



INNOVATION IS THE KEY.
SUSTAINABILITY LEADS THE WAY.

Innovation Support & SSbD

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Outline

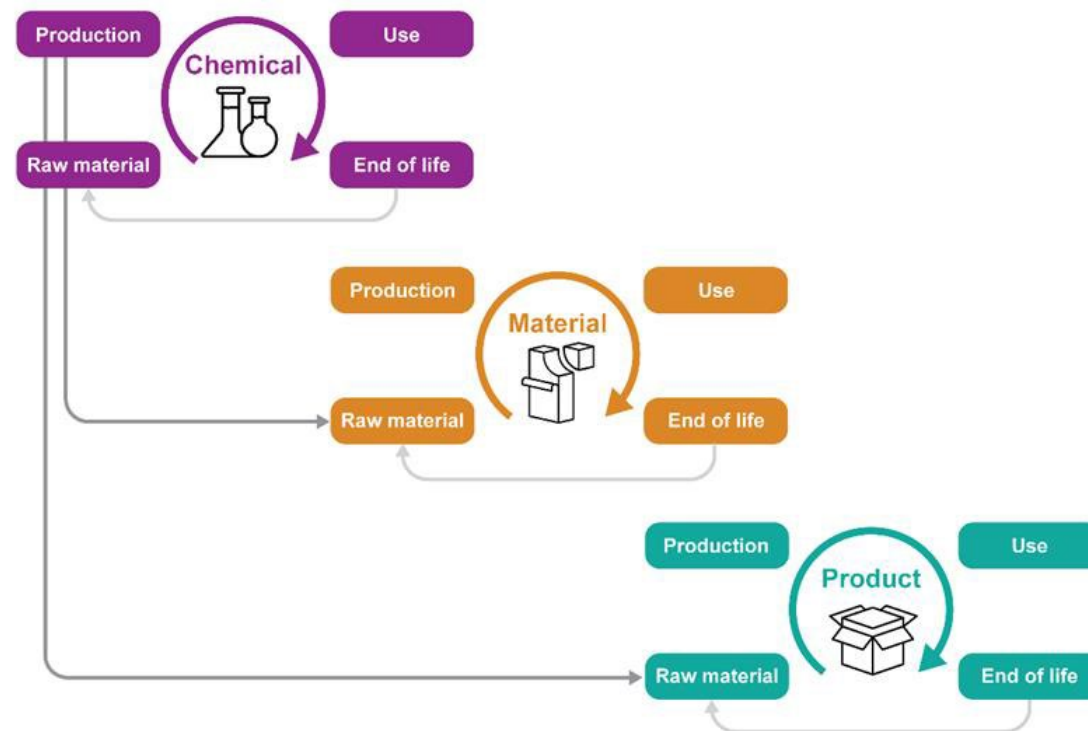
- ✓ Let's talk about 'What is SSbD' and the JRC SSbD Framework
- ✓ How can we apply SSbD in the pharma sector
- ✓ How can BNN support you in this endeavour?

Let's talk about ,What is SSbD'

Safe-and-Sustainable-by-Design Definition

... it can be defined as a **pre-market approach to chemicals and materials design** that focuses on providing a function (or service), while **avoiding volumes and chemical and material 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 and materials in particular in relation to **climate change, resource use, and protecting ecosystems and biodiversity, adopting a lifecycle perspective** (EC2020a)

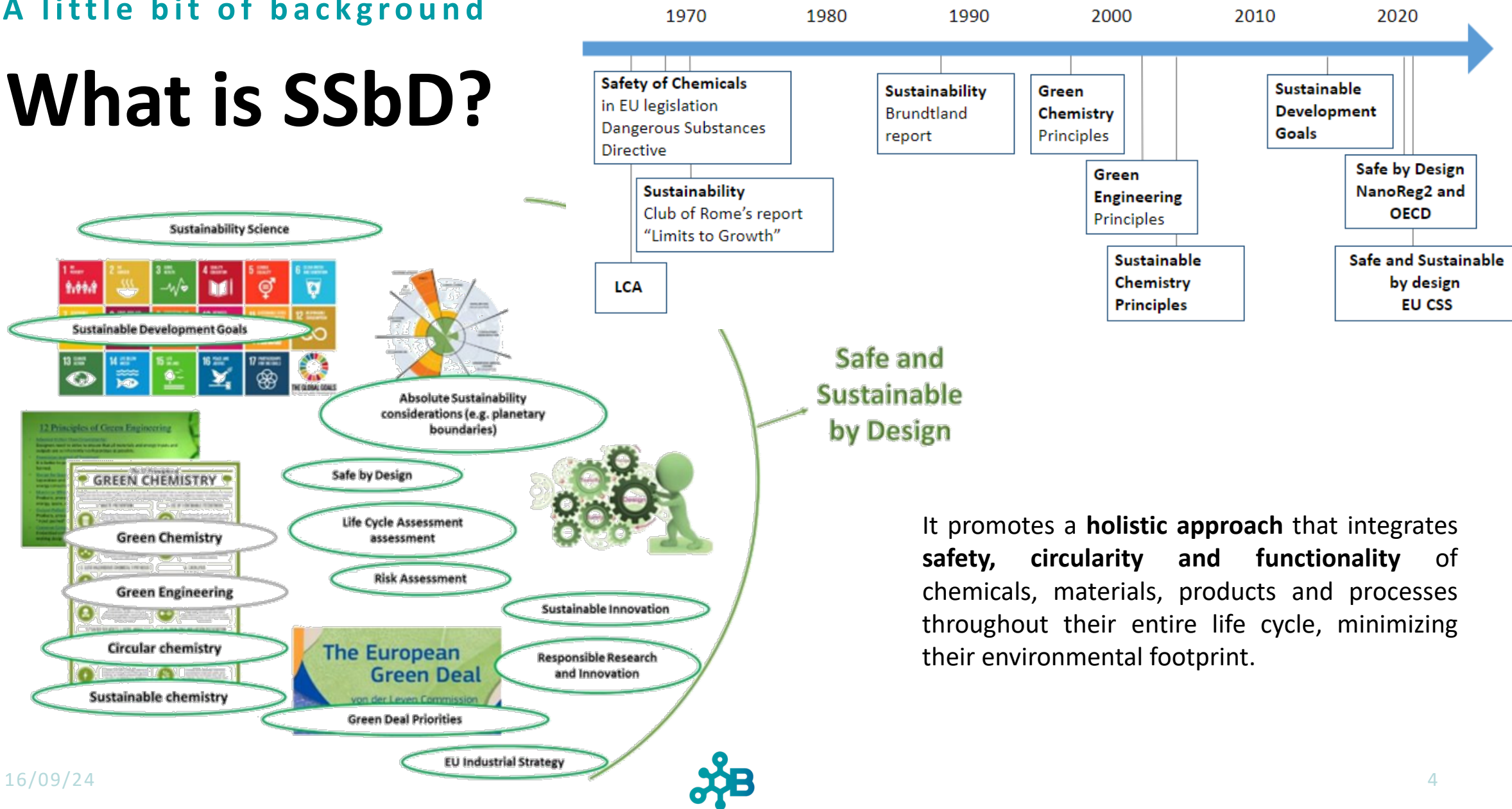
Framework for the definition of criteria and evaluation procedure for chemicals and materials (2022) – JRC Technical Report



Simplified representation of the life cycle of a chemical and its use in the life cycle of materials and products. Each stage is connected to the other via logistics (transport and distribution stages)

A little bit of background

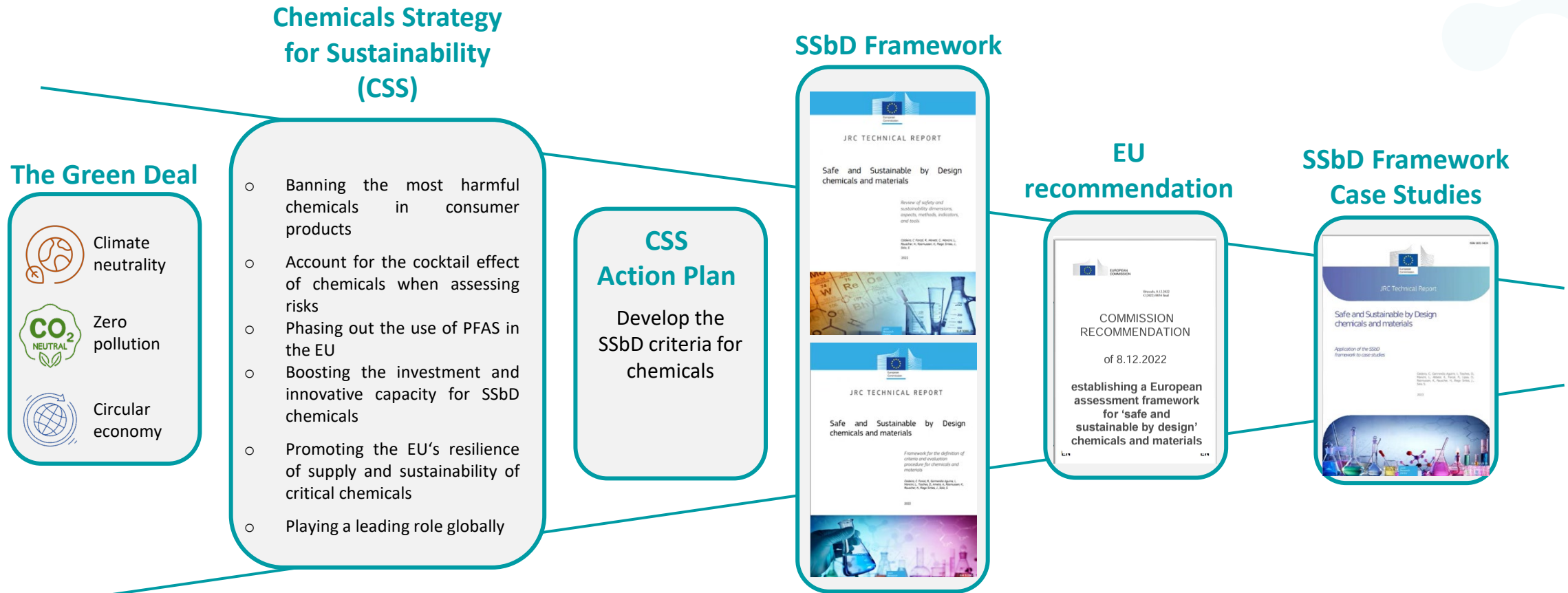
What is SSbD?



It promotes a **holistic approach** that integrates **safety, circularity and functionality** of chemicals, materials, products and processes throughout their entire life cycle, minimizing their environmental footprint.

The Policy context for a key tool to boost innovation and growth

JRC - SSbD Framework



Review of safety and sustainability dimensions, aspects, methods, indicators, and tools (2022). DOI 10.2760/879069

Framework for the definition of criteria and evaluation procedure for chemicals and materials (2022). DOI 10.2760/487955

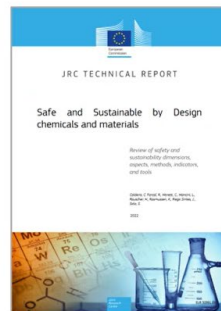
Application of the SSbD framework to case studies. (2023). DOI 10.2760/329423

Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials. (2022). <https://eur-lex.europa.eu/eli/reco/2022/2510/oj>



During 2024

Next steps:



1.
Review of safety and sustainability dimensions, aspects, methods, indicators and tools
(JRC 2022)



2.
Framework for the definition of criteria and evaluation procedure for chemicals and materials
(JRC 2022)



3.
Application of the SSbD framework to case studies
(JRC 2023)



4.
Methodological Guidance
(JRC 2024)



Start the revision of the framework & definition of criteria to guide the design process of chemicals and materials 2025

Steps of the framework

JRC SSbD framework

- It is a **voluntary** approach
- It is an **iterative** approach (taking into account increasingly amount of data generated and collected)
- It requires the **innovation process** to be **evaluated periodically**
- It is recommended to start **applying** it as **early as possible** in the innovation process

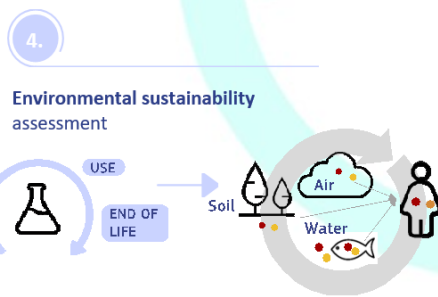
Intrinsic properties of the chemical/material to understand the hazard profile



Referred to the production process from the raw material extraction (natural resources) to production of the chemical/material including recycling or waste management.



Assess whether the use in the final application poses any risk to human health and environment



Considers the environmental impacts along the entire life cycle by LCA, covering all the life cycle stages, including consideration of its functionality (intended use)

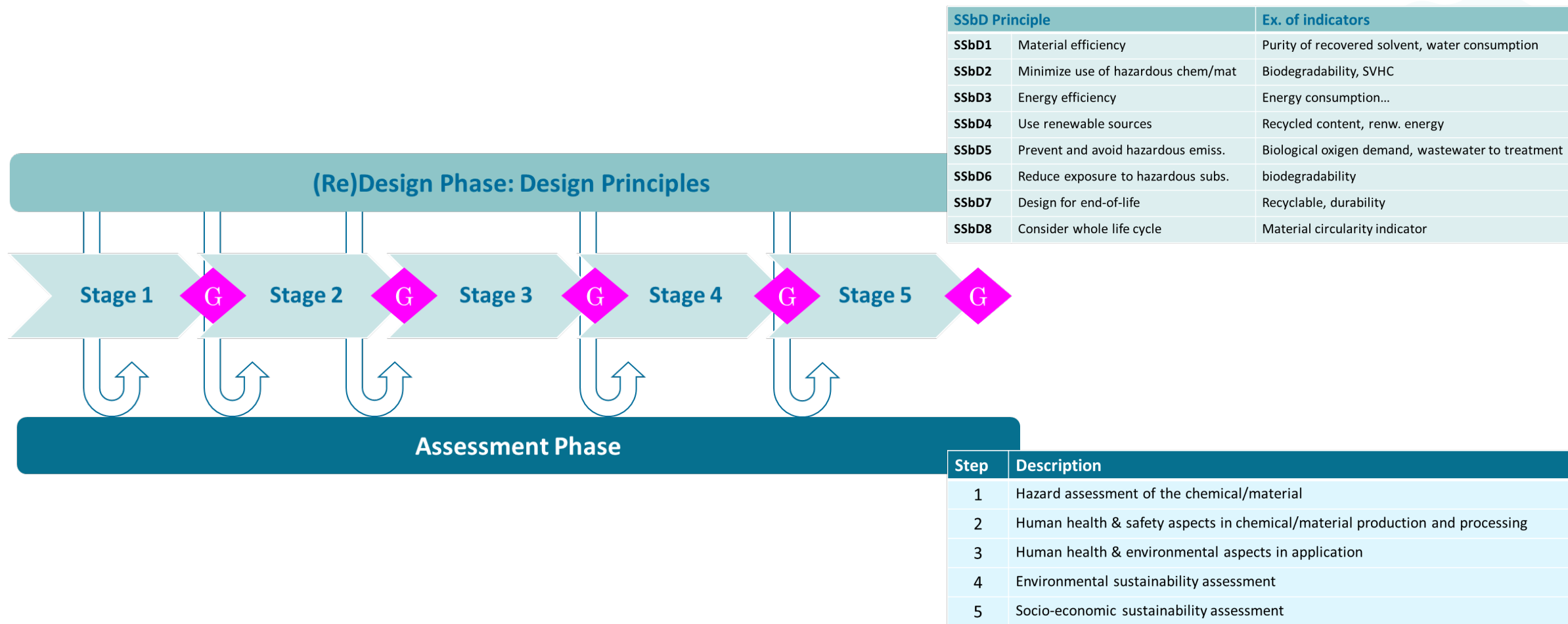


- Step 1, 2 and 3 covers the **Safety dimension**
- Step 4 covers the **Environmental dimension**
- Step 5 covers the **Social and Economic dimensions**



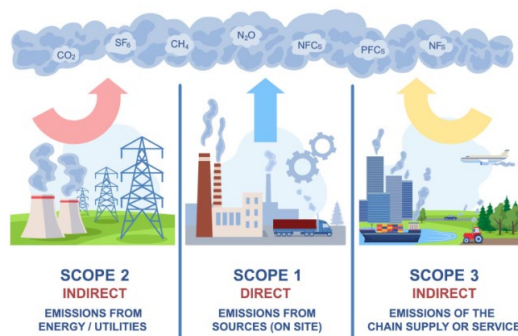
Source: Safe and Sustainable by Design chemicals and materials – Methodological guidance. doi:10.2760/28450 KJ-NA-31-942-EN-N

An iterative process with two components



Pharma impact on the environment

1. Greenhouse gas emissions. Healthcare accounts to around 5% of worldwide emissions



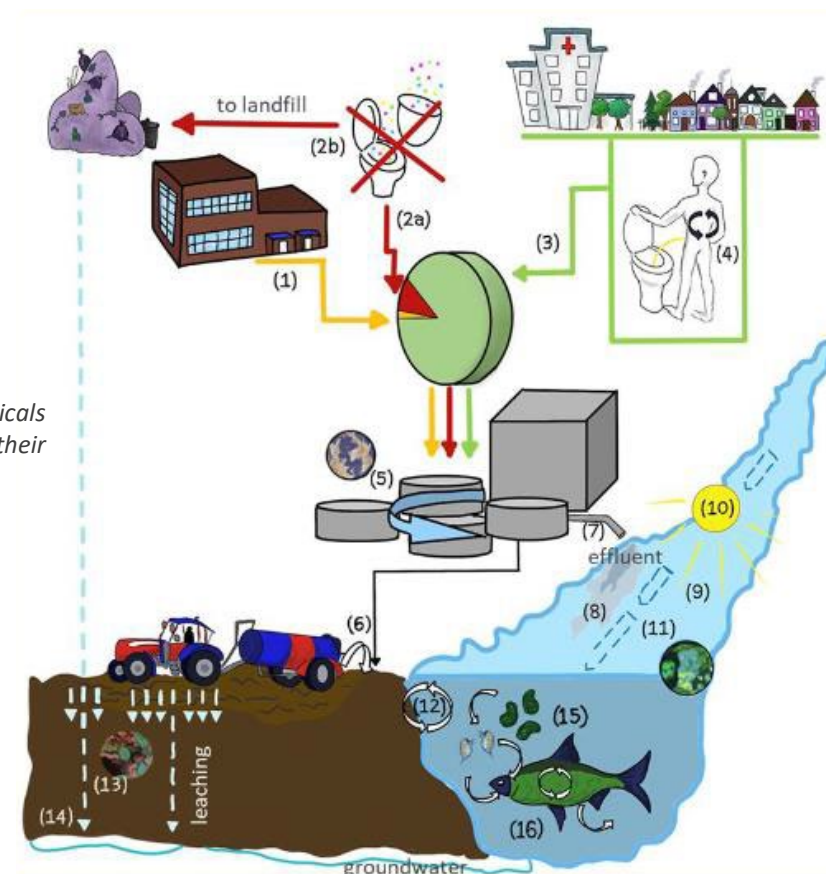
2. Large amounts of Waste (single use products, e.g., gloves, syringes) also during production



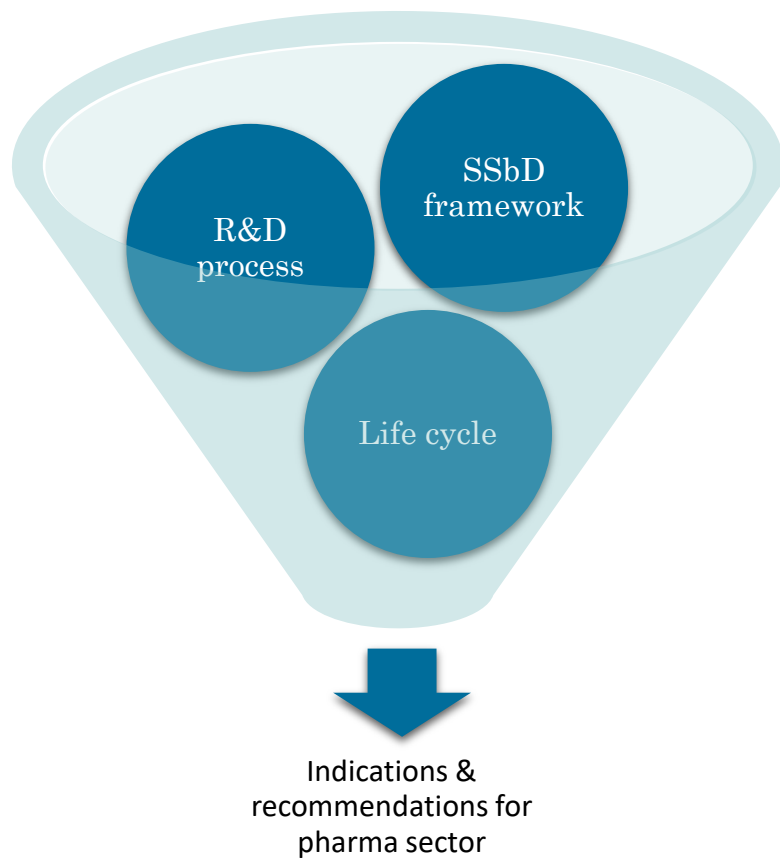
3. Environmental Pollution

With direct effects on environmental species and biodiversity

Routes of entry of pharmaceuticals into the environment, and their distribution and breakdown.
(Bramke et al (2023))



Considerations



Understanding SSbD framework & R&D pharma process

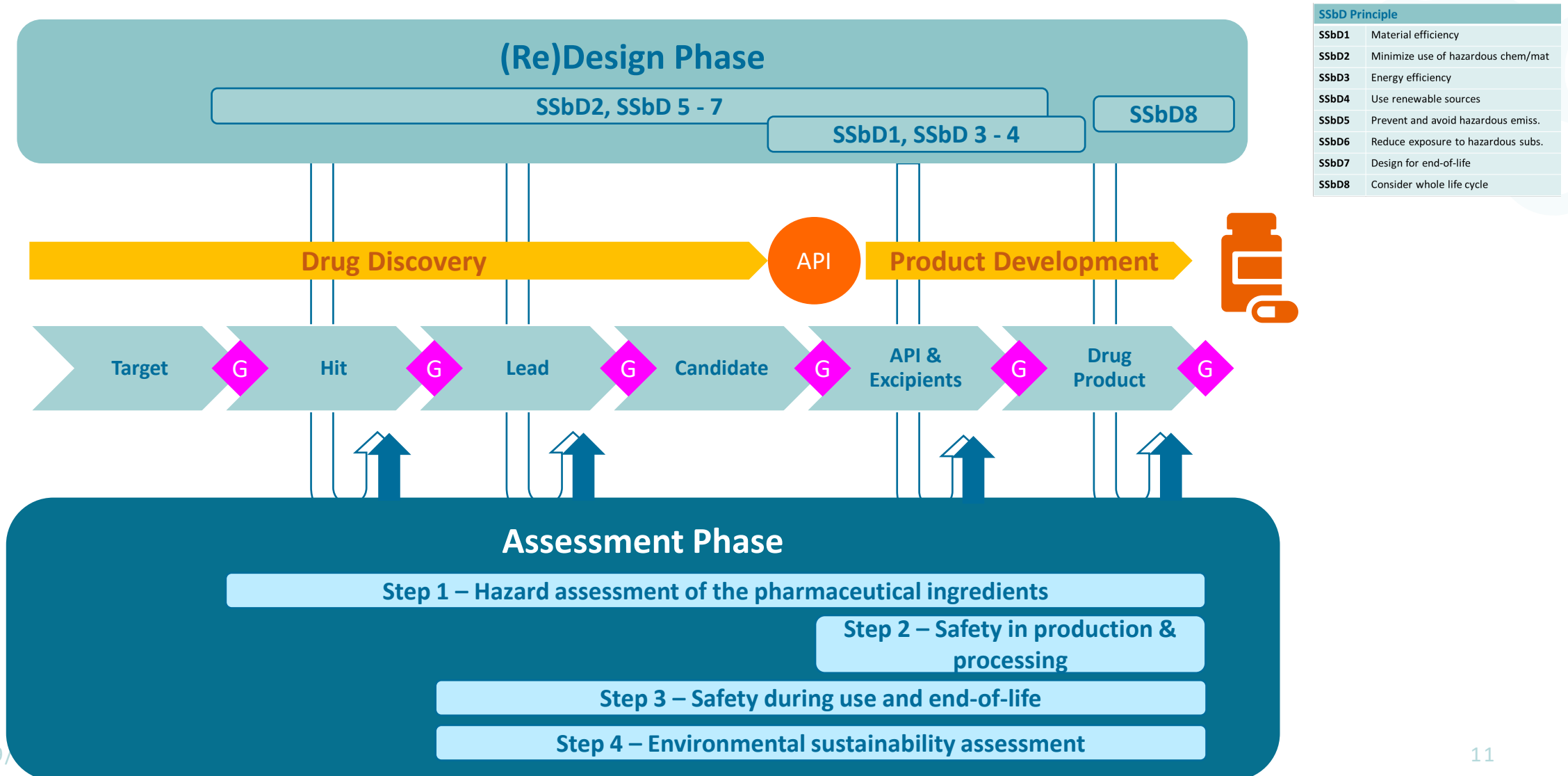
Searching for common features betw. SSbD and R&D

Taking LC perspective to align SSbD assessment to pharma LC

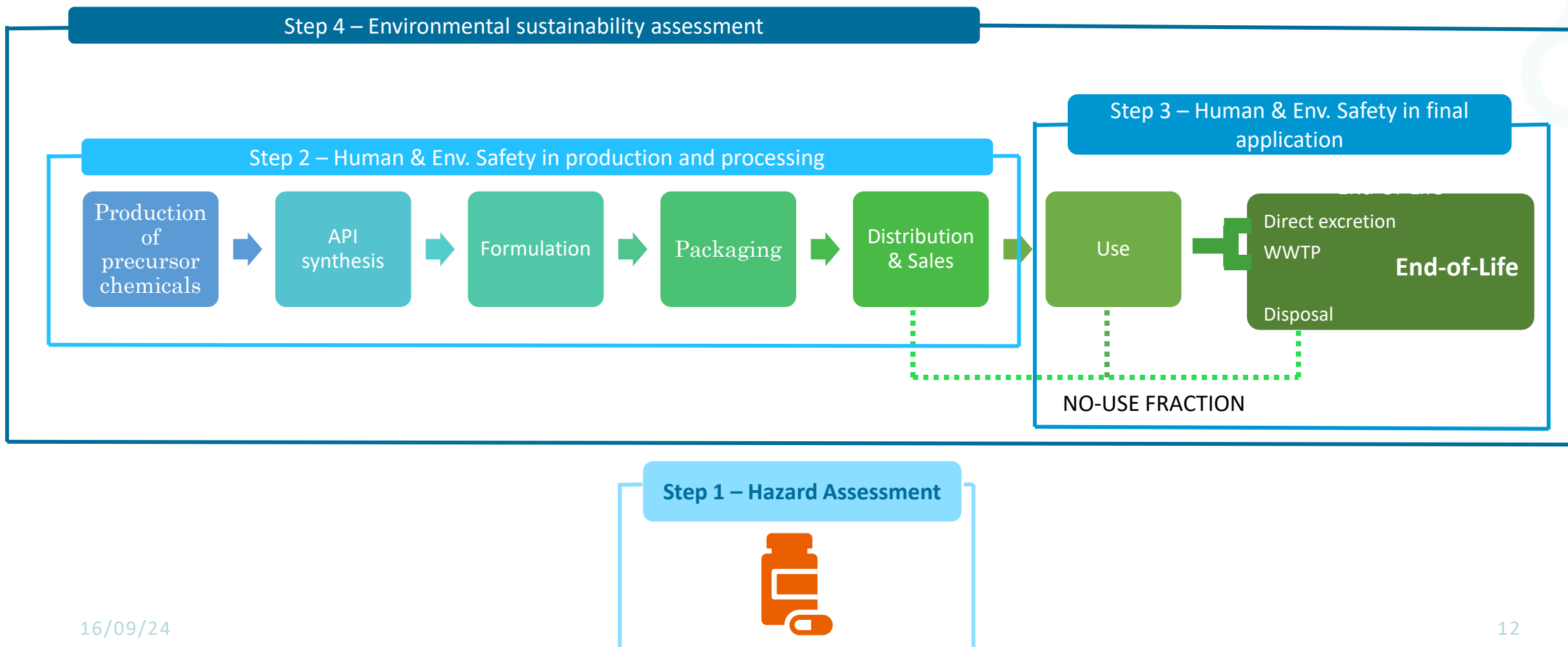
Considering availability of data on safety & sustainability during R&D to allocate design principles and assessment steps to R&D workflow

Proposing indications & recommendations

SSbD Design principles & Assessment Steps



Alignment of the SSbD Assessment Steps



How can BNN support you in this endeavour?

BNN Innovation Support

BNN provides end-to-end solutions for innovation-driven product development combining science, technology, regulatory and business-related know-how. By balancing clients' technical, regulatory and commercial interests using a sound science-based and strategic approach, BNN supports your company along the entire innovation process.



Go Sustainable



BNN works with you to develop **strategies and comprehensive methodologies to assess safety and sustainability issues**, especially when dealing with advanced materials. Together, we create **science-driven holistic approaches to continuously optimize your R&D&I activities towards SSbD**.

- Assessment of critical hotspots
- Risk assessment and mitigation strategies
- Research in occupational health & safety
- Toxicology & Ecotoxicology assessment
- Environmental fate & impact
- Socio-economic analysis & ethics

Go Compliant

BNN offers you **insights into** the latest national and international **standardization activities**, **EU policy trends** as well as **EU regulations**, and formulates strategies to prepare your technology for current and future EU legislation. **Regulatory Advice and Operational guidance** and implementation for **(nano)pharmaceuticals and MD/IVD**.



- Regulatory & Development Roadmap
- Gap Analysis
- Interaction with Regulators
- Orphan Drug Designation
- Paediatric Investigational Plan
- Due Diligence
- Representation for SME
- Standardized Test Methods

Turn your idea into reality

Go to Market



By **combining** our **knowledge of technology** and **business fields**, **innovation practices** and **strategic guidance**, BNN helps you achieve business success and **ensure your idea creates long-term and sustainable value**.

- Access to information about new technologies/trends/SoA
- Competitors analysis & SWOT
- Business model generation
- Personalized mentoring & graphic design support to plot your idea turning it into a sellable concept
- Valorisation process guidance for your technology
- Business plan generation

Connect to partners & communicate your findings

Go Beyond



BNN links you with an **extensive network of partners** to address any **data gaps** that arise and **ensure steady progress** towards your objectives.

- Empowering & building strength by gathering together all relevant stakeholders
- Coordination of National Technology Platforms (Nanomedicine-AT, SusChem-AT and Advanced Microfluidics Initiative)
- Coordination of International Clusters and Networks (EU-NSC, SusChem-EU)
- Building of small, medium and large consortia for initiatives and projects.
- Leading scientific communication
- Branding

Unleash potential through optimal training

Go Smarter



Get familiar with different concepts and complementary knowledge, such as **Safe-and-Sustainable-by-Design (SSbD)** or **regulatory** and **business aspects**, and discover the possibilities **to optimize the innovation process** and therefore find the best solution at each phase.

- In-house trainings
- On-line trainings
- Customized trainings

Thank
you!