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Presentation of PHOENIX Austrian Partners' Expertise

Safe-and-Sustainable-by-Design & its added value for nanopharmaceuticals

NANOMEDICINE-AUSTRIA WEBINAR

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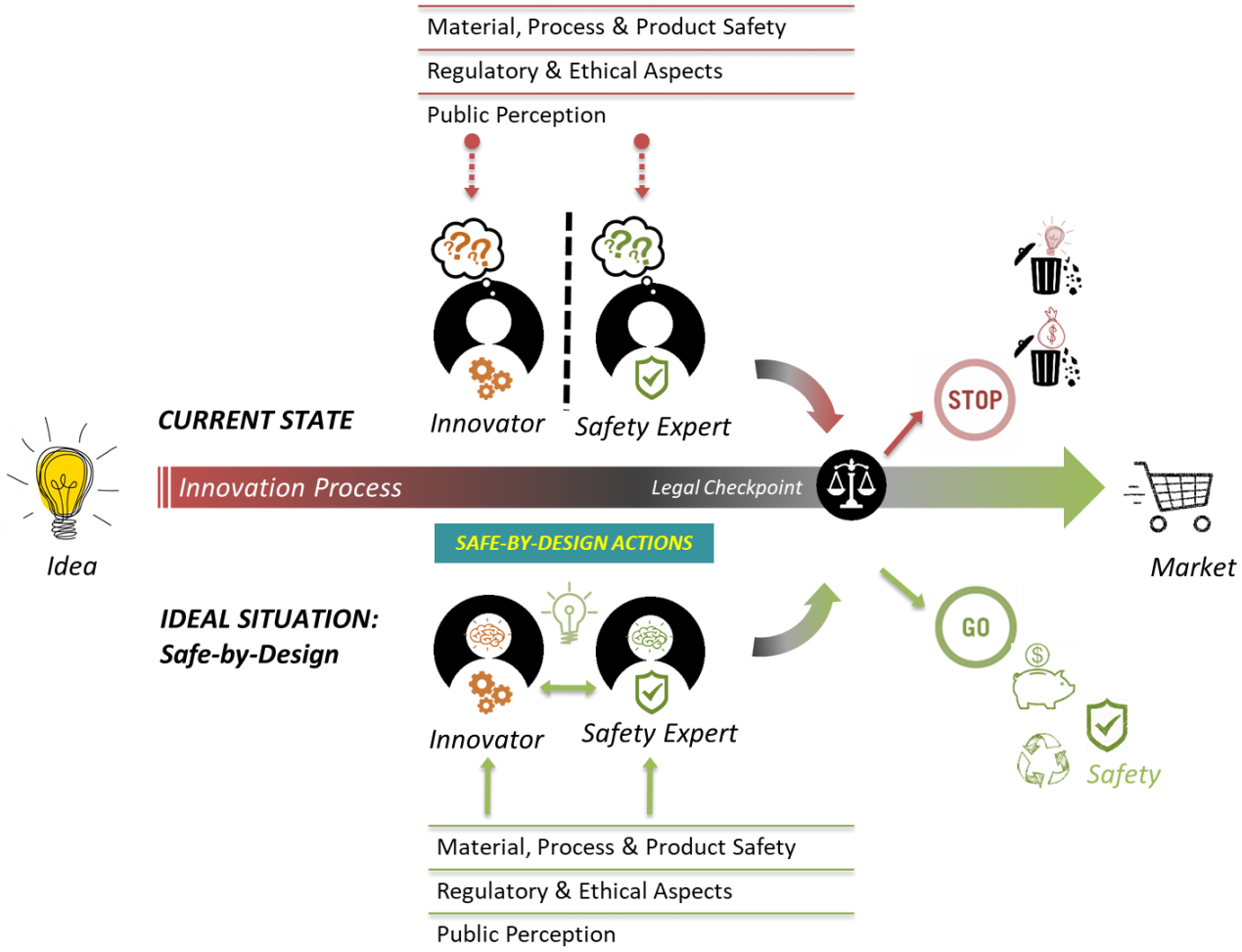
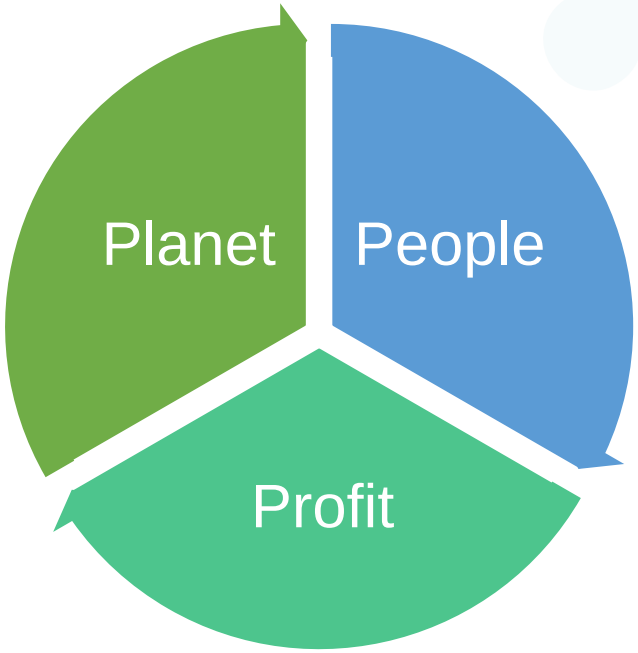
Safe-by-Design (SbD)

- Technological innovations present a challenge to health & environmental risk assessment
- Rapid innovation causes a gap between technology and suitable risk assessment tools / frameworks
- Reduce uncertainties and minimize risks to humans & the environment, starting at an early phase of the innovation process and covering the whole innovation value chain → **'Safe-by-Design' concept**

SbD benefit – timely experts' interaction



Integration of Sustainability



- Three dimensions of sustainability: PEOPLE – PLANET – PROFIT
- Addressing societal, environmental & economic aspects
- Broad topic that includes safety but goes far beyond: a sustainable material must be safe, while a safe material is not automatically sustainable
- Include sustainability into SbD → **“Safe-and-Sustainable-by-Design” Concept**

Policy context

- ✔ **Sustainability is a cross-sectoral "hot topic"**
- ✔ **High priority in the European Union, the UN & their strategies, e.g.:**
  - 2030 Agenda for Sustainable Development
  - Paris Agreement on Climate Change
  - European Green Deal
  - EU's chemicals strategy for sustainability
  - Circular economy action plan

JRC Framework for Safe-and-Sustainable-by-Design (SSbD)

- *Safe-and-Sustainable-by-Design (SSbD) is an approach to the design, development and use of chemicals and materials that focuses on providing a function (or service), while reducing harmful impacts to human health and the environment*

Published reports:
doi:10.2760/68587
doi:10.2760/404991

JRC Framework for Safe and Sustainable-by-Design (SSbD)

1-(Re)Design Phase

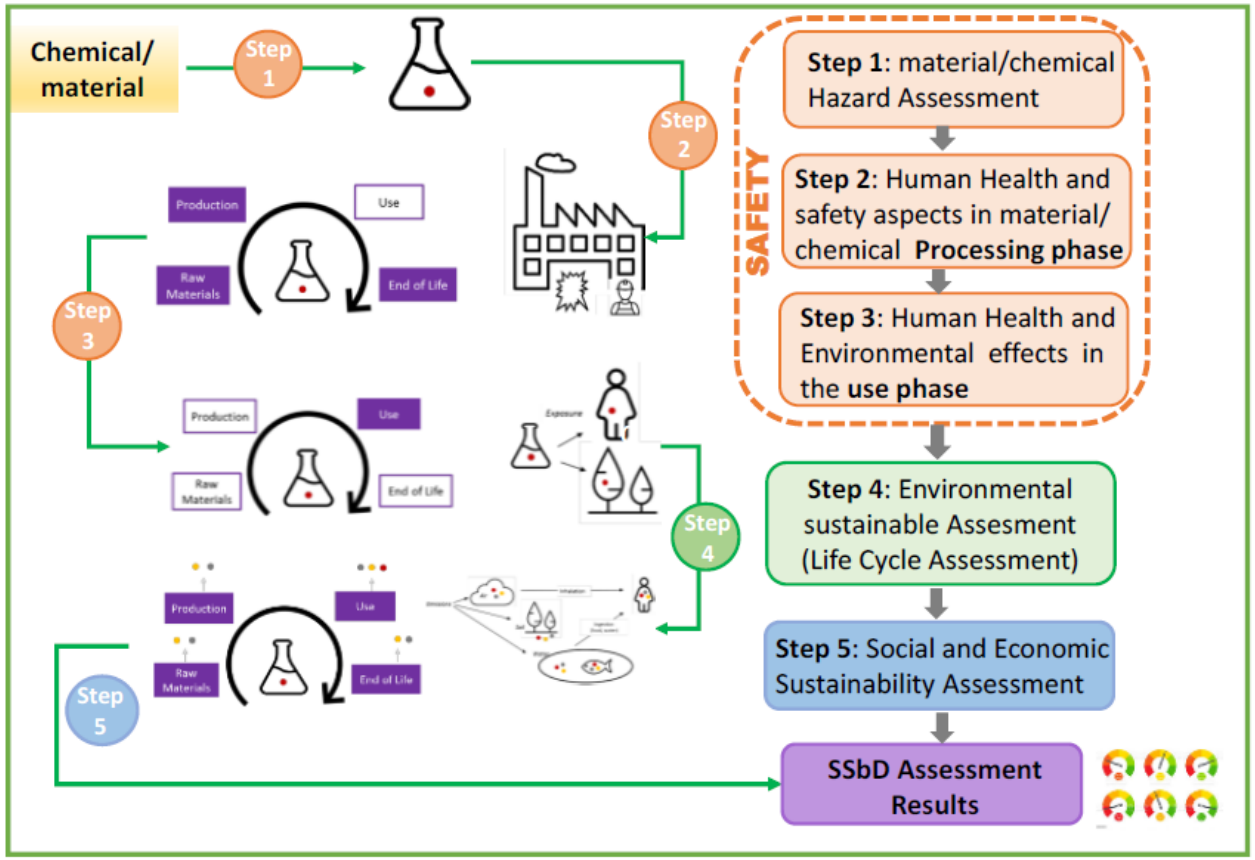
Design guiding principles are proposed to support the design of chemical an materials

- Green chemistry
- Green Engineering
- Sustainable Chemistry
- Safe by design

List of SSbD principles recomended by the JRC SSbD frame work

SSbD1	Material efficiency
SSbD2	Minimize the use of hazardous chemicals/materials
SSbD3	Design for energy efficiency
SSbD4	Use renewable sources
SSbD5	Prevent and avoid hazardous emissions
SSbD6	Reduce exposure to hazardous substances
SSbD7	Design for end of life
SSbD8	Consider the whole Life Cycle

2-SUSTAINABILITY ASSESSMENT



SSbD: Added value

- Different settings and options during the innovation process are assessed,
- with the clear aim to **design materials, processes and (interim) products as safe & sustainable as possible**
- while **keeping the technical requirements,**
- **complying** with current and future **regulations**
- and **keeping costs as low as possible.**

Challenges in the pharma sector

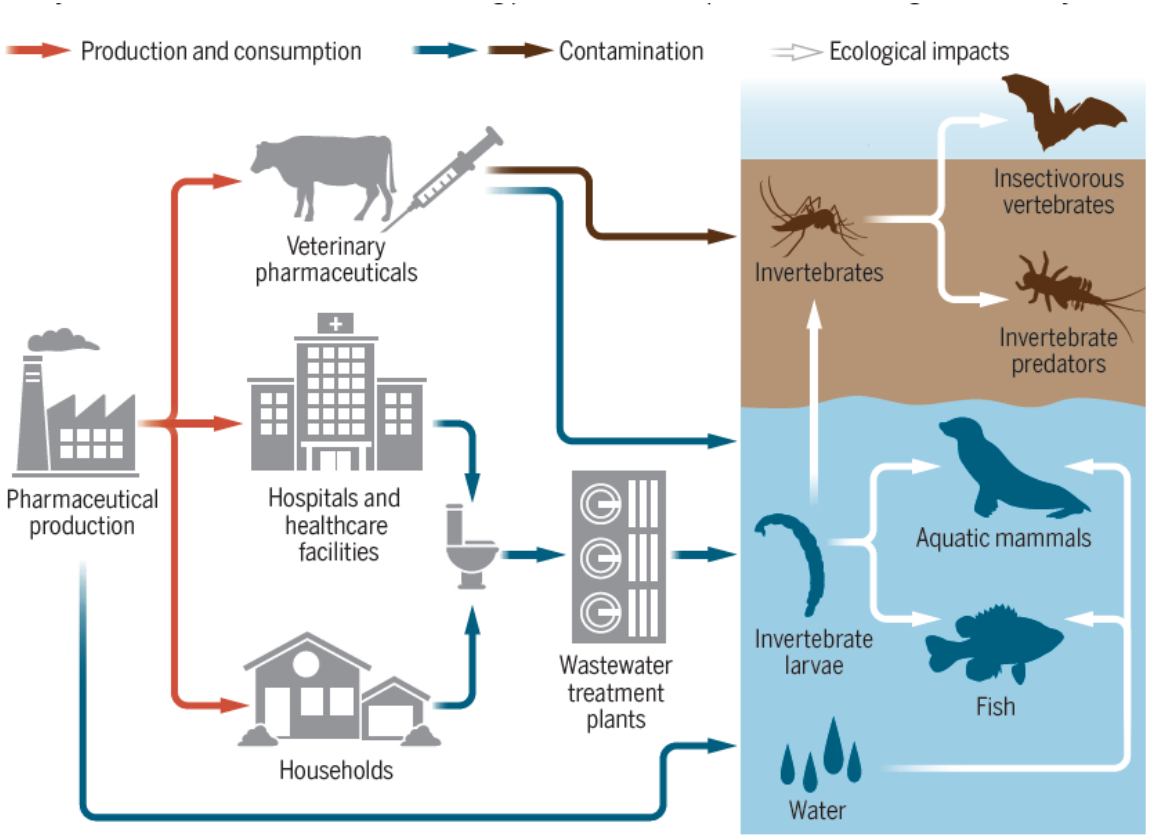
COVID-19 Pandemic

Since early 2020 and the start of the COVID-19 pandemic, the **global pharmaceutical industry has shown itself robust and flexible in meeting unprecedented challenges**. The rapid development and distribution of vaccines has highlighted not only **its ability to respond to dire circumstances**, but also the **capacity and agility in its supply chains**.

Nevertheless, behind the short-term challenges with which it has dealt so well lie long-term issues that must be addressed, **not least the need to improve progress towards sustainability goals**.

https://datwyler.com/files/pages/data/downloads/esg-report-2022-esg-in-pharma/b366277519-1651479943/datwyler.com_esg-report_2022_esg-in-pharma.en.pdf

Pharmaceuticals route to the environment (PIE)



Pharmaceuticals are produced by industrial facilities and are consumed in agricultural production, hospitals, healthcare facilities, and households. They are **released into the environment**, for example, through dung, urine, and wastewater, unless properly regulated and waste products are treated.

PIE in Europe:

- 88% from patients use – 30-90% of the APIs is excreted from our bodies and ends up in waterways/soil
- 10% from incorrect disposal of products
- 2% from production

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8777701/
https://doi.org/10.1016/j.scp.2022.100834
https://www.efpia.eu/media/637033/eera-document_final.pdf

GHG emissions of the pharma sector

Pharma is a major contributor to green-house gas emissions.

Designing less carbon-intensive pharmaceutical facilities will have huge positive impact moving forwards.

One reason the spotlight is on the pharma sector is because **it is a major contributor to global greenhouse gas (GHG) emissions**, but its **impact on the environment is multi-faceted**. This impact derives from:

- R&D activity,
- supply chains,
- transport and logistics,
- the disposal of pharmaceutical products,
- and chemistry.

Indeed, a 2019 study by the Booth School of Engineering Practice & Technology, McMaster University, found that the **pharmaceutical industry emission intensity is about 55% higher** than that of the automotive industry.

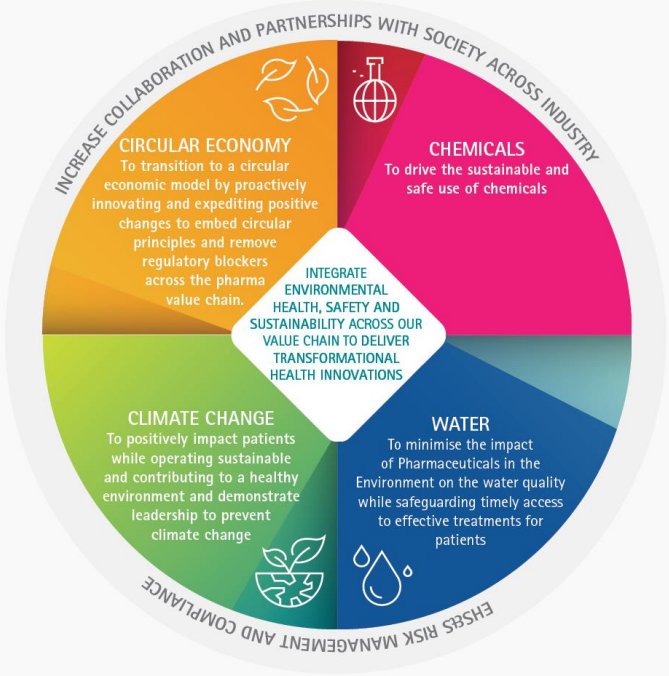
https://datwyler.com/files/pages/data/downloads/esg-report-2022-esg-in-pharma/b366277519-1651479943/datwyler.com_esg-report_2022_esg-in-pharma.en.pdf

European Federation of Pharmaceutical Industries and Associations

Building a healthier and more environmentally sustainable future

The pharmaceutical industry is committed to building a **healthier and more environmentally sustainable future**.

EFPIA strongly supports the overarching objectives of the 'Chemicals Strategy for Sustainability (CSS) Towards a Toxic-free Environment'



https://www.efpia.eu/

Take home messages

- ✔ **Sustainability is to become a high priority in the pharma sector**
- ✔ **SSbD supports to find the best solution from an early innovation phase**
- ✔ **Continuous optimization is needed to become more sustainable – the higher the TRL, the more data should be available**

Take home messages

- ✓ To claim & prove that SSbD is embedded in your innovation pathway within your company, is a clear benefit compared to your competitors and makes your materials, processes and products future-proof
- ✓ Multidisciplinary experts' cooperation is needed
- ✓ BNN guides and supports you towards implementing SSbD and keeping pace with latest developments in this area

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THANK YOU FOR YOUR ATTENTION!