SAFE AND SUSTAINABLE BY DESIGN FRAMEWORK

Institut Grand Ducal de Luxembourg – Section des Sciences

25/2/2025

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INTRODUCTION TO SSBD – EU CONTEXT

Zero pollution

Climate neutrality

Circular economy

- ✓ **Phase out** the most **harmful** (not only SVHCs) substances
- ✓ **Substitute**, as far as possible, all other **substances of concern**, or minimise and track them
- ✓ New approaches to tackle release and emissions across all life cycle stages
- ✓ Make sure that the substitution materials also contribute to other Green Deal objectives

Safe and Sustainable by Design (SSbD) framework

(Caldeira et al. 2022)

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INTRODUCTION TO SSBD

- European framework (developed by JRC in 2022) to support R&I activities towards safe and sustainable by design materials and chemicals
- Addressed to all stakeholders (industry, academia, RTOs and more)
- Testing period of 2 years → revision in 2025 based on stakeholders' feedback (2023-2024)

EUROPEAN COMMISSION

Brussels, 8.12.2022
C(2022) 8854 final

COMMISSION RECOMMENDATION

of 8.12.2022

establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials

European Commission

Filename	**SSbD reporting template**
Version	2.0
Latest update	15-May-2024
Contacts	RTD-SUSTAINABLE-BY-DESIGN@ec.europa.eu JRC-SSBD@ec.europa.eu *(for questions related with the reporting template)*
Testing phase	*The European Commission Recommendation of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' (SSbD) chemicals and materials* announced the testing phase for the SSbD framework. The **Recommendation** launched a testing period and a voluntary reporting mechanism. Based on the feedback, the Commission will launch a revision of the framework. The testing period counts on the engagement of stakeholders.
Goal of the Reporting Template	To collect feedback during the testing phase on: a) **activities promonting the SSbD framework** in R&I programmes and policies, and b) the **SSbD framework's feasibility and applicability** via testing with case studies, and to initially guide the users through the SSbD framework.
Audience	It is addressed to **Member States, industry, academia, research and technology organisations** or other stakeholders willing to test and provide feedback on the SSbD framework.

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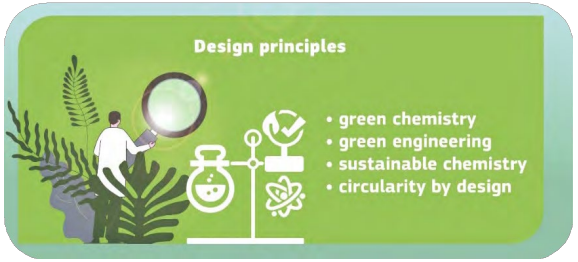
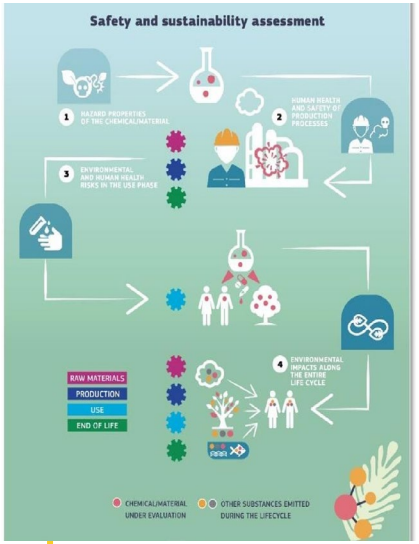
THE SSBD FRAMEWORK



Stage 1: guiding (re)design principles

- Principles to be considered to maximize the possibility of a successful safety and sustainability assessment outcome



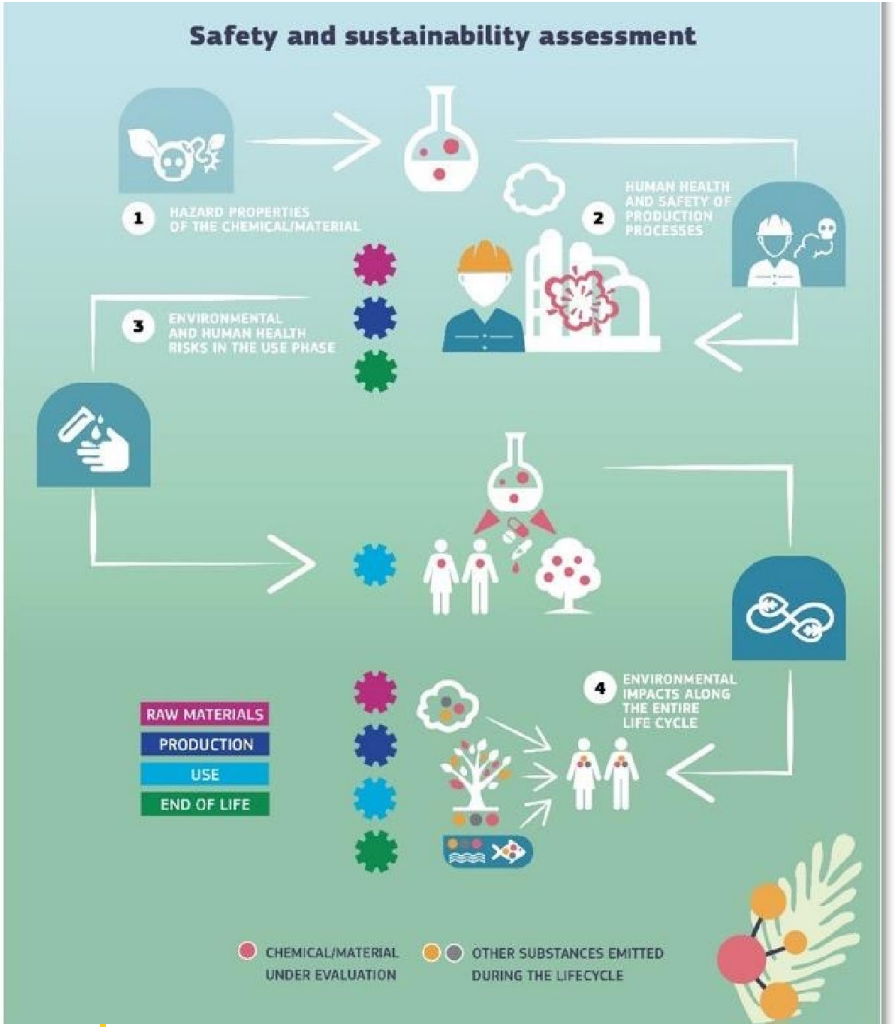
Stage 2: safety and sustainability assessment

- **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



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:

Aspects and indicators	Methodology and tools	Proposal for the definition of criteria	Evaluation procedure

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LIST AND SSBD

Three LIST groups:

- Environmental Policies (EPS)
- Environmental Health (EH)
- Life Cycle Sustainability Assessment (LCSA)

LIST activities related to

- Preliminary assessments of safety – environmental sustainability – policy recommendations
- **Steps 1 – 2 – 3** – Safety screening, hazard assessment, NAMs / *in vitro* toxicology, toxicity and eco-toxicity testing
- **Step 4** – Life Cycle Assessment, indicators, sustainability criteria
- Step 5 – Social LCA. Social Acceptability and Life Cycle Costing

Projects

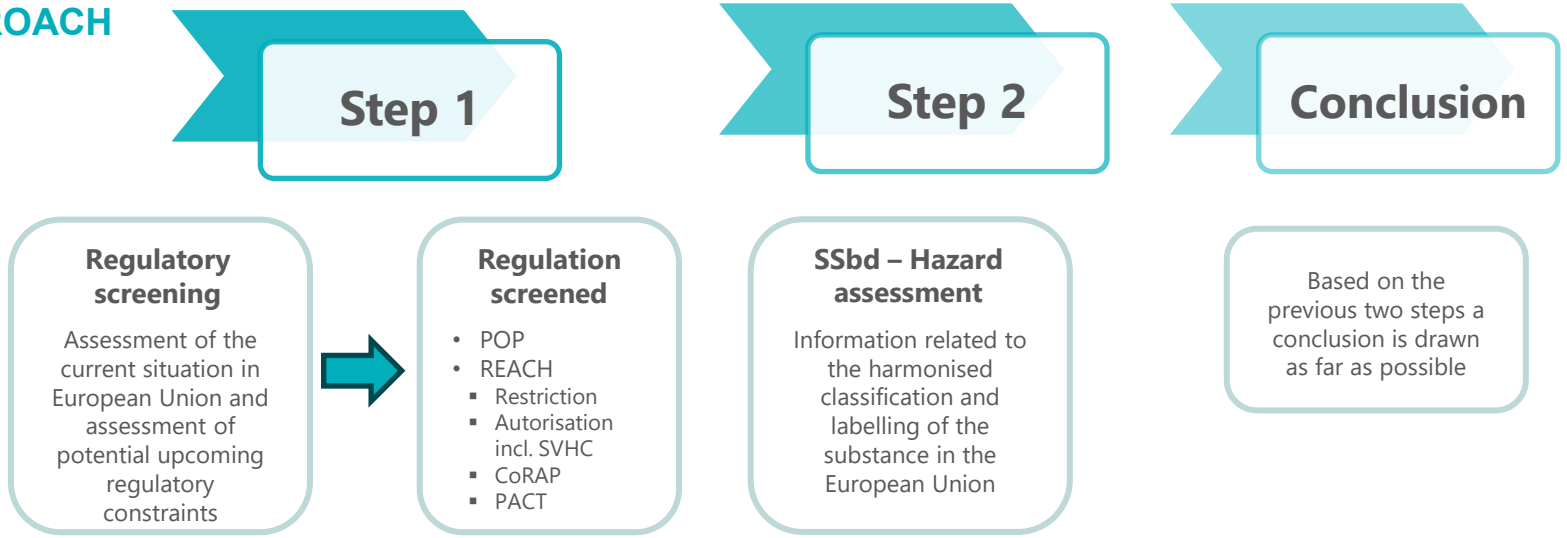
- CHIASMA - in vitro and in silico methods NAMs for SSbD
- INSIGHT / PINK (sister projects of CHIASMA) – Integrated impact assessment and Computational models for SSbD, respectively
- ZeroF – bio-based coatings to replace PFAS (textile/packaging)
- Superbark – bio-based adhesives and coatings from bark (packaging/wood)
- SUNRISE - Integrated Impact Assessment Framework for SSbD decision making

STEP 1: REGULATORY SCREENING

SCOPE

Regulatory screening is part of a sustainability analysis of substances, e.g. within SSbD Step 1, and the aim is to provide regulatory advice on RDI activities and uses of substances. It can also support decisions on the substitution of substances that could potentially become restricted or banned in the short or medium term. Consideration of regulatory constraints in the innovation process can be a way to translate future challenges in legislation into today's innovative opportunities.

APPROACH



STEP 1: REGULATORY SCREENING

Level of concern

RESULTS

For each step of the regulatory screening, different level of concern are assigned to the substances screened.

1. Hazard classification		
Benchmarks	Hazard (REACH and CLP criteria)	Justification (List Name)
Benchmark 1	Avoid – Chemical of concern	
Benchmark 2	Use – Search safer alternative – Improvement potential	
Benchmark 3	Use – Low concern	
Not assignable	Lack of information – Further data needed	
2. Regulatory status (current and anticipation)		
Benchmarks	Regulatory status	Justification (List Name)
Benchmark 1	Avoid – Restriction in place or intention	
Benchmark 2	Use – Future restriction possible – Analysis of alternatives	
Benchmark 3	Use – Chemical not restricted	
Not assignable	Lack of information – Further data needed	
3. Conclusion		
Benchmarks	Substitution pressure through hazard and regulatory status	Justification (List Name)
Benchmark 1	Substitute – Avoid	
Benchmark 2	Use – Monitor regulatory status – Analysis of alternatives	
Benchmark 3	Use – No regulatory constraints/substitution need identified	
Not assignable	Lack of information – Further data needed	

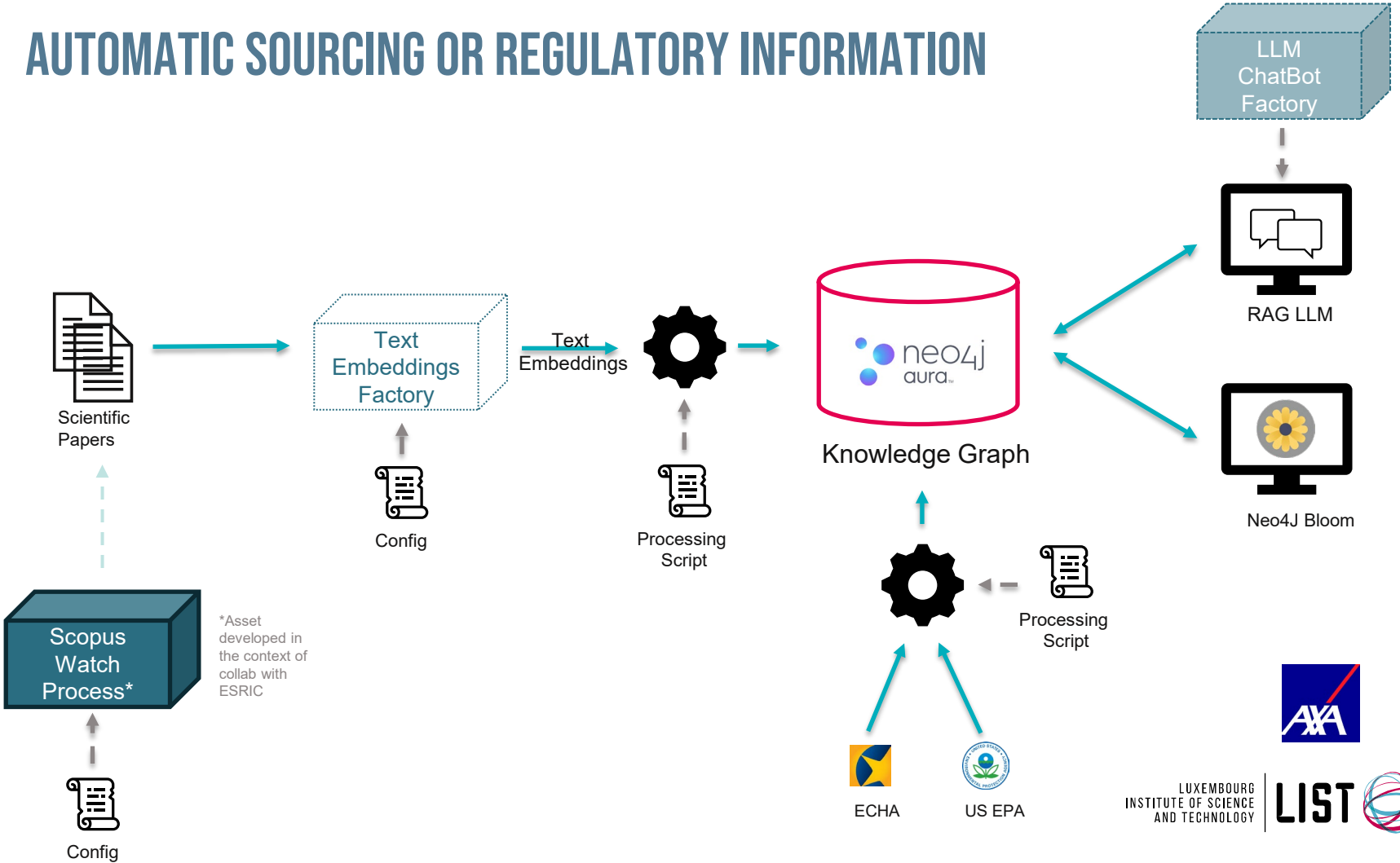
EXAMPLE: SSBD REGULATORY SCREENING - HEU AMUSENS

SUMMARY OF REGULATORY SCREENING

	Regulatory screening					CLH process		
Substance name	**POP**	**REACH**		**SVHC**	**Scoring**	**CLH Annex VI**	**Scoring SSbD**	**Conclusion**
		Restriction	**Authorisation**		3 level (red, yellow, green)	All classifications (list)	Level 0,1,2,3 (color)	
Tricobalt tetraoxide	No	No	No	No	Benchmark 3	Not applicable	Level 3	***Regulatory screening*** : **Use is allowed** as there are no current and future regulatory constraints ***SSbD - Hazard assessment*** : No harmonised classification, the **substance passes the SSbD hazard assessment**
Diindium trioxide	No	No	No	No	Benchmark 3	Not applicable	Level 3	***Regulatory screening:*** **Use is allowed** as there are no current and future regulatory constraints ***SSbD - Hazard assessment*** : No harmonised classification, the **substance passes the SSbD hazard assessment**
Copper oxide	No	No	No	No	Benchmark 3	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Level 1	***Regulatory screening:*** **Use is allowed** as there are no current and future regulatory constraints ***SSbD - Hazard assessmen*** **t**: Harmonised classification for environmental hazard classes with the highest category. The substance passes the cut-off criteria but failed the next level related to the substances of concern. The **substance passes the SSbD hazard assessment and the use is possible but it is recommended to search for a safer alternative**
Tin dioxide	No	No	No	No	Benchmark 3	Not applicable	Level 3	***Regulatory screening:*** **Use is allowed** as there are no current and future regulatory constraints ***SSbD - Hazard assessment*** : No harmonised classification, the **substance passes the SSbD hazard assessment**
Titanium oxide	No	No	No	No	Benchmark 3	Not applicable	Level 3	***Regulatory screening*** **: Use is allowed** as there are no current and future regulatory constraints ***SSbD - Hazard assessment*** : No harmonised classification, the **substance passes the SSbD hazard assessment**
Divanadium pentaoxide								

CLH: ECHA registry of classification and labelling

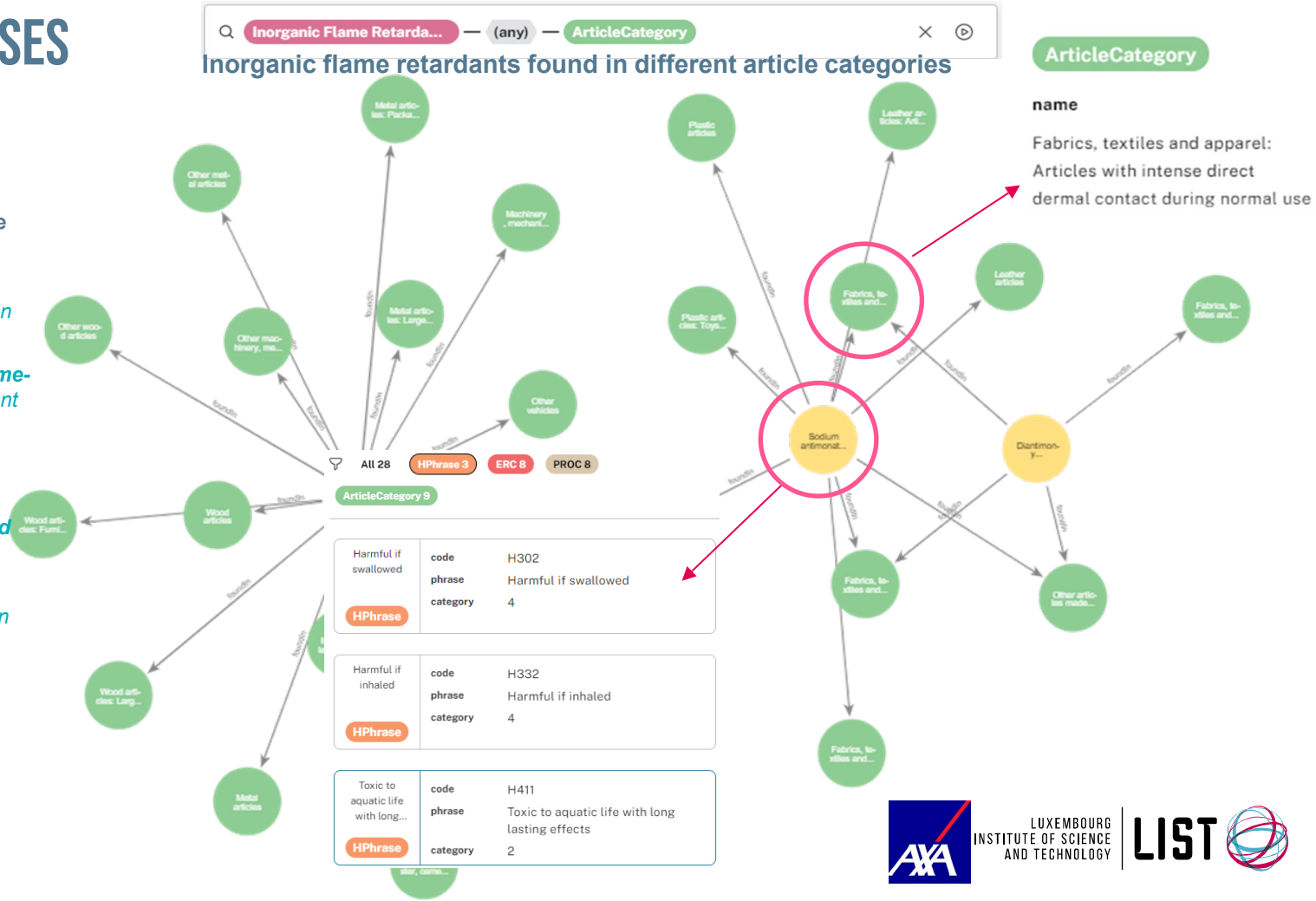
AUTOMATIC SOURCING OR REGULATORY INFORMATION



EXAMPLE CASES

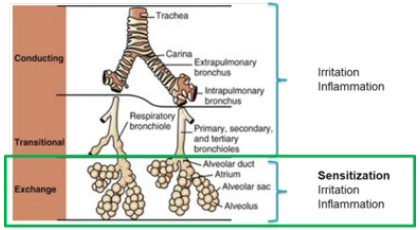
Example questions that can be answered from the graph:

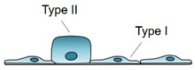
- *Find substances with **given Hazard Phrase** present in an **Article Category ?***
- *What are the hazards of **flame-retardant** substances present in an **Article Category ?***
- *What hazards are found in **Product Category ?***
- *Find substances with **Hazard Class** with **given tonnage band** on EU market ?*
- *Find most common hazard in **Article Category***



STEP 3: HAZARD ASSESSMENT

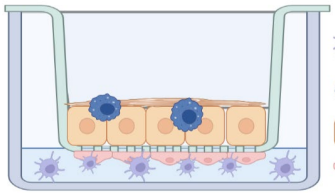
Human anatomy





Alveoli

ALIsens model



- THP-1 (monocytes/dendritic) cells
- Macrophages, *PMA treated THP-1*
- A549 (epithelial) cells
- EA.hy926 (endothelial) cells

Main Features

- Based on multiple cell lines
- 3D orientation
- Air-Liquid-Interface
- Presence of immune system
- Suitable for regulatory applications and R&D applications
- Only existing model able to predict respiratory sensitization and irritation

Biological endpoints

- Cytotoxicity
- Irritation / Inflammation (e.g. measurement of pro-inflammatory cytokines
- Respiratory sensitization (cell surface markers, release of cytokines, gene expression)
- Genotoxicity (COMET, γH2AX)
- Disease specific biological endpoints (e.g. lung fibrosis)

Wide selection of exposure devices

VitroCell PowderX
ALI exposure (dry material)

TECAN D300e
Semi-ALI exposure
(liquid)

VitroCell Continuous flow
ALI exposure (liquid/dry)

VitroCell Cloud
ALI exposure (liquid)

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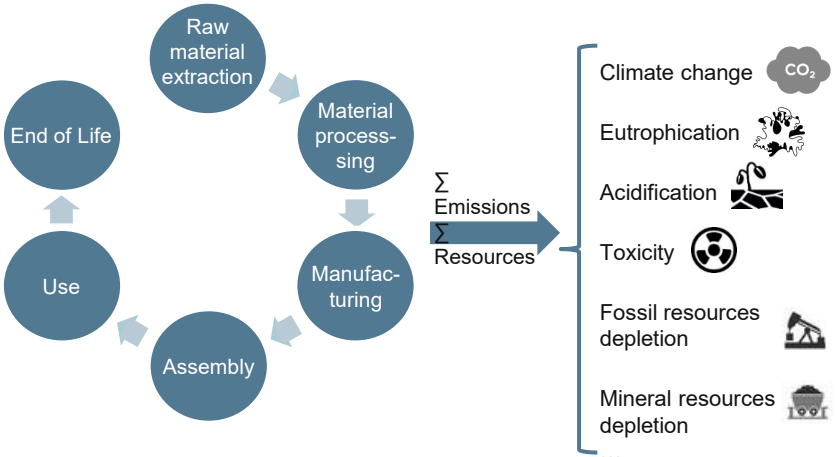
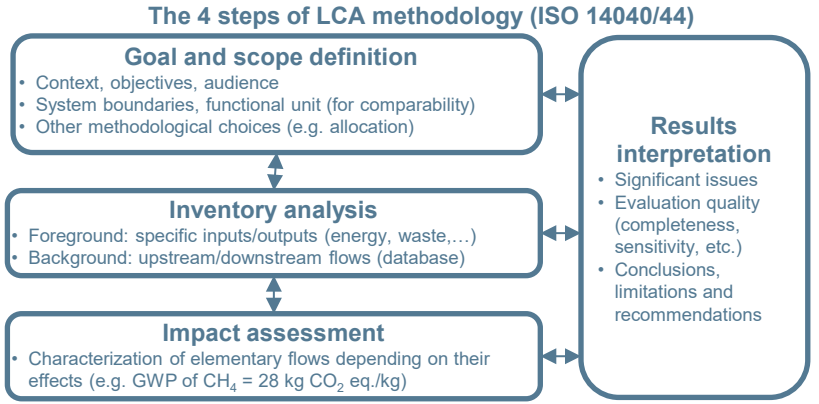
STEP 4: ENVIRONMENTAL ASSESSMENT

Life Cycle Assessment (LCA) methodology (ISO 14040)

- Life cycle & multicriteria approach to identify the transfer of impacts (inter-phase or inter-impact types)
- Comparison of scenarios providing the same function (e.g., transporting 1 tonne of product over 100 km in Europe)
- Need data regarding all input and output flows for the studied processes → critical aspect for LCA study quality
- Generic data used to complete the life cycle and quantify all emissions and natural resources (direct & indirect)





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STEP 4: ENVIRONMENTAL ASSESSMENT

Life Cycle Assessment (LCA) methodology

- Evaluation of potential environmental impacts, expressed by comparing the effects to a reference substance
- Conventionally a relative approach but towards an “absolute environmental sustainability assessment”

$$Impact_i = \sum_j m_j \times CF_{i,j}$$

Amount of flow in the inventory

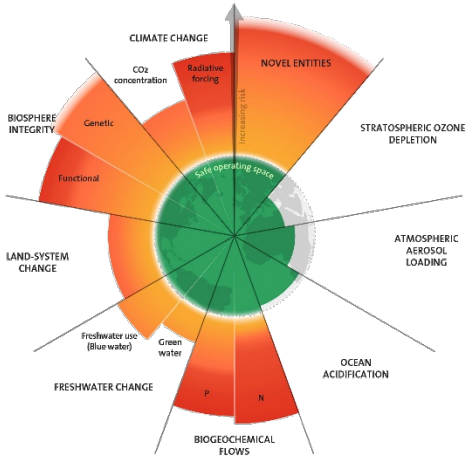
Characterization factor expressing the impact of the specific flow per unit

New materials toxic? If so, new factors to be developed…

Impact category	Unit	Description
Climate change	kg CO_2-eq	Radiative forcing of GHGs over 100 years
Ozone depletion	kg CFC-11-eq	Destructive effects on the stratospheric ozone layer over 100 years
Ionizing radiation	kBq U235-eq	Human exposure to radioactive material
Photochemical ozone formation	kg NMVOC-eq	Tropospheric ozone concentration increase due to VOCs oxidation
Particulate matter	disease inc.	Disease incidence due to particulate matter emissions
Human toxicity, non-cancer	CTUh	Increased non-cancer cases in human population
Human toxicity, cancer	CTUh	Increased cancer diseases in human population
Acidification	molc H^+-eq	Critical load exceedance in terrestrial ecosystems due to acidifying substances deposition
Eutrophication, freshwater	kg P-eq	Increase of phosphorous concentration in water
Eutrophication, marine	kg N-eq	Increase of nitrogen concentration in water
Eutrophication, terrestrial	molc N-eq	Critical load exceedance in terrestrial ecosystems due to eutrophying substances deposition
Ecotoxicity, freshwater	CTUe	Potentially affected fraction of species in freshwater
Land use	-	Index of soil quality
Water use	m^3 depriv.	Deprivation-weighted water consumption
Resource use, fossils	MJ	Fossil resources depletion based on lower heating values
Resource use, minerals and metals	kg Sb-eq	Mineral and metals resource depletion based on use-to-availability ratio

Aggregation into single score possible

Planetary boundaries concept



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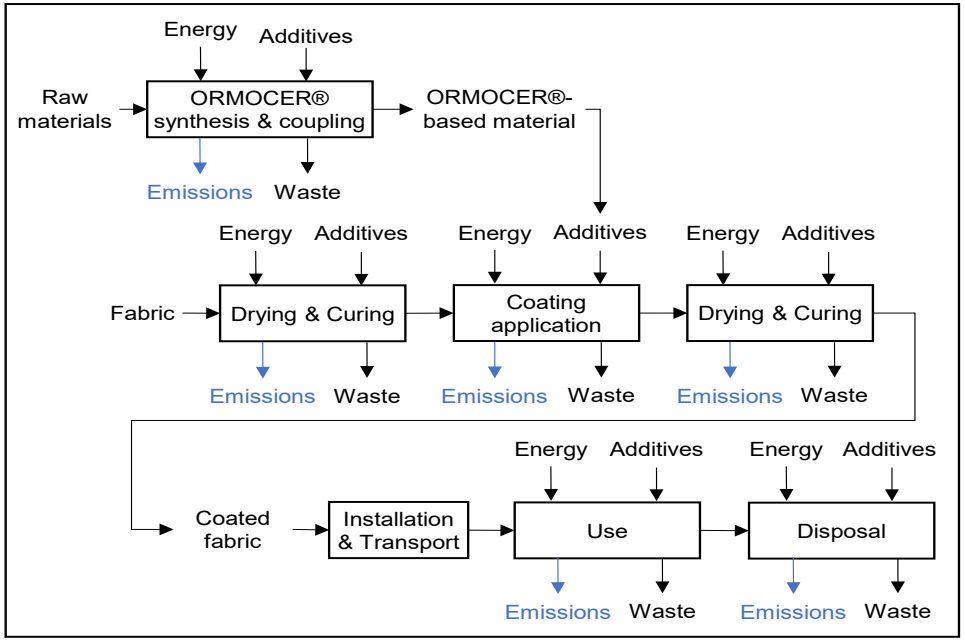
EXAMPLE: TEXTILE APPLICATION OF NEW OIL REPELLENT

System boundaries for the SSbD evaluation of the textile application



Textile sector

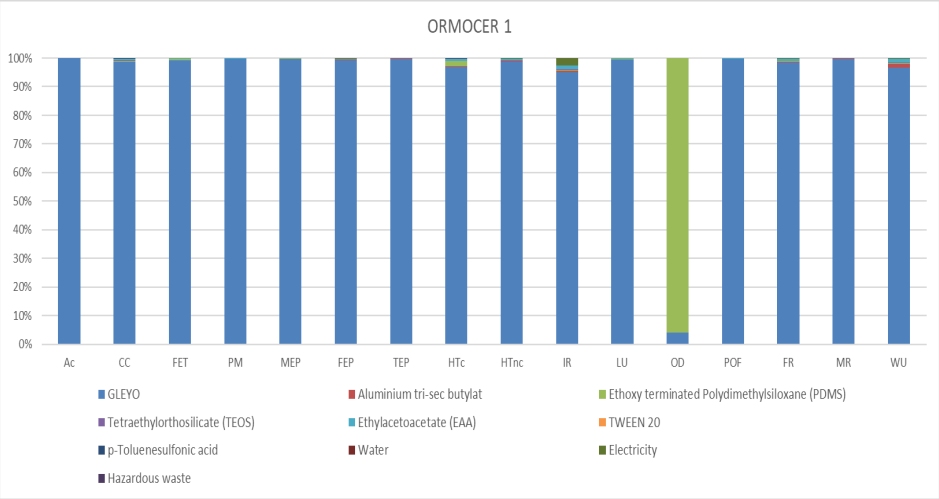
- Comparison per m^2, additional oil repellence
- Reference scenario: C6 coating
- ORMOCER® coating alternative scenarios:
  - Testing of various precursors and reactants
  - Testing of padding & exhaustion coating
  - Testing of thermal & UV curing processes

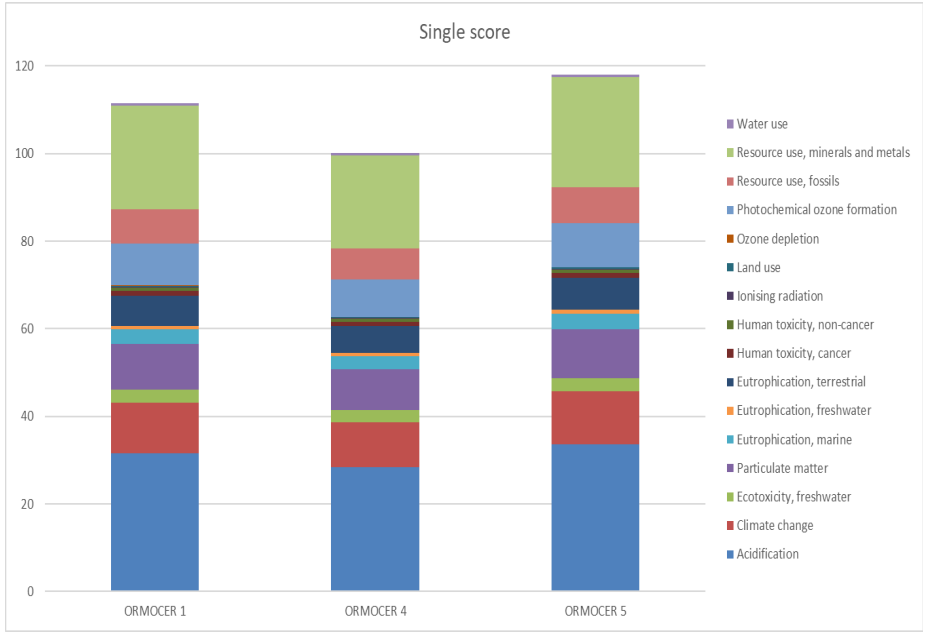
Co-funded by the European Union
Also funded by the Swiss State Secretariat for Education, Research and Innovation (SERI)

Environmental screening – ORMOCER system only

Impacts of 1 kg of ORMOCER system synthesis:

- Majority of impacts due to use of GLEYO to perform the inorganic network
- Due to consumption of platinum as catalyst according to the reference preparation method selected (although in trace quantities)





Co-funded by the European Union

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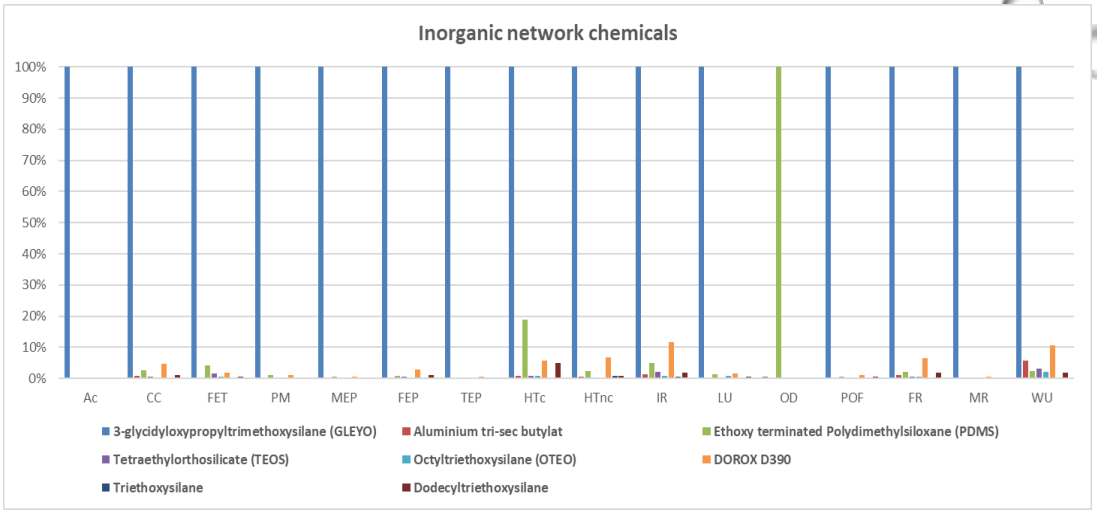
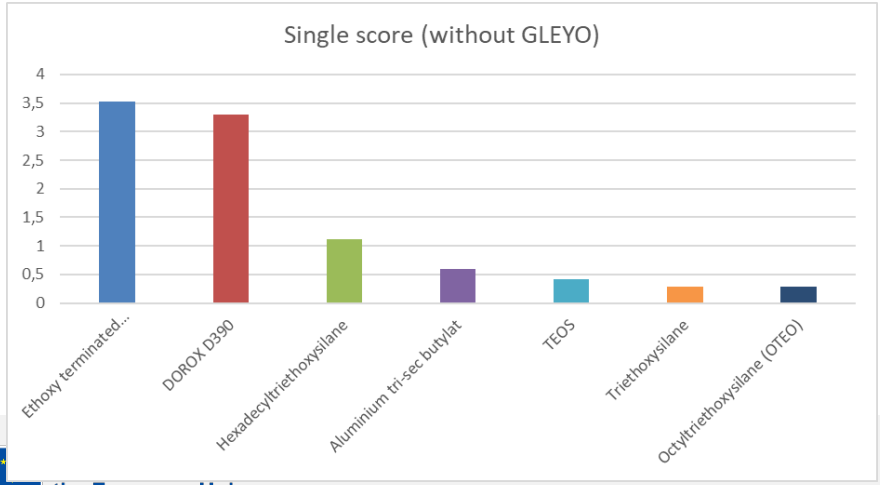
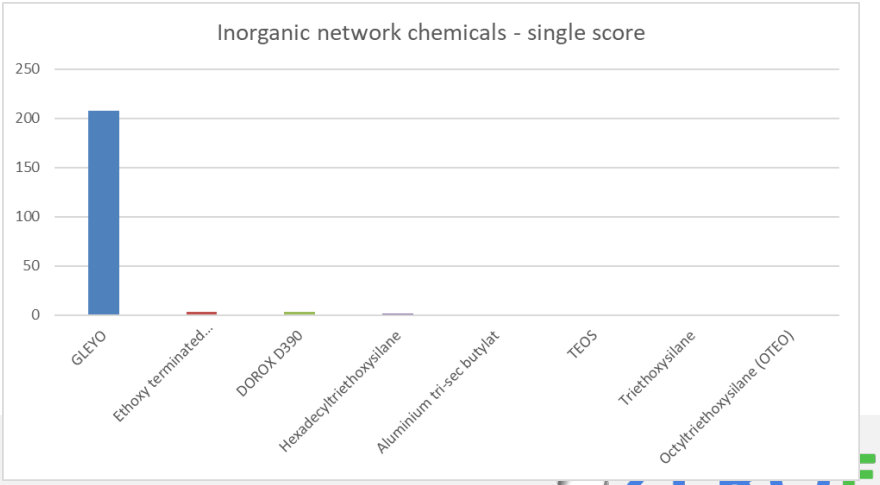
Environmental screening – ORMOCER chemicals

- Inorganic network chemicals with highest impacts per 1 kg of ORMOCER system
- GLEYO has the highest environmental burden of all available alternatives



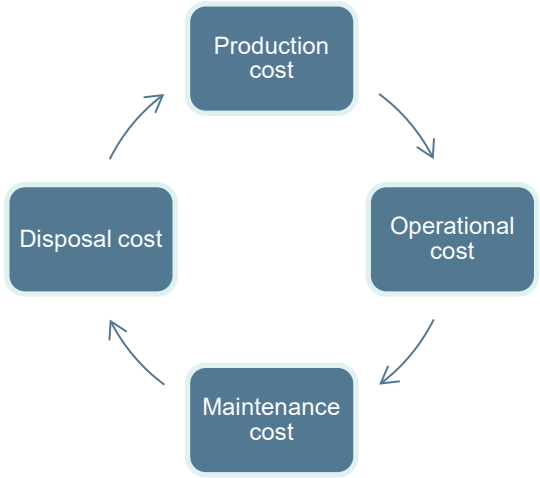




STEP 5: ECONOMIC AND SOCIAL ASSESSMENT

Life cycle cost (LCC) methodology

- Life cycle approach to assess all costs related to a product or service over the entire life cycle from production over use until disposal
- Decision-making during design based on upfront and long-term costs
- Comparison of alternatives providing the same function
- Need data regarding all input and output flows for the studied processes → critical aspect for LCC study quality



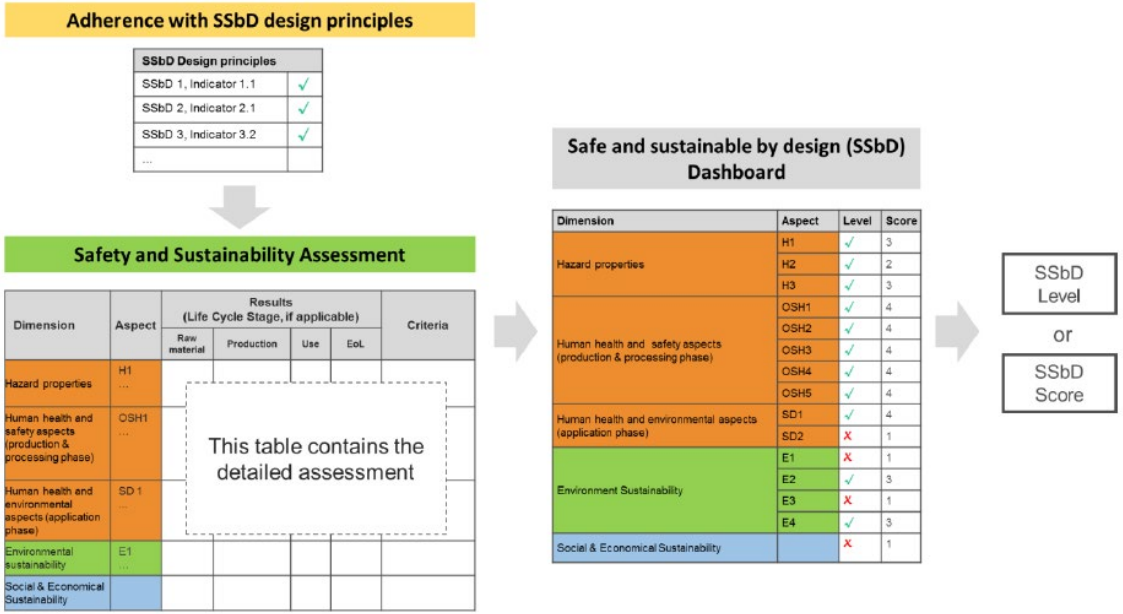
Social acceptance

- Acceptance of new technology – understanding the benefits
- Behaviour change – Capability, Opportunity and Motivation for the use of new concepts, willingness to pay
- Segmentation of European consumers to better understand the need for additional information

Awareness raising campaign

- Results from earlier stages to support the design of the campaign

INTEGRATION FOR SSBD SUPPORT



- Overview of all SSbD criteria for an integrated analysis
- One single SSbD score can be useful to rank alternatives but detailed analysis necessary to identify trade-offs and required improvements
- Multi-criteria decision analysis (MCDA) possible, although the associated settings and data quality to be carefully analysed, avoid compensation

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