscher
- Presentations on Asian (Pr. Muhammad Nizam Awang), EU (Anthony Bochon) and US (Paul Majkowski) liability régimes
- Presentation of a legal paper on SSbD as regulatory approach by Pr. Leonie Reins
- Round table with Pr. Andrew Nelson, Dr. Hubert Rauscher, Dalila Antunes and Ignasi Gispert

# SSbD soft law integration is not likely to entail a paradigm shift in liability assessment

- Hypothesis that a “by design” approach would entail a paradigm shift with the burden of compliant design on inventors / scientists rather than on manufacturers or importers (as it is currently the case)
- SABYDOMA second legal workshop (5<sup>th</sup> June 2023) : conclusion is that neither the EU Commission Recommendation of 8<sup>th</sup> December 2022 nor any further implementation of the SSbD concept (as currently understood) would entail a paradigm shift in liability regimes
- Exception : integration of the SSbD concept in EU chemicals legislation in the same way the privacy by design approach was integrated in the GDPR
- Hypothesis of the rise of “by design” approaches in EU regulatory policies (“privacy by design”, “circular by design”, “benign by design”)



# But we have to consider the bigger picture





# A REGULATORY INNOVATION HUB (RIH) FOR MEDICAL DEVICES INCORPORATING OR CONSISTING OF NANOMATERIALS [RIH-NanoMDs]

- The European Green Deal (EGD), presented by the Commission in December 2019 needs to be understood as a radical systemic change.
- It proposes a new growth model founded on ecological primacy, where social and economic regimes are ecologically bound.
- The depth and scale of the changes needed within production and consumption processes urgently require technical, social, and organizational innovations.
- Transformational solutions require a systemic approach.

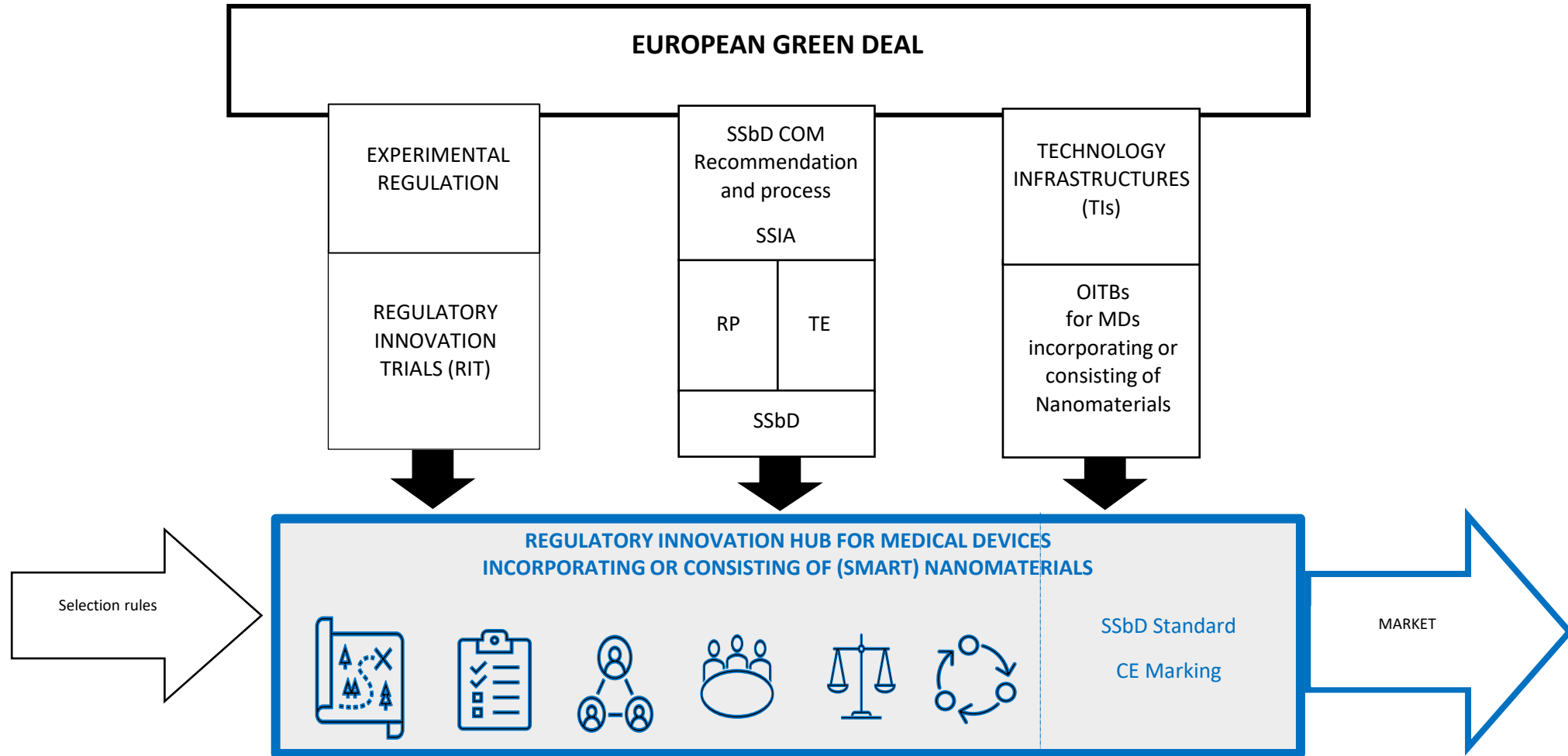
- EGD represents a systemic change. For such reason, all policies and regulations need to be critically reviewed to ensure that they effectively contribute to the realization of the Sustainable Development Goals (SDG). To reach this goal, the EGD brings a **new understanding of the Better Regulation strategy**. The new approach towards the Better Regulation strategy demands to rethink and review all regulations, to become an active tool for transformative changes towards the new green and circular model (regulation with purpose).

- EGD emphasizes the importance and urgency of safe and sustainable innovations to help structural change. To ensure that such innovations can reach the market, it is underlined the need for innovation friendly environments (Technology Infrastructures -OITB-) and ex-ante innovation friendly regulation. The EGD encourage experimentation in general and Regulatory Experimentation specifically.

- EGD brings a new understanding of Chemical policy and regulation. **The Chemical Strategy for Sustainability introduces the concept of Safety and Sustainability by Design (SSbD) that may open the way to a new understanding of (nano)regulation in the chemical sector and beyond.**

- EGD emphasizes the importance of developing regulation based on **standardization** (on testing methods, management systems or interoperability solutions). COM (2022)31 EU Strategy on Standardisation propose to generalize and harmonize what has been already included in Regulation (EU) 2017/745 on Medical Devices (MDR), the so-called **COMMON SPECIFICATIONS (CS)**, a Commission power to adopt technical or common specifications via implementing acts in specific cases. To be used where harmonized standards are absent and insufficient.

# But we have to consider the bigger picture



# RIH-NanoMDs

- Limited connection between “regulation” and “technological infrastructures”. OITBs may offer legal advice, but regulators and the regulatory process itself is outside its scope. Integrating both concepts within a RIH, can help us achieve the objectives of “adequate socio-technical frameworks” and “regulatory friendly regulation” (New European Innovation Agenda Strategy).
- Testing a regulation based on SSbD standards and operationalized within the framework of the New Approach to Harmonization and Standardization may promotes S&S nano-developments rather than trying to control a narrow understanding of risk. We are called to analyse whether a different regulatory model better serves the EGD and the achievement of the SDGs.
- To truly achieve an ex-ante innovation friendly regulation, we need regulatory courage to try new regulatory frameworks. The good news is that RIT allows for safe experimentation areas while showing real commitment towards the implementation of the EGD in our sector.

# What is coming next ?

- Legal paper to be published on SSRN with contributions from
  - Scientists
  - Policy makers
  - Lawyers
- Focus of the legal paper on
  - The scientific context
  - EU regulatory and policy framework
  - Legal definition of SSbD
  - Liability aspects
- Future publication of a shorter version in a peer-reviewed law journal
- Submission of deliverable D6.10



**Thank you for your  
attention!**

# Roundtable discussion

*Moderated by Anthony Bochon (G&S)*

# Agenda

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**10:25**    **Conclusion and end of the workshop**  
by Anthony Bochon (G&S)

# Roundtable – Experts on SSbD: our panellists



**Anthony Bochon**



Hubert Rauscher



Ms Eva Valsami-Jones



Mr Denis Sarigiannis



Mr Victor Puntès



Andrew Nelson



Ms Anne Chloe Devic



Mr Henrik Edin



Ms Blanca Suarez



Mr Sean Kelly

# Roundtable – Question 1



→ **Question to Andrew Nelson with further answer of ALL**

How did SABYDOMA contribute to SSbD during the project runtime?

# Roundtable – Question 2

## → Question to (almost) ALL

Which progress have you seen in SSbD (not just in theory but also in the implementation) in the last 1.5 years, since the EC recommendation of SSbD?

# Roundtable – Question 3

**→ Question to (almost) ALL**

In your opinion is the last workshop conclusion still relevant?

# Roundtable – Question 4

→ **Question to (almost) ALL**

What are in your opinion the challenges SSbD can face in the future?



# Roundtable – Question 5

## → Question to ALL

Is the EC recommendation the proper tool for advancing in SSbD?

# Questions?



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# Thank you for your participation!

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