

# Safe and Sustainable-by-Design Implementing the Framework

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1st MACRAMÉ Regulatory Risk Assessors Summit  
Berlin, 27-28 November 2023

*The views expressed in this presentation are purely those of the authors and may not in any circumstances be regarded as stating an official position of the European Commission*

# The JRC: Science for policy

## Joint Research Centre: Our mission

As the science and knowledge service of the European Commission our mission is to support EU policies with independent evidence throughout the whole policy cycle.

Independent of private, commercial or national interests  
Works for more than 40 European Commission's policy departments

Today's focus:  
Implementing the Framework for Safe and Sustainable by Design Chemicals and Materials



HQ in **Bruxelles**, scientific sites in **5 Member States**:

- Belgium (Geel)
- **Italy (Ispra)**
- The Netherlands (Petten)
- Spain (Sevilla)
- Germany (Karlsruhe)

# Outline

- A bit of policy context
- **The European Commission's framework for Safe and Sustainable-by-Design Chemicals and Materials – brief overview**
- How R&I can contribute to the implementation of the Framework
- Linking priorities

# Policy context for the SSbD Framework

# Policy context

## The EU Green Deal



Cutting pollution  
("zero" pollution)



Climate neutrality



Circular economy

## Chemicals Strategy for Sustainability (CSS)

- **boost innovation** for **safe and sustainable** chemicals
- **phase out the most harmful** (not only SVHCs) **substances** and
- **substitute**, as far as possible, **all other substances of concern**, and otherwise minimise and track them.



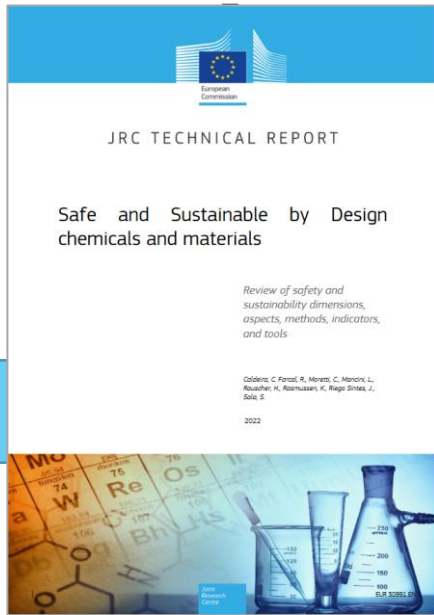
New approaches to tackle releases and emissions across all life cycle stages, and move towards zero-pollution for air, water, soil and biota.

## CSS Action Plan

Develop safe and sustainable-by-design (SSbD) criteria for chemicals

# Milestones of the SSbD framework

## Review of existing frameworks and initiatives



2022

## Framework for the definition of criteria and evaluation procedure for chemicals and materials



EC Recommendation

## Application of the framework to case study



2023

- Caldeira et al. (2022). *Safe and Sustainable by Design chemicals and materials Review of safety and sustainability dimensions, aspects, methods, indicators, and tools*. <https://doi.org/10.2760/879069>
- Caldeira, et al. (2022). *Safe and Sustainable chemicals by design chemicals and materials - Framework for the definition of criteria and evaluation procedure for chemicals and materials*. <https://doi.org/10.2760/487955>
- Caldeira et al. (2023). *Safe and Sustainable by Design chemicals and materials - Application of the SSbD framework to case studies*. <https://doi.org/10.2760/329423>
- European Commission. (2022). *Commission recommendation of 8.12.2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials*. Brussels, 8.12.2022 C(2022) 8854 final <https://eur-lex.europa.eu/eli/reco/2022/2510/oj>

# The SSbD Framework

## Brief overview



# Objectives of the Framework



JRC TECHNICAL REPORT

Safe and Sustainable by Design  
chemicals and materials

*Framework for the definition of  
criteria and evaluation  
procedure for chemicals and  
materials*

Caldelira, C., Forcal, R., Garmendia Aguirre, I.,  
Moncini, L., Toscher, O., Armetto, A., Baumstark, K.,  
Rauscher, H., Riego Sintes, J., Solo, S.

2022



- **Drive innovation** towards the green industrial transition, and becoming a global reference for safety and sustainability targets
- Providing guidance on **criteria development** for the design of **new** Safe and Sustainable by Design chemicals/materials;
- **Minimising or, as far as possible, eliminating the impact on human health, climate and the environment** (air, water, soil) along the entire chemical's and material's life cycle;
  - Phase out the **existing** most harmful substances
  - Substitute, as far as possible, **existing** substances of concern, and otherwise minimise their production and use and track them
- **Enabling comparative assessment of new/existing** chemicals and materials based on safety and sustainability performance for a given function or application context.

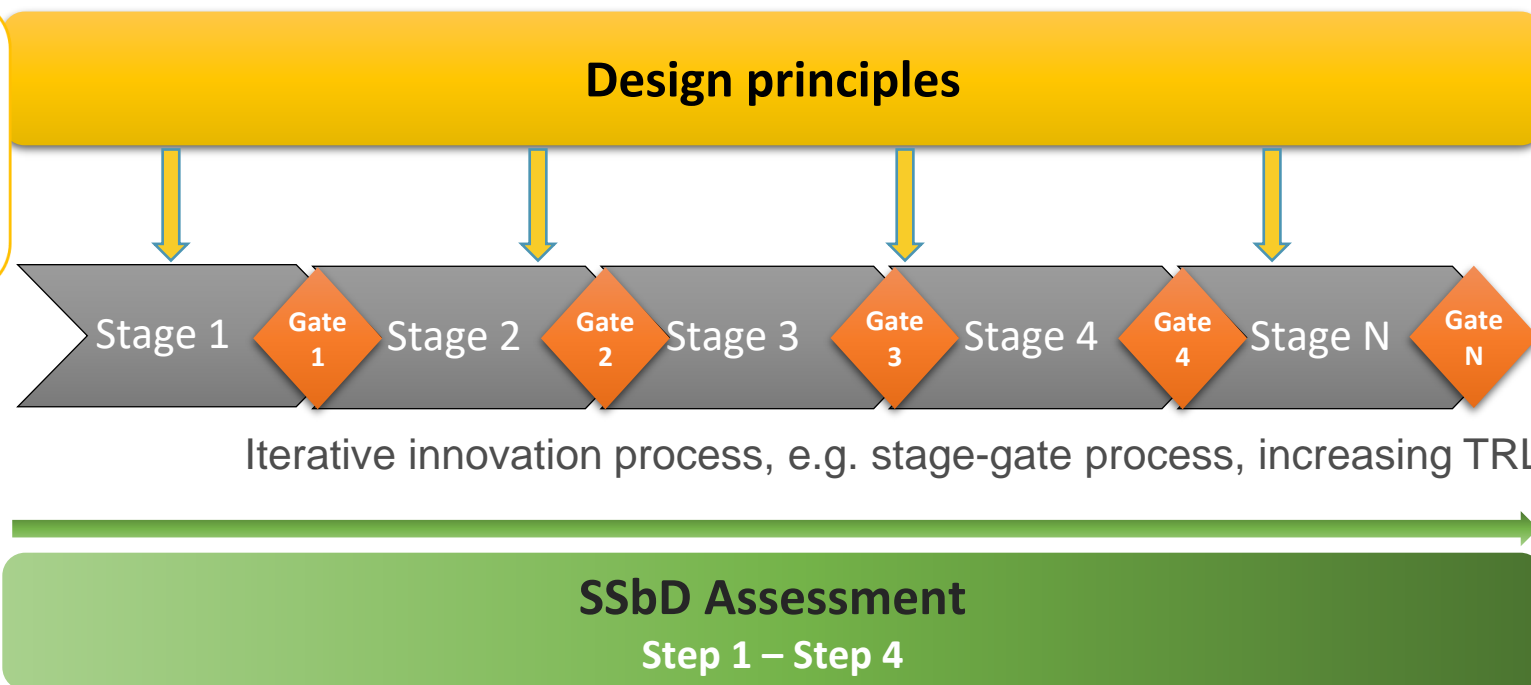
**The SSbD Framework is a holistic COM recommended R&I approach addressing safety and sustainability of chemicals and materials along the entire life cycle, beyond current regulatory compliance**

👉 **Enabling change through R&I**



# Structure of the framework

- Strategies and principles can be followed such as:
- Green chemistry
  - Green engineering
  - Sustainable Chemistry
  - Safe by design
  - ...



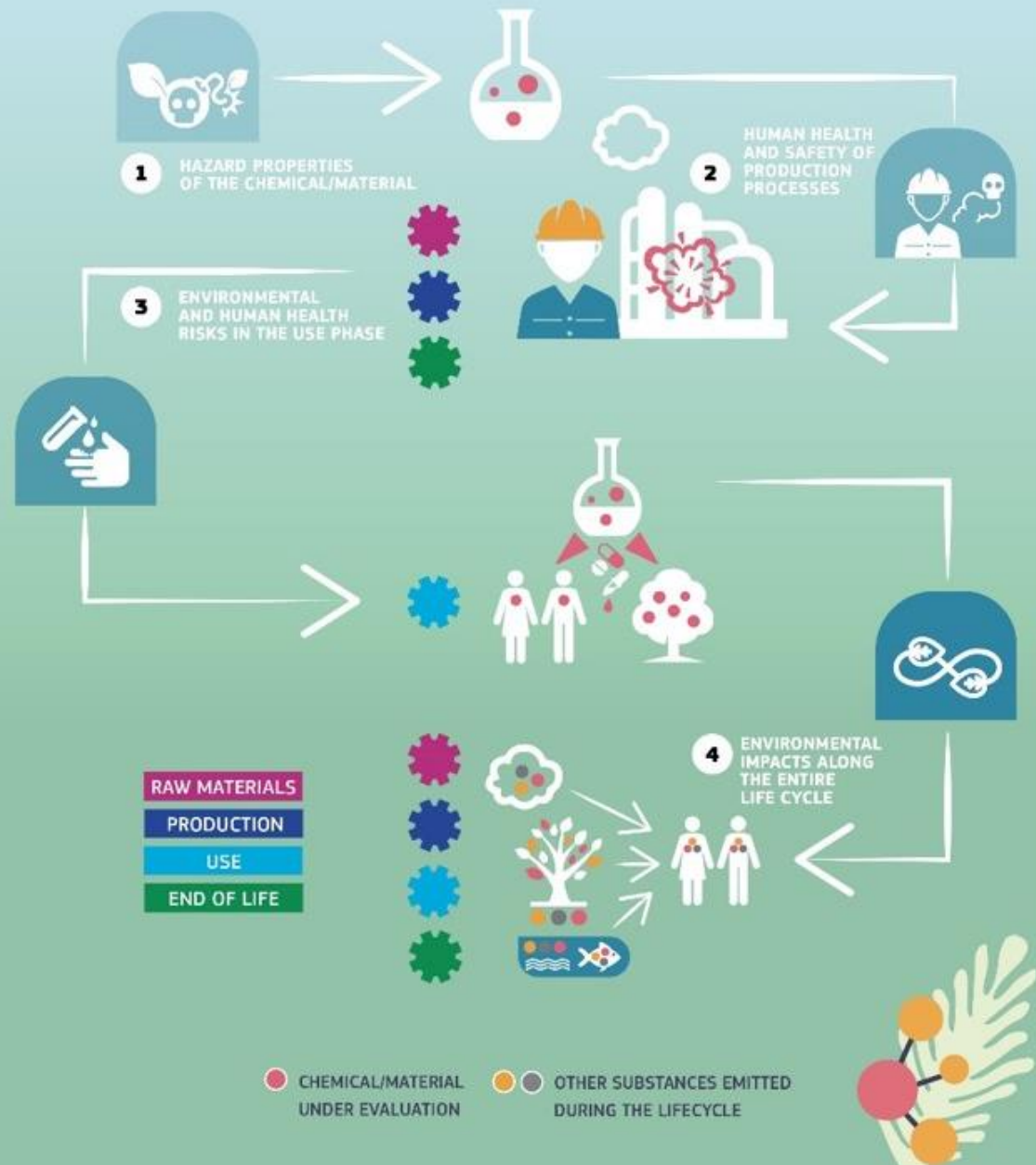
Term '**by design**':

**Molecular design** - to design new chemicals and materials based on their chemical structure

**Process design** - to make the production process safer and more sustainable, both for chemicals and materials being developed and for existing chemicals and materials

**Product design** - where the results of the SSbD assessment support the selection of the chemicals or materials to meet the functional demands of the final product in which they are used

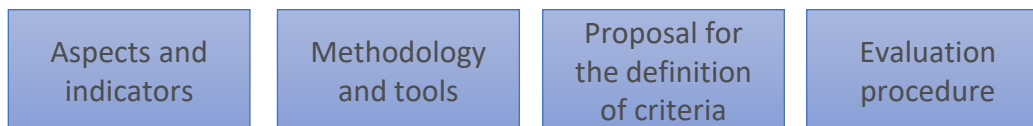
## Safety and sustainability assessment



# SSbD framework: The assessment

- The safety and sustainability assessment includes four steps:
  - **Step 1** - Hazard assessment of the chemical/material
  - **Step 2** - Human health and safety aspects in the chemical/material production and processing phase
  - **Step 3** - Human health and environmental aspects in the final application phase
  - **Step 4** - Environmental sustainability assessment

For each step the framework refers to:



Caldeira, et al. (2022). *Safe and Sustainable chemicals by design chemicals and materials - Framework for the definition of criteria and evaluation procedure for chemicals and materials.* <https://doi.org/10.2760/487955>  
European Commission. (2022). *Commission recommendation of 8.12.2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials.* Brussels, 8.12.2022 C(2022) 8854 final <https://eur-lex.europa.eu/eli/reco/2022/2510/oj>

# Step 1 - Hazard assessment of the chemical/material

**Intrinsic properties** of the chemical or material



**Hazard profile**

Human health  
Environment  
Physical

**Group A:** The most harmful substances (according to the CSS), including **substances of very high concern (SVHC)**

**Group B: Substances of concern**, as described in the CSS and defined in the ecodesign proposal for sustainable products (but not included in Group A)

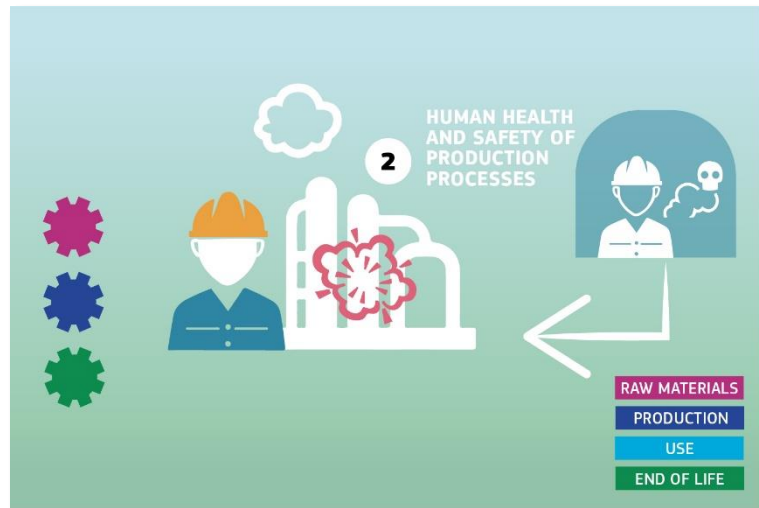
**Group C:** includes the other hazard classes not in Groups A or B

**Tiered approach** is proposed in order to characterize hazards as early as possible at the innovation stage



**1** HAZARD PROPERTIES OF THE CHEMICAL/MATERIAL

## Step 2 - Human health and safety aspects of the chemical/material in the **production and processing** phase



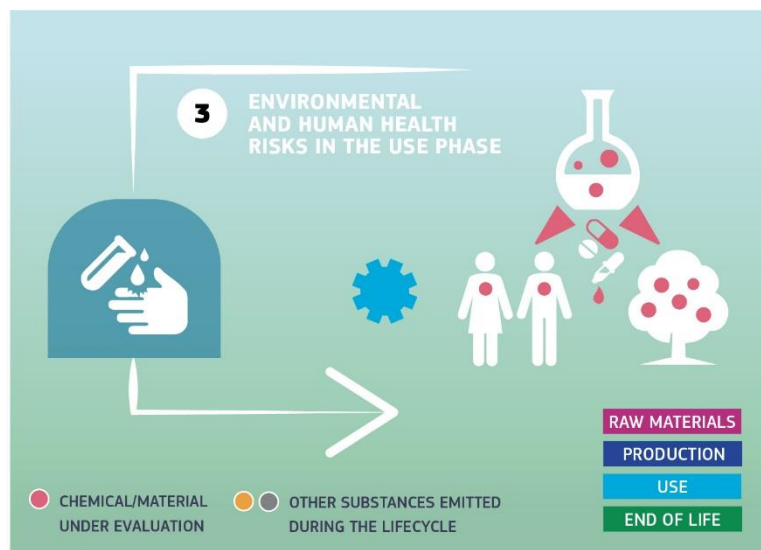
### Occupational health and safety during the production and processing of the chemical or material

- For the assessment the hazards and workers exposure are considered:
  - Physical properties of the chemical or material
  - Hazards of chemicals used in the process
  - Amount of the chemical or material used
  - Frequency and duration of exposure
  - Operational conditions
  - Risk management measures

# Step 3 - Human health and environmental aspects in the final application phase

Risks of the final application of the material or chemical

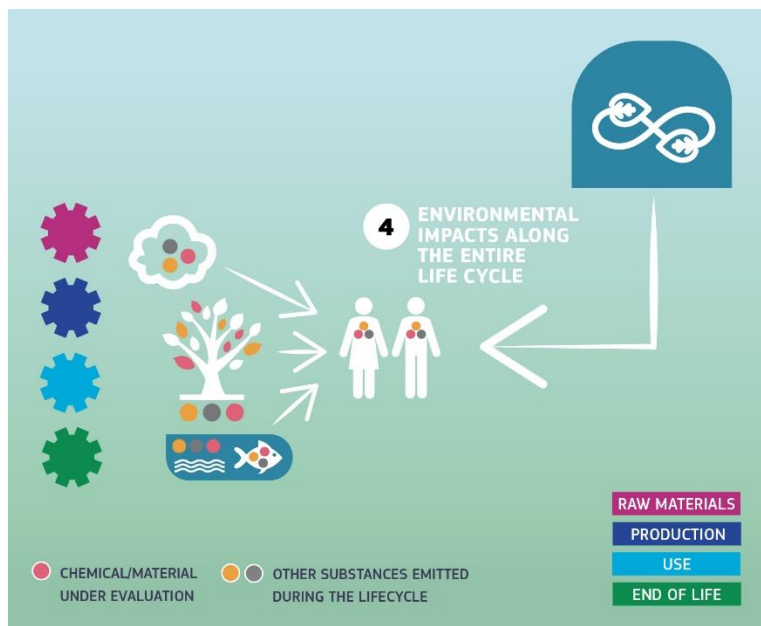
Use-specific exposure to the chemical or material and the associated risks to the human health and the environment



- Hazards of chemical or material
- Physical-chemical properties
- Concentration of the chemical or material in the application
- Use conditions
- Frequency and duration of use

# Step 4 - Environmental sustainability assessment

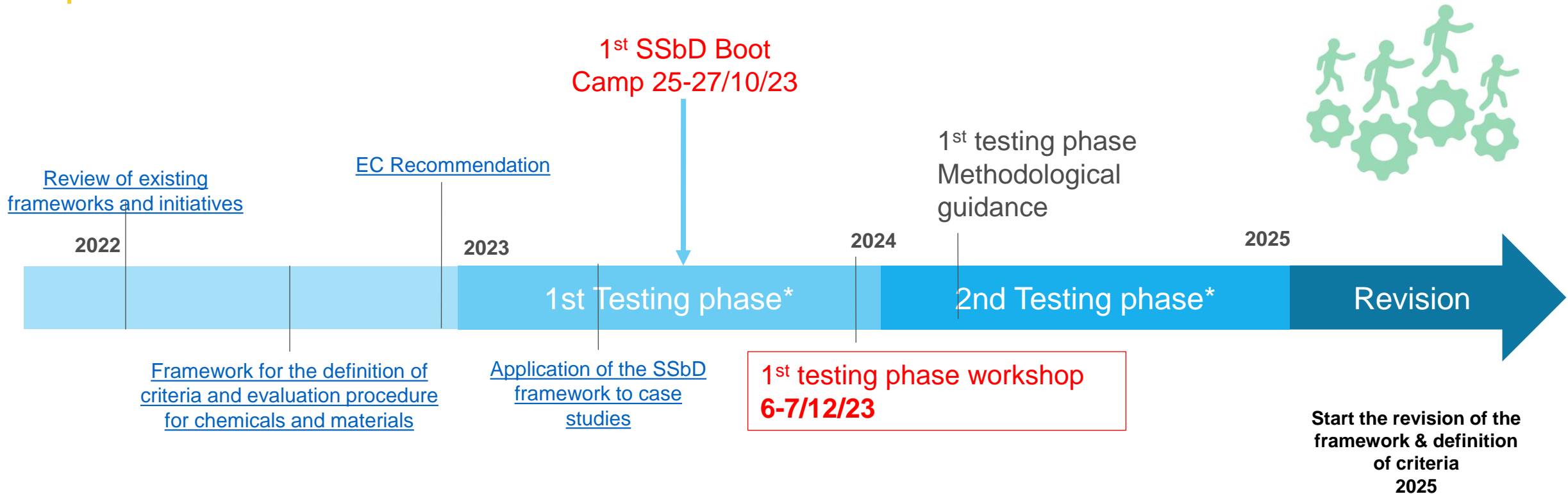
**Environmental sustainability impacts along the entire chemical/material life cycle**, by means of an LCA



The environmental footprint impact assessment method (PEF) is recommended to be used that consists of a minimum set of impacts to assess

- **Toxicity:** human toxicity and ecotoxicity
- **Climate change**
- **Pollution:** ozone depletion, particulate matter/respiratory inorganics, ionising radiation, photochemical ozone formation, acidification, eutrophication
- **Resources:** land use, water use, other resources use (minerals and metals, energy carriers)

# SSbD Chronological overview



\*For more information: [Safe and sustainable by design \(europa.eu\)](https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies/chemicals-and-advanced-materials/safe-and-sustainable-design_en)

\*[https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies/chemicals-and-advanced-materials/safe-and-sustainable-design\\_en](https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/key-enabling-technologies/chemicals-and-advanced-materials/safe-and-sustainable-design_en)

# SSbD Boot Camp



MAKING CHEMICALS AND MATERIALS SAFE AND SUSTAINABLE TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT.

**SAFE AND SUSTAINABLE BY DESIGN BOOT CAMP**

The Joint Research Centre (JRC) – the European Commission's (EC) science and knowledge service – in collaboration with the Partnership for the Assessment of Risks from Chemicals (PARC) are pleased to announce the first edition of the 'Safe and Sustainable by Design' (SSbD) Boot Camp programme.

**When:**  
25-27 October 2023  
Wednesday 14:30 CEST - Friday 14:30 CEST

**Where:**  
EC Joint Research Centre,  
Ispra, Italy

**Who should attend?**  
Researchers and Practitioners  
with relevant technical-  
scientific background

**Language:**  
English

PARC Partnership for the Assessment of Risks from Chemicals

European Commission

- 3 days intensive hands-on training on SSbD (25-27/10/2023)
- 38 participants “trainees”
- Trainers internal and external (involved in SSbD studies)
- Highly interdisciplinarity (new) approach, experts are scarce
- Experts come from the safety OR sustainability field
- **Practical “hands-on” training is key**
- **Building the cases: understanding...**
  - Functional unit
  - System boundaries
  - Foreground & background system
  - Life Cycle Inventory
  - RA legal requirements & beyond
  - Test methods – computational approaches - NAMs
  - Data availability and flow

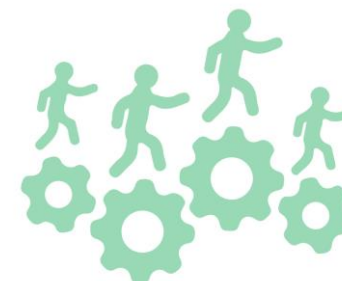
Boot Camp 2024 .... to be announced



# Next steps



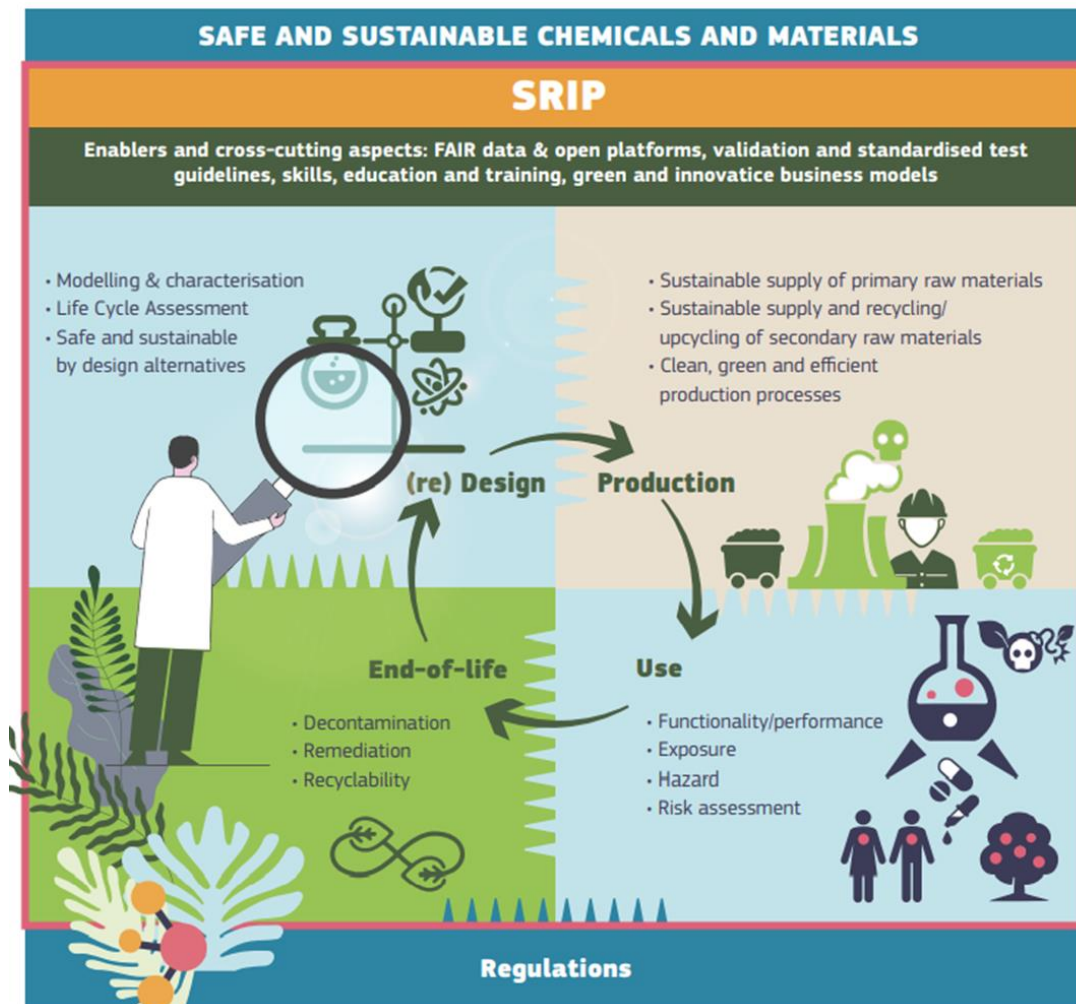
- Next SSbD workshop 6-7 December in Brussels, hybrid
  - Input from 1<sup>st</sup> testing period
  - > 100 persons in presence, > 600 registrations online
- Methodological Guidance and FAQ (Q2 2024)
- 2<sup>nd</sup> reporting period Q2 2024
- Updated reporting template Q2 2024
- Continue enhancing collaboration among HE projects, enlarge the community
- SETAC Europe 34<sup>th</sup> annual conference (Seville 5-9 May 2024):
  - COM&SETAC workshop on SSbD
  - Scientific session “SSbD Advanced Materials: What does it take? (Track 7.08)
  - Open for submissions until 29/11/23



# How R&I can contribute to the implementation of the Framework

# Strategic Research and Innovation Plan for safe and sustainable Chemicals and Materials

published 2022



The Commission will refer to this SRIP in the Horizon Europe work programme as an overarching strategy.

Chapter 4:  
Safe and sustainable by design

# Expectations from Member States, industry, academia, RTOs



- Use the framework when developing chemicals and materials - **Ind**, **Aca**, **RTOs**
- Make available FAIR data for 'safe and sustainable by design' assessment – **MS**, **Ind**, **Aca**, **RTOs**
- Support the improvement of assessment methods, models and tools – **MS**, **Ind**, **Aca**, **RTOs**
- Support the development of professional training (**Ind**) and educational curricula (**MS**, **Aca**) on skills related to safety and sustainability of chemicals and materials
- Report to the EC during the testing period

# SSbD in Horizon Europe



## Pillar 2

### Global Challenges and European Industrial Competitiveness

#### Cluster 4

Digital, Industry and Space

#### Cluster 5

Climate Energy and Mobility

#### Cluster 6

Food, Bioeconomy, Natural Resources, Agriculture and Environment

SSbD framework referred to in **CL4**, **CL5** and **CL6**

SSbD also referenced in topics under the **Innovative Health Initiative**, **Circular Bio-based Europe** and is being discussed in the SRIA of **'Batteries for EU'**

e.g. 12 projects in HE-CL4-RESILIENCE already granted, start early 2024

# Cluster 4 - Digital, Industry and Space SSbD in Horizon Europe

## Deadline 7 February 2024 / 24 September 2024 (2-stage)



### HORIZON-CL4-RESILIENCE-01-24: Development of safe and sustainable by design alternatives (IA)

Single Stage	Innovation Action	EUR 59M in topic EUR 12-15M per project	SSbD approach should be considered as a reference in the proposal
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### HORIZON-CL4-RESILIENCE-01-35: Biodegradable polymers for sustainable packaging materials (IA)

Two Stage	Innovation Action	EUR 31M in topic EUR 6-8M per project	SSbD approach should be considered as a baseline in the proposal
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### HORIZON-CL4-RESILIENCE-01-36: Advanced biomaterials for the Health Care (IA)

Two Stage	Innovation Action	EUR 31M in topic EUR 6-8M per project	The biomaterials should be SSbD, taking also into account any specific requirements
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# Cluster 5 – Climate, Energy and Mobility



## HORIZON-CL5-2024-D2-01-02: Non-Li Sustainable Batteries with European Supply Chains for Stationary

Single Stage	Innovation Action	EUR 21M in topic EUR 7M per project	Develop and demonstrate sustainable and safe non-Li battery solutions [...] aligning [with the EC Recommendation on SSbD chemicals and materials
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## HORIZON-CL5-2024-D2-02-02: Post-Li-ion technologies and relevant manufacturing techniques for mobility applications (Generation 5)

Single Stage	Research & Innovation Action	EUR 15M in topic EUR 5M per project	... delivering SSbD approach for batteries for batteries reduced in size and weight...
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## HORIZON-CL5-2024-D2-02-03: Size and weight reduction of cell and packaging of batteries system, integrating lightweight and functional materials, innovative thermal management and SSbD

Single Stage	Innovation Action	EUR 16M in topic EUR 8M per project	...delivering a SSbD approach for batteries... use of lightweight and multifunctional materials (including NM) that are SSbD in alignment with the COM Recommendation. SSbD Framework should be considered as a reference in the proposal
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# Cluster 6 – Food, Bioeconomy, Natural Resources, Agriculture and Environment

## HORIZON-CL6-2024-CircBio-01-3: Innovative circular solutions for furniture

Single Stage	Innovation Action	EUR 10M in topic EUR 5M per project	Proposals should fully incorporate the SSbD approach
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## HORIZON-CL6-2024-CircBio-02-1-two-stage: Circular solutions for textile value chains through innovative sorting, recycling, and design for recycling

Two Stage	Research & Innovation Action	EUR 15M in topic EUR 5M per project	Proposals should fully incorporate the SSbD approach
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# Linking priorities

# EU Policy news



STATE OF THE UNION 2023

**State of the Union Address** by President von der Leyen, 13 September 2023

- “*we enter the next phase of the European Green Deal*”

**Letter of Intent** by President von der Leyen to the President of the European Parliament, and to the Prime Minister of Spain, which currently holds the Presidency of the Council

- New key priority for 2024: **Advanced Materials for Industrial Leadership**

MEMBER STATES CONSULTATION WORKSHOP – 23 October 2023

- A coordinated **Action Plan with Member States on advanced materials R&I** will be one of the activities in a forthcoming Commission Communication

# Linking European Policy Priorities



Climate neutrality



Cutting pollution ("zero" pollution)



Circular economy



- Chemicals Strategy for Sustainability
- New Industrial Strategy for Europe
- Farm-to-Fork strategy
- Zero Pollution Action Plan
- Safe and Sustainable by Design Framework



- **Advanced Materials** for industrial leadership

- Industrial Strategy and the Green Deal Industrial Plan
- Zero Pollution Action Plan
- Chemicals Strategy for Sustainability
- Sustainable Products Initiative
- Critical Raw Materials Act
- Net Zero Industry Act

**SSbD links the European Green Deal with Advanced Materials for Industrial Leadership**

# Regulatory aspects

# Non-binding and binding regulatory initiatives



- Commission Recommendation on the SSbD Framework (8/12/2022) is legally **non-binding**  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022H2510>



- **New hazard classes in CLP (2022):** Commission delegated **Regulation** (EU) 2023/707
- **Critical Raw Materials Act (2023):** COM (2023) 160 - **Proposal** for a **Regulation** of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials – (CRM)
- **Ecodesign (2022):** COM (2022) 142 final - **Proposal** for a **Regulation** establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC – (ESPR) → *Product passport*

# Conclusions



- The SSbD Framework is a holistic COM recommended R&I approach addressing safety and sustainability of chemicals and materials along the entire life cycle, beyond current regulatory compliance
- In 2024 a methodological guidance will be provided and the 2<sup>nd</sup> testing phase will be launched
- As the framework is an R&I approach, R&I contributions are essential
- The SRIP in the Horizon Europe work programme serves as an overarching strategy to support R&I
- SSbD links the European Green Deal with Advanced Materials for Industrial Leadership
- New, legally binding provisions relevant for SSbD are available or in preparation (sustainability: proposals for CRM and ESPR regulation)

Many thanks to Sofie Norager and Vangelis Daskalopoulos (DG RTD)

# Thank you



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